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#### Prior Authorization Criteria

Effective 12/01/2022

### abiraterone

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members with severe hepatic impairment (Child-Pugh Class C). Members that have experienced disease progression while on abiraterone acetate. Concomitant use with Erleada, Xtandi, Provenge, Taxotere or Jevtana.
Required Medical Information	Prostate Cancer (mCRPC). The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC). The member will be using abiraterone acetate in combination with prednisone. Prostate Cancer (mCSPC). The member has diagnosis of castration-sensitive prostate cancer plus one of the following scenarios: metastatic (stage IV) disease AND is high risk (e.g. Gleason score of 8 or more, at least three bone lesions, or presence of measurable visceral metastases) OR Node-positive (any T, N1) OR localized disease with high risk features (e.g. a PSA level greater than 4 ng per milliliter with a doubling time of less than 6 months, a PSA level greater than 20 ng per milliliter, nodal or metastatic relapse, or adjuvant or neoadjuvant therapy lasting less than 12 months of total ADT and completed at least 12 months previously) that is persistent or recurrent after prior radical prostatectomy and/or radiation therapy. Member will be using abiraterone acetate in combination with prednisone and one of the following applies: in combination with LHRH analog (e.g. Lupron, Trelstar) OR has previous bilateral orchiectomy.
Age Restriction	NA

## abiraterone

<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 months duration
<b>Other Criteria</b>	NA

# ABRAXANE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Breast Cancer. The member has a diagnosis of metastatic (Stage IV) or recurrent breast cancer. The member received prior therapy that included an anthracycline (unless contraindicated). The member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications. Non-small Cell Lung Cancer (NSCLC). The member has a diagnosis of locally advanced, recurrent or metastatic NSCLC. Member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications AND member has squamous histology where Abraxane will be given in combo with Keytruda and carboplatin as first line therapy OR member will be using Abraxane as monotherapy or in combo with carboplatin AND One of the following apply: will be using for first line therapy OR member will be using as subsequent therapy for EGFR mutation-positive tumors after prior therapy (e.g., erlotinib) OR The member will be using as subsequent therapy for ALK-positive tumors after prior therapy (e.g., crizotinib, brigatinib) OR member will be using as subsequent therapy for ROS-1 positive disease after prior therapy (e.g., crizotinib) OR member will be using as subsequent therapy for BRAF V600E positive disease OR The member will be using as subsequent therapy after pembrolizumab and EGFR, ALK, BRAF V600E, and ROS-1 negative disease OR member has metastatic NSCLC, non- squamous histology with no EGFR or ALK genomic tumor aberrations AND Abraxane will be given combo with Tecentriq and carboplatin as first line therapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## ABRAXANE

Other Criteria	<p>Ovarian Cancer. The member has a diagnosis of epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer. The member meets one of the following criteria: Progressive, stable or persistent disease on primary chemotherapy OR Recurrent disease. The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications. Pancreatic Cancer: The member has a diagnosis of pancreatic cancer and Abraxane is being used in combination with gemcitabine as neoadjuvant therapy or The member has a diagnosis of metastatic pancreatic cancer AND The member will be using Abraxane in combination with gemcitabine. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member will be using Abraxane (nab-paclitaxel) as monotherapy AND The member will be using Abraxane (nab-paclitaxel) as second-line or subsequent therapy after progression on BRAF targeted therapy AND The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications.</p>
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## acitretin

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Pregnant or breastfeeding members, members with severe renal impairment or failure, members with severe hepatic dysfunction.
Required Medical Information	Member must have a diagnosis of severe cutaneous psoriasis including plaque, guttate, erythrodermic, palmar-plantar, and pustular types AND the member has had previous treatment, contraindication, or intolerance to methotrexate or cyclosporine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## ACTIMMUNE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Chronic Granulomatous Disease (CGD): The member has chronic granulomatous disease (CGD). The member is using Actimmune to reduce the frequency and severity of infections. Severe Malignant Osteopetrosis: The member has severe malignant osteopetrosis confirmed by biopsy. The member is using Actimmune to delay time to disease progression.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year
Other Criteria	NA

## acyclovir

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	The member must have a diagnosis of genital herpes OR member has a diagnosis of non-life-threatening mucocutaneous Herpes Simplex Virus (HSV) infection and is immunocompromised. The member has had previous treatment, contraindication, or intolerance with oral acyclovir and one of the following: valacyclovir or famciclovir.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## ADCETRIS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Adcetris.
Required Medical Information	<p>Hodgkin lymphoma. Diagnosis of relapsed or refractory Hodgkin lymphoma. The member has documented evidence of progression following an autologous stem cell transplant OR is not a candidate for an autologous stem cell transplant but documented evidence of progression on at least two previous multi-agent chemotherapy regimens OR the member will be using Adcetris (brentuximab) as palliative therapy for older adults (age greater than 60). The member will be using Adcetris as monotherapy or in combination with bendamustine. Systemic Anaplastic Large Cell Lymphoma (sALCL). Diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma. The member has documented evidence of progression on at least one prior multi-agent chemotherapy regimen The member will be using Adcetris (brentuximab vedotin) as monotherapy. Disease has confirmed CD30 positivity. Hodgkin Lymphoma Post-auto-HSCT Consolidation: The member has a diagnosis of classical Hodgkin lymphoma AND The member will be using Adcetris (brentuximab vedotin) as post-autologous hematopoietic stem cell transplant (HSCT) consolidation AND The member is at high risk of post-autologous HSCT relapse or progression (must meet at least one of the following criteria): Refractory disease to front-line therapy, Relapsed disease within 12 months to front-line therapy, Relapsed disease with extranodal disease to front-line therapy. Previously untreated Hodgkin lymphoma. The member has a diagnosis of stage III or IV classical Hodgkin lymphoma AND The member has previously untreated disease AND The member will be using Adcetris (brentuximab vedotin) in combination with doxorubicin, vinblastine, and dacarbazine.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL) or CD30-expressing Mycosis Fungoides (MF). The member has a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) AND The member has received at least one prior systemic therapy AND The member will be using Adcetris (brentuximab vedotin) as monotherapy.



## ADEMPAS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Chronic Thromboembolic Pulmonary Hypertension (CTEPH). The member must have a diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) AND The member must have CTEPH classified as inoperable or persistent/recurrent after surgical treatment (i.e. pulmonary endarterectomy). Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## AFINITOR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on everolimus.
Required Medical Information	Advanced Renal Cell Carcinoma (RCC). The member has a diagnosis of advanced /metastatic renal cell carcinoma (stage IV) AND the member experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome) AND Afinitor (everolimus) is given as monotherapy or being given in combination with Lenvima (lenvatinib). The member has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis AND The member requires therapeutic intervention but is not a candidate for curative surgical resection. Neuroendocrine Tumors: The member has disease that is unresectable, locally advanced or metastatic and one of the following applies: The member has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) OR The member has a diagnosis of progressive, well differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. The member has a diagnosis of recurrent or not responsive to primary treatment or relapsed Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma AND Afinitor (everolimus) will be used as monotherapy.
Age Restriction	TSC associated partial onset seizures: Member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## AFINITOR

Other Criteria	Angiomyolipoma and Tuberous Sclerosis Complex (TSC).The member has a diagnosis of renal angiomyolipoma and tuberous sclerosis complex AND Immediate surgery is not required. Metastatic Breast Cancer. The member has a diagnosis of hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic disease AND the member has been treated with endocrine therapy (e.g. letrozole, anastrozole) within one year AND The member will use Afinitor (everolimus) in combination with exemestane or fulvestrant (Faslodex). Tuberous sclerosis complex (TSC)- associated partial onset seizures [Adults and Pediatrics]: The member has diagnosis of TSC- associated partial onset seizures AND Afinitor Disperz (everolimus tablets for oral solution) is being used as adjunctive therapy.
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## AFINITOR DISPERZ

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on everolimus.
Required Medical Information	Advanced Renal Cell Carcinoma (RCC). The member has a diagnosis of advanced /metastatic renal cell carcinoma (stage IV) AND the member experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome) AND Afinitor (everolimus) is given as monotherapy or being given in combination with Lenvima (lenvatinib). The member has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis AND The member requires therapeutic intervention but is not a candidate for curative surgical resection. Neuroendocrine Tumors: The member has disease that is unresectable, locally advanced or metastatic and one of the following applies: The member has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) OR The member has a diagnosis of progressive, well differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. The member has a diagnosis of recurrent or not responsive to primary treatment or relapsed Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma AND Afinitor (everolimus) will be used as monotherapy.
Age Restriction	TSC associated partial onset seizures: Member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## AFINITOR DISPERZ

Other Criteria	Angiomyolipoma and Tuberous Sclerosis Complex (TSC).The member has a diagnosis of renal angiomyolipoma and tuberous sclerosis complex AND Immediate surgery is not required. Metastatic Breast Cancer. The member has a diagnosis of hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic disease AND the member has been treated with endocrine therapy (e.g. letrozole, anastrozole) within one year AND The member will use Afinitor (everolimus) in combination with exemestane or fulvestrant (Faslodex). Tuberous sclerosis complex (TSC)- associated partial onset seizures [Adults and Pediatrics]: The member has diagnosis of TSC- associated partial onset seizures AND Afinitor Disperz (everolimus tablets for oral solution) is being used as adjunctive therapy.
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## AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Episodic or Chronic Migraine. Initial therapy: The member has documented history of greater than or equal to 4 migraine days per month AND the member has been unable to achieve at least a 2 day reduction in migraine headache days per month after previous treatment (of at least 2 months) with one of the following oral preventative medications: Divaproex, Topiramate, Metoprolol, Propranolol, or Timolol. Reauthorization: The member has experienced a positive clinical response (e.g. sustained decrease in migraine days per month).
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 3 months. Reauth: Plan Year Duration.
Other Criteria	NA

## ALECENSA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on Alecensa (alectinib).
Required Medical Information	Non-small Cell Lung Cancer:The member has recurrent or metastatic non-small cell lung cancer AND The member has documented anaplastic lymphoma kinase (ALK)-positive disease AND The member will be using Alecensa (alectinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## ALIMTA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR pemetrexed is being used as a single agent after prior chemotherapy. Pemetrexed is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with pemetrexed OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration



## ALIMTA

Other Criteria	<p>Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.</p>
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## ALIQOPA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib)
Required Medical Information	Follicular Lymphoma: The member has a diagnosis of follicular lymphoma AND The member has relapsed, refractory, or progressive disease AND The member has received at least two prior systemic therapies AND The member will be using Aliqopa as monotherapy
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## alosetron

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Should not be initiated in members with constipation OR with anatomic or biochemical abnormalities of the gastrointestinal tract OR Members with a history of chronic or severe constipation or with a history of sequelae from constipation OR History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions OR History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state OR Current or history of Crohn's disease or ulcerative colitis OR Active diverticulitis or a history of diverticulitis OR Patients with severe hepatic impairment.
Required Medical Information	The member has a diagnosis of severe diarrhea-predominant irritable bowel syndrome AND has chronic IBS symptoms (lasting 6 months or longer) AND the member has had previous treatment, contraindication, or intolerance to one antidiarrheal agent (e.g. loperamide) and one antispasmodic agent (e.g. dicyclomine). Reauthorization criteria: In addition to the above clinical criteria, the member must have a positive clinical response from alosetron HCl.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ALUNBRIG

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant ALK inhibitors (e.g., Zykadia [certinib], Alecensa [alectinib]). Members experience disease progression on Alunbrig (brigatinib).
Required Medical Information	Non-Small cell lung cancer: The member has a diagnosis of advanced or metastatic NSCLC with documented anaplastic lymphoma kinase (ALK) positivity AND Alunbrig will be given as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## alyq

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ambrisentan

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has a diagnosis of idiopathic pulmonary fibrosis.
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## APTOM

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use of oxcarbazepine
Required Medical Information	Partial-Onset Seizures. Diagnosis of partial-onset seizures. Prior therapy with, contraindication, or intolerance to at least two other drugs for controlling partial-onset seizures (e.g. carbamazepine, lamotrigine, levetiracetam, topiramate). Inadequately controlled seizures.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome: The member has a diagnosis of Cryopyrin-Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). Recurrent Pericarditis: Member has a diagnosis of recurrent pericarditis defined by: presentation of symptoms of acute pericarditis after a symptom-free interval of at least 4 weeks. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) The member has a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA).
<b>Age Restriction</b>	Member must be 12 years of age or older for Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Recurrent Pericarditis indications. Age restriction does not apply to DIRA.
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	



## arformoterol

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Asthma, in the absence of concurrent medication containing inhaled corticosteroid and comorbid COPD diagnosis.
Required Medical Information	Maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disease (COPD),including chronic bronchitis and emphysema. The member has a diagnosis of COPD. The member must have previous treatment with contraindication or intolerance with Perforomist (formoterol).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## arsenic trioxide

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Acute Promyelocytic Leukemia (APL). The member has a diagnosis of acute promyelocytic leukemia AND the member will be using Trisenox (arsenic trioxide) for induction therapy, consolidation therapy, or relapsed disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## ARZERRA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Arzerra/ofatumumab will require prior authorization. For new starts only. This agent may be considered medically necessary when the following criteria are met: The patient has a diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia (CLL). Chronic Lymphocytic Leukemia (CLL) Previously Untreated: The member has a diagnosis of chronic lymphocytic leukemia AND The member has not previously received treatment for CLL AND one of the following applies: The member may use in combination with chlorambucil when fludarabine-based therapy is not appropriate OR the member will be using in combination with bendamustine. CLL: Chronic Lymphocytic Leukemia, Extended Treatment: The member has a diagnosis of recurrent or progressive chronic lymphocytic leukemia AND The member is in complete or partial response after at least two lines of therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## asenapine maleate

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Schizophrenia/Bipolar I Disorder, manic or mixed episodes. The member must be utilizing asenapine for treatment of schizophrenia or bipolar I disorder. The member must have prior therapy or intolerance or contraindication to at least two of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## ASPARLAS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on or following Asparlas (calaspargase pegol-mknl). Members with a history of serious thrombosis with prior asparaginase therapy. Members with a history of pancreatitis with prior asparaginase therapy. Members with a history of serious hemorrhagic events with prior asparaginase therapy. Members with total bilirubin more than 10 times the upper limit of normal.
Required Medical Information	Acute Lymphoblastic Leukemia (ALL): The member has a diagnosis of acute lymphoblastic leukemia (ALL) AND The member will be using Asparlas (calaspargase pegol-mknl) as a component of a multi-agent chemotherapy regimen.
Age Restriction	The age of the member is less than or equal to 21 years.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## AUGMENTIN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Member must have a previous treatment, intolerance or contraindication to an AB-rated generic equivalent product.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	plan year
Other Criteria	NA

# AUSTEDO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Initial Therapy - TD: The member is utilizing Austedo (deutetrabenazine) for the treatment of tardive dyskinesia that is associated with the use of dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) OR Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member is utilizing Austedo (deutetrabenazine) for the treatment of TD that is not associated with other medication therapies (e.g. dopamine receptor-blocking agents). AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks. Continuation- TD: The member has a documented improvement or maintenance of symptoms while on Austedo (deutetrabenazine) (e.g. reduction in Abnormal Involuntary Movement Scale [AIMS] score or Dyskinesia Identification System: Condensed User Scale [DISCUS] from baseline) AND the provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks. Initial Therapy - Chorea with HD: Diagnosis of chorea associated with Huntington's disease AND Inadequate symptom control (e.g. no improvement in total maximal chorea [TMC] score, no improvement in overall motor function) on previous treatment with tetrabenazine therapy or intolerance to tetrabenazine AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks. Continuation - Chorea with HD: The member has a documented improvement or maintenance of symptoms (e.g. reduction in total maximal chorea [TMC] score, improvement in overall motor function) with Austedo (deutetrabenazine) AND the provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks.</p>
Age Restriction	Member is 18 years of age or older (Tardive Dyskinesia).
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 3 months, Reauthorization: Plan Year Duration
Other Criteria	

## AUVELITY

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review



## AVASTIN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Used in lung cancer members that have small cell or squamous cell disease, recent hemoptysis, history of bleeding, continuing anticoagulation, or as a single agent (unless maintenance as described in Coverage Determinations). Should not be initiated in members with recent hemoptysis. Should not be used in members who experience a severe arterial thromboembolic event. Should not be used in members with gastrointestinal perforation. Bevacizumab should not be used in members with fistula formation involving internal organs. Bevacizumab should not be used in members experiencing a hypertensive crisis or hypertensive encephalopathy. Bevacizumab should not be used for at least 28 days following major surgery or until surgical incision is fully healed. Bevacizumab may not be used in conjunction with Vectibix. Bevacizumab may not be used in conjunction with Erbitux. Bevacizumab may not be used in the adjuvant or neoadjuvant setting (except in epithelial ovarian, fallopian tube, or primary peritoneal cancer adjuvant setting). Bevacizumab should not be continued or restarted after disease progression with the exception of metastatic colorectal cancer.

## AVASTIN

<b>Required Medical Information</b>	<p>Alymsys (bevacizumab-maly) oncology requests: must have an intolerance or contraindication with Avastin, Mvasi, or Zirabev and meet criteria below. Metastatic colorectal cancer: Diagnosis of metastatic colorectal cancer AND 1 of the following apply: bevacizumab in combo with fluoropyrimidine (e.g., 5-fluorouracil or capecitabine) based chemo for 1st or 2nd-line therapy OR combo with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemo for 2nd-line therapy in patients who have progressed on 1st-line bevacizumab-containing regimens. Non-small cell lung cancer (non-squamous cell histology). NSCLC with non-squamous cell histology AND using bevacizumab in combo with cisplatin or carboplatin based regimens for unresectable, locally advanced, recurrent, or metastatic NSCLC AND 1 of the following apply: using for 1st line therapy OR as subsequent therapy immediately after 1 of the following situations: EGFR mutation-positive tumors after prior therapy (e.g., erlotinib, afatinib) [if cytotoxic therapy not previously given] OR ALK-positive tumors after prior therapy (e.g., crizotinib, brigatinib) [if cytotoxic therapy not previously given] OR ROS-1 positive disease after prior therapy (e.g., crizotinib) [if cytotoxic therapy not previously given] OR Pembrolizumab (with PD-L1 expression of greater than 1%) administered as 1st line therapy and EGFR, ALK, BRAF V600E, and ROS1 negative tumors (if cytotoxic therapy not previously given) OR has BRAF V600E positive disease (if cytotoxic therapy not previously given) OR as single-agent continuation maintenance therapy if bevacizumab was used as 1st line treatment for recurrence or metastasis OR has disease with no EGFR or ALK genomic tumor aberrations AND will be given in combo with carboplatin and paclitaxel and Tecentriq as 1st line therapy followed by maintenance therapy with Tecentriq and bevacizumab. Hepatocellular carcinoma: unresectable or metastatic HCC AND used as 1st line therapy in combo with Tecentriq.</p>
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 Months Duration. Ocular indications: Plan Year Duration

## AVASTIN

Other Criteria	<p>Metastatic breast cancer (Effectiveness based on improvement in progression-free survival. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab). Member has metastatic HER-2 negative breast cancer AND is using bevacizumab in combo with paclitaxel. Recurrent Ovarian Cancer. Bevacizumab is being used to treat recurrent or persistent ovarian cancer for 1 of the following situations: in combo with liposomal doxorubicin or weekly paclitaxel or topotecan for platinum resistant disease or as monotherapy or in combo with carboplatin and gemcitabine for platinum sensitive disease. Stage IV/Metastatic (Unresectable) RCC. Member has RCC and is using bevacizumab to treat stage IV unresectable kidney cancer in combo with interferon alpha OR is using bevacizumab as systemic therapy for non-clear cell histology. Recurrent Primary CNS Tumor (including Glioblastoma multiforme). Diagnosis of progressive or recurrent glioblastoma or anaplastic glioma AND Bevacizumab is being used as a single agent or in combo with irinotecan, carmustine, lomustine or temozolomide. Member does not have a CNS hemorrhage. Soft Tissue Sarcoma. Diagnosis of angiosarcoma and bevacizumab is being used as a single agent OR member has a diagnosis of solitary fibrous tumor and hemangiopericytoma and bevacizumab is being used in combo with temozolomide. Macular Retinal Edema. Avastin is being used to treat central or branch retinal vein occlusion with macular retinal edema. Cervical Cancer: member has recurrent, or metastatic cervical cancer AND Bevacizumab will be used in combo (if not previously used as first line therapy) with paclitaxel and cisplatin or carboplatin and paclitaxel or paclitaxel and topotecan as first line therapy. Endometrial Cancer: progressive endometrial cancer AND Bevacizumab will be used as a single-agent. Malignant Pleural Mesothelioma. Diagnosis of unresectable malignant pleural mesothelioma and bevacizumab will be used in combo with cisplatin and pemetrexed followed by bevacizumab monotherapy for maintenance therapy (for responders). Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer AND has Stage III or IV disease AND bevacizumab is initially being given in combo with carboplatin and paclitaxel after initial surgical resection followed by bevacizumab monotherapy OR advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability as defined by FDA approved test AND Member is in complete response or partial response to 1st line treatment with platinum-based chemo AND Bevacizumab is given in combo with Lynparza. Age Related Macular Degeneration (Avastin requests only). Diabetic Macular Edema (Avastin requests only).</p>
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## AYVAKIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Ayvakit (avapritinib).
Required Medical Information	Gastrointestinal Stromal tumor. The member has documented PDGFRA exon 18 mutation-positive unresectable or metastatic gastrointestinal stromal tumor (including PDGFRA D842V) AND Ayvakit (avapritinib) will be given as monotherapy. Advanced systemic mastocytosis: The member has a diagnosis of advanced systemic mastocytosis (AdvSM), including systemic mastocytosis with an associated hematological neoplasm and mast cell leukemia AND Ayvakit is not recommended for the treatment of members with AdvSM with platelet counts of less than $50 \times 10^9 /L$ AND Ayvakit (avapritinib) is administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	

## azacitidine

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with hypomethylators (e.g. azacitidine, decitabine) . Applies to azacitidine only: the member must not have a diagnosis of advanced malignant hepatic tumors.
Required Medical Information	Myelodysplastic Syndromes. The member has a diagnosis of myelodysplastic syndrome AND For requests for decitabine, the member has contraindication to, intolerance to, or unable to achieve treatment goals with azacitidine AND one of the following scenarios apply: The member has a Revised International Prognostic Scoring System (IPSS-R) of higher risk disease (i.e. intermediate, high, very high) OR The member has a Revised International Prognostic Scoring System (IPSS-R) of lower risk disease (i.e. very low, low, or intermediate) AND one of the following sets of criteria applies: Clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts OR Member has symptomatic anemia AND No 5q deletion AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND Serum erythropoietin levels less than or equal to 500 mU/mL AND An inadequate response to erythropoietins alone or in combination with Revlimid (lenalidomide) AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND 5q deletion AND An inadequate response or intolerance to Revlimid (lenalidomide) AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy. Myeloproliferative Neoplasms: The member has a diagnosis of myelofibrosis (MF)-accelerated phase or MF-blast phase/acute myeloid leukemia. Acute Myelogenous Leukemia (AML). The member has a diagnosis of AML.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## BALVERSA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Urothelial Cancer: The member has a diagnosis of locally advanced or metastatic urothelial carcinoma AND the member has identification of a susceptible FGFR3 or FGFR2 genetic alteration documented in the medical record [e.g., FGFR3 gene mutations (R284C, S249C, G370C, Y373C), FGFR gene fusions (FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7) AND the member will be using Balversa (erdafitinib) as a single agent for subsequent therapy after disease progression during or following at least one prior line of platinum-containing systemic chemotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## BAVENCIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	NA
<b>Exclusion Criteria</b>	The member has experienced disease progression on Bavencio (avelumab). The member has experienced disease progression while on or following PD-1/PD-L1 therapy (e.g Keytruda, Opdivo, Tecentriq, Imfinzi). The member has experienced disease progression while on or following Yervoy.
<b>Required Medical Information</b>	Merkel Cell Carcinoma (Adults). The member has a diagnosis of metastatic Merkel cell carcinoma AND Member will be using Bavencio as monotherapy. Merkel Cell Carcinoma (Pediatrics). The member has a diagnosis of metastatic Merkel cell carcinoma AND Member will be using Bavencio as monotherapy. Urothelial Cancer. The member has a diagnosis of locally advanced or metastatic urothelial cancer AND the member will be using Bavencio (avelumab) as monotherapy AND One of the following apply: The member will be using Bavencio (avelumab) as second or subsequent line systemic therapy OR the member has had disease progression within 12 months of neoadjuvant or adjuvant chemotherapy OR The member will be using Bavencio (avelumab) as maintenance treatment if there is no disease progression with first-line platinum-containing chemotherapy. Renal Cell Carcinoma. The member has a diagnosis of advanced or metastatic renal cell carcinoma AND Bavencio (avelumab) will be given in combination with Inlyta (axitinib) as first-line therapy.
<b>Age Restriction</b>	Pediatric Merkel Cell Carcinoma - member must be 12 years of age or older.
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 months duration
<b>Other Criteria</b>	NA

## BELEODAQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	Members that have experienced disease progression while on Beleodaq (belinostat). Members on concomitant Istodax (romidepsin), Zolinza (vorinostat), or Folutyn (pralatrexate) therapy.
<b>Required Medical Information</b>	Peripheral T-Cell Lymphoma (PTCL). The member must have a diagnosis of relapsed OR refractory peripheral T-cell lymphoma (PTCL).
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	six month duration
<b>Other Criteria</b>	NA



## BENDEKA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who experience disease progression on bendamustine containing regimens.
Required Medical Information	Chronic Lymphocytic Leukemia (CLL). The member has a diagnosis of CLL without del(17p)/TP53 mutation and with or without del(11q) AND bendamustine is being used for relapsed or refractory disease or as first line therapy. Multiple Myeloma (MM). The member has a diagnosis of MM AND bendamustine is being used for disease relapse or for progressive or refractory disease. Non-Hodgkin's Lymphoma: The member has a diagnosis of follicular lymphoma, gastric MALT lymphoma or nongastric MALT lymphoma and is using Bendamustine. The member has a diagnosis of mantle cell lymphoma and bendamustine is being used as one of the following: Less aggressive induction therapy OR Second-line therapy for relapsed, refractory or progressive disease. The member has a diagnosis of primary cutaneous B-cell lymphoma (primary cutaneous marginal zone or follicle center B-cell lymphoma) and bendamustine is being used as a single agent or in combination with rituximab in one of the following: Refractory generalized cutaneous disease OR generalized extracutaneous disease as initial therapy or for relapse. The member has a diagnosis of splenic marginal zone lymphoma and bendamustine is being used as one of the following: First-line therapy for disease progression following initial treatment for splenomegaly OR Second-line or subsequent therapy for progressive disease. The member has a diagnosis of diffuse large B-cell lymphoma and bendamustine is being used as second-line therapy or subsequent therapy .The member has a diagnosis of AIDS-related B-cell lymphoma and bendamustine is being used as second-line therapy or subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration.
Other Criteria	Waldenström's Macroglobulinemia:The member has Waldenström's macroglobulinemia or lymphoplasmacytic lymphoma and bendamustine is being used as one of the following: Primary therapy OR Progressive or relapsed disease. Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND bendamustine will be used as subsequent therapy for relapsed or refractory disease.

# BENLYSTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	Severe active central nervous system lupus.
<b>Required Medical Information</b>	Systemic Lupus Erythematosus (SLE). The member must have a diagnosis of active systemic lupus erythematosus (SLE). The member must be auto-antibody positive in the absence of any drugs for SLE defined as: ANA titer greater than or equal 1:80 or anti-dsDNA level greater than or equal 30 I/mL. The member must be utilizing Benlysta (belimumab) in combination with standard treatment regimens for SLE which may include: corticosteroids (e.g. prednisone), hydroxychloroquine, azathioprine. Lupus Nephritis: The member must have a diagnosis of active lupus nephritis AND the member must be utilizing Benlysta in combination with standard therapy (e.g. corticosteroids with mycophenolate or cyclophosphamide).
<b>Age Restriction</b>	Lupus Nephritis: The member is 5 years of age or older.
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	

## BESPONSA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Besponsa (inotuzumab ozogamicin)
Required Medical Information	Acute Lymphoblastic Leukemia: The member has a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL)AND The member has relapsed or refractory disease AND The member has documented CD22 blasts found in bone marrow or peripheral blood AND The member will be using Besponsa (inotuzumab ozogamicin) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Six month durations (up to a maximum of 6 cycles)
Other Criteria	NA

## BETASERON

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## bexarotene

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that are pregnant. Members on concomitant retinoid therapy.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Targretin (bexarotene) capsules). The member will be using Targretin as primary treatment OR Member has experienced disease progression, contraindication, or intolerance to at least one prior systemic therapy for cutaneous manifestations of cutaneous T-cell lymphoma. Cutaneous T-cell Lymphoma. Targretin (bexarotene) 1% topical gel/jelly). The member will be using Targretin as primary treatment OR Member has experienced disease progression, contraindications, or intolerance to at least one prior CTCL therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## BLENREP

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on anti-BCMA-directed therapy.
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has relapsed/refractory disease AND The member has received at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib), and an immunomodulatory agent (e.g. lenalidomide) AND The member is using Blenrep (belantamab mafodotin-blmf) as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## bortezomib

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on bortezomib.
Required Medical Information	Mantle Cell Lymphoma (MCL): The member has a diagnosis of Mantle Cell Lymphoma(MCL). Multiple Myeloma. The member has a diagnosis of Multiple Myeloma. Waldenström's Macroglobulinemia. The member has a diagnosis of Waldenström's macroglobulinemia AND Velcade (bortezomib) is being used for primary therapy, progressive or relapsed disease or salvage therapy for disease that does not respond to primary therapy AND Velcade (bortezomib) is being used as monotherapy, in combination with Dexamethasone, or in combination with a rituximab product. For brand Velcade intravenous requests, the member will need to have documented failure and/or intolerance to generic bortezomib intravenous (applies to Part B requests only).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## bosentan

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## BOSULIF

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Bosulif (bosutinib). The member has one of the following mutations: T315I, V299L, G250E, or F317L.
Required Medical Information	Chronic Myelogenous Leukemia. The member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (CML) AND One of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated and one of the following applies: Intermediate- or high-risk score for disease progression OR Low risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The member has a diagnosis of chronic phase CML that has received previous treatment AND Low-, intermediate-, or high-risk score for disease progression.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## BRAFTOVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Tafenlar (dabrafenib), or Mekinist (trametinib) OR Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafenlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma - Unresectable or metastatic. The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib). Colorectal Cancer - [Braftovi (encorafenib) requests only]: The member has documented BRAFV600E metastatic metastatic colorectal cancer and progressive disease on prior therapy AND Braftovi (encorafenib) is given in combination with Erbitux (cetuximab).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month durations or as determined through clinical review
Other Criteria	NA

## BRIVIACT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-onset seizures. Member must have a diagnosis of partial-onset seizures. Member has had prior therapy with levetiracetam AND one of the following: topiramate, carbamazepine, gabapentin, divalproex, or lamotrigine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## BROVANA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Asthma, in the absence of concurrent medication containing inhaled corticosteroid and comorbid COPD diagnosis.
Required Medical Information	Maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The member has a diagnosis of COPD. The member must have previous treatment with contraindication or intolerance with Perforomist (formoterol).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## BRUKINSA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a BTK inhibitor (e.g. ibrutinib, acalabrutinib, zanabrutinib).
Required Medical Information	Mantle cell lymphoma: The member has a diagnosis of mantle cell lymphoma AND The member has received at least one prior therapy AND The member will be using Brukinsa (zanabrutinib) as monotherapy. Marginal Zone Lymphoma: The member has a diagnosis of marginal zone lymphoma (MZL) AND The member is using Brukinsa (zanubrutinib) as second line or subsequent for refractory or progressive disease AND The member has received at least one regimen containing anti-CD20 product (e.g. rituximab product) AND The member has a medical reason as to why Imbruvica (ibrutinib) cannot be started or continued AND The member will be using Brukinsa (zanubrutinib) as monotherapy. Waldenström's Macroglobulinemia: The member has a diagnosis of Waldenström's macroglobulinemia (WM) AND the member will be using Brukinsa (zanubrutinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	

## budesonide

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Mild to moderate active Crohn's disease: The member must have a diagnosis of mild to moderate active Crohn's disease. Autoimmune hepatitis: Member must have a diagnosis of autoimmune hepatitis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CABLIVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Acquired Thrombotic Thrombocytopenic Purpura: Member has a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) AND member has achieved a normalized platelet count following plasma exchange (PEX) in combination with Cablivi (caplacizumab-yhdp) and immunosuppressive therapy (e.g. rituximab) during inpatient treatment of TTP. Reauthorization: member continues to have evidence of ongoing disease (e.g. suppressed or unstable ADAMTS13 levels) AND member is still currently receiving therapy AND member has had 2 or fewer recurrences while actively receiving Cablivi.
Age Restriction	Member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 months duration
Other Criteria	NA

## CABOMETYX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on cabozantinib.
Required Medical Information	Renal cell carcinoma: The member has advanced renal cell carcinoma AND one of the following applies: the member will be using Cabometyx (cabozantinib) as monotherapy OR the member will be using Cabometyx (cabozantinib) in combination with Opdivo (nivolumab) as first line therapy. Hepatocellular carcinoma. The member has a diagnosis of hepatocellular carcinoma AND The member has been previously treated with a first line therapy (e.g., sorafenib) AND Cabometyx (cabozantinib) will be given as monotherapy. Thyroid Cancer: The member has a diagnosis of locally advanced or metastatic differentiated thyroid cancer AND Member has experienced disease progression following prior anti-VEGF targeted therapy AND Member is radioactive iodine refractory or ineligible AND Cabometyx (cabozantinib) will be administered as monotherapy.
Age Restriction	Thyroid Cancer: Member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	



## calcipotriene

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Psoriasis: The member must have a diagnosis of plaque psoriasis AND has had previous treatment, contraindication or intolerance with topical triamcinolone 0.5% AND topical betamethasone dipropionate.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CALQUENCE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on or following Calquence (acalabrutinib).
Required Medical Information	Mantle Cell Lymphoma: The member had a diagnosis of mantle cell lymphoma AND the member has received at least one prior therapy AND the member will be using Calquence (acalabrutinib) as monotherapy. Chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL): member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on or following Calquence (acalabrutinib).
Required Medical Information	Mantle Cell Lymphoma: The member had a diagnosis of mantle cell lymphoma AND the member has received at least one prior therapy AND the member will be using Calquence (acalabrutinib) as monotherapy. Chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL): member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CAMZYOS

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review

## CAPLYTA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Schizophrenia. The member must have a diagnosis of schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to at least two of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole. Bipolar I or II Disorder (Dipolar Depression): The member must have a diagnosis of bipolar I or II disorder (bipolar depression) AND the member must have documentation of prior therapy, intolerance, or contraindication to quetiapine and at least one of the following: risperidone, olanzapine, ziprasidone, or aripiprazole.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## CAPRELSA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Vandetanib.
Required Medical Information	Thyroid Cancer. The member has a diagnosis of locally advanced or metastatic medullary thyroid cancer AND The member has symptomatic or progressive disease OR the member has a diagnosis of symptomatic iodine refractory follicular carcinoma or Hurthle cell carcinoma or papillary carcinoma AND unresectable recurrent or persistent locoregional disease or metastatic disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 months duration
Other Criteria	NA

## CARBAGLU

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The member has acute or chronic hyperammonemia due to deficiency of hepatic enzyme N-acetylglutamate synthase (NAGS). Acute hyperammonemia due to PAA or MMA deficiency: the member has acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	

## carglumic acid

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has acute or chronic hyperammonemia due to deficiency of hepatic enzyme N-acetylglutamate synthase (NAGS). Acute hyperammonemia due to PAA or MMA deficiency: the member has acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## CAYSTON

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients with a forced expiratory volume in one second (FEV1) less than 25% or greater than 75% predicted. Patients colonized with Burkholderia cepacia.
Required Medical Information	Cystic Fibrosis. The member must have a diagnosis of cystic fibrosis (CF). The member is colonized with Pseudomonas aeruginosa. The member must have a short or long-acting beta-agonist bronchodilator (e.g. albuterol or formoterol), and will be utilized prior to Cayston.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year duration
Other Criteria	

## CERDELGA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concurrent use of a strong or moderate CYP2D6 inhibitor (eg. paroxetine, terbinafine) and a strong or moderate CYP3A inhibitor (eg. ketoconazole, fluconazole) in patients who are EMs or IMs. Concurrent use of a strong CYP3A inhibitor in patients who are IMs or PMs (eg. ketoconazole).
Required Medical Information	Type 1 Gaucher's disease: The member has a diagnosis of type 1 Gaucher's disease AND Member is a CYP2D6 poor metabolizer (PM), extensive metabolizer (EM), or intermediate metabolizer (IM) as confirmed by an FDA-approved genetic test.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CEREZYME

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Cerezyme (imiglucerase) will require prior authorization. These agents may be considered medically necessary when the following criteria are met: Confirmed diagnosis of Type 1 Gaucher disease, resulting in one or more of the following conditions: Anemia, Thrombocytopenia, Bone disease, Hepatomegaly, Splenomegaly.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CHENODAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	A nonvisualizing gallbladder confirmed by two consecutive single doses of dye OR Radiopaque (calcified) stones OR Pregnancy OR Patients with known hepatocyte dysfunction OR Patients with biliary tract disease including bile ductal abnormalities such as intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis OR Patients with gallstone complications or gallbladder disease necessitating surgery due to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-GI fistula.
Required Medical Information	The member has a diagnosis of radiolucent gallstones in well-opacifying gallbladders AND the member is not a candidate for laparoscopic cholecystectomy AND the member must have had previous treatment with, contraindication, or intolerance to ursodiol.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## CHOLBAM

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	<p>Bile acid synthesis disorders due to single enzyme defects initial review: The member must have a diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects confirmed by Fast Atom Bombardment Ionization analysis (FAB-MS) (e.g. 3<math>\beta</math>-hydroxy-<math>\Delta</math>5-C27-steroid oxidoreductase (3<math>\beta</math>-HSD) deficiency, <math>\Delta</math>4-3-oxosteroid 5<math>\beta</math>-reductase (AKR1D1) deficiency, cerebrotendinous xanthomatosis (CTX), or 2-[or a-] methylacyl-CoA racemase (AMACR) deficiency). Adjunctive treatment of peroxisomal disorders: The member must have a diagnosis of a peroxisomal disorder (PD) confirmed by Fast Atom Bombardment Ionization analysis (FAB-MS), including: Zellweger Syndrome or Neonatal Adrenoleukodystrophy or Generalized Peroxisomal Disorder or Refsum Disease or Peroxisomal disorder of unknown type) AND The member must have signs and symptoms of liver disease (e.g. jaundice, hepatomegaly, dark urine, discolored stools), steatorrhea or complications from decreased fat soluble vitamin absorption. Continuation of therapy: The member must show improvement in liver function within 3 months of the start of treatment without complete biliary obstruction: Alanine transaminase (ALT) or aspartate transaminase (AST) values reduced to less than 50 U/L or baseline levels reduced by 80% AND Total bilirubin values reduced to less than or equal to 1 mg/dL.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 3 months. Continuation of Therapy: Plan Year Duration.
Other Criteria	NA

## CHORIONIC GONADOTROPIN, HUMAN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Obesity, Female or male infertility, Erectile Dysfunction, Precocious puberty, Prostatic carcinoma or other androgen-dependent neoplasm.
Required Medical Information	NA
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## CLINDAGEL

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member has a diagnosis of acne vulgaris AND has had previous treatment or intolerance with two of the following topical products: adapalene gel, clindamycin gel (generic Ceocin-T gel)/ lotion/solution/pledgets* or erythromycin solution. *Clindamycin gel/lotion/solution have additional prior authorization requirements.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## clindamycin phosphate

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member has a diagnosis of acne vulgaris AND has had previous treatment or intolerance with two of the following topical products: adapalene gel, clindamycin gel (generic Ceocin-T gel)/ lotion/solution/pledgets* or erythromycin solution. *Clindamycin gel/lotion/solution have additional prior authorization requirements.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## clobazam

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Lennox-Gastaut Syndrome. Member has diagnosis of seizures associated with LGS.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## clozapine

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	The member must be using clozapine orally disintegrating tablet for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## COMETRIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	The member has experienced disease progression while on Cometriq (cabozantinib). Members on concomitant tyrosine kinase inhibitors.
<b>Required Medical Information</b>	Metastatic Medullary Thyroid Carcinoma. The member has a diagnosis of progressive, metastatic medullary thyroid carcinoma MTC.
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	six month duration
<b>Other Criteria</b>	NA

## CONTRAVE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Weight Management: Upon initiation of treatment with obesity medication, Body Mass Index (BMI) is at Least 30 kg/m <sup>2</sup> (obese) OR 27 kg/m <sup>2</sup> (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes). Member will be evaluated by prescribing physician to determine if at least 5% of baseline body weight has been lost at 12 weeks and at least every 6 months thereafter for continued treatment with obesity medication.
Age Restriction	18 years or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## COPAXONE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## COPIKTRA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib, duvelisib).
Required Medical Information	Chronic lymphocytic leukemia. The member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) AND the member has relapsed or refractory disease AND The member will be using Copiktra (duvelisib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration.
Other Criteria	

## CORLANOR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Heart rate maintained exclusively by pacemaker.
Required Medical Information	<p>Heart Failure (Adult Patients): The member must meet ALL of the following criteria: have a diagnosis of NYHA Class II, III, or IV heart failure AND Documentation of left ventricular ejection fraction less than or equal to 35% AND The member must be in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute AND Documentation of blood pressure greater than or equal to 90/50 mmHg AND Documentation of previous treatment, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker (e.g., carvedilol 50 mg daily, metoprolol 200 mg daily, or bisoprolol 10 mg daily) AND In patients with Severe Hepatic Impairment (Child-Pugh Class C) - Provider attests that the risk versus benefit of severe hypotension has been considered, and the benefits of treatment outweigh the risks.</p> <p>Heart Failure (Pediatric Patients) The member must meet ALL of the following criteria: The member must have a diagnosis of NYHA Class II, III, or IV heart failure AND Documentation of left ventricular ejection fraction less than or equal to 45% AND The member has been clinically stable for at least 4 weeks and on optimized medical therapy AND The member is in sinus rhythm AND In patients with Severe Hepatic Impairment (Child-Pugh Class C) - Provider attests that the risk versus benefit of severe hypotension has been considered, and the benefits of treatment outweigh the risks AND One of the following: The member is 6 to 12 months of age and has a resting heart rate of greater than or equal to 105 beats per minute OR The member is 1 to less than 3 years of age and has a resting heart rate of greater than or equal to 95 beats per minute OR The member is 3 to less than 5 years of age and has a resting heart rate of greater than or equal to 75 beats per minute OR The member is greater than 5 years of age and has a resting heart rate of greater than or equal to 70 beats per minute.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Reauthorization Criteria (Adult and Pediatric Patients): Member has continued clinical benefit from Corlanor (ivabradine) as defined by maintenance of decreased Heart rate compared to initiation of Corlanor treatment.

# COSENTYX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication to all DMARDs. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis-related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen).
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, and Non-radiographic axial spondyloarthritis: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis-related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	



## COSENTYX (2 SYRINGES)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication to all DMARDs. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis-related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen).
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, and Non-radiographic axial spondyloarthritis: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis-related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## COSENTYX PEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication to all DMARDs. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis-related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen).
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, and Non-radiographic axial spondyloarthritis: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis-related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## COSENTYX PEN (2 PENS)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication to all DMARDs. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis-related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen).
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, and Non-radiographic axial spondyloarthritis: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis-related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## COTELLIC

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on Cotellic as a single agent. Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Tafinlar (dabrafenib), Mekinist (trametinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Cotellic. Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## CRESEMBA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Familial short QT syndrome.
Required Medical Information	Invasive Aspergillosis and Invasive Mucormycosis: Member must have diagnosis of invasive aspergillosis or invasive mucormycosis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# CRYSVITA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Oral phosphate within one week of starting Crysvida (burosumab) therapy. Vitamin D analogs within one week of starting Crysvida therapy. Serum phosphorus levels within or above normal range for age. Severe renal impairment or end stage renal disease.
Required Medical Information	X-Linked Hypophosphatemia (XLH) Initial approval: Member must have diagnosis of XLH supported by both of the following: Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL OR a positive PHEX test AND a reduction in the ratio of the maximum rate of tubular phosphate reabsorption to the glomerular filtration rate (TmP/GFR). Member must have clinical signs and symptoms of XLH (e.g. rickets, growth impairment, musculoskeletal pain, fractures). Continuation of therapy: Member must have been previously treated with Crysvida (burosumab). Member has experienced improvement in serum phosphorous concentrations while on Crysvida therapy. Member has experienced a positive clinical response (e.g. reduction in musculoskeletal pain, improvement in skeletal deformities, reduction in fractures, linear growth). Tumor-Induced Osteomalacia (TIO) - Initial Approval: The member must have a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia supported by BOTH of the following: Serum fibroblast growth factor 23 (FGF23) level of greater than 30 pg/mL AND A reduction in the ratio of the maximum rate of tubular phosphate reabsorption to the glomerular filtration rate (TmP/GFR) AND The disease must be associated with phosphaturic mesenchymal tumors AND The disease cannot be curatively resected or localized AND The member must have clinical signs and symptoms of TIO (muscle weakness, skeletal weakness, muscle pain, fatigue, hypophosphatemia Tumor-Induced Osteomalacia (TIO) - Continuation of Therapy: The member must have been previously treated with Crysvida (burosumab) AND The member has experienced an increase in serum phosphorus from baseline while on Crysvida (burosumab) AND The member has experienced a positive clinical response (e.g. reduction in muscle weakness, muscle pain, fatigue, etc).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 4 months duration. Continuation of therapy: Plan Year Duration
Other Criteria	

# CYRAMZA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Cyramza (ramuciruma).
Required Medical Information	<p>Gastric Cancer: member has a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal adenocarcinoma AND the member has disease progression or intolerance on or after prior therapy with platinum-based and/or fluoropyrimidine-based chemotherapy AND Cyramza (ramucirumab) will be used as subsequent therapy AND will be used as monotherapy or in combination with paclitaxel. Non-Small Cell Lung Cancer: The member has a diagnosis of metastatic non-small cell lung cancer AND The member has disease progression or intolerance on or following platinum-based chemotherapy AND For members with EGFR or ALK genomic aberrations, the member has disease progression on FDA-approved therapy for these aberrations and Cyramza will be used in combination with Docetaxel OR member has documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations AND is given in combo with erlotinib as first line therapy. Colorectal Cancer: The member has a diagnosis of unresectable or metastatic colorectal cancer AND Primary treatment in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin calcium, and irinotecan) for unresectable metachronuous metastases and previous treatment with FOLFOX (fluorouracil, leucovorin calcium, and oxaliplatin) or CapeOX (capecitabine, oxaliplatin) as adjuvant therapy has been given OR The member has disease progression on or after prior therapy with a bevacizumab product, oxaliplatin, and a fluoropyrimidine (e.g. 5-fluorouracil, capecitabine) AND Cyramza is given in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) or irinotecan as therapy after first progression of disease if irinotecan was not previously given. Esophageal Cancer: The member has a diagnosis of unresectable locally advanced or metastatic or recurrent esophageal adenocarcinoma with an Eastern Cooperative Oncology Group (ECOG) performance status 0-2 AND Cyramza will be used as second line therapy with or without paclitaxel.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## CYRAMZA

Other Criteria	Hepatocellular Carcinoma: The member has a diagnosis of metastatic or unresectable hepatocellular carcinoma AND the member has received prior treatment with a first line therapy (e.g.,sorafenib) AND the member has alpha feta protein greater than or equal to 400 ng/ml AND Cyramza (ramucirumab) will be given as a single agent as subsequent therapy.
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## CYSTARAN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Cystinosis: The member has a diagnosis of cystinosis AND The member is using cysteamine ophthalmic solution in the treatment of corneal cystine crystal accumulation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## dalfampridine

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	History of seizure disorder. Moderate to severe renal impairment (CrCl less 50ml/min).
Required Medical Information	Multiple Sclerosis. Member must have a diagnosis of one of the four types of multiple sclerosis: Relapse Remitting or Primary Progressive or Secondary Progressive or Progressive Relapsing. Patient must be ambulatory. Initial timed 25-foot walk T25W test or another objective measure of gait that provides evidence of significant walking impairment related to multiple sclerosis. Reauthorization Criteria. Documentation of improvement in walking using the T25W test or another objective measure of gait.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial Auth: 6 months. Reauth: Plan Year Duration.
Other Criteria	NA

## DANYELZA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members receiving Danyelza (naxitamab) as monotherapy. Members that have experienced disease progression while on Danyelza (naxitamabggqk).
Required Medical Information	Relapsed or Refractory Neuroblastoma: The member has a diagnosis of relapsed or refractory high-risk neuroblastoma AND The disease is in the bone or bone marrow AND The member has achieved a partial or minor response or stable disease to prior therapy AND Danyelza (naxitamab-ggqk) will be used in combination with Leukine (sargramostim).
Age Restriction	The member is 1 year of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## DARZALEX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while taking Darzalex (daratumumab).
Required Medical Information	<p>Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member will be using Darzalex (daratumumab) for newly diagnosed disease AND the member is ineligible for autologous stem cell transplant AND the member will be using Darzalex (daratumumab) in combination with bortezomib, melphalan, and prednisone OR the member will be using Darzalex in combination with lenalidomide and dexamethasone OR the member is eligible for autologous stem cell transplant AND the member will be using Darzalex in combination with bortezomib, thalidomide, and dexamethasone OR the member will be using Darzalex (daratumumab) for relapsed, progressive, or refractory disease in one of the following scenarios: The member will be using Darzalex (daratumumab) in combination with Pomalyst (pomalidomide) and dexamethasone AND the member has received at least two prior therapies, including lenalidomide and a proteasome inhibitor (e.g. bortezomib, carfilzomib, or ixazomib) OR The member will be using Darzalex (daratumumab) in combination with Velcade (bortezomib) and dexamethasone OR The member will be using Darzalex (daratumumab) in combination with Revlimid (lenalidomide) and dexamethasone OR the member will be using Darzalex (daratumumab) in combination with Kyprolis (carfilzomib) OR The member will be using Darzalex (daratumumab) as monotherapy and one of the following applies: The member has received at least three prior lines of therapy, which must have included a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide) OR The member is double-refractory to a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide). Omission of corticosteroid from regimen is allowed if intolerance/contraindication.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## DARZALEX FASPRO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while taking daratumumab. Members who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB (Applicable to Light chain (AL) amyloidosis indication only).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member will be using Darzalex (daratumumab) Faspro for newly diagnosed disease AND the member is ineligible for autologous stem cell transplant AND the member will be using Darzalex Faspro in combination with bortezomib, melphalan, and prednisone OR the member will be using Darzalex Faspro in combination with lenalidomide and dexamethasone OR the member will be using Darzalex Faspro for relapsed or progressive disease in one of the following scenarios: in combination with Velcade (bortezomib) and dexamethasone OR in combination with Kyprolis (carfilzomib) and dexamethasone OR in combination with Revlimid (lenalidomide) and dexamethasone OR in combination with Pomalyst (pomalidomide) and dexamethasone OR as monotherapy and one of the following applies: The member has received at least three prior lines of therapy, which must have included a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide) OR The member is double-refractory to a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide). Omission of corticosteroid from regimen is allowed if intolerance/contraindication. Light Chain Amyloidosis: The member has a diagnosis of light chain amyloidosis AND The member will be using Darzalex Faspro for newly diagnosed disease AND The member will be using in combination with bortezomib, cyclophosphamide, and dexamethasone. Omission of corticosteroid from regimen is allowed if intolerance/contraindication.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## DAURISMO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on Daurismo (glasdegib).
Required Medical Information	Acute Myeloid Leukemia. The member has a diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND One of the following applies: The member is age 75 years or older OR The member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. severe cardiac disease, baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2, or baseline serum creatinine greater than 1.3 mg/dL) AND The member will be using Daurismo (glasdegib) in combination with low-dose Cytarabine. Acute Myeloid Leukemia - Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member will be using Daurismo (glasdegib) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months) AND Daurismo (glasdegib) has not been administered continuously AND Daurismo (glasdegib) was not stopped due to the development of clinical resistance.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## decitabine

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with hypomethylators (e.g. azacitidine, decitabine) . Applies to azacitidine only: the member must not have a diagnosis of advanced malignant hepatic tumors.
Required Medical Information	Myelodysplastic Syndromes. The member has a diagnosis of myelodysplastic syndrome AND For requests for decitabine, the member has contraindication to, intolerance to, or unable to achieve treatment goals with azacitidine AND one of the following scenarios apply: The member has a Revised International Prognostic Scoring System (IPSS-R) of higher risk disease (i.e. intermediate, high, very high) OR The member has a Revised International Prognostic Scoring System (IPSS-R) of lower risk disease (i.e. very low, low, or intermediate) AND one of the following sets of criteria applies: Clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts OR Member has symptomatic anemia AND No 5q deletion AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND Serum erythropoietin levels less than or equal to 500 mU/mL AND An inadequate response to erythropoietins alone or in combination with Revlimid (lenalidomide) AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND 5q deletion AND An inadequate response or intolerance to Revlimid (lenalidomide) AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy. Myeloproliferative Neoplasms: The member has a diagnosis of myelofibrosis (MF)-accelerated phase or MF-blast phase/acute myeloid leukemia. Acute Myelogenous Leukemia (AML). The member has a diagnosis of AML.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## deferasirox

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients on concomitant deferoxamine or deferipone. The member has platelet counts less 50,000.
Required Medical Information	Chronic Iron Toxicity (hemosiderosis) Secondary to Transfusional Iron Overload. Initial Request: The Member must meet ALL of the following criteria: Diagnosis of chronic iron overload (hemosiderosis) secondary to multiple RBC transfusions AND Ferritin level greater than 1000 mcg/L (ferritin should consistently be above 1000 mcg/L to necessitate treatment). Continuation of Therapy Request: The Member must meet ALL of the following criteria: Ferritin level must be consistently above 500mcg/L (deferasirox should be stopped if Ferritin level is consistently below 500 mcg/L.). Chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes: The member must meet ALL of the following criteria: The member has a diagnosis of chronic iron overload with non-transfusion dependent thalassemia (NTDT) syndrome AND The member has liver iron (Fe) concentration of at least 5mg/gm of liver dry weight AND The member has a serum ferritin greater than 300 mcg/L.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## DIACOMIT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Dravet syndrome: The member has a diagnosis of Dravet syndrome by a specialist (i.e. neurologist or epileptologist) AND The member is refractory on current therapy (e.g experiencing generalized tonicclonic or clonic seizures within the past 28 days) AND The member is taking concomitant clobazam therapy.
Age Restriction	The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## diclofenac epolamine

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Topical treatment of acute pain due to minor strains, sprains, and contusions. The patient has a documented symptomatic acute pain condition.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## diclofenac sodium

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Actinic Keratosis: The member has a diagnosis of actinic keratosis. The member has trial, intolerance, or contraindication to generic imiquimod 5% cream or topical fluorouracil.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## dihydroergotamine

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute treatment of moderate to severe migraine headaches with or without aura AND has had previous treatment, intolerance, or contraindication to two of the following: naproxen tablet, naratriptan tablet, rizatriptan tablet, sumatriptan tablet.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## dimethyl fumarate

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## DOJOLVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Long-Chain Fatty Acid Oxidation Disorders: The member has a diagnosis of long-chain fatty acid disorders (e.g. Very Long-chain acylCoA Dehydrogenase [VLCAD] deficiency, Carnitine Palmitoyltransferase 2 [CPT2] deficiency, Mitochondrial Trifunctional Protein [TFP] Deficiency, Long-chain 3 hydroxyacylCoA Dehydrogenase [LCHAD] deficiency) AND Genetic and/or molecular testing has been performed to confirm diagnosis (e.g. positive for pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## doxorubicin, peg-liposomal

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Ovarian Cancer: The member has a diagnosis of persistent or recurrent ovarian cancer and one of the following applies: if platinum sensitive, in combination with carboplatin OR if platinum resistant, as a single agent or in combination with bevacizumab product OR The member has a diagnosis ovarian cancer and Liposomal doxorubicin will be used in combination with carboplatin and one of the following applies: perioperative treatment in members who are poor surgical candidates or low likelihood of optimal cytoreduction or adjuvant treatment or primary treatment in members with incomplete previous surgery or staging.</p> <p>Breast Cancer: The member has a diagnosis of recurrent or metastatic HER-2-negative breast cancer AND The member has disease progression after treatment with or intolerance to anthracycline based therapy (e.g. Doxorubicin (conventional, epirubicin).</p> <p>Hodgkin Lymphoma: The member has a diagnosis of relapsed or refractory Hodgkins Lymphoma AND The member will be using liposomal doxorubicin as second-line or subsequent therapy AND The member has disease progression after treatment with or intolerance to anthracycline based therapy.</p> <p>Kaposi's Sarcoma: The member has a diagnosis of AIDS-related Kaposi's sarcoma AND One of the following criteria applies: The member has had prior treatment, intolerance, or contraindication to prior systemic chemotherapy or the member is using Liposomal doxorubicin as first line therapy.</p> <p>Multiple Myeloma: The member has a diagnosis of relapsed or refractory multiple myeloma AND The member will be using liposomal doxorubicin in combination with bortezomib.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## doxorubicin, peg-liposomal

Other Criteria	Non-Hodgkin's lymphoma: The member has a diagnosis of T-Cell Leukemia or Lymphoma AND Liposomal doxorubicin is given in combination with gemcitabine and vinorelbine and one of the following: for non-responders as first line therapy or for refractory disease after two primary treatment prior to proceeding to transplant OR The member has diagnosis of diffuse large B cell lymphoma AND Liposomal doxorubicin is given in combination with RCDOP (rituximab product, cyclophosphamide, vincristine and prednisone) in members with documented poor ventricular or very frail OR The member has a diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS) and liposomal doxorubicin is given and one of the following: primary treatment OR as combination therapy with gemcitabine and vinorelbine prior to proceeding to transplant OR The member has a diagnosis of relapsed or refractory peripheral T-cell lymphoma (not otherwise specified or enteropathy associated Tcell lymphoma) AND Liposomal doxorubicin is given as subsequent therapy in combination therapy with gemcitabine and vinorelbine prior to proceeding to transplant.
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## DRIZALMA SPRINKLE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Major Depressive Disorder, Generalized Anxiety Disorder, or Diabetic Peripheral Neuropathic Pain: The member has a diagnosis of Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), or Diabetic Peripheral Neuropathic Pain (DPNP). The member has prior therapy, intolerance, or contraindication with venlafaxine (IR or ER) AND duloxetine. Chronic Musculoskeletal Pain, Fibromyalgia: The member has a diagnosis of Chronic Musculoskeletal Pain or Fibromyalgia (FM). The member has prior therapy, intolerance, or contraindication with duloxetine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## DUAVEE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Abnormal uterine bleeding. Known or past history of breast cancer. Active or past history of venous thromboembolism (e.g. pulmonary embolism, deep vein thrombosis). Known estrogen-dependent neoplasia. Active or past history of arterial thromboembolism (e.g. stroke and myocardial infarction). Duavee should not be used in members who are pregnant or lactating. Known hepatic impairment or liver disease. Known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders. Concurrent use with estrogens, progestins, or estrogen agonists/antagonists.
Required Medical Information	Treatment of moderate to severe vasomotor symptoms associated with menopause:Diagnosis of moderate to severe vasomotor symptoms associated with menopause AND The member must have had previous treatment, intolerance or contraindication to a SSRI [e.g. citalopram, fluoxetine, paroxetine hydrochloride] or venlafaxine. Prevention of osteoporosis: For the prevention of osteoporosis in a member who is postmenopausal AND the member must have had previous treatment, intolerance, or contraindication to either alendronate or Evista (raloxifene).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## DUPIXENT PEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	For asthma indication only: Not for the relief of acute bronchospasm or status asthmaticus.
Required Medical Information	<p>Atopic Dermatitis. Initial Review: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema that is pink-red to deep or bright red, moderate to severe induration/population, frequent to incessant itching, frequent to nightly loss of sleep) AND The member has had previous treatment, intolerance to, or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/gel/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. tacrolimus)</p> <p>Reauthorization: The member has had an improvement in atopic dermatitis symptoms which has been sustained. Eosinophilic Esophagitis (EoE) Initial Review: Member must meet all of the following criteria: 40 kg (88 pounds) or higher, Diagnosis of eosinophilic esophagitis (EOE) identified by endoscopic biopsy with evidence of peak cell count of greater than or equal to 15 eosinophils per high power field in 2 or more biopsied esophageal regions, two or more episodes of dysphagia per week, unable to achieve adequate control of symptoms with guideline directed therapy (e.g., generic high dose proton pump inhibitors or topical corticosteroids). Continuation of therapy: member must meet all the following criteria: 40 kg (88 pounds) or higher, reduction of esophagitis symptoms identified by one of the following: endoscopic biopsy shows evidence of histological remission or reduction of symptoms (e.g., Decreased episodes of dysphagia).</p>
Age Restriction	<p>Atopic dermatitis: The member must be 6 months of age or older.</p> <p>Chronic rhinosinusitis with nasal polyposis: The member must be 18 years of age or older. Eosinophilic Esophagitis: 12 years of age or older.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT PEN

Other Criteria	<p>Moderate-to-severe asthma with an eosinophilic phenotypic or with oral corticosteroid dependent asthma. Initial Review: The member has a diagnosis of moderate-to-severe asthma AND The member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of: greater than or equal to 150 cells/uL at therapy initiation, OR greater than or equal to 300 cells/uL in the previous 12 months, OR The member has oral corticosteroid-dependent asthma AND The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy in combination with a long acting beta agonist (eg formoterol). Reauthorization. Member is currently stable on therapy AND Member will continue on asthma controller inhalers: inhaled corticosteroid with a long-acting beta2-agonist (e.g. Flovent HFA/Diskus, Arnuity Ellipta, Serevent Diskus, Striverdi Respimat, Advair Diskus, Breo Ellipta, Symbicort HFA).</p> <p>Chronic Rhinosinusitis with Nasal Polyposis. Initial Review: The member must have a diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Dupixent (dupilumab) will be used in conjunction with a daily intranasal corticosteroid spray AND The member has been unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. Reauthorization: The member has had an improvement in symptoms (e.g. decrease in nasal congestion, decrease in polyp size, improvement in ability to smell) which has been sustained AND Member will continue intranasal corticosteroid spray therapy.</p>
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## DUPIXENT SYRINGE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	For asthma indication only: Not for the relief of acute bronchospasm or status asthmaticus.
Required Medical Information	<p>Atopic Dermatitis. Initial Review: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema that is pink-red to deep or bright red, moderate to severe induration/population, frequent to incessant itching, frequent to nightly loss of sleep) AND The member has had previous treatment, intolerance to, or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/gel/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. tacrolimus)</p> <p>Reauthorization: The member has had an improvement in atopic dermatitis symptoms which has been sustained. Eosinophilic Esophagitis (EoE) Initial Review: Member must meet all of the following criteria: 40 kg (88 pounds) or higher, Diagnosis of eosinophilic esophagitis (EOE) identified by endoscopic biopsy with evidence of peak cell count of greater than or equal to 15 eosinophils per high power field in 2 or more biopsied esophageal regions, two or more episodes of dysphagia per week, unable to achieve adequate control of symptoms with guideline directed therapy (e.g., generic high dose proton pump inhibitors or topical corticosteroids). Continuation of therapy: member must meet all the following criteria: 40 kg (88 pounds) or higher, reduction of esophagitis symptoms identified by one of the following: endoscopic biopsy shows evidence of histological remission or reduction of symptoms (e.g., Decreased episodes of dysphagia).</p>
Age Restriction	<p>Atopic dermatitis: The member must be 6 months of age or older.</p> <p>Chronic rhinosinusitis with nasal polyposis: The member must be 18 years of age or older. Eosinophilic Esophagitis: 12 years of age or older.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT SYRINGE

Other Criteria	<p>Moderate-to-severe asthma with an eosinophilic phenotypic or with oral corticosteroid dependent asthma. Initial Review: The member has a diagnosis of moderate-to-severe asthma AND The member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of: greater than or equal to 150 cells/uL at therapy initiation, OR greater than or equal to 300 cells/uL in the previous 12 months, OR The member has oral corticosteroid-dependent asthma AND The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy in combination with a long acting beta agonist (eg formoterol). Reauthorization. Member is currently stable on therapy AND Member will continue on asthma controller inhalers: inhaled corticosteroid with a long-acting beta2-agonist (e.g. Flovent HFA/Diskus, Arnuity Ellipta, Serevent Diskus, Striverdi Respimat, Advair Diskus, Breo Ellipta, Symbicort HFA).</p> <p>Chronic Rhinosinusitis with Nasal Polyposis. Initial Review: The member must have a diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Dupixent (dupilumab) will be used in conjunction with a daily intranasal corticosteroid spray AND The member has been unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. Reauthorization: The member has had an improvement in symptoms (e.g. decrease in nasal congestion, decrease in polyp size, improvement in ability to smell) which has been sustained AND Member will continue intranasal corticosteroid spray therapy.</p>
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## econazole

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member must be using the requested antifungal topically for the treatment of an active susceptible fungal infection AND has had previous treatment within the past 12 months, contraindication, or intolerance to two of the following: clotrimazole cream, ciclopirox 0.77% cream/gel/suspension, or ketoconazole cream.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## EGRIFTA SV

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Egrifta (tesamorelin) therapy is not considered medically necessary for members with the following concomitant conditions: The member must not have an active malignancy. Pregnancy.
Required Medical Information	HIV-Associated Lipodystrophy. The member must have a diagnosis of HIV-associated lipodystrophy. The member must utilize Egrifta (tesamorelin) to reduce excess fat for the abdominal area. The member must be/have been on a protease inhibitor (PI) and/or nucleoside reverse transcriptase inhibitor (NRTI).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year
Other Criteria	



## ELELYSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	NA
<b>Required Medical Information</b>	Gaucher Disease. The member has a confirmed diagnosis of Type 1 Gaucher disease.
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner.
<b>Coverage Duration</b>	Plan Year Duration.
<b>Other Criteria</b>	NA

## ELIGARD

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ELIGARD (3 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ELIGARD (4 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ELIGARD (6 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ELZONRIS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has disease progression while on Elzonris (tagraxofusp-erzs). The member has documented active central nervous system involvement by blastic plasmacytoid dendritic cell neoplasm (BPDCN).
Required Medical Information	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN): The member has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) according to World Health Organization (WHO) classification AND the member is able to be an inpatient for at least the first complete course of therapy plus an additional 24 hours for observation. Reauthorization Criteria: The provider attests that the member has received ongoing clinical benefit and has not experienced unacceptable toxicities.
Age Restriction	The member must be 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## EMGALITY PEN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Episodic or Chronic Migraine. Initial therapy: The member has documented history of greater than or equal to 4 migraine days per month AND the member has been unable to achieve at least a 2 day reduction in migraine headache days per month after previous treatment (of at least 2 months) with one of the following oral preventative medications: Divalproex, Topiramate, Metoprolol, Propranolol, or Timolol. Reauthorization: The member has experienced a positive clinical response (e.g. sustained decrease in migraine days per month).
Age Restriction	The member is 18 years of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 3 months. Reauth: Plan Year Duration
Other Criteria	NA

## EMGALITY SYRINGE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Episodic or Chronic Migraine. Initial therapy: The member has documented history of greater than or equal to 4 migraine days per month AND the member has been unable to achieve at least a 2 day reduction in migraine headache days per month after previous treatment (of at least 2 months) with one of the following oral preventative medications: Divalproex, Topiramate, Metoprolol, Propranolol, or Timolol. Reauthorization: The member has experienced a positive clinical response (e.g. sustained decrease in migraine days per month).
Age Restriction	The member is 18 years of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 3 months. Reauth: Plan Year Duration
Other Criteria	NA



## EMPLICITI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members with disease progression while on Empliciti (elotuzumab)
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND One of the following scenarios apply: The member has disease progression after receiving one to three prior lines of therapy AND Empliciti (elotuzumab) will be given in combination with lenalidomide (Revlimid) and dexamethasone OR in combination with bortezomib (Velcade) and dexamethasone OR The member has disease progression after receiving at least two prior therapies, including lenalidomide and a proteasome inhibitor AND Empliciti (elotuzumab) will be given in combination with pomalidomide (Pomalyst) and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## EMSAM

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Pheochromocytoma.
Required Medical Information	Major Depressive Disorder: The member is at least 12 years of age. The member is an adult with a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D). The member has had prior therapy, intolerance, or contraindication with a generic SSRI (e.g. citalopram, fluoxetine, paroxetine, or sertraline), generic SNRI (e.g. venlafaxine or duloxetine), a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) OR mirtazapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# ENBREL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis: The member has a diagnosis of ankylosing spondylitis. The member has prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Plaque Psoriasis: Diagnosis of chronic moderate to severe plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis: Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis: Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs.
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## ENBREL MINI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis: The member has a diagnosis of ankylosing spondylitis. The member has prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Plaque Psoriasis: Diagnosis of chronic moderate to severe plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis: Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis: Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs.
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## ENBREL SURECLICK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis: The member has a diagnosis of ankylosing spondylitis. The member has prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Plaque Psoriasis: Diagnosis of chronic moderate to severe plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis: Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis: Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs.
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# ENHERTU

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Breast cancer: The member has a diagnosis of unresectable or metastatic breast cancer AND The disease is human epidermal growth factor receptor 2 (HER2) positive AND The member has received prior anti-HER2 based regimens [e.g., Perjeta (pertuzumab)- based regimens, Kadcyla (ado-trastuzumab emtansine)] in the metastatic setting OR in the neoadjuvant or adjuvant setting and has developed disease recurrence and one of the following applies: during or within six months of completing therapy OR during or within twelve months of completing Perjeta-containing regimens. Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.</p> <p>Gastric or Gastroesophageal Junction Adenocarcinoma: The member has a diagnosis of locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND the disease is human epidermal growth factor receptor 2 (HER2) positive AND The member has received prior treatment with prior trastuzumab-based regimen AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.</p> <p>HER2-Low Breast cancer: the member has a diagnosis of unresectable or metastatic breast cancer AND the disease is human epidermal growth factor receptor 2 (HER2) low (defined as IHC 1+ or IHC 2+/ISH-negative) AND the member has: received prior chemotherapy regimen(s) in the metastatic setting (e.g. capecitabine, Eribulin, gemcitabine, paclitaxel) OR developed disease recurrence during or within six months of completing adjuvant chemotherapy AND the member has received at least one line of endocrine therapy if the breast cancer subtype is hormone receptor positive (HR+), unless the member is contraindicated to endocrine therapy AND the member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## ENHERTU

Other Criteria	HER2-Mutant Non-Small Cell Lung Cancer: the member has a diagnosis of unresectable or metastatic non-small cell lung cancer (NSCLC) AND NSCLC is documented (HER2 (ERBB2)) mutant AND the member has received a prior systemic therapy (e.g. platinum-based therapy, immunotherapy) AND the member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.
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## ENVARUSUS XR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must have had a kidney transplant AND Must be using Envarsus XR for prophylaxis of organ rejection AND Must be using in combination with other immunosuppressants.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## EPCLUSA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Hepatitis C Virus Genotypes: The member must have a diagnosis of chronic hepatitis C (HCV). Baseline HCV RNA must be documented. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. For all genotypes, criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restriction	
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	12 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	

## EPIDIOLEX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	<p>Dravet Syndrome: The member has a diagnosis of seizures associated with Dravet Syndrome AND Epidiolex is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has had prior therapy with, contraindication, or intolerance to at least one other drug used for the treatment of Dravet Syndrome (e.g. clobazam, valproic acid, topiramate). Lennox-Gastaut: The member has a diagnosis of seizures associated with Lennox-Gastaut syndrome AND Epidiolex is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has had prior therapy with, contraindication, or intolerance to at least one other drug used for the treatment of Lennox-Gastaut syndrome (e.g. topiramate, lamotrigine). Tuberous Sclerosis Complex: The member has a diagnosis of seizures associated with Tuberous Sclerosis Complex. Reauthorization (all indications): The member has experienced an improvement in seizure frequency from documented pre-treatment baseline.</p>
Age Restriction	The member is at least 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## epoprostenol (glycine)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Heart failure caused by reduced left ventricular ejection fraction.
Required Medical Information	Pulmonary Arterial Hypertension (PAH). Higher Risk: Member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization AND Member has WHO/NYHA Functional Class IV symptoms or is classified as high risk. Determinants of high risk include: Clinical evidence of RV failure, Rapid progression of symptoms, Shorter 6MW distance (less than 300m), Peak VO2 less than 10.4 mL/kg/min for CPET, Pericardial effusion, significant RV enlargement/dysfunction, or right atrial enlargement on echocardiography, RAP greater than 20mmHg, CI less than 2.0 L/min/m2 and/or Significantly elevated BNP. Lower Risk: Member diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization with WHO/NYHA Functional Class II or III symptoms. AND member must have had prior therapy, intolerance or contraindication to an ERA (e.g., ambrisentan, bosentan, Opsumit (macitentan)), AND either a PDE5 inhibitor (e.g., sildenafil, tadalafil) OR Adempas (riociguat).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## EPRONTIA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Migraine Prophylaxis: Member is using for prophylaxis of migraine headache AND has had previous treatment with or intolerance to immediate release topiramate tablet or capsule AND has had previous treatment, intolerance, or contraindication with propranolol or timolol.</p> <p>Epilepsy Adjunctive Therapy: Member has a diagnosis of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) AND Concomitant use of at least one antiepileptic medication (e.g. lamotrigine, carbamazepine, levetiracetam) AND Has had previous treatment with or intolerance to immediate release topiramate tablet or capsule AND Has unsuccessful control of seizures as determined by treating physician.</p> <p>Epilepsy Monotherapy: Member must have diagnosis of partial-onset seizures or primary generalized tonic-clonic seizures AND Member has had previous treatment with or intolerance to immediate release topiramate tablet or capsule AND Has unsuccessful control of seizures as determined by treating physician.</p>
Age Restriction	<p>Migraine Prophylaxis: Member must be 12 years of age or older.</p> <p>Epilepsy indications: Member must be 2 years of age or older.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

# ERBITUX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Metastatic colorectal cancer patients with RAS mutations should not receive cetuximab due to known lack of response and possible worse outcomes in this population. Member has disease progression on Vectibix or Erbutux. Erbitux may not be used in conjunction with Vectibix, Tarceva or Iressa (all are EGFR inhibitors). Erbitux may not be used in conjunction with Avastin.
Required Medical Information	Metastatic Colorectal Cancer (mCRC). Diagnosis of Metastatic (stage IV) Colorectal Cancer. The member has mCRC that expresses verified wild-type (normal) KRAS/NRAS. Applies to new starts only. Erbitux (cetuximab) may be used as one of the following: monotherapy in mCRC members intolerant to irinotecan or who have experienced disease progression following therapy with both irinotecan and oxaliplatin based therapy OR combination with irinotecan-based therapy or with fluorouracil based therapy (e.g. FOLFOX, FOLFIRI) OR member experiences progressive disease on prior therapy and Erbitux is in combination with Braftovi for documented BRAFV600E mCRC. Head and Neck Cancer. Diagnosis of locally or regionally squamous cell advanced Head and Neck Cancer with concomitant XRT OR The member has recurrent or metastatic squamous cell Head and Neck Cancer and is receiving Erbitux (cetuximab) monotherapy after experiencing disease progression following platinum based therapy (may also be used in conjunction with a platinum agent). OR The member has advanced or recurrent squamous cell Head and Neck Cancer that is unresectable or the member is unfit for surgery OR The member has a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck AND The member is receiving Erbitux (cetuximab) in combination with platinum-based therapy with 5-Fluorouracil.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## ergotamine-caffeine

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Acute Migraine. Acute treatment of migraines AND has had previous treatment, intolerance, or contraindication to one of the following: naratriptan, rizatriptan, sumatriptan.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ERIVEDGE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Erivedge (vismodegib) therapy is not considered medically necessary for members with the following concomitant conditions:Members that have experienced disease progression while on Erivedge (vismodegib). Members that are using Erivedge (vismodegib) as neoadjuvant therapy.
Required Medical Information	Advanced Basal Cell Carcinoma.The member has a diagnosis of metastatic basal cell carcinoma OR The member has a diagnosis of locally advanced basal cell carcinoma AND one of the following applies: The member has disease that has recurred following surgery OR the member is not a candidate for surgery AND radiation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## ERLEADA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Erleada (apalutamide). Concoitant use with an androgen receptor inhibitor or androgen synthesis inhibitor (e.g., enzalutamide, abiraterone, nilutamide, flutamide, bicalutamide) due to lack of evidence supporting efficacy and safety.
Required Medical Information	Prostate Cancer (non-metastatic castration resistant): The member has a diagnosis of non-metastatic castration resistant prostate cancer AND the member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog). Prostate Cancer (metastatic castration-sensitive): The member has a diagnosis of metastatic castration-sensitive prostate cancer AND the member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



## erlotinib

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors.
Required Medical Information	Pancreatic Cancer: The member has a diagnosis of unresectable, locally advanced or metastatic pancreatic cancer. AND erlotinib is being used in combination with Gemzar (gemcitabine). Non-small cell lung cancer. The member has a diagnosis of metastatic NSCLC AND all of the following apply: The member has known documented activated EGFR mutation (such as E19del in exon 19 or L858R in exon 21). Renal Cell Carcinoma: Diagnosis of relapsed or unresectable stage IV renal cell carcinoma with non clear histology and erlotinib will be used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## ERWINAZE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Erwinaze (asparaginase Erwinia chrysanthemi) therapy is not considered medically necessary for members with the following concomitant conditions: Members with a history of serious pancreatitis with prior asparaginase based therapy, Members with a history of serious thrombosis with prior asparaginase based therapy, Members with a history of serious hemorrhagic events with prior asparaginase based therapy, Members that have experienced disease progression while on asparaginase based therapy.
Required Medical Information	Erwinaze (asparaginase Erwinia chrysanthemi) will require prior authorization. This agent may be considered medically necessary when the following criteria are met: Acute Lymphoblastic Leukemia (ALL). The member has a diagnosis of ALL. The member has documented, Grade 2 - 4 hypersensitivity (based on Common Terminology Toxicity Criteria) as a result of prior treatment with Oncaspar (pegaspargase). The member is using Erwinaze (asparaginase Erwinia chrysanthemi) as a component of a multi-agent chemotherapeutic regimen.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## ESBRIET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Idiopathic Pulmonary Fibrosis (IPF): The member meets ALL of the following criteria: Diagnosis of idiopathic pulmonary fibrosis by exclusion of clinically significant environmental exposure or explanation for pulmonary fibrosis or interstitial lung disease (e.g. drugs, asbestos, beryllium, radiation, and domestic birds, radiation, sarcoidosis, hypersensitivity pneumonitis, bronchiolitis, obliterans organizing pneumonia, human immunodeficiency virus (HIV), viral hepatitis, or cancer). AND Documentation of Pulmonary Fibrosis by one of the following: computed tomography (CT) scan is indicative of usual interstitial pneumonia (UIP) OR a surgical lung biopsy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## EULEXIN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prostate Cancer: the member has a diagnosis of prostate cancer AND the member will be using Eulexin (flutamide) alone or in combination therapy with a luteinizing hormone-releasing hormone (LHRH) analog.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## everolimus (antineoplastic)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on everolimus.
Required Medical Information	Advanced Renal Cell Carcinoma (RCC). The member has a diagnosis of advanced /metastatic renal cell carcinoma (stage IV) AND the member experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome) AND Afinitor (everolimus) is given as monotherapy or being given in combination with Lenvima (lenvatinib). The member has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis AND The member requires therapeutic intervention but is not a candidate for curative surgical resection. Neuroendocrine Tumors: The member has disease that is unresectable, locally advanced or metastatic and one of the following applies: The member has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) OR The member has a diagnosis of progressive, well differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. The member has a diagnosis of recurrent or not responsive to primary treatment or relapsed Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma AND Afinitor (everolimus) will be used as monotherapy.
Age Restriction	TSC associated partial onset seizures: Member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## everolimus (antineoplastic)

Other Criteria	Angiomyolipoma and Tuberous Sclerosis Complex (TSC).The member has a diagnosis of renal angiomyolipoma and tuberous sclerosis complex AND Immediate surgery is not required. Metastatic Breast Cancer. The member has a diagnosis of hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic disease AND the member has been treated with endocrine therapy (e.g. letrozole, anastrozole) within one year AND The member will use Afinitor (everolimus) in combination with exemestane or fulvestrant (Faslodex). Tuberous sclerosis complex (TSC)- associated partial onset seizures [Adults and Pediatrics]: The member has diagnosis of TSC- associated partial onset seizures AND Afinitor Disperz (everolimus tablets for oral solution) is being used as adjunctive therapy.
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# EVOMELA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Multiple Myeloma:The member has a diagnosis of mutiple myeloma. The member is utilizing Evomela as:High-dose conditioning treatment prior to stem cell transplantation OR Palliative treatment in members for whom oral therapy is not appropriate. Systemic Light Chain Amyloidosis: The member has a diagnosis of systemic light chain amyloidosis.The member will receive Evomela as:Primary treatment AND High-dose single-agent therapy with stem cell transplant.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six month durations
Other Criteria	NA

## EXKIVITY

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Exkivity (mobocertinib).
Required Medical Information	Metastatic Non-Small Cell Lung Cancer (NSCLC): The member has locally advanced or metastatic NSCLC AND The NSCLC has documented EGFR exon 20 insertion mutation AND The member has experienced disease progression on platinum based therapy AND Exkivity (mobocertinib) is administered as single agent as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	



## FANAPT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Schizophrenia. The member must be utilizing it for treatment of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole.
Age Restriction	The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year duration.
Other Criteria	NA

# FARYDAK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression on Farydak (panobinostat).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has received at least two prior regimens, including both bortezomib and an immunomodulatory drug (thalidomide, lenalidomide, pomalidomide) AND one of the following applies: The member will be using Farydak (panobinostat) in combination with bortezomib and dexamethasone OR the member will be using Farydak (panobinostat) in combination with Kyprolis (carfilzomib) OR the member will be using Farydak (panobinostat) in combination with Revlimid (lenalidomide) and dexamethasone.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	6 months duration.
Other Criteria	NA

## FASENRA PEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Severe Asthma with an Eosinophilic Phenotype: The member has a diagnosis of severe asthma AND the member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of greater than or equal to 150 cells/<math>\mu</math>L at therapy initiation OR greater than or equal to 300 cells/<math>\mu</math>L in the previous 12 months. The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy (e.g. mometasone greater than 400mcg daily, fluticasone greater than 440 mcg daily) in combination with a long acting beta agonist (e.g. formoterol).</p> <p>Continuation of therapy: Member is currently stable on therapy. Member will continue on asthma controller inhalers: inhaled corticosteroids (ICS) with or without a long-acting beta2-agonist (LABA). Eosinophilic Granulomatosis with Polyangiitis (EGPA): The member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the member has a baseline elevated peripheral blood eosinophil level of greater than 10% of total leukocyte count AND two or more systemic manifestations of EGPA. The member has been unable to achieve adequate control of EGPA while on oral corticosteroid therapy (e.g. prednisone, methylprednisolone). Hypereosinophilic Syndrome (HES) - Nucala only: The member has a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than or equal to 1000 cells/<math>\mu</math>L.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	<p>Chronic Rhinosinusitis with Nasal Polyposis - Nucala Only: Initial Review- The member must meet ALL of the following criteria: Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Nucala (mepolizumab) will be used in conjunction with a daily intranasal corticosteroid spray AND member is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy.</p> <p>Continuation of Therapy - The member must meet ALL of the following criteria: Improvement in symptoms (e.g., decrease in nasal congestion, decrease in polyp size, improvement in ability to smell) which has been sustained AND continuing intranasal corticosteroid spray therapy.</p>

## fentanyl citrate

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Treatment of acute or post-operative pain.
Required Medical Information	The member is currently diagnosed with cancer. Fentanyl citrate is required to manage breakthrough cancer pain. The member is currently taking opioid therapy and is opioid tolerant. Tolerance is defined as any of the following: greater than or equal 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, 60 mg oral hydrocodone/day for greater than or equal 1 week, An equianalgesic dose of another opioid for greater than or equal 1 week.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## FETZIMA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Major depressive disorder: The member must be utilizing Fetzima for treatment of major depressive disorder. For new starts only: The member must have a documentation of prior therapy, intolerance, or contraindication to a serotonin and norepinephrine reuptake inhibitor (SNRI) AND a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) or mirtazapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## fingolimod

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# FINTEPLA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Treatment with a monoamine oxidase inhibitor within the last 14 days.
Required Medical Information	Dravet Syndrome: The member has a diagnosis of Dravet syndrome AND the member is experiencing seizures associated with Dravet syndrome on current therapy at baseline AND The member has had previous treatment with valproic acid AND fenfluramine will be taken concomitantly with another anti-epileptic supported for the treatment of seizures associated with Dravet Syndrome (e.g. valproic acid, clobazam, topiramate). Lennox-Gastaut Syndrome: The member has a diagnosis of Lennox-Gastaut Syndrome AND the member has had prior therapy with, contraindication, or intolerance to at least two antiepileptics supported for the treatment of Lennox-Gastaut syndrome (e.g. topiramate, lamotrigine) AND Fintepla (fenfluramine) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist).
Age Restriction	The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## FIRDAPSE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	History of seizures (not to be inferred from pharmacy claims)
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS). The member has a confirmed diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) by a specialist (e.g. neurologist) AND The diagnosis is supported by results from a clinical evaluation (e.g. electromyography or the presence of autoantibodies directed against VGCC {voltagegated calcium channels}).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## FIRMAGON

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## FIRMAGON KIT W DILUENT SYRINGE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## FOLOTYN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on pralatrexate.
Required Medical Information	Peripheral T-cell Lymphoma(PTCL):relapsed or refractory. Pralatrexate is being used to treat relapsed or refractory peripheral T-cell lymphoma (PTCL) (eg peripheral T-cell lymphoma, not otherwise specified: angioimmunoblastic T-cell lymphoma, anaplastic large cell lymphoma or enteropathy-associated T-cell lymphoma.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months
Other Criteria	NA

## formoterol fumarate

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Asthma, in the absence of concurrent medication containing inhaled corticosteroid and comorbid COPD diagnosis.
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD).Diagnosis of Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema, requiring maintenance treatment of bronchoconstriction.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## FORTEO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	The member is postmenopausal with a diagnosis of osteoporosis. The member is at high risk for osteoporotic fracture as evident by one of the following: The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate, ibandronate, pamidronate). The member is taking sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone). The member is at high risk for osteoporotic fracture as evident by one of the following: The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment, contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate, ibrandronate, pamidronate). The member has a diagnosis of primary or hypogonadal osteoporosis, who is at high risk for fracture, defined as history of osteoporotic fracture, or who have multiple risk factors for fracture.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan year duration.
Other Criteria	NA

## FOTIVDA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Fotivda (tivozanib).
Required Medical Information	Relapsed or refractory advanced renal cell carcinoma: The member has a diagnosis of relapsed or refractory advanced renal cell carcinoma AND The member has received two prior systemic therapies (e.g., immunology checkpoint inhibitors, cabozantinib, axitinib) AND Fotivda (tivozanib) is given as a single agent for subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

# FULPHILA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgastrim-sndz or filgastrim-aafi), tbo-filgratim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose). Same day administration with myelosuppressive chemotherapy or therapeutic (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis. The member must have a diagnosis of non-myeloid malignancy (e.g. solid tumors) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to pegfilgrastim injection AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy OR Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours) OR Bone marrow involvement by tumor OR Recent surgery and/or open wounds OR Liver dysfunction (bilirubin greater than 2.0 mg/dL) OR Renal dysfunction (creatinine clearance less than 50 mL/min) OR Age greater than 65 receiving full chemotherapy dose intensity Or Previous neutropenic fever complication from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 months duration
Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.

## fulvestrant

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Faslodex.
Required Medical Information	Breast Cancer. The member is post-menopausal or premenopausal but receiving ovarian ablation/suppression AND The member has a diagnosis of hormone receptor (HR)- positive metastatic breast cancer AND The member experienced disease progression, intolerance, or has a contraindication to endocrine therapy AND Faslodex (fulvestrant) is given as monotherapy OR The member has HR-positive and human epidermal growth factor receptor 2 negative breast cancer AND one of the following applies: The post-menopausal member has not previously been treated with endocrine therapy for advanced disease and Faslodex (fulvestrant) will be used as monotherapy OR Faslodex (fulvestrant) is given in combination with Kisqali (ribociclib) as initial endocrine based therapy OR Faslodex (fulvestrant) is given in combination with Ibrance (palbociclib) or Verzenio (abemaciclib) or Kisqali (ribociclib) as subsequent therapy after disease progression on or following endocrine based therapy (e.g., anastrozole) for their recurrent disease OR Faslodex (fulvestrant) is given in combination with Ibrance (palbociclib) or Verzenio (abemaciclib) or Kisqali (ribociclib) as subsequent therapy after disease progression on or following endocrine based therapy (e.g., anastrozole) for their metastatic disease OR Faslodex (fulvestrant) is given in combination with Afinitor (everolimus) for disease that has been treated with endocrine therapy (e.g. letrozole, anastrozole) OR Faslodex (fulvestrant) is given in combination with Piqray (alpelisib) for disease progression on or after endocrine based therapy (e.g. anastrozole, palbociclib) within one year of PIK3CA mutated disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



## FYCOMPA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Partial-onset seizures: Inadequately controlled partial-onset seizures. Adjunctive treatment for members with generalized tonic-clonic seizures: Inadequately controlled partial-onset seizures and concomitant use of at least one antiepileptic medication.
Age Restriction	Adjunctive treatment for generalized tonic-clonic seizures: Age 12 years and older. Partial-onset seizures: age 4 years and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## GAMUNEX-C

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	<p>For Medicare Part D requests, Humana's preferred product is Gamunex-C. Diagnosis of a primary humoral immunodeficiency disorder such as: primary immunoglobulin deficiency syndrome, X-linked immunodeficiency with hyperimmunoglobulin, etc)OR Documented hypogammaglobulinemia (IgG less than 600mg/dl) Idiopathic/Immune Thrombocytopenia Purpura. Diagnosis of Acute ITP with any of the following: Management of acute bleeding due to severe thrombocytopenia (platelets less than 30,000/<math>\mu</math>L),To increase platelet counts prior major surgical procedures, Severe thrombocytopenia (platelets less than 20,000/<math>\mu</math>L), at risk for intracerebral hemorrhage. Diagnosis of Chronic ITP and ALL of the following are met:Prior treatment has included corticosteroids, No concurrent illness explaining thrombocytopenia, Platelets persistently at or below 20,000/<math>\mu</math>L.Chronic Lymphocytic Leukemia (CLL, B-cell).With either of the following present: Hypogammaglobulinemia ( IgG less than 600mg/dL),Recurrent bacterial infections associated with B-cell CLL. Kawasaki Disease. Diagnosed with Kawasaki Syndrome within ten days of onset of disease manifestations or is diagnosed after ten days of disease onset and continues to exhibit manifestations of inflammation or evolving coronary artery disease.IVIG is used in combination with high dose aspirin for the prevention of coronary artery aneurysms.Bone Marrow Transplant (BMT). Member is hypogammaglobulinemic (IgG less than 400mg/dL). Hematopoietic Stem Cell Transplantation (HSCT). Is within first 100 days of allogeneic hematopoietic stem cell transplantation. Is experiencing hypogammaglobulinemia (serum IgG level less than 400 mg/dL). AIDS/HIV. Has any of the following conditions: CD4+ T-cell counts greater than or equal 200/mm<sup>3</sup>, to prevent maternal transmission of HIV infection, IVIG is used in conjunction with zidovudine to prevent serious bacterial infections in HIV-infected members who have hypogammaglobulinemia (serum IgG less than 400 mg/dL).</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## GAMUNEX-C

Other Criteria	<p>Infections in Low-Birthweight Neonates. Prophylaxis and treatment of infections in high-risk, preterm, low-birth weight members. Diagnosed with staphylococcal / streptococcal toxic shock syndrome. Infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or has persistent oliguria with pulmonary edema. Diagnosed with autoimmune neutropenia and G-CSF therapy is not appropriate. Autoimmune Hemolytic Anemia. Is refractory to corticosteroid therapy and splenectomy. Myasthenia Gravis. Is experiencing acute myasthenic crisis with decompensation. Other treatments have been unsuccessful (e.g., corticosteroids, azathioprine, cyclosporine, and cyclophosphamide). Guillain-Barre Syndrome. Is severely affected by the disease and requires an aid to walk. Diagnosed with biopsy-proven polymyositis OR dermatomyositis and has failed treatment with corticosteroids and azathioprine or methotrexate. Diagnosed with multifocal motor neuropathy confirmed by electrophysiologic studies. Diagnosed with relapsing-remitting multiple sclerosis and has failed conventional therapy (Betaseron, Avonex, etc.). Parvovirus B19 Infection, chronic. Chronic Parvovirus B19 infection with severe anemia associated with bone marrow suppression. Chronic Inflammatory Demyelinating Polyneuropathies. Not responded to corticosteroid treatment. One of the following criteria are met: Electrodiagnostic evidence of demyelinating neuropathy in at least two limbs, OR There is muscle weakness and diagnostic testing was conducted in accordance with AAN diagnostic criteria. Diagnosis of Lambert-Eaton myasthenic syndrome confirmed by electrophysiologic studies. Has not responded to diaminopyridine, azathioprine, corticosteroids, or anticholinesterases. Neonate is diagnosed with isoimmune hemolytic disease. Allosensitized Solid Organ Transplantation. Allosensitized members who are awaiting solid organ transplant. Multiple Myeloma. Has life-threatening infections. Autoimmune Blistering Diseases. Biopsy-proven diagnosis of an autoimmune blistering disease such as epidermolysis bullosa acquisita, etc. Has tried and failed conventional therapy or has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. Stiff-Person Syndrome. Other interventions (diazepam) have been unsuccessful. Systemic Lupus Erythematosus. Active/chronic SLE that is refractory to corticosteroid therapy or in members with hemolytic anemia/ thrombocytopenia. Prevention of Bacterial / Viral Infections in Non-primary Immunodeficiency Members. Experiencing iatrogenically induced or disease associated immunosuppression. Or diagnosed with hematologic malignancy.</p>
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## GATTEX 30-VIAL

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Short Bowel Syndrome initial review: Member has a diagnosis of Short Bowel Syndrome. Member is dependent on parenteral support (ie. parenteral nutrition and/or intravenous fluids). Member does not have active gastrointestinal malignancy. Member does not have biliary and/or pancreatic disease. Reauthorization: Member does not have active gastrointestinal malignancy. Member does not have biliary and/or pancreatic disease. Need for parenteral support (ie. parenteral nutrition and/or intravenous fluids) has decreased in volume (mL) from baseline weekly requirement at start of Gattex treatment and as documented by actual change in volume. (Note: discontinuation of parental support would be considered a decrease in volume from baseline).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 Month Duration
Other Criteria	NA

## GATTEX ONE-VIAL

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Short Bowel Syndrome initial review: Member has a diagnosis of Short Bowel Syndrome. Member is dependent on parenteral support (ie. parenteral nutrition and/or intravenous fluids). Member does not have active gastrointestinal malignancy. Member does not have biliary and/or pancreatic disease. Reauthorization: Member does not have active gastrointestinal malignancy. Member does not have biliary and/or pancreatic disease. Need for parenteral support (ie. parenteral nutrition and/or intravenous fluids) has decreased in volume (mL) from baseline weekly requirement at start of Gattex treatment and as documented by actual change in volume. (Note: discontinuation of parental support would be considered a decrease in volume from baseline).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 Month Duration
Other Criteria	NA

## GAVRETO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on RET inhibitors (e.g., pralsetinib, selpercatinib).
Required Medical Information	Non-small cell lung cancer: The member has a diagnosis of metastatic non-small lung cancer AND the disease is documented as RET fusion positive AND Gavreto (pralsetinib) is being used as monotherapy. Medullary Thyroid cancer: The member has a diagnosis of metastatic or advanced medullary thyroid cancer AND The disease is documented RET mutant AND Gavreto (pralsetinib) is being used as monotherapy for systemic therapy. Thyroid cancer: The member has a diagnosis of metastatic or advanced thyroid cancer AND The disease is documented RET fusion positive AND The disease is radioactive iodine refractory AND Gavreto (pralsetinib) is being used as monotherapy for systemic therapy.
Age Restriction	Thyroid Cancer and Medullary Thyroid Cancer: The member is 12 years of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

# GAZYVA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Gazyva (obinutuzumab). The member will be using obinutuzumab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Required Medical Information	Chronic Lymphocytic Leukemia: The member must have a diagnosis of chronic lymphocytic leukemia AND The member is using Gazyva (obinutuzumab) in combination with Chlorambucil OR the member is using Gazyva (obinutuzumab) in combination with bendamustine OR the member is using Gazyva (obinutuzumab) in combination with Venclexta (venetoclax) OR the member is using Gazyva (obinutuzumab) as monotherapy. Follicular Lymphoma: The member has a diagnosis of follicular lymphoma AND One of the following sets of criteria apply: The member will be using Gazyva (obinutuzumab) for first line therapy OR The member has relapsed after, or is refractory to, a rituximab-containing regimen (defined as progression on or within 6 months of prior rituximab product therapy) AND The member will initially be using Gazyva (obinutuzumab) in combination with chemotherapy (e.g. CHOP, CVP, bendamustine) (after 6-8 cycles Gazyva (obinutuzumab) may be continued as monotherapy per reauthorization criteria below). Follicular Lymphoma--Reauthorization Criteria: The member has achieved stable disease, complete response, or partial response after therapy with Gazyva (obinutuzumab) in combination with chemotherapy (e.g. CHOP, CVP, bendamustine).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	CLL: 6 months. Follicular Lymphoma: Initial auth: 6 months, Reauth: Plan Year Duration
Other Criteria	NA

## GILENYA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



# GILOTRIF

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND the following apply: The member has a documented non-resistant epidermal growth factor receptor (EGFR) mutation (sensitizing EGFR mutation e.g., exon 19 deletion, L861Q, S768I, G719X, L858R) AND The member is using Gilotrif (afatinib) as monotherapy (without concomitant chemotherapy) OR squamous cell histology after disease progression on platinum containing chemotherapy and is using Gilotrif (afatinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## glatiramer

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## glatopa

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# HAEGARDA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use for acute treatment of HAE attack. Evidence of autoantibodies against the C1INH protein. Evidence of underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks. Use in combination with other agents approved for prophylactic treatment of HAE attack (e.g. Cinryze).
Required Medical Information	Hereditary Angioedema (HAE) Prophylaxis: The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Low evidence of C4 level (i.e. C4 level below lower limit of normal laboratory reference range) AND Low C1 inhibitor (C1INH) antigenic level (i.e. C1INH level below lower limit of normal laboratory reference range) OR Low C1INH functional level (i.e. functional C1INH less than 50% or below lower limit of normal laboratory reference range) OR Known HAE-causing C1INH mutation. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level. The member must be using Haegarda for prophylaxis to prevent attacks of HAE.
Age Restriction	The member must be 6 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## HALAVEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Breast Cancer. The member has a diagnosis of metastatic breast cancer AND The member has progressive disease following at least two chemotherapeutic regimens for the treatment of metastatic disease AND The member has had prior therapy, contraindication or intolerance with an anthracycline and a taxane in either the adjuvant or metastatic setting.Liposarcoma: The member has a diagnosis of unresectable or metastatic liposarcoma and has received a prior anthracycline containing regimen.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six months
Other Criteria	NA

# HARVONI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other Direct Acting Antivirals (e.g. HCV protease inhibitors, polymerase inhibitors, NS5A inhibitors).
Required Medical Information	<p>Chronic Hepatitis C: Member must have a diagnosis of chronic hepatitis C infection. Member must have documented Genotypes 1a,1b,4,5 and 6 infection. HCV RNA level must be documented prior to therapy. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C - GT1 treatment naive without cirrhosis and HCV RNA under 6 million will be approved for 8 weeks. Pediatrics: Member must have a diagnosis of chronic hepatitis C infection. Member must have documented Genotype 1, 4, 5 or 6 infection. HCV RNA level must be documented prior to therapy. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C Post Liver Transplant - Member must have received a liver transplant, Must must have experienced recurrent HCV infection post-transplant in the allograft liver, Member must be at least 18 years of age, Member must have document genotype 1, 4, 5 or 6 infection, Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C With Decompensated Cirrhosis - Member must have diagnosis of chronic hepatitis C with decompensated cirrhosis, Member must be at least 18 years of age, Member must have genotype 1, 4, 5 or 6 infection, Member must be tested for the presence of HBV by screening for surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. For all genotypes, criteria will be applied consistent with current AASLD-IDSA guidance.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	8 to 24 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	

# HERCEPTIN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	For Ogivri, Herzuma or Ontruzant requests: member must have an intolerance or contraindication Herceptin (trastuzumab) OR Trazimera (trastuzumab-qyyp) OR Kanjinti (trastuzumab-anns) and meets below criteria: Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease. Gastric Cancer: The member has a diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma and HER2 positive disease AND trastuzumab is being used in combination with cisplatin and fluorouracil or capecitabine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## HERCEPTIN HYLECTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member is using concomitantly with Kadcyła (ado-trastuzumab emtansine). Member has a diagnosis of gastric or GEJ or esophageal carcinoma.
Required Medical Information	Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease AND Member has intolerance or prior treatment with Herceptin (trastuzumab) or Trazimera (trastuzumab-qyyp) or Kanjinti (trastuzumab-anns) and one of the following applies: Member is receiving Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) as adjuvant treatment and In combination with paclitaxel or docetaxel following doxorubicin and cyclophosphamide or In combination with docetaxel and carboplatin or Monotherapy following multimodality anthracycline based therapy OR Member is receiving Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) as treatment for metastatic disease and In combination with paclitaxel as first line treatment or monotherapy following one or more combination chemotherapy treatments.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## HETLIOZ

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-24-Hour Sleep-Wake Disorder. The member must utilize HetlioZ for the treatment of Non-24-Hour Sleep-Wake Disorder AND member has diagnosis of total blindness (i.e no light perception) in both eyes. Smith-Magenis Syndrome (SMS): The member has a documented diagnosis of SMS and documented evidence of nighttime sleep disturbances associated with SMS.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## HETLIOZ LQ

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-24-Hour Sleep-Wake Disorder. The member must utilize Hetlloz for the treatment of Non-24-Hour Sleep-Wake Disorder AND member has diagnosis of total blindness (i.e no light perception) in both eyes. Smith-Magenis Syndrome (SMS): The member has a documented diagnosis of SMS and documented evidence of nighttime sleep disturbances associated with SMS.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# HUMIRA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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# HUMIRA PEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA PEN

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA PEN CROHNS-UC-HS START

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA PEN CROHNS-UC-HS START

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA PEN PSOR-UEVITS-ADOL HS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA PEN PSOR-UVEITS-ADOL HS

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA(CF)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF)

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA(CF) PEDI CROHNS STARTER

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEDI CROHNS STARTER

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA(CF) PEN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA(CF) PEN CROHNS-UC-HS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN CROHNS-UC-HS

Other Criteria	<p>Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).</p>
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## HUMIRA(CF) PEN PEDIATRIC UC

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN PEDIATRIC UC

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HUMIRA(CF) PEN PSOR-UV-ADOL HS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Psoriatic Arthritis. Diagnosis of active psoriatic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, leflunomide) or contraindication with all DMARDs. Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments.
Age Restriction	The member must be at least 18 years of age for the following indications: Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis. The member must be two years of age or older and have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis or Uveitis. Must be six years or older for Crohns Disease. Must be 12 years or older for Hidradenitis Suppurativa. Must be 5 years or older for Ulcerative Colitis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN PSOR-UV-ADOL HS

Other Criteria	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. The member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) OR Immunomodulators (e.g. azathioprine or 6-mercaptopurine). Crohn's Disease: The member must have moderately to severely active Crohn's disease. The member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g.azathioprine, 6-mercaptopurine, methotrexate). Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine, tacrolimus).
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## HYFTOR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Facial Angiofibroma: the member must meet all of the following criteria: diagnosis of tuberous sclerosis complex (TSC), experiencing greater than or equal to three facial angiofibromas, and is not receiving systemic mTOR inhibitor therapy (e.g. everolimus).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## ibandronate

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	In patients with severe renal impairment (patients with serum creatinine greater than 200uMol/L [2.3 mg/dL] or creatinine clearance less than 30mL/min.
Required Medical Information	Postmenopausal Osteoporosis: The member is a postmenopausal with a diagnosis of osteoporosis or at high risk for osteoporosis. The member has new fractures or significant loss of bone mineral density despite previous treatment contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate, ibandronate, pamidronate).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year
Other Criteria	NA



## IBRANCE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member is on concomitant abemaciclib or ribociclib. Member has experienced disease progression on CDK 4/6 inhibitor (e.g., ribociclib, abemaciclib).
Required Medical Information	Breast Cancer: The member has a diagnosis of estrogen receptor-positive and human epidermal growth factor receptor 2-negative breast cancer AND one of the following applies: The member will be using Ibrance in combination with an aromatase inhibitor (e.g., letrozole) as initial endocrine-based therapy for their recurrent disease OR The member will be taking Ibrance (palbociclib) in combination with an aromatase inhibitor (e.g., letrozole) as initial endocrine based therapy for their metastatic disease or the member will be using Ibrance in combination with Faslodex as subsequent therapy after disease progression on or following endocrine based therapy ( e.g. anastrozole) for their recurrent disease or the member will be using Ibrance in combination with Faslodex as subsequent therapy after disease progression on or following endocrine based therapy (e.g. anastrozole) for their metastatic disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	6 months duration.
Other Criteria	NA

## icatibant

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use for prophylaxis of HAE attack. Evidence of autoantibodies against the C1INH protein. Evidence of underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks. Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest).
Required Medical Information	Hereditary Angioedema (HAE): The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Low evidence of C4 level (i.e. C4 level below lower limit of normal laboratory reference range) AND Low C1 inhibitor (i.e. C1INH level below lower limit of normal laboratory reference range) antigenic level (C1INH less than 19 mg/dL) OR Low C1INH functional level (i.e. functional C1INH less than 50% or below lower limit of normal laboratory reference range) OR Known HAE-causing C1INH mutation. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level. The member is using icatibant for treatment of acute attacks of HAE.
Age Restriction	The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# ICLUSIG

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Iclusig (ponatinib). Members on concomitant tyrosine kinase inhibitors.
Required Medical Information	Chronic Myeloid Leukemia (chronic phase):The member has a diagnosis of chronic phase chronic myeloid leukemia (CML) AND one of the following apply: The member has an intolerance, resistance, or contraindication to at least two available tyrosine kinase inhibitors indicated for the treatment of CML OR The member has a documented T315I mutation. Chronic Myeloid Leukemia (accelerated or blast phase): The member has a diagnosis of accelerated or blast phase chronic myeloid leukemia (CML) AND one of the following apply: There are no other kinase inhibitors indicated OR the member has a documented T315I mutation. Acute Lymphoblastic Leukemia: The member has a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) AND one of the following apply: There are no other kinase inhibitors indicated OR The member has a documented T315I mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## IDHIFA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression while on or following Idhifa(enasidenib)
Required Medical Information	Acute Myeloid Leukemia - Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member has a documented IDH2 mutation AND One of the following applies: The member will be using Idhifa (enasidenib) as monotherapy OR the member will be using Idhifa (enasidenib) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months). Acute Myeloid Leukemia - Newly diagnosed: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has newly diagnosed disease AND the member is not a candidate for intensive induction therapy due to comorbidities AND the member has a documented IDH2 mutation AND the member will be using Idhifa (enasidenib) as monotherapy.
Age Restriction	The member is 60 years of age or older for newly diagnosed AML.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	NA

## imatinib

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients on concomitant tyrosine kinase inhibitors. Patients that have experienced disease progression while on imatinib.
Required Medical Information	The member has a diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR The member has a diagnosis of Ph+ CML that is in accelerated phase or blast crisis. Acute lymphoid leukemia (ALL). The member has a diagnosis of Ph+ ALL that is relapsed, refractory, or newly diagnosed and imatinib is being added to consolidation or induction therapy OR the member has a diagnosis of PH+ALL and receiving maintenance therapy. The member has a diagnosis of Kit (CD117)-positive GIST. The member has a diagnosis of Dermatofibrosarcoma protuberans (DFSP) that is adjuvant (positive surgical margins following excision) unresectable, recurrent, and/or metastatic. The member has a diagnosis of chronic eosinophilic leukemia or hypereosinophilic syndrome. The member has a diagnosis of MDS or chronic MPD that is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangement.(ex. Chronic myelomonocyte leukemia, atypical chronic myeloid leukemia, juvenile myelomonocyte leukemia).The member has a diagnosis of aggressive systemic mastocytosis. The member must not harbor the D816v mutation of C-kit. Melanoma. The member has a diagnosis of unresectable melanoma with activating mutation of C-kit. Imatinib will be used as single agent in subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Pediatric indications: The patient has a diagnosis of Philadelphia chromosome positive (Ph+) CML that is newly diagnosed in chronic phase OR The patient has a diagnosis of Ph+ CML that is in chronic phase with disease recurrence after stem cell transplant OR The patient has a diagnosis of Ph+ CML that is in chronic phase after failure of interferon-alpha therapy. Acute Lymphoid Leukemia (ALL). The member is newly diagnosed with Ph+ ALL AND the member will be using imatinib in combination with chemotherapy.

# IMBRUVICA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Imbruvica (ibrutinib).
Required Medical Information	Mantle Cell Lymphoma: The member has a diagnosis of Mantle Cell Lymphoma (MCL) AND The member has received at least one prior therapy for the treatment of MCL AND The member is using Imbruvica as monotherapy. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). Waldenstrom's Macroglobulinemia: The member has a diagnosis of Waldenstrom's macroglobulinemia AND The member is using Imbruvica (ibrutinib) as monotherapy or in combination with a rituximab product. Marginal Zone Lymphoma: The member has a diagnosis of marginal zone lymphoma AND The member is using Imbruvica (ibrutinib) as second line or subsequent for refractory or progressive disease AND The member is using Imbruvica (ibrutinib) as monotherapy. Chronic Graft Versus Host Disease (adult): The member has a diagnosis of chronic graft versus host disease (cGVHD) AND The member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g. corticosteroids). Chronic Graft Versus Host Disease (pediatric): The member has a diagnosis of chronic graft versus host disease (cGVHD) AND The member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g. corticosteroids).
Age Restriction	pediatric cGVHD: Member age is 1 year or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# IMFINZI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on anti-PD-1/PD-L1 therapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Tecentriq (atezolizumab), Imfinzi (durvalumab)]. For NSCLC, member has not exceeded a maximum of twelve (12) months of therapy.
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): Member has diagnosis of unresectable stage III non-small cell lung cancer (NSCLC) AND Imfinzi (durvalumab) will be used as consolidation therapy after completion of concurrent platinum containing chemotherapy and radiation AND Member has not experienced progression of disease after at least two cycles of chemotherapy and radiation AND Imfinzi (durvalumab) will be used as monotherapy. Small Cell Lung Cancer: The member has a diagnosis of extensive-stage small cell lung cancer AND Imfinzi will be given in combination with etoposide and carboplatin as first line therapy followed by maintenance therapy with Imfinzi as a single agent. Biliary Tract Cancer: the member has a diagnosis of locally advanced or metastatic biliary tract cancer AND the member will be using Imfinzi (durvalumab) in combination with gemcitabine and cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	6 months Duration.
Other Criteria	

## IMJUDO

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review



## IMLYGIC

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members who are immunocompromised. Members who are pregnant. Members that have experienced disease progression while on Imlygic (talimogene laherparepvec). Concomitant therapy with anti-PD-1/PD-L1 agents (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]).
Required Medical Information	Unresectable Melanoma: The member must have one of the following melanoma diagnoses: unresectable Stage III with in-transit metastases, unresectable local/satellite recurrence (may also have in-transit metastases), unresectable or distant metastatic disease. The member will receive Imlygic as an intralesional therapy into cutaneous, subcutaneous, or nodal lesions that are visible on the skin, palpable, or detectable by ultrasound guidance.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## INCRELEX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The bone epiphyses are closed.
Required Medical Information	Member has a diagnosis of GH gene deletion with development of neutralizing antibodies to GH OR The patient has a diagnosis of severe primary IGF-1 deficiency defined by:height standard deviation score below or equal -3.0 and basal IGF-1 standard deviation score below or equal -3.0 and normal or elevated growth hormone.
Age Restriction	The patient is 2 years or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# INGREZZA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Tardive Dyskinesia Initial therapy. The member is utilizing Ingrezza (valbenazine) for the treatment of moderate to severe tardive dyskinesia as seen by the following: the member has abnormal involuntary movements related to treatment with one or more dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) or Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member will be using Ingrezza for the treatment of moderate to severe tardive dyskinesia that is not associated with other medication therapies (e.g. dopamine blocking agents). AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks AND the member has had previous treatment, contraindication, or intolerance to Austedo (deutetrabenazine). Tardive Dyskinesia - Reauthorization: The member has a documented improvement or maintenance of symptoms while on Ingrezza (valbenazine) (e.g. reduction in Abnormal Involuntary Movement Scale [AIMS] score or Dyskinesia Identification System: Condensed User Scale [DISCUS] from baseline) AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks.</p>
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 3 months. Reauthorization: Plan Year Duration
Other Criteria	

## INGREZZA INITIATION PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Tardive Dyskinesia Initial therapy. The member is utilizing Ingrezza (valbenazine) for the treatment of moderate to severe tardive dyskinesia as seen by the following: the member has abnormal involuntary movements related to treatment with one or more dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) or Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member will be using Ingrezza for the treatment of moderate to severe tardive dyskinesia that is not associated with other medication therapies (e.g. dopamine blocking agents). AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks AND the member has had previous treatment, contraindication, or intolerance to Austedo (deutetrabenazine). Tardive Dyskinesia - Reauthorization: The member has a documented improvement or maintenance of symptoms while on Ingrezza (valbenazine) (e.g. reduction in Abnormal Involuntary Movement Scale [AIMS] score or Dyskinesia Identification System: Condensed User Scale [DISCUS] from baseline) AND The provider attests that the risk versus benefit of depression and suicidality has been considered, and the benefits of treatment outweigh the risks.</p>
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 3 months. Reauthorization: Plan Year Duration
Other Criteria	

## INLYTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Inlyta (axitinib).
Required Medical Information	Renal Cell Carcinoma: The member has a diagnosis of advanced renal cell carcinoma AND Inlyta will be given as one of the following: monotherapy AND the member has a medical reason as to why Cabometyx (cabozantinib) can not be initiated or continued OR in combination with Keytruda or Bavencio as first-line therapy. Advanced Thyroid Carcinoma: The member has a diagnosis of advanced/metastatic follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma and clinical trials are not available or appropriate AND The member has disease that is not responsive to radio-iodine treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## INQOVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on hypomethylators (e.g. azacitidine, decitabine).
Required Medical Information	Myelodysplastic Syndromes - Chronic Myelomonocytic Leukemia: The member has a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo or secondary MDS OR chronic myelomonocytic leukemia (CMML) AND the member will be using Inqovi (decitabine and cedazuridine) as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## INREBIC

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Inrebic (fedratinib).
Required Medical Information	Myelofibrosis: The member has a diagnosis of primary myelofibrosis or secondary myelofibrosis (i.e. post-polycythemia vera or post-essential thrombocythemia) AND The member has one of the following risk categories, as defined by accepted risk stratification tools for myelofibrosis (e.g. International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or DIPSS-PLUS): Intermediate-2 risk disease OR High-risk disease AND the member will be using Inrebic (fedratinib) as monotherapy AND The member has a medical reason as to why Jakafi (ruxolitinib) cannot be used. Reauthorization criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement) AND physician attestation that the member has not experienced unacceptable toxicities.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth: 6 months duration. Reauthorization: 6 months Duration.
Other Criteria	NA

## INTRON A

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Chronic Hepatitis C. Diagnosis of chronic hepatitis C with compensated liver disease (without jaundice, ascites, active gastrointestinal bleeding, encephalopathy). Documentation of quantitative HCV RNA (viral load). For members 18 years of age older: For treatment naïve members with Hepatitis C, the member must first consider pegylated products (Pegasys or Peg-Intron plus ribavirin) or have a contraindication or other clinical circumstance preventing them from using before the member will be eligible to receive Intron A. For members 3 - 17 years of age: Intron A must be used in combination with ribavirin. Chronic Hepatitis B: Diagnosis of chronic HBeAG-positive hepatitis B with compensated liver. Must have ALT greater than 2x the upper limit of normal and have HBV DNA greater than 20,000 IU/ml. Hairy Cell Leukemia. Diagnosis of hairy cell leukemia. Malignant Melanoma. Diagnosis of malignant melanoma and utilizing Intron A as an adjuvant therapy to surgical treatment. Follicular Non-Hodgkin's Lymphoma. Diagnosis of follicular non-Hodgkin's lymphoma. Must be utilizing Intron A in conjunction with anthracycline-containing combination chemotherapy. Condylomata Acuminata. Diagnosis of condylomata acuminata involving external surfaces of the genital and perianal areas. AIDS-Related Kaposi's Sarcoma. Diagnosis of AIDS-related Kaposi's sarcoma.
Age Restriction	Chronic Hep C must 3 years or older. Must be 18 years or older for Hairy Cell Leukemia, Malignant Melanoma, Follicular Non-Hodgkins Lymphoma, Condylomata Acuminata, AIDS-related Kaposi's Sarcoma. 1 year or older for Chronic Hep B.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	HepC:24months, Melanoma,lymphoma:PlanYear,leukemia,HepB:6 months,Condylomata:3weeks,Kaposi:4months
Other Criteria	NA



# IRESSA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) AND the following applies: The member has a documented epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation AND The member is using Iressa (gefitinib) as monotherapy (without concomitant chemotherapy).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

# ISTODAX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on romidepsin. Members on concomitant hypomethylator (e.g. vorinostat) therapy.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Istodax (romidepsin) is being used to treat cutaneous T-cell lymphoma AND one of the following applies: the member will be using Istodax (romidepsin) as primary biologic systemic therapy OR the member has received at least one prior therapy. Peripheral T-cell Lymphoma (PTCL). Istodax (romidepsin) is being used to treat relapsed or refractory peripheral T-cell lymphoma. The member has received at least one prior therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## IXEMPRA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced severe (CTC grade 3/4) hypersensitivity reactions to medications formulated with Cremophor EL/ polyoxyethylated castor oil. Ixemptra (ixabepilone) should be discontinued after disease progression constituting treatment failure.
Required Medical Information	Breast Cancer. The member has a diagnosis of locally advanced or metastatic breast cancer and one of the following: When used as monotherapy: the member has disease that is refractory or resistant to an anthracycline (e.g. Doxorubicin), a taxane (e.g. paclitaxel) and Xeloda (capecitabine) OR When used in conjunction with Xeloda (capecitabine) (or 5-FU/fluorouracil): the member has disease that is refractory to both an anthracycline (e.g. Doxorubicin), and a taxane (e.g. paclitaxel) (or further anthracycline therapy is contraindicated and disease is refractory to a taxane).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six months
Other Criteria	NA

# JAKAFI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Jakafi (ruxolitinib) therapy is not considered medically necessary for members with the following concomitant conditions: Members that have experienced disease progression while on Jakafi (ruxolitinib). Members on concomitant tyrosine kinase inhibitors or immunomodulatory medications (example: Revlimid/lenalidomide)
Required Medical Information	Myelofibrosis. The member has a documented diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis AND The member has one of the following risk categories, as defined by International Prognostic Scoring System (IPSS): Symptomatic low risk disease OR Symptomatic intermediate-1 risk disease OR Intermediate-2 risk disease OR High risk disease. The member will be using Jakafi (ruxolitinib) as monotherapy (excludes medically necessary supportive agents). Polycythemia Vera: The member has a diagnosis of polycythemia vera AND The member has not achieved treatment goals, has an intolerance, or contraindication to hydroxyurea. Acute Graft Versus Host Disease: The member has a diagnosis of steroid-refractory acute graft versus host disease. Reauthorization criteria. Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement, hematocrit control) AND Physician attestation that the member has not experienced unacceptable toxicities. Chronic Graft Versus Host Disease (cGVHD): The member has a diagnosis of chronic graft-versus-host disease (cGVHD) AND the member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g., corticosteroids). Reauthorization criteria. Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement, hematocrit control) AND Physician attestation that the member has not experienced unacceptable toxicities.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial Authorization: Plan Year Duration. Reauthorization: Plan Year Duration.
Other Criteria	

## javygtor

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Initial: The member has a diagnosis of PKU. Reauth - The member has tetrahydrobiopterin -(BH4) responsive PKU defined by: The member has achieved a greater than or equal to a 20% reduction in blood phenylalanine concentration from pre-treatment baseline OR the member has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescriber.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	First approval: three months. if response is positive extended for plan year duration.
Other Criteria	NA

# JEMPERLI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g.,nivolumab, pembrolizumab).
Required Medical Information	Endometrial cancer: The member has diagnosis of recurrent or advanced endometrial cancer AND The member has documented dMMR endometrial cancer AND The member has progressed on prior platinum containing regimen AND There is a medical reason why Keytruda (pembrolizumab) cannot be initiated as subsequent therapy AND Jemperli (dostarlimab-gxly) is administered as monotherapy as subsequent therapy. Solid tumors (dMMR): The member has a diagnosis of unresectable or metastatic documented mismatch repair deficient (d-MMR) solid tumors AND the member has disease that has progressed on prior therapy with no alternative treatments AND The member has a medical reason why Keytruda (pembrolizumab) cannot be initiated as subsequent therapy AND Jemperli (dostarlimab-gxly) is administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## JEVTANA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Jevtana should not be administered to patients with neutrophils less than or equal to 1,500/mm <sup>3</sup> . Jevtana should not be given to patients with hepatic impairment (total bilirubin greater than 3 x ULN. Concomitant use with abiraterone acetate, Yonsa, or Xtandi.
Required Medical Information	Hormone-Refractory Metastatic Prostate Cancer. The member must have a diagnosis of hormone-refractory metastatic prostate cancer. The member must have previously been treated with a docetaxol-containing treatment regimen. The member must be taking Jevtana in combination with concurrent corticosteroid (e.g., dexamethasone, prednisone).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KADCYLA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on Kadcyla (ado-trastuzumab emtansine. Use in the adjuvant setting. Members on concomitant trastuzumab product, Tykerb (lapatinib), or Perjeta (pertuzumab).
Required Medical Information	Metastatic Breast Cancer. The member has a diagnosis of metastatic breast cancer and HER2 (human epidermal growth factor receptor2) positive disease AND the member is using Kadcyla (ado-trastuzumab emtansine) as monotherapy AND the member has received prior therapy with a trastuzumab product and a taxane (eg. paclitaxel, docetaxel), separately or in combination and one of the following applies: Received prior treatment for metastatic disease. Recurrence occurred during or within six months of completing adjuvant therapy. Early Breast cancer: The member has a diagnosis of early HER 2 positive breast AND the member has received neoadjuvant taxane (e.g. paclitaxel) and trastuzumab containing regimen AND the member is receiving Kadcyla (ado-trastuzumab emtansine) as adjuvant treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



## KALYDECO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Cystic Fibrosis: The member has a diagnosis of Cystic Fibrosis. The member has a documentation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical literature and/or in vitro assay data.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KANJINTI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	For Ogivri, Herzuma or Ontruzant requests: member must have an intolerance or contraindication Herceptin (trastuzumab) OR Trazimera (trastuzumab-qyyp) OR Kanjinti (trastuzumab-anns) and meets below criteria: Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease. Gastric Cancer: The member has a diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma and HER2 positive disease AND trastuzumab is being used in combination with cisplatin and fluorouracil or capecitabine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## KERENDIA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic kidney disease associated with type 2 diabetes: The member has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) AND The member has serum potassium less than or equal to 5.0 mEq/L upon initiation of therapy AND The member is currently receiving, unless contraindicated or intolerant, the maximally tolerated dose of: Either an angiotensin-converting enzyme inhibitor (e.g. Lisinopril) OR an angiotensin receptor blocker (e.g. losartan).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## KESIMPTA PEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Relapsing Forms of Multiple Sclerosis: The member has a diagnosis of one of the following: A relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease, OR Clinically isolated syndrome (CIS).
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	

## ketoconazole

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Systemic Fungal Infection: member has a diagnosis of a systemic fungal infection (i.e., blastomycosis, coccidioidomycosis, histoplasmosis, paracoccidioidomycosis, chromomycosis). Prophylaxis - Transplanted Organ Rejection: member has a transplanted organ AND member will concurrently receive immunosuppressant therapy with cyclosporine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KEVZARA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Moderate to Severe Rheumatoid Arthritis: The member must have a diagnosis of moderately to severely active rheumatoid arthritis AND the member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, cyclosporine, leflunomide) or contraindication to all DMARDs.
Age Restriction	The member must be at least 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KEYTRUDA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g., nivolumab, atezolizumab). Member requiring urgent cytoreductive therapy (applicable to PMBCL only). Member not to exceed one year of total adjuvant treatment (applicable to melanoma and renal cell carcinoma only).
Required Medical Information	Melanoma: unresectable or metastatic melanoma OR melanoma OR stage IIB, IIC, or III melanoma AND as monotherapy for adjuvant treatment after complete resection with involvement of lymph node(s). NSCLC-1st Line: metastatic NSCLC AND 1 of the following applies: disease with PD-L1 expression [TPS greater than or equal to 1%] with no EGFR or ALK genomic tumor aberrations and as 1st line AND tumor expresses PD-L1 as determined by an FDA-approved test AND used as monotherapy OR nonsquamous histology with no EGFR or ALK genomic tumor aberrations and in combo with pemetrexed and carboplatin or cisplatin as 1st line therapy followed by Keytruda maintenance in combo with pemetrexed OR squamous histology and used in combo with carboplatin and paclitaxel or Abraxane as 1st line followed by Keytruda maintenance OR stage III NSCLC and not candidate for surgical resection or definitive chemoradiation AND PD-L1 expression with no EGFR or ALK genomic tumor aberrations and as 1st line AND Tumor expresses PD-L1 as determined by an FDA-approved test AND as monotherapy. NSCLC-Subsequent: metastatic NSCLC AND progression on or following chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND Tumor expresses PD-L1 as determined by an FDA-approved test AND as monotherapy. Head-Neck Cancer: recurrent or metastatic non-nasopharyngeal head and neck squamous cell carcinoma AND 1 of following: disease progression on platinum-containing chemo and as monotherapy OR in combo with platinum and 5-FU for 1st line treatment OR monotherapy in 1st line and disease expresses CPS score greater than or equal to 1 as detected by an FDA-approved test. Hodgkin's Lymphoma-Adult: as monotherapy for refractory or relapsed disease. Hodgkin's Lymphoma-Peds: monotherapy and 1 of following: Refractory disease OR Relapsed after 2 or more lines of prior therapy. CSCC: recurrent or metastatic CSCC AND disease is not amenable to curative surgery or radiation AND used as a monotherapy.
Age Restriction	Stage IIB, IIC, or III melanoma - member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner

## KEYTRUDA

Coverage Duration	6 months duration
Other Criteria	<p>MSI-High/d-MMR Solid tumors: unresectable or metastatic documented microsatellite instability-high or mismatch repair deficient solid tumors (excluding pediatric patients with MSI-H central nervous system cancers) AND 1 of the following: disease that progressed on prior therapy with no alternative treatments and as monotherapy OR colorectal cancer AND 1 of the following: Keytruda as monotherapy and as subsequent therapy after progression on fluoropyrimidine, oxaliplatin, and irinotecan or 1st line as monotherapy in unresectable or metastatic colorectal cancer.</p> <p>Urothelial Cancer: locally advanced or metastatic urothelial cancer AND as monotherapy AND 1 of the following: initial therapy in members who are ineligible for cisplatin containing chemotherapy and disease expressing CPS score greater than or equal to 10 OR initial therapy in members ineligible to receive platinum containing chemo regardless of PD-L1 status OR as subsequent therapy after disease progression within 12 months of neoadjuvant or adjuvant chemo. Cervical Cancer: recurrent or metastatic cervical cancer AND disease progression on or after chemo AND disease expresses CPS score greater than or equal to 1 as determined by an FDA approved test AND as monotherapy OR persistent, recurrent, or metastatic cervical cancer AND cancer express CPS score of greater than or equal to 1 as determined by an FDA approved test and will be used with chemo, with or without bevacizumab, as 1st line therapy. Primary Mediastinal Large B-Cell Lymphoma [Adults and pediatrics]: relapsed or refractory disease after 2 or more prior lines of treatment AND as monotherapy. Merkel cell carcinoma-Adult and pediatric: recurrent locally advanced or metastatic merkel cell carcinoma AND as monotherapy. HCC: has prior therapy with a 1st line therapy (e.g., sorafenib) AND as monotherapy. RCC: advanced or metastatic RCC AND in combo with Inlyta or Lenvima as 1st line therapy.</p> <p>Esophageal Cancer: recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus AND disease expresses PD-L1 as determined by an FDA approved test AND given as subsequent therapy as a single agent. Endometrial cancer: metastatic or recurrent endometrial cancer AND not MSI-H or dMMR AND not candidate for surgery or radiation AND has experienced disease progression on prior systemic therapy AND given in combo with Lenvima as subsequent therapy. NMIBC with carcinoma in situ AND ineligible for or has elected not to undergo cystectomy AND has BCG-unresponsive disease, defined as persistent or recurrent high-grade bladder cancer within 6 months of intravesical BCG therapy AND as monotherapy. TMB-H Solid tumors: unresectable or metastatic solid tumors with documented TMB-H [greater than or equal to 10 mutations/megabase] (excluding pediatric patients with TMB-H central nervous system cancers) AND disease progressed on prior therapy with no alternative treatments AND given as monotherapy.</p>



# KIMMTRAK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Kimmtrak (tebentafusp-tebn).
Required Medical Information	Metastatic Uveal Melanoma: the member has a diagnosis of unresectable or metastatic uveal melanoma AND the member has documentation of HLA-A 02:01 positive disease by assay results AND Kimmtrak (tebentafusp-tebn) will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## KISQALI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member is on concomitant palbociclib or abemaciclib. Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, abemaciclib).
Required Medical Information	Breast Cancer-Combination with Aromatase Inhibitors. The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (Her2neu)-negative breast cancer AND the member is post-menopausal AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine therapy AND the member has a medical reason as to why Ibrance (palbociclib) and Verzenio (abemaciclib) cannot be started or continued as initial endocrine based therapy OR The member will be using Kisqali (ribociclib) in combination with aromatase inhibitor (e.g., letrozole) as initial endocrine-based therapy for their metastatic disease AND The member is pre/peri menopausal and taking LHRH agonist (eg, leuprolide) concomitantly or treated with ovarian ablation. Breast Cancer- Combination with Faslodex (fulvestrant). The member has a diagnosis of hormone receptor-positive and human epidermal growth factor receptor 2-negative breast cancer and one of the following applies: The member will be using Kisqali (ribociclib) in combination with Faslodex (fulvestrant) as initial endocrine based therapy AND The member is post-menopausal OR the member will be using Kisqali (ribociclib) in combination with Faslodex (fulvestrant) as subsequent therapy AND The member has a medical reason as to why Ibrance (palbociclib) AND Verzenio (abemaciclib) cannot be started or continued as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## KISQALI FEMARA CO-PACK

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member is on concomitant palbociclib or abemaciclib. Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, abemaciclib).
Required Medical Information	Breast Cancer-Combination with Aromatase Inhibitors. The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (Her2neu)-negative breast cancer AND the member is post-menopausal AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine therapy AND the member has a medical reason as to why Ibrance (palbociclib) and Verzenio (abemaciclib) cannot be started or continued as initial endocrine based therapy OR The member will be using Kisqali (ribociclib) in combination with aromatase inhibitor (e.g., letrozole) as initial endocrine-based therapy for their metastatic disease AND The member is pre/peri menopausal and taking LHRH agonist (eg, leuprolide) concomitantly or treated with ovarian ablation. Breast Cancer- Combination with Faslodex (fulvestrant). The member has a diagnosis of hormone receptor-positive and human epidermal growth factor receptor 2-negative breast cancer and one of the following applies: The member will be using Kisqali (ribociclib) in combination with Faslodex (fulvestrant) as initial endocrine based therapy AND The member is post-menopausal OR the member will be using Kisqali (ribociclib) in combination with Faslodex (fulvestrant) as subsequent therapy AND The member has a medical reason as to why Ibrance (palbociclib) AND Verzenio (abemaciclib) cannot be started or continued as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## KORLYM

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Pregnancy. Members with a history of unexplained vaginal bleeding. Members with endometrial hyperplasia with atypia or endometrial carcinoma. Concurrent long-term corticosteroid use.
Required Medical Information	Hyperglycemia secondary to hypercortisolism. Diagnosis of endogenous Cushing's syndrome. AND Type 2 diabetes mellitus or glucose intolerance. AND Failed surgery or are not candidates for surgery.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KOSELUGO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experienced disease progression on Koselugo (selumetinib)
Required Medical Information	Neurofibromatosis type 1: The member has a diagnosis of neurofibromatosis type 1 which is symptomatic, inoperable plexiform neurofibromas and Koselugo (selumetinib) is given as a monotherapy
Age Restriction	The member is 2 years of age up to 18 years of age (labeled for use in pediatric patients only).
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## KYNMOBI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Parkinson's "off" episodes: The member has a diagnosis of Parkinson's disease AND is currently taking carbidopa/levodopa and will continue taking carbidopa/levodopa with Kynmobi AND is experiencing breakthrough "off" periods related to their Parkinson's disease despite optimized therapy AND has had previous treatment, contraindication, or intolerance to at least one of the following: A dopamine agonist (e.g. ropinirole, pramipexole) OR a COMT inhibitor (e.g. entacapone) OR a MAO-B inhibitor (e.g. selegiline).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# KYPROLIS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members receiving concomitant therapy with a proteasome inhibitor. The member has experienced disease progression while on Kyprolis (carfilzomib).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of Multiple Myeloma AND The member is using Kyprolis (carfilzomib) as a single agent or in combination with dexamethasone for disease relapse or progressive disease OR the member will be using Kyprolis (carfilzomib) in combination with Farydak (panobinostat) and the member has received at least two prior regimens, including both bortezomib and an immunomodulatory drug (e.g. thalidomide, lenalidomide, pomalidomide) OR the member will be using Kyprolis (carfilzomib) in combination with Pomalyst (pomalidomide) and dexamethasone and the member has received at least two prior therapies, including an immunomodulatory agent (e.g. thalidomide, lenalidomide, pomalidomide) and a proteasome inhibitor (e.g. bortezomib) (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND the member has demonstrated disease progression on or within 60 days of completion of the last therapy OR The member will be using Kyprolis (carfilzomib) in combination with Revlimid (lenalidomide) and dexamethasone or in combination with cyclophosphamide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) and one of the following applies: Is using as primary therapy OR Using for treatment of disease relapse (disease relapse must be after 6 months following primary chemotherapy with the same regimen) or progressive disease OR the member will be using Kyprolis (carfilzomib) in combination with Darzalex (daratumumab) and dexamethasone and the member has received at least one prior line of therapy (Omission of corticosteroid from regimen is allowed if intolerance/contraindication).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	Waldenstrom's Macroglobulinemia: The member has a diagnosis of Waldenstrom's macroglobulinemia AND Kyprolis (carfilzomib) will be used as a component of CaRD regimen (carfilzomib, rituximab, and dexamethasone) as primary therapy (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) OR for relapsed disease (if CaRD previously used as primary therapy relapse must occur after 24 months).

## lanreotide

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	For generic lanreotide requests: member has had prior therapy with or intolerance to brand Somatuline Depot AND meets clinical criteria. Diagnosis of acromegaly. The patient has a diagnosis of acromegaly. The patient has had an inadequate response to or cannot be treated with surgical resection OR The patient has had an inadequate response to or cannot be treated with radiation therapy. Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs): The member has a diagnosis of unresectable, well- or moderately-differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors. Carcinoid Syndrome: The member has a diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	



# LATUDA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Diagnosis of Schizophrenia or Schizoaffective Disorder: The member must have prior therapy, intolerance or contraindication to at least 2 of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole. Diagnosis of Bipolar I Disorder (Bipolar Depression): The member must have documentation of prior therapy, intolerance, or contraindication to quetiapine.
Age Restriction	For diagnosis of Schizophrenia or schizoaffective disorder, the member must be 13 years of age or older. For diagnosis of Bipolar I Disorder (Bipolar Depression), the member must be 10 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ledipasvir-sofosbuvir

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other Direct Acting Antivirals (e.g. HCV protease inhibitors, polymerase inhibitors, NS5A inhibitors).
Required Medical Information	<p>Chronic Hepatitis C: Member must have a diagnosis of chronic hepatitis C infection. Member must have documented Genotypes 1a,1b,4,5 and 6 infection. HCV RNA level must be documented prior to therapy. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C - GT1 treatment naive without cirrhosis and HCV RNA under 6 million will be approved for 8 weeks. Pediatrics: Member must have a diagnosis of chronic hepatitis C infection. Member must have documented Genotype 1, 4, 5 or 6 infection. HCV RNA level must be documented prior to therapy. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C Post Liver Transplant - Member must have received a liver transplant, Must must have experienced recurrent HCV infection post-transplant in the allograft liver, Member must be at least 18 years of age, Member must have document genotype 1, 4, 5 or 6 infection, Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. Chronic Hepatitis C With Decompensated Cirrhosis - Member must have diagnosis of chronic hepatitis C with decompensated cirrhosis, Member must be at least 18 years of age, Member must have genotype 1, 4, 5 or 6 infection, Member must be tested for the presence of HBV by screening for surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. For all genotypes, criteria will be applied consistent with current AASLD-IDSA guidance.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	8 to 24 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	

## lenalidomide

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant Thalomid (thalidomide) or Pomalyst (pomalidomide). Members that have experienced disease progression while on Revlimid (lenalidomide).
Required Medical Information	<p>Myelodysplastic Syndromes (MDS) with 5Q deletion. The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has a documented deletion 5q chromosomal abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent.</p> <p>Myelodysplastic Syndromes (MDS) without 5Q deletion (non-5Q deletion). The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has no documented 5q deletion abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent.</p> <p>Multiple Myeloma. Diagnosis of active Multiple Myeloma or Systemic Light Chain Amyloidosis. Primary induction OR for relapsed/refractory disease, Revlimid (lenalidomide) therapy should be utilized in conjunction with dexamethasone if no contraindication. As maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplantation. For Reauthorizations: The approval duration may be continued for six additional months if benefit is shown via no evidence of disease progression/treatment failure.</p> <p>Chronic Lymphoid Leukemia. Diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia (CLL). For Reauthorizations: The approval duration may be continued for six additional months if benefit is shown via no evidence of disease progression.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## lenalidomide

Other Criteria	<p>Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND The member has relapsed or refractory disease AND The member will be using for third line or subsequent systemic therapy.</p> <p>Non-Hodgkin Lymphoma: The member has one of the following diagnoses: AIDS-related B-cell lymphoma, diffuse large B-cell lymphoma, mucosa-associated lymphoid tissue (MALT) lymphoma [either gastric or nongastric], primary cutaneous B-cell lymphoma, marginal zone lymphoma, or mantle cell lymphoma AND The member has relapsed or refractory disease OR The member has a diagnosis of follicular lymphoma AND The member will use as first line therapy or for relapsed or refractory disease.</p>
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# LENVIMA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Lenvima (lenvatinib).
Required Medical Information	<p>Thyroid Cancer: The member has a diagnosis of locally recurrent or metastatic, progressive differentiated thyroid cancer (i.e. papillary carcinoma, follicular carcinoma or Hürthle cell carcinoma) AND The tumors are not responsive to radio-iodine treatment AND Lenvima (lenvatinib) will be used as monotherapy. Renal Cell Carcinoma. The member has a diagnosis of advanced renal cell carcinoma AND the member is using in combination with Afinitor (everolimus) AND the member has experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome). Hepatocellular Carcinoma: The member has a diagnosis of unresectable carcinoma AND Lenvima (lenvatinib) will be given as a single agent as first line therapy.</p> <p>Endometrial cancer: The member has a diagnosis of metastatic or recurrent endometrial cancer AND The disease is not MSI-H or dMMR AND The member is not a candidate for surgery or radiation AND The member has experienced disease progression on prior systemic therapy AND Lenvima (lenvatinib) will be given in combination with Keytruda (pembrolizumab) as subsequent therapy. Renal cell carcinoma- first line therapy: The member has a diagnosis of advanced renal cell carcinoma AND Lenvima (lenvatinib) will be given in combination with Keytruda (pembrolizumab) as first line therapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## leuprolide (3 month)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## levoleucovorin calcium

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Fusilev (levoleucovorin) is considered not medically necessary for members with the following concomitant conditions:Members with pernicious anemia or megaloblastic anemia secondary to the lack of vitamin B12
Required Medical Information	Fusilev/levoleucovorin will require prior authorization and may be considered medically necessary when the following criteria are met: Levoleucovorin rescue is indicated after high-dose methotrexate therapy in osteosarcoma. The patient is being treated with methotrexate for osteosarcoma. The patient has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium efficacy or due to leucovorin calcium formulation necessitating a change in therapy. Levoleucovorin is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists.The patient has been treated with methotrexate or other folic acid antagonist and is currently exhibiting signs of toxicity likely due to aforementioned therapy.The patient has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium efficacy or due to leucovorin calcium formulation necessitating a change in therapy.Advanced Metastatic Colorectal Cancer.The member has advanced metastatic colorectal cancer.The member is receiving palliative treatment with combination chemotherapy with 5-fluorouracil.The member has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium efficacy or due to leucovorin calcium formulation necessitating a change in therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six months
Other Criteria	NA

## LIBTAYO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression on or after prior PD-1/PD-L1 inhibitor (e.g., Keytruda).
Required Medical Information	Cutaneous squamous cell carcinoma. The member has a diagnosis of locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) AND the disease is not amenable to curative surgery or radiation AND Libtayo (cemiplimab-rwlc) is being used as a monotherapy. Basal cell carcinoma (BCC): The member has locally advanced BCC or metastatic BCC AND the disease has been treated with prior hedgehog pathway inhibitor OR treatment with a hedgehog pathway inhibitor is inappropriate AND Libtayo (cemiplimab-rwlc) is given monotherapy. Non-small cell lung cancer (NSCLC): The member has a diagnosis of NSCLC without tumor aberrations (e.g., EGFR, ALK, ROS-1) AND The disease is locally advanced (not amenable to surgery or definitive chemoradiation) or metastatic AND The tumor expresses documented high PD-L1 expression [Tumor Proportion Score (TPS) greater than or equal to 50%] AND Libtayo (cemiplimab-rwlc) is given as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA



## lidocaine

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Post-Herpetic Neuralgia. The member must have a diagnosis of post-herpetic neuralgia. Diabetic Neuropathy. The member must have a diagnosis of diabetic neuropathy. Neuropathic cancer pain. The member must have a diagnosis of neuropathic cancer pain. Chronic Back Pain: The member must have a diagnosis of chronic back pain. Pain associated with hip or knee osteoarthritis: the member must have a diagnosis of pain associated with hip or knee osteoarthritis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# LONSURF

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Lonsurf.
Required Medical Information	Metastatic Colorectal Cancer: The member has a diagnosis of metastatic colorectal cancer AND The member is using Lonsurf as monotherapy AND The member has experienced disease progression, intolerance, or contraindication with ALL of the following therapies: fluoropyrimidine-based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and anti-VEGF therapy (e.g. bevacizumab, ziv-aflibercept) AND If the member is RAS wild-type: the member has experienced disease progression, intolerance, or contraindication with anti-EGFR therapy (e.g. cetuximab or panitumumab). Gastric cancer. The member has recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND The member has experienced disease progression on or after two lines of therapy including fluoropyrimidine, platinum (e.g., cisplatin), either taxane (e.g., paclitaxel) or irinotecan and if appropriate, HER2/neu-targeted therapy (e.g., trastuzumab) AND Lonsurf will be given subsequent therapy as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	NA

## LORBRENA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant ALK inhibitors (e.g., Zykadia [certinib], Alecensa [alectinib]). Members experience disease progression on Lorbrena (lorlatinib).
Required Medical Information	Non-small cell lung cancer. The member has a diagnosis of metastatic NSCLC with documented anaplastic lymphoma kinase (ALK) positivity AND Lorbrena (lorlatinib) will be given as monotherapy AND one of the following applies in the metastatic setting: as first line therapy AND the member has a medical reason as to why Alecensa (alectinib) or Alunbrig (brigatinib) cannot be initiated or continued as first line therapy OR Subsequent therapy after disease progression on prior ALK inhibitor (e.g., alectinib, brigatinib). Non- small cell lung cancer [ROS-1 rearrangement]: The member has a diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer AND The disease is positive for documented ROS-1 rearrangement and following disease progression on Xalkori (crizotinib), Rozlytrek (entrectinib), or Zykadia (ceritinib) AND Lorbrena (lorlatinib) will be given as a single agent as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

# LUMAKRAS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experienced disease progression on Lumakras.
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of locally advanced or metastatic NSCLC AND The NSCLC has documented KRAS G12C mutation AND The member has experienced disease progression on one prior therapy AND Lumakras (sotorasib) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

# LUMOXITI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Lumoxiti (moxetumomab pasudotox-tdfk).
Required Medical Information	Hairy cell leukemia. The member has a diagnosis of relapsed or refractory hairy cell leukemia AND The member has received at least two prior therapies, including treatment with a purine nucleoside analog (e.g. cladribine, pentostatin) AND The member will be using Lumoxiti (moxetumomab pasudotox-tdfk) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## LUPRON DEPOT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## LUPRON DEPOT (3 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## LUPRON DEPOT (4 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA



## LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## LUPRON DEPOT-PED

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## LUPRON DEPOT-PED (3 MONTH)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomyoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Recurrent Ovarian Cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor. Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	NA

## LYBALVI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use of opioids. Episode of acute opioid withdrawal.
Required Medical Information	Schizophrenia or Bipolar I Disorder (Bipolar Depression): The member must have a diagnosis of schizophrenia or bipolar I disorder (bipolar depression) AND the member must have documentation of clinically significant weight gain from baseline body weight at maximally tolerated efficacious dosage after initiation of therapy with generic olanzapine or member has documented intolerance to generic olanzapine that is unrelated to weight gain AND The member must have documentation of prior therapy, intolerance, or contraindication to at least one of the following generic atypical antipsychotics: risperidone, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

# LYNPARZA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g. Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)]. Adjuvant setting for High-Risk Early Breast Cancer: member is taking Lynparza (olaparib) total treatment for more than one year.
Required Medical Information	<p>Breast Cancer: Member has a diagnosis of recurrent or metastatic breast cancer AND Member has deleterious germline or suspected germline BRCA-mutated disease as detected by an FDA-approved test AND Member has HER-2 negative disease, hormone receptor positive or negative, treated with prior chemotherapy and/or endocrine therapy AND Lynparza will be used as subsequent therapy as a single agent. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer First Line Maintenance Therapy: The member has a diagnosis of advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND member's disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation or genomic instability. Member is in complete response or partial response to first line treatment with platinum based chemotherapy. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer Second Line Maintenance Therapy: The member has a diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member has been treated with at least two prior lines of platinum based chemotherapy AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Lynparza (olaparib) tablets as monotherapy. *Discontinue Avastin before initiating maintenance therapy with Lynparza. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer Fourth Line Treatment: The member has a diagnosis of advanced ovarian cancer AND The member has deleterious or suspected deleterious germline BRCA mutation (as detected by an FDA-approved test) AND The member has been treated with three or more prior lines of chemotherapy AND The member will be using Lynparza (olaparib) as monotherapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration

## LYNPARZA

Other Criteria	<p>Pancreatic Adenocarcinoma - First line maintenance therapy: Member has a diagnosis of metastatic pancreatic adenocarcinoma AND member has deleterious germline or suspected germline BRCA-mutated disease AND member's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Metastatic Castration-Resistant Prostate Cancer (mCRPC): Member has a diagnosis metastatic castration-resistant prostate cancer (mCRPC) AND Member has documented deleterious or suspected deleterious germline, or somatic homologous recombination repair (HRR) gene-mutated disease AND Member has experienced progressive disease following prior treatment with Xtandi (enzalutamide) or abiraterone AND Member will use Lynparza (olaparib) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog). Breast Cancer (Adjuvant): Member has a diagnosis of high-risk early breast cancer AND Member has deleterious germline or suspected germline BRCA-mutated disease as detected by an FDA-approved test AND Member has HER-2 negative disease, hormone receptor positive or negative, treated with prior chemotherapy AND Lynparza will be used as subsequent therapy as a single agent. High Risk early breast cancer defined as patients who: 1. Received prior neoadjuvant chemotherapy: patients with either triple negative breast cancer (TNBC) or hormone receptor positive breast cancer must have had residual invasive cancer in the breast and/or the resected lymph nodes (nonpathologic complete response) at the time of surgery. Additionally, patients with hormone receptor positive breast cancer must have had a score of greater than or equal to 3 based on pretreatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade. 2. TNBC with greater than or equal to pT2 or greater than or equal to pN1 prior to adjuvant chemotherapy 3. HR+/HER2-negative with greater than or equal to 4 positive lymph nodes prior to adjuvant chemotherapy.</p>
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## LYTGOBI

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review

## MARGENZA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Margenza (margetuximab-cmkb).
Required Medical Information	Breast cancer: The member has a diagnosis of metastatic breast cancer AND The disease is documented HER2 neu positive AND The member has received two prior anti-HER2 neu based therapies (including trastuzumab products) where one therapy was given in the metastatic setting AND Margenza (margetuximab-cmkb) is given in combination with chemotherapy (gemcitabine, eribulin, vinorelbine, capecitabine) as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA



## MARQIBO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who have experienced disease progression on Marqibo (vincristine sulfate liposome injection).
Required Medical Information	Acute Lymphoblastic Leukemia: The member has a diagnosis of relapsed/refractory Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) or member has a diagnosis of Philadelphia chromosome (Ph+) disease that is refractory to tyrosine kinase inhibitor therapy AND Marqibo will be used as a single-agent salvage therapy AND The member has had disease progression following vincristine sulfate AND One of the following applies: The member is beyond second relapse. The member has had disease progression following two or more therapies.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## MEKINIST

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	<p>Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Mekinist (trametinib).</p> <p>Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib).]</p> <p>Adjuvant melanoma only: member is taking Mekinist (trametinib) total treatment for more than one year.</p>
Required Medical Information	<p>Melanoma-Unresectable or Metastatic: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Mekinist as a single-agent (member has not received prior BRAF-inhibitor therapy) OR in combination with Tafinlar (dabrafenib). Non-small cell lung cancer: The member has a diagnosis of recurrent or metastatic non-small cell lung cancer(NSCLC) AND The member has a documented BRAF V600E mutation AND The member will be using Mekinist (trametinib) in combination with Tafinlar (dabrafenib).</p> <p>Melanoma - Adjuvant. The member has a diagnosis of stage III melanoma AND The member has undergone lymph node resection of involved lymph nodes AND The member has a documented BRAF V600 activating mutation AND The member will be using Mekinist (trametinib) in combination with Tafinlar (dabrafenib) for adjuvant treatment.</p> <p>Anaplastic Thyroid Cancer. The member has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND The member has a documented V600E mutation AND The member has no satisfactory locoregional treatment options AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Metastatic Solid Tumors: the member has a diagnosis of unresectable or metastatic solid tumors with documented BRAF V600E mutation AND the member has disease that has progressed on prior therapy and has no satisfactory alternative treatments AND Mekinist is given in combination with Tafinlar.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## MEKTOVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Tafenlar (dabrafenib), or Mekinist (trametinib) OR Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafenlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma - Unresectable or metastatic. The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib). Colorectal Cancer - [Braftovi (encorafenib) requests only]: The member has documented BRAFV600E metastatic metastatic colorectal cancer and progressive disease on prior therapy AND Braftovi (encorafenib) is given in combination with Erbitux (cetuximab).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month durations or as determined through clinical review
Other Criteria	NA

## memantine

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Diagnosis of Autism or Atypical Autism (PDD)
Required Medical Information	NA
Age Restriction	An automatic approval if member is greater than 26 years of age.Prior Auth required for age 26 or younger.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration.
Other Criteria	NA

## modafinil

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Excessive Daytime Sleepiness.For the treatment of excessive daytime sleepiness or hypersomnolence associated with Narcolepsy,obstructive sleep apnea,or due to sleep problems resulting from circadian rhythm disruption (i.e., shift-work sleep disorder). Steinert myotonic dystrophy syndrome.Member must have hypersomnia due to Steinert myotonic dystrophy syndrome.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## molindone

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older. Drug or alcohol induced severe central nervous system depression.
Required Medical Information	Schizophrenia: The member must utilize molindone hydrochloride for the management of clinically diagnosed schizophrenia. The member must have documentation of prior therapy, intolerance, or contraindication to two (2) of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan Year Duration.
Other Criteria	NA

# MONJUVI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on anti-CD-19-directed therapy.
Required Medical Information	Diffuse large B-cell lymphoma: The member has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma (e.g. follicular lymphoma) AND The member has relapsed or refractory disease AND The member is not eligible for autologous stem cell transplant AND The member will be using Monjuvi (tafasitamab-cxix) in combination with lenalidomide for a maximum of 12 cycles, then Monjuvi (tafasitamab-cxix) can be used as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## MOZOBIL

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Treatment or prophylaxis of neutropenia or febrile neutropenia. Concomitant use with sargramostim or within seven days of pegfilgrastim dose. Same day administration with myelosuppressive chemotherapy or radiation. Use beyond four consecutive days or use after completion of stem cell harvest/apheresis. Mozobil is not intended for stem cell mobilization and harvest in patients with leukemia.
Required Medical Information	Autologous transplantation in patients with non-Hodgkin's Lymphoma (NHL) or Multiple Myeloma (MM): The member must have a diagnosis of non-Hodgkin's Lymphoma (NHL) or multiple myeloma (MM) AND Mozobil (plerixafor) must be used in combination with filgrastim, biosimilar filgrastim, or tbo-filgrastim AND Mozobil (plerixafor) must be a component of an autologous stem cell transplant mobilization protocol.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	30 days. Mozobil will be approved for a 30-day interval once per transplant.
Other Criteria	NA



## MVASI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Used in lung cancer members that have small cell or squamous cell disease, recent hemoptysis, history of bleeding, continuing anticoagulation, or as a single agent (unless maintenance as described in Coverage Determinations). Should not be initiated in members with recent hemoptysis. Should not be used in members who experience a severe arterial thromboembolic event. Should not be used in members with gastrointestinal perforation. Bevacizumab should not be used in members with fistula formation involving internal organs. Bevacizumab should not be used in members experiencing a hypertensive crisis or hypertensive encephalopathy. Bevacizumab should not be used for at least 28 days following major surgery or until surgical incision is fully healed. Bevacizumab may not be used in conjunction with Vectibix. Bevacizumab may not be used in conjunction with Erbitux. Bevacizumab may not be used in the adjuvant or neoadjuvant setting (except in epithelial ovarian, fallopian tube, or primary peritoneal cancer adjuvant setting). Bevacizumab should not be continued or restarted after disease progression with the exception of metastatic colorectal cancer.

## MVASI

<b>Required Medical Information</b>	<p>Alymsys (bevacizumab-maly) oncology requests: must have an intolerance or contraindication with Avastin, Mvasi, or Zirabev and meet criteria below. Metastatic colorectal cancer: Diagnosis of metastatic colorectal cancer AND 1 of the following apply: bevacizumab in combo with fluoropyrimidine (e.g., 5-fluorouracil or capecitabine) based chemo for 1st or 2nd-line therapy OR combo with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemo for 2nd-line therapy in patients who have progressed on 1st-line bevacizumab-containing regimens. Non-small cell lung cancer (non-squamous cell histology). NSCLC with non-squamous cell histology AND using bevacizumab in combo with cisplatin or carboplatin based regimens for unresectable, locally advanced, recurrent, or metastatic NSCLC AND 1 of the following apply: using for 1st line therapy OR as subsequent therapy immediately after 1 of the following situations: EGFR mutation-positive tumors after prior therapy (e.g., erlotinib, afatinib) [if cytotoxic therapy not previously given] OR ALK-positive tumors after prior therapy (e.g., crizotinib, brigatinib) [if cytotoxic therapy not previously given] OR ROS-1 positive disease after prior therapy (e.g., crizotinib) [if cytotoxic therapy not previously given] OR Pembrolizumab (with PD-L1 expression of greater than 1%) administered as 1st line therapy and EGFR, ALK, BRAF V600E, and ROS1 negative tumors (if cytotoxic therapy not previously given) OR has BRAF V600E positive disease (if cytotoxic therapy not previously given) OR as single-agent continuation maintenance therapy if bevacizumab was used as 1st line treatment for recurrence or metastasis OR has disease with no EGFR or ALK genomic tumor aberrations AND will be given in combo with carboplatin and paclitaxel and Tecentriq as 1st line therapy followed by maintenance therapy with Tecentriq and bevacizumab. Hepatocellular carcinoma: unresectable or metastatic HCC AND used as 1st line therapy in combo with Tecentriq.</p>
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 Months Duration. Ocular indications: Plan Year Duration

## MVASI

Other Criteria	<p>Metastatic breast cancer (Effectiveness based on improvement in progression-free survival. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab). Member has metastatic HER-2 negative breast cancer AND is using bevacizumab in combo with paclitaxel. Recurrent Ovarian Cancer. Bevacizumab is being used to treat recurrent or persistent ovarian cancer for 1 of the following situations: in combo with liposomal doxorubicin or weekly paclitaxel or topotecan for platinum resistant disease or as monotherapy or in combo with carboplatin and gemcitabine for platinum sensitive disease. Stage IV/Metastatic (Unresectable) RCC. Member has RCC and is using bevacizumab to treat stage IV unresectable kidney cancer in combo with interferon alpha OR is using bevacizumab as systemic therapy for non-clear cell histology. Recurrent Primary CNS Tumor (including Glioblastoma multiforme). Diagnosis of progressive or recurrent glioblastoma or anaplastic glioma AND Bevacizumab is being used as a single agent or in combo with irinotecan, carmustine, lomustine or temozolomide. Member does not have a CNS hemorrhage. Soft Tissue Sarcoma. Diagnosis of angiosarcoma and bevacizumab is being used as a single agent OR member has a diagnosis of solitary fibrous tumor and hemangiopericytoma and bevacizumab is being used in combo with temozolomide. Macular Retinal Edema. Avastin is being used to treat central or branch retinal vein occlusion with macular retinal edema. Cervical Cancer: member has recurrent, or metastatic cervical cancer AND Bevacizumab will be used in combo (if not previously used as first line therapy) with paclitaxel and cisplatin or carboplatin and paclitaxel or paclitaxel and topotecan as first line therapy. Endometrial Cancer: progressive endometrial cancer AND Bevacizumab will be used as a single-agent. Malignant Pleural Mesothelioma. Diagnosis of unresectable malignant pleural mesothelioma and bevacizumab will be used in combo with cisplatin and pemetrexed followed by bevacizumab monotherapy for maintenance therapy (for responders). Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer AND has Stage III or IV disease AND bevacizumab is initially being given in combo with carboplatin and paclitaxel after initial surgical resection followed by bevacizumab monotherapy OR advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability as defined by FDA approved test AND Member is in complete response or partial response to 1st line treatment with platinum-based chemo AND Bevacizumab is given in combo with Lynparza. Age Related Macular Degeneration (Avastin requests only). Diabetic Macular Edema (Avastin requests only).</p>
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## MYALEPT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Partial lipodystrophy OR Liver disease including non-alcoholic steatohepatitis (NASH) OR HIV related lipodystrophy OR Diabetes mellitus and hypertriglyceridemia without concurrent evidence of congenital or acquired generalized lipodystrophy OR Generalized obesity not associated with congenital leptin deficiency.
Required Medical Information	Congenital of Acquired Lipodystrophy: The member has a diagnosis of congenital OR acquired generalized lipodystrophy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

# MYLOTARG

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression on Mylotarg (gemtuzumab ozogamicin)
Required Medical Information	Acute Myelogenous Leukemia: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has documented CD33-positive disease AND One of the following applies: the member has newly-diagnosed disease and is an adult or pediatric patient one month or older OR the member has relapsed/refractory disease and is an adult or pediatric patient 2 years and older.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Newly dx AML:6 months(max 1 cycle induction-8 cycles consolidation) Rel/Ref AML:3months(max 1 cycle)
Other Criteria	NA

## NATPARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	Patients with hypoparathyroidism caused by calcium-sensing receptor mutations. Patients with acute post-surgical hypoparathyroidism due to surgery within the past 4 months.
<b>Required Medical Information</b>	Hypocalcemia in patients with hypoparathyroidism: Member must have a diagnosis of hypocalcemia secondary to hypoparathyroidism
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	NA

## NERLYNX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has disease progression on Nerlynx (neratinib). Member is taking Nerlynx (neratinib) total treatment for more than one year [applicable only to early stage breast cancer].
Required Medical Information	Early stage Breast Cancer: Initial Therapy. The member has early stage (i.e. Stage I, II, III) documented HER2 + positive disease AND The member has completed adjuvant therapy with a trastuzumab containing treatment AND Nerlynx (neratinib) is being used for the treatment in extended adjuvant setting AND The member is taking antidiarrheal prophylaxis (loperamide) concomitantly during the first two cycles. Continuation of therapy. The member is not experiencing any of the following situations: Grade 4 any adverse event [e.g., diarrhea, ALT (greater than 20 times ULN), bilirubin (greater than 10 times ULN)], Greater than or equal to grade 2 diarrhea with Nerlynx (neratinib dosing of 120mg per day AND If any of the above severe adverse reactions have been experienced, then provider has given a rationale for benefit of continued use that outweighs risk. Metastatic Breast Cancer. The member has metastatic or advanced breast cancer and all of the following apply: The member has documented HER2 positive disease and The member has received two or more prior anti-HER2 based regimens in the metastatic setting and Nerlynx (neratinib) is given in combination with capecitabine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Early stage: Initial - 3 months, Continuation therapy- 9 months. Metastatic or advanced: 6 months
Other Criteria	NA

# NEULASTA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgastrim-sndz or filgastrim-aafi), tbo-filgratim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose). Same day administration with myelosuppressive chemotherapy or therapeutic (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis. The member must have a diagnosis of non-myeloid malignancy (e.g. solid tumors) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to pegfilgrastim injection AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy OR Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours) OR Bone marrow involvement by tumor OR Recent surgery and/or open wounds OR Liver dysfunction (bilirubin greater than 2.0 mg/dL) OR Renal dysfunction (creatinine clearance less than 50 mL/min) OR Age greater than 65 receiving full chemotherapy dose intensity Or Previous neutropenic fever complication from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 months duration
Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.



# NEULASTA ONPRO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgastrim-sndz or filgastrim-aafi), tbo-filgratim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose). Same day administration with myelosuppressive chemotherapy or therapeutic (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis. The member must have a diagnosis of non-myeloid malignancy (e.g. solid tumors) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to pegfilgrastim injection AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy OR Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours) OR Bone marrow involvement by tumor OR Recent surgery and/or open wounds OR Liver dysfunction (bilirubin greater than 2.0 mg/dL) OR Renal dysfunction (creatinine clearance less than 50 mL/min) OR Age greater than 65 receiving full chemotherapy dose intensity Or Previous neutropenic fever complication from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 months duration
Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.

# NEXAVAR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Nexavar (sorafenib).
Required Medical Information	Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma (stage IV) AND the member has experienced intolerance, contraindication, or unable to achieve treatment goals with Cabometyx (cabozantinib) as second line therapy (e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome). Liver Carcinoma: Diagnosis of unresectable hepatocellular (liver) carcinoma. Thyroid Carcinoma: Diagnosis of advanced metastatic medullary carcinoma (thyroid carcinoma) OR The member has a diagnosis of advanced, clinically progressive and/or symptomatic papillary carcinoma, follicular carcinoma or Hürthle cell carcinoma AND Tumors are not responsive to radio-iodine treatment. Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST) AND The member experienced disease progression with imatinib or Sutent (sunitinib) or Stivarga (regorafenib).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## NEXLETOL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member must meet all of the following criteria: Diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR established atherosclerotic cardiovascular disease (ASCVD). One of the following: Used as adjunctive therapy after failure to achieve goal LDL-C reduction on maximally-tolerated statin (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR Statin Intolerant (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## NEXLIZET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member meets all of the following criteria: Diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR established atherosclerotic cardiovascular disease (ASCVD). One of the following: Used as adjunctive therapy after failure to achieve goal LDL-C reduction on maximally-tolerated statin (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR Statin Intolerant (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## NINLARO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with proteasome inhibitors. Members with disease progression on Ninlaro (ixazomib).
Required Medical Information	Multiple Myeloma: second line. The member has a diagnosis of relapsed or refractory multiple myeloma AND Ninlaro (ixazomib) will be used after disease progression on at least one prior therapy AND Ninlaro (ixazomib) will be used in combination with either dexamethasone OR lenalidomide and dexamethasone or cyclophosphamide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication). Multiple Myeloma: third line or subsequent. The member has a diagnosis of relapsed or refractory multiple myeloma AND Ninlaro (ixazomib) will be used after disease progression on at least two prior therapies AND Ninlaro (ixazomib) will be used in combination with pomalidomide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The members has demonstrated disease progression on or within 60 days of completion of the last therapy. Multiple Myeloma (maintenance): The member has a diagnosis of multiple myeloma AND Ninlaro (ixazomib) will be used as monotherapy AND Ninlaro (ixazomib) will be used as maintenance therapy. Multiple Myeloma: primary therapy. The member has a diagnosis of symptomatic multiple myeloma AND The request is for primary therapy AND One of the following sets of criteria applies: In combination with lenalidomide and dexamethasone AND member is not a transplant candidate OR in combination with cyclophosphamide and dexamethasone AND member is a transplant candidate. (Omission of corticosteroid from regimen is allowed if intolerance/contraindication).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## NIVESTYM

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgrastim-sndz or filgrastim-aafi), tbo-filgrastim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose).
Required Medical Information	Neutropenia in Myelodysplastic Syndromes. The member must have a diagnosis of neutropenia associated with myelodysplastic syndrome. Treatment of Febrile Neutropenia: The member must have a diagnosis of febrile neutropenia AND biosimilar filgrastim must be used in adjunct with appropriate antibiotics in high risk members. Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following myelosuppressive chemotherapy: The member must have a diagnosis of non-myeloid malignancy (e.g. breast cancer, lung cancer) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to starting biosimilar filgrastim injections AND The member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 Months Duration

## NIVESTYM

Other Criteria	<p>Febrile Neutropenia Prophylaxis, in members with acute myeloid leukemia receiving chemotherapy: The member must have a diagnosis Acute Myeloid Leukemia (AML). The member must be receiving either induction chemotherapy OR consolidation Chemotherapy AND the member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy.</p> <p>Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following Hematopoietic Stem Cell Transplant (HCST): The member must have had a Hematopoietic Stem Cell Transplant (HCST) (e.g. bone marrow transplant, peripheral-blood progenitor cell (PBPC) transplant) for a non-myeloid malignancy AND the member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy. Harvesting of peripheral blood stem cells. The member must be scheduled for autologous peripheral-blood stem cell (PBSC) transplantation, storing cells for a possible future autologous transplant, or donating stem cells for an allogeneic or syngeneic PBSC transplant. Neutropenic disorder, chronic (Severe), Symptomatic: The member must have a diagnosis of congenital, cyclic, or idiopathic neutropenia. Neutropenia in AIDS patients. The member must have a diagnosis of AIDS with neutropenia. Treatment of Aplastic Anemia. The member must have a diagnosis of Aplastic Anemia. Treatment of Agranulocytosis. The member must have a diagnosis of congenital or drug induced agranulocytosis. Hematopoietic Syndrome of Acute radiation syndrome. The member has been acutely exposed to myelosuppressive doses of radiation.</p>
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## NOXAFIL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prophylaxis against Invasive Aspergillus and Candida Infections. The member must be using it for prophylaxis against invasive Aspergillus or Candida infections, and The member must be severely immunocompromised (such as hematopoietic stem cell transplant recipient with graft-vs-host disease, or neutropenic patients with acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS).Treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes. The member must have documentation for treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes, and The member must have documented resistant strains of or clinically refractory to standard antifungal agents (e.g. voriconazole, itraconazole) or those who can not receive other antifungal agents due to potential toxicities, intolerance, or contraindications.Treatment of Oropharyngeal or Esophageal Candidiasis.The member must have a diagnosis for oropharyngeal or esophageal candidiasis and The member has a documented inadequate response/refractory or intolerant to itraconazole and fluconazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## NUBEQA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Nubeqa (darolutamide). Concomitant use with an androgen receptor inhibitor or androgen synthesis inhibitor (e.g. enzalutamide, abiraterone, nilutamide, flutamide, bicalutamide) due to lack of evidence supporting efficacy and safety.
Required Medical Information	Prostate Cancer (non-metastatic castration-resistant): The member has a diagnosis of non-metastatic castration-resistant prostate cancer AND the member will use Nubeqa (darolutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

# NUCALA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Severe Asthma with an Eosinophilic Phenotype: The member has a diagnosis of severe asthma AND the member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of greater than or equal to 150 cells/<math>\mu</math>L at therapy initiation OR greater than or equal to 300 cells/<math>\mu</math>L in the previous 12 months. The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy (e.g. mometasone greater than 400mcg daily, fluticasone greater than 440 mcg daily) in combination with a long acting beta agonist (e.g. formoterol).</p> <p>Continuation of therapy: Member is currently stable on therapy. Member will continue on asthma controller inhalers: inhaled corticosteroids (ICS) with or without a long-acting beta2-agonist (LABA). Eosinophilic Granulomatosis with Polyangiitis (EGPA): The member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the member has a baseline elevated peripheral blood eosinophil level of greater than 10% of total leukocyte count AND two or more systemic manifestations of EGPA. The member has been unable to achieve adequate control of EGPA while on oral corticosteroid therapy (e.g. prednisone, methylprednisolone). Hypereosinophilic Syndrome (HES) - Nucala only: The member has a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than or equal to 1000 cells/<math>\mu</math>L.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	<p>Chronic Rhinosinusitis with Nasal Polyposis - Nucala Only: Initial Review- The member must meet ALL of the following criteria: Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Nucala (mepolizumab) will be used in conjunction with a daily intranasal corticosteroid spray AND member is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy.</p> <p>Continuation of Therapy - The member must meet ALL of the following criteria: Improvement in symptoms (e.g., decrease in nasal congestion, decrease in polyp size, improvement in ability to smell) which has been sustained AND continuing intranasal corticosteroid spray therapy.</p>

## NUEDEXTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pseudobulbar Affect: The member must have a diagnosis of Pseudobulbar Affect (PBA) secondary to brain injury or underlying neurologic disease (e.g., stroke, multiple sclerosis, ALS, Parkinson's disease, traumatic brain injury) AND The member is experiencing characteristic behavior episodes (e.g inappropriate laughing or crying) consistent with PBA at baseline AND the provider attests that the risk of QT prolongation with Nuedexta has been considered, and benefits of treatment outweigh risks. Reauthorization: Documented improvement in behavior with Nuedexta (e.g. reduction in episodes of inappropriate laughing or crying) AND the provider attests that the risk of QT prolongation with Nuedexta has been considered, and benefits of treatment outweigh risks.
Age Restriction	Member must be 18 years of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial and Reauth: Plan Year Duration
Other Criteria	NA

## NUPLAZID

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Dementia related psychosis(in the absence of an approvable diagnosis)for members 65 years of age or older.
Required Medical Information	Parkinson's Disease Psychosis: The member is using Nuplazid for the treatment of hallucinations and delusions associated with Parkinson's disease (PD) psychosis AND the symptoms of psychosis have appeared after the diagnosis of PD AND psychosis is not related to other causes other than PD. Reauthorization: Documentation must be provided demonstrating an improvement in symptoms of psychosis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 3 months. Reauthorization: 6 months.
Other Criteria	NA

## nyamyc

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## nystatin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## nystop

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## octreotide acetate

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	<p>Acromegaly: The member must have a diagnosis of Acromegaly. Must have had an inadequate response to surgery/radiation or for whom surgical resection/radiation is not an option. Treatment of metastatic carcinoid tumors. Must have a diagnosis of a carcinoid tumor. Patient must have severe diarrhea and flushing resulting from carcinoid tumor. Treatment of vasoactive intestinal peptide tumors (VIPomas). Patient must be diagnosed with a vasoactive intestinal peptide tumor. Patient must have diagnosis of profuse watery diarrhea associated with VIP-secreting tumor. Treatment of chemotherapy or radiation induced diarrhea. Patient must have grade 3 or above diarrhea according to NCI common toxicity. Patient must have NCI grade 1 or 2 diarrhea and have failed treatment with loperamide or diphenoxylate and atropine. Treatment of severe secretory diarrhea in acquired immune deficiency syndrome (AIDS) patients. Patient must have diagnosis of severe diarrhea resulting from acquired immune deficiency syndrome (AIDS). Patient must have tried and failed antimicrobial agents (eg. ciprofloxacin or metronidazole) and/or anti-motility agents (eg. loperamide or diphenoxylate and atropine). Reversal of life-threatening hypotension due to carcinoid crisis during induction of anesthesia. Patient must have life-threatening hypotension due to carcinoid crisis.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## ODOMZO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Odomzo.
Required Medical Information	Basal Cell Carcinoma: The member has a diagnosis of locally advanced or metastatic basal cell carcinoma AND The member has experienced recurrence or disease progression following surgery or radiation OR has a contraindication to surgery or radiation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## OFEV

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a Chronic Fibrosing Interstitial Lung Disease[ILD] (e.g., Idiopathic Pulmonary Fibrosis [IPF], Hypersensitivity pneumonitis, Autoimmune ILD, Rheumatoid arthritis-associated ILD [RA-ILD], Systemic Sclerosis-associated ILD [SSc-ILD], Mixed Connective Tissue Disease-associated ILD, Idiopathic non-specific interstitial pneumonia, Unclassifiable Idiopathic Interstitial Pneumonia, Exposure-related ILDs, Sarcoidosis with Fibrosing ILD, in addition to other chronic fibrosing ILDs) confirmed by one of the following: Computer Tomography (CT) with evidence of fibrosis OR Lung Biopsy. Member has a progressive phenotype confirmed by one of the following: Diagnosis is for Idiopathic Pulmonary Fibrosis OR Has had a relative decline in FVC of at least 10% OR worsening respiratory symptoms OR increased extent of fibrotic change on CT scan.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# OMNITROPE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	<p>Pediatric growth hormone discontinuation. Increase in height velocity is less than 2 cm total growth in one year of therapy: OR Final adult height has been achieved (member's calculated mid-parental height). The epiphyses have closed. Constitutional delay of growth and development. Skeletal dysplasias (e.g., achondroplasia, kyphomelic dysplasia). Osteogenesis imperfect. "Somatopause" in older adults. Infertility. Burn injuries. Obesity/morbid obesity. Hypophosphatemia (hypophosphatemic rickets). Muscular dystrophy. Cystic fibrosis. Spina bifida. Juvenile rheumatoid arthritis. Osteoporosis. Post-traumatic stress disorder. Depression. Hypertension. Corticosteroid-induced pituitary ablation. Precocious puberty. Chronic fatigue syndrome. Crohn's disease . Anti-aging . Growth retardation due to amphetamines. Chronic catabolic states, including respiratory failure, pharmacologic glucocorticoid administration, and inflammatory bowel disease. Down syndrome and other syndromes associated with short stature and increased susceptibility to neoplasms (Bloom syndrome, Fanconi syndrome).</p>

## OMNITROPE

<b>Required Medical Information</b>	GH Therapy in Adults (18 or older). Must have previous tx with Omnitrope. Adult-onset GHD either alone or with multiple hormone deficiencies (hypopituitarism) as a result of pituitary, hypothalamic disease, surgery, radiation, or trauma OR has a diagnosis of childhood-onset GHD. A subnormal response to two standard GH stimulation tests (1 must be insulin tolerance test [ITT]). If contraindication to ITT, a subnormal response to a standardized stimulation test must be provided along with Insulin like growth factor. Acceptable tests are ITT, glucagon, and macimorelin test. Assay type must be documented. Subnormal response to ITT is defined as peak serum GH level less than or equal to 5 ng/ml. Subnormal response to glucagon stimulation test is: Less than or equal to 3 mcg/L in patients with a BMI of less than 25 kg/m <sup>2</sup> OR Less than or equal to 3 mcg/L in patients with a BMI of 25 - 30 kg/m <sup>2</sup> and high pre-test probability, Less than or equal to 1 mcg/L in patients with a BMI of 25 - 30 kg/m <sup>2</sup> and a low pre-test probability OR Less than or equal to 1 mcg/L in patients with a BMI of greater than 30 kg/m <sup>2</sup> . Subnormal response to the macimorelin test is defined as peak serum GH level less than or equal to 2.8 mcg/L. For ITT, blood glucose nadir of less than 40mg/dL must be documented. Certain patient subtypes (e.g. those with organic hypothalamic-pituitary disease and biochemical evidence of multiple pituitary hormone deficiencies (MPHD)) together with low-serum IGF-1 levels (less than -2.0 standard deviation score [SDS]) with genetic defects affecting the hypothalamic-pituitary axes, and hypothalamic-pituitary structural brain defects, can be diagnosed with adult GHD without performing GH-stimulation test. In patients with less than or equal to 2 pituitary hormone deficiencies, low-serum IGF-1 levels (less than -2.0 SDS) alone are not enough for a diagnosis of adult GHD, one GH-stimulation test is required to confirm the diagnosis.
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration

## OMNITROPE

Other Criteria	<p>GHT in Children (less than 18). GH failure associated with GH deficiency. Bone age is at least 1 year or 2 SDs delayed compared to chronological age AND epiphyses not closed. Growth rate is less than: 4.5 cm/yr for age over 4, 7cm/yr for ages 2-4, 9 cm/yr for ages 1-2. Two GH stimulation test results with GH secretion less than 10 ng/ml. Acceptable tests include L-dopa, arginine, clonidine, glucagon, exercise, insulin-induced hypoglycemia. Small for gestational age. Born small for gestational age, defined as birth weight or length 2 or more SDs below the mean for gestational age: and fails to catch up growth by age 2 years, defined as height 2 or more SDs below the mean for age and sex. Short Stature Homeobox-Containing Gene (SHOX) Deficiency. Children with SHOX deficiency whose epiphyses are not closed. Chronic Renal insufficiency. Children with CRI and growth retardation who meet both: metabolic abnormalities have been corrected, and steroid usage has been reduced to a minimum AND At least 1 of the following criteria is met: has severe growth retardation with height SDS more than 3 SDS below the mean for chronological age and sex: OR has moderate growth retardation with height SDS between -2 and -3 SDS below the mean for chronological age and sex and decreased growth rate (GV measured over 1 year below 25th percentile for age and sex): OR Child exhibits severe deceleration in growth rate (GV measured over 1 year -2 SDS below the mean for age,sex). Prader-Willi Syndrome or Turner's Syndrome. Diagnosis of growth failure due to Prader-Willi syndrome OR Diagnosis of short stature associated with Turner's syndrome AND At least 1 of the following: severe growth retardation with height SDS more than 3 SDS below the mean for chronological age and sex: OR Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean for chronological age and sex and decreased growth rate (GV measured over 1 year below 25th percentile for age and sex): OR Child exhibits severe deceleration in growth rate (GV measured over 1 year -2 SDS below the mean for age and sex). For Prader Willi Syndrome only: Is not severely obese or has a severe respiratory impairment . Noonan Syndrome. Height 2 SDS or more below the mean for chronological age and sex: AND GV measured over 1 year prior to initiation of therapy of 1 or more SDS below the mean for age and sex.</p>
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## ONCASPAR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following Oncaspar. Members with a history of serious thrombosis with prior asparaginase therapy. Members with a history of pancreatitis with prior asparaginase therapy. Members with a history of serious hemorrhagic events with prior asparaginase therapy. Members with total bilirubin more than 10 times the upper limit of normal.
Required Medical Information	Acute Lymphoblastic Leukemia: The member has a diagnosis of acute lymphoblastic leukemia (ALL) AND the member will be using Oncaspar (pegaspargase) as a component of a multi-agent chemotherapy regimen.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## ONIVYDE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Monotherapy with Onivyde (liposomal irinotecan). Members that have experienced disease progression while on Onivyde (liposomal irinotecan).
Required Medical Information	Pancreatic Cancer: The member has a diagnosis of metastatic adenocarcinoma of the pancreas. The member has previously received gemcitabine based therapy or fluoropyrimidine based therapy (not including irinotecan) and experienced disease progression. The member will be using Onivyde (liposomal irinotecan) in combination with fluorouracil and leucovorin.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## ONUREG

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on hypomethylators (e.g. azacitidine, decitabine).
Required Medical Information	Acute Myeloid Leukemia: The member has a diagnosis of acute myeloid leukemia AND The member is using Onureg (azacitidine) for post-remission therapy AND The member has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy AND The member is not able to complete or declines intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant) AND The member will use Onureg (azacitidine) as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA



## OPDIVO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant melanoma only: member is taking Opdivo (nivolumab) total treatment for more than one year. Neoadjuvant NSCLC only: member is taking Opdivo (nivolumab) total treatment in combination with platinum-doublet chemotherapy for more than 3 cycles.
Required Medical Information	Melanoma: must have a diagnosis of unresectable or metastatic melanoma AND will be using Opdivo (nivolumab) in combination with Yervoy (ipilimumab) OR the member will be using Opdivo as monotherapy. Melanoma-Adjuvant: member has diagnosis of stage III or stage IV melanoma AND has undergone complete resection of disease AND will be using Opdivo as adjuvant treatment AND will be using Opdivo as monotherapy. Non-Small Cell Lung Cancer-subsequent therapy: member must have a diagnosis of metastatic squamous or non-squamous NSCLC AND member has experienced disease progression on or after chemotherapy and EGFR inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib]), if EGFR mutation positive or ALK inhibitor (e.g., Xalkori (crizotinib)), if ALK positive AND will be using Opdivo as monotherapy. Renal Cell Carcinoma (RCC): member has a diagnosis of advanced RCC AND The member will be using Opdivo as monotherapy AND one of the following applies: the member has predominant clear cell histology and will be using Opdivo as subsequent therapy OR the member has non-clear cell histology OR The member will be using Opdivo in combination with Yervoy AND has intermediate or poor risk disease, based on International Metastatic Renal Cell Carcinoma Database Consortium Criteria AND has predominant clear cell histology AND will be using for first line therapy OR member is using Opdivo in combo with Cabometyx AND will be using for first line therapy. Classical Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin Lymphoma AND The member has relapsed or refractory disease AND The member will be using Opdivo as monotherapy AND The member will be using as third-line or subsequent therapy AND One of the following criteria applies: The member will be using Opdivo following autologous stem cell transplant OR The member is transplant ineligible (based on comorbidity or failure of second-line chemotherapy) OR The member will be using post-allogeneic transplant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner

## OPDIVO

<b>Coverage Duration</b>	6 months duration
<b>Other Criteria</b>	<p>Non-nasopharyngeal recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) AND using as monotherapy AND disease progression on or after platinum based therapy. Locally advanced or metastatic urothelial cancer AND will use Opdivo as monotherapy AND 1 of the following apply: use as a 2nd or subsequent line-therapy OR Disease progression within 12 months of neoadjuvant or adjuvant chemo OR has high risk of recurrence after radical surgical resection of disease. Hepatocellular Carcinoma and has received prior treatment with a Nexavar (sorafenib) AND will be using in combo with Yervoy. Unresectable or metastatic colorectal cancer with documented Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) AND will be using as monotherapy or in combo with ipilimumab AND 1 of the following applies: disease that has progressed following treatment with oxaliplatin-, irinotecan-, or fluoropyrimidine-based therapy OR has unresectable metachronous metastases and previously received adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months. Non-small cell lung cancer (NSCLC) 1st Line Therapy: metastatic NSCLC AND 1 of the following applies: Disease with PD-L1 expression greater than or equal to 1% with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND Tumor expresses PD-L1 as determined by an FDA-approved test AND in combo with Yervoy OR Disease with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND in combo with Yervoy AND used in combo with 2 cycles of platinum doublet chemotherapy. Esophageal cancer: unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus and 1 of the following apply: disease progressed after prior fluoropyrimidine- and platinum-based chemo AND will be given as subsequent monotherapy OR in combo with fluoropyrimidine- and platinum containing chemotherapy for 1st line treatment OR as 1st line treatment in combo with Yervoy. Unresectable malignant pleural mesothelioma AND 1 of the following scenarios applies: 1st-line treatment AND in combo with Yervoy OR as subsequent treatment, if not administered 1st-line AND as single agent OR in combo with Yervoy. Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (advanced or metastatic): given with a regimen containing fluoropyrimidine- and platinum-based chemo. Esophageal or Gastroesophageal Junction cancer (residual disease post-surgery and preoperative chemoradiation): received neoadjuvant chemoradiation AND complete surgical resection of esophageal or gastroesophageal junction AND has residual pathologic disease AND given as subsequent monotherapy. NSCLC- Neoadjuvant Therapy: early stage NSCLC AND must have resectable disease (tumors greater than 4 cm or node positive) AND will be using in the neoadjuvant setting, in combo with platinum-doublet chemo.</p>

## OPDUALAG

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g., nivolumab, atezolizumab). Members on concomitant Zelboraf (vemurafenib), Tafinlar (dabrafenib), Mekinist (trametinib) or Cotellic (cobimetinib) therapy. Safety and efficacy have not been established.
Required Medical Information	Melanoma: Unresectable or metastatic melanoma: The member must have a diagnosis of unresectable or metastatic melanoma AND Opdualag is administered as monotherapy AND there is a medical reason why Keytruda or Opdivo as monotherapy or Opdivo in combination with Yervoy cannot be initiated or continued.
Age Restriction	The member must be 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## OPSUMIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## ORGOVYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	NA
<b>Exclusion Criteria</b>	Concomitant use with other LHRH agents. Pediatric members less than 18 years old.
<b>Required Medical Information</b>	Prostate Cancer: The member has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	12 Months Duration
<b>Other Criteria</b>	NA

## ORKAMBI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis:The member has a diagnosis of Cystic Fibrosis.The member has documentation of a homozygous F508del mutation in the CFTR gene.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## OSPHERA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Undiagnosed abnormal genital bleeding. Known or suspected estrogen dependent neoplasia, OR Active DVT, pulmonary embolism (PE), or a history of these conditions, OR Active arterial thromboembolic disease (e.g. stroke and myocardial infarction or a history of these conditions).
Required Medical Information	The member must be a post-menopausal woman AND the member must have vulvar and/or vaginal atrophy AND the member must have moderate to severe dyspareunia. Treatment of moderate to severe vaginal dryness: The member must have moderate to severe vaginal dryness.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## OTEZLA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND the member has had prior therapy or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide), or a contraindication with all DMARDs. Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy or intolerance to one or more oral systemic treatments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments OR the member has a diagnosis of mild plaque psoriasis (e.g. involvement of less than 3% of body surface area) AND member has had prior therapy, contraindication, or intolerance with a high potency topical corticosteroid (e.g. triamcinolone 0.5%, betamethasone dipropionate/dipropionate augmented, or clobetasol) AND has had prior therapy, contraindication, or intolerance with a topical vitamin D product (e.g. calcipotriene cream or solution). Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND Otezla (apremilast) will be used for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance to topical corticosteroid therapy (e.g. triamcinolone oral paste).</p>
Age Restriction	Member is 18 years of age or older for treatment of oral ulcers associated with Behcet's Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## OTEZLA STARTER

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND the member has had prior therapy or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide), or a contraindication with all DMARDs. Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy or intolerance to one or more oral systemic treatments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments OR the member has a diagnosis of mild plaque psoriasis (e.g. involvement of less than 3% of body surface area) AND member has had prior therapy, contraindication, or intolerance with a high potency topical corticosteroid (e.g. triamcinolone 0.5%, betamethasone dipropionate/dipropionate augmented, or clobetasol) AND has had prior therapy, contraindication, or intolerance with a topical vitamin D product (e.g. calcipotriene cream or solution). Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND Otezla (apremilast) will be used for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance to topical corticosteroid therapy (e.g. triamcinolone oral paste).</p>
Age Restriction	Member is 18 years of age or older for treatment of oral ulcers associated with Behcet's Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## oxandrolone

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Enhancement of athletic performance.
Required Medical Information	Cachexia associated with AIDS wasting syndrome: weight loss from cancer chemotherapy, severe burns, spinal cord injury, Corticosteroid-induced protein catabolism, Symptomatic treatment of bone pain accompanying osteoporosis, Alcoholic hepatitis, Turner Syndrome, Constitutional delay in growth and puberty, Duchenne muscular dystrophy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## paclitaxel protein-bound

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Breast Cancer. The member has a diagnosis of metastatic (Stage IV) or recurrent breast cancer. The member received prior therapy that included an anthracycline (unless contraindicated). The member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications. Non-small Cell Lung Cancer (NSCLC). The member has a diagnosis of locally advanced, recurrent or metastatic NSCLC. Member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications AND member has squamous histology where Abraxane will be given in combo with Keytruda and carboplatin as first line therapy OR member will be using Abraxane as monotherapy or in combo with carboplatin AND One of the following apply: will be using for first line therapy OR member will be using as subsequent therapy for EGFR mutation-positive tumors after prior therapy (e.g., erlotinib) OR The member will be using as subsequent therapy for ALK-positive tumors after prior therapy (e.g., crizotinib, brigatinib) OR member will be using as subsequent therapy for ROS-1 positive disease after prior therapy (e.g., crizotinib) OR member will be using as subsequent therapy for BRAF V600E positive disease OR The member will be using as subsequent therapy after pembrolizumab and EGFR, ALK, BRAF V600E, and ROS-1 negative disease OR member has metastatic NSCLC, non- squamous histology with no EGFR or ALK genomic tumor aberrations AND Abraxane will be given combo with Tecentriq and carboplatin as first line therapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## paclitaxel protein-bound

Other Criteria	<p>Ovarian Cancer. The member has a diagnosis of epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer. The member meets one of the following criteria: Progressive, stable or persistent disease on primary chemotherapy OR Recurrent disease. The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications. Pancreatic Cancer: The member has a diagnosis of pancreatic cancer and Abraxane is being used in combination with gemcitabine as neoadjuvant therapy or The member has a diagnosis of metastatic pancreatic cancer AND The member will be using Abraxane in combination with gemcitabine. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member will be using Abraxane (nab-paclitaxel) as monotherapy AND The member will be using Abraxane (nab-paclitaxel) as second-line or subsequent therapy after progression on BRAF targeted therapy AND The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications.</p>
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## PADCEV

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Bladder Cancer. The member has locally advanced or metastatic bladder cancer AND The member has received prior treatment with a platinum-containing chemotherapy AND The member has received previous treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## PANRETIN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of AIDS-related Kaposi's sarcoma AND systemic therapy is not required.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## PEGASYS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Pediatric members less than 3 years of age because safety and effectiveness have not been established, autoimmune disease, decompensated cirrhosis.
Required Medical Information	Chronic Hepatitis B - Adults: The member must have a diagnosis of chronic hepatitis B AND The member must have compensated liver disease AND The member must have evidence of viral replication AND The member must have evidence of liver inflammation AND The member must have had prior therapy, contraindication, or intolerance with tenofovir disoproxil fumarate AND entecavir. Chronic Hepatitis B - Pediatrics: The member must have a diagnosis of chronic hepatitis B AND The member must be non-cirrhotic AND The member must be HBeAg-positive AND The member must have evidence of viral replication AND The member must have elevation in serum alanine aminotransferase (ALT) AND the member must have had prior therapy, contraindication, or intolerance with tenofovir disoproxil fumarate AND entecavir. Chronic Hepatitis C - Adults: The member must have a diagnosis of chronic hepatitis C AND HCV ribonucleic acid (RNA) level must be documented prior to therapy AND The member has compensated liver disease AND Pegasys (peginterferon alpha-2a) will be taken in combination with at least 1 other medication indicated for the treatment of chronic Hepatitis C AND In members with genotypes 2 or 3, the member has had previous treatment, contraindication, or intolerance to Epclusa OR In members with genotypes 1,4,5 or 6, The member has had previous treatment, contraindication, or intolerance to Epclusa AND Harvoni. Chronic Hepatitis C - Pediatrics: The member must have a diagnosis of chronic hepatitis C AND HCV ribonucleic acid (RNA) level must be documented prior to therapy AND The member has compensated liver disease AND Pegasys (peginterferon alpha-2a) will be taken in combination with ribavirin AND In members with genotypes 2 or 3, the member has had previous treatment, contraindication, or intolerance to Epclusa OR In members with genotypes 1,4,5 or 6, the member has had previous treatment, contraindication, or intolerance to Epclusa AND Harvoni.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 to 120 week treatment course depending on the disease state and/or genotype.
Other Criteria	For all genotypes, criteria will be applied consistent with current AASLD-IDSA guidance.

## PEMAZYRE

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experienced disease progression on Pemazyre (pemigatinib)
Required Medical Information	Cholangiocarcinoma: The member has unresectable locally advanced or metastatic cholangiocarcinoma and the disease is fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test and the member has received prior treatment and Pemazyre (pemigatinib) is given as a single agent for subsequent therapy
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	NA



## pemetrexed

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR pemetrexed is being used as a single agent after prior chemotherapy. Pemetrexed is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with pemetrexed OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## pemetrexed

Other Criteria	Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
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## pemetrexed disodium

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: pemetrexed is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0-2 or pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR pemetrexed is being used as a single agent after prior chemotherapy. Pemetrexed is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with pemetrexed OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## pemetrexed disodium

Other Criteria	Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
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## PEPAXTO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Pepaxto (melphalan flufenamide). Use as a conditioning regimen for transplant.
Required Medical Information	Multiple Myeloma (Relapsed or Refractory): The member must have a diagnosis of multiple myeloma AND The member has relapsed or refractory disease AND The member must have received at least four prior lines of therapy including an immunomodulatory agent (e.g. lenalidomide, pomalidomide), a proteasome inhibitor (e.g. bortezomib, carfilzomib), and an anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) AND Pepaxto (melphalan flufenamide) will be taken in combination with dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The member is not stem cell transplant-eligible.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## PERFOROMIST

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Asthma, in the absence of concurrent medication containing inhaled corticosteroid and comorbid COPD diagnosis.
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD).Diagnosis of Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema, requiring maintenance treatment of bronchoconstriction.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## PERJETA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member exceeds a total treatment of 52 weeks or 18 treatment cycles (applicable to neoadjuvant and/or adjuvant treatment).
Required Medical Information	Metastatic Breast Cancer. Diagnosis of metastatic breast cancer. The member has a diagnosis of metastatic breast cancer and HER2 (human epidermal growth factor receptor2) positive disease AND one of the following applies: will be receiving Perjeta (pertuzumab) in combination with trastuzumab product and docetaxel or paclitaxel and has not received prior anti-HER2 therapy or chemotherapy for metastatic disease OR the member has received prior cytotoxic therapy with or without trastuzumab product for second or subsequent line of therapy. Early Stage Breast Cancer. The member has a diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) and HER2 positive disease AND Perjeta (pertuzumab) will be used as neoadjuvant treatment as part of a complete treatment regimen and one of the following applies: in combination with trastuzumab product and docetaxel or paclitaxel (after completion of combination of doxorubicin plus cyclophosphamide regimen) or in combination with TCH (docetaxel, carboplatin, and trastuzumab product) OR The member has a diagnosis of early stage HER2 positive breast cancer at high risk of recurrence (e.g., node positive disease, hormone receptor negative, T2 non-metastatic disease) AND Perjeta (pertuzumab) will be used as adjuvant therapy and one of the following applies: combination with trastuzumab product and paclitaxel or docetaxel (following doxorubicin plus cyclophosphamide regimen) or docetaxel plus carboplatin.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## pimecrolimus

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Must have a diagnosis of atopic dermatitis or psoriasis have had previous treatment with one of the following topical generic products: triamcinolone 0.025%, 0.1%, 0.5% , mometasone, betamethasone dipropionate.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## PIQRAY

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members have severe hypersensitivity to Piqray (alpelisib). Members has experienced disease progression on PIK3CA inhibitors (e.g., alpelisib).
Required Medical Information	Breast Cancer: The member has a diagnosis of advanced or metastatic hormone receptor positive, human epidermal growth factor receptor 2 (HER 2) negative breast cancer and PIK3CA mutated as detected by FDA approved test AND the member has experienced disease progression on or after endocrine based therapy within one year (e.g., anastrozole, palbociclib) AND Piqray (alpelisib) will be given in combination with fulvestrant as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## pirfenidone

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Idiopathic Pulmonary Fibrosis (IPF): The member meets ALL of the following criteria: Diagnosis of idiopathic pulmonary fibrosis by exclusion of clinically significant environmental exposure or explanation for pulmonary fibrosis or interstitial lung disease (e.g. drugs, asbestos, beryllium, radiation, and domestic birds, radiation, sarcoidosis, hypersensitivity pneumonitis, bronchiolitis, obliterans organizing pneumonia, human immunodeficiency virus (HIV), viral hepatitis, or cancer). AND Documentation of Pulmonary Fibrosis by one of the following: computed tomography (CT) scan is indicative of usual interstitial pneumonia (UIP) OR a surgical lung biopsy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## POLIVY

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression on Polivy (polatuzumab vedotin-piiq). The member has baseline Grade 2 or higher peripheral neuropathy. The member has active central nervous system lymphoma. The member has transformation from indolent lymphoma (e.g. follicular lymphoma) into diffuse large B-cell lymphoma. The member has received prior allogeneic hematopoietic stem cell transplant (HSCT).
Required Medical Information	Diffuse large B-cell lymphoma: the member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma AND the member has received at least two prior lines of therapy AND the member will be using in combination with bendamustine and a rituximab product.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 months duration
Other Criteria	NA

## POMALYST

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members receiving concomitant therapy with an immunomodulator. The member has experienced disease progression while on Pomalyst (pomalidomide).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of Multiple Myeloma AND The member has received at least two previous therapies AND The member has demonstrated disease progression while on Revlimid (lenalidomide) OR Thalomid (thalidomide) AND The member demonstrated disease progression while on a protease inhibitor (e.g. bortezomib, carfilzomib) AND The member demonstrated disease progression on or within 60 days of completion of the last therapy regimen [does not apply to requests for combination with Darzalex (daratumumab) plus dexamethasone or elotuzumab plus dexamethasone or Sarclisa (isatuximab) plus dexamethasone] AND The member will be using Pomalyst in one of the following regimens: in combination with dexamethasone and daratumumab, with dexamethasone and elotuzumab, with dexamethasone and ixazomib, with dexamethasone and cyclophosphamide, with dexamethasone, with dexamethasone and bortezomib, with dexamethasone and carfilzomib, dexamethasone and Sarclisa (isatuximab), dexamethasone and Xpovio (selinexor), or as a single agent (Omission of corticosteroid from regimen is allowed if intolerance/contraindication). Kaposi Sarcoma: The member has a diagnosis of AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy OR The member has a diagnosis of Kaposi sarcoma that is HIV-negative.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## PORTRAZZA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Portrazza (necitumumab).
Required Medical Information	Non-Small Cell Lung Cancer: The member has a diagnosis of metastatic squamous non-small cell lung cancer AND The member will be initially using Portrazza (necitumumab) in combination with gemcitabine and cisplatin AND The member will be using Portrazza (necitumumab) as first-line treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six month duration
Other Criteria	NA

## posaconazole

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prophylaxis against Invasive Aspergillus and Candida Infections. The member must be using it for prophylaxis against invasive Aspergillus or Candida infections, and The member must be severely immunocompromised (such as hematopoietic stem cell transplant recipient with graft-vs-host disease, or neutropenic patients with acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS).Treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes. The member must have documentation for treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes, and The member must have documented resistant strains of or clinically refractory to standard antifungal agents (e.g. voriconazole, itraconazole) or those who can not receive other antifungal agents due to potential toxicities, intolerance, or contraindications.Treatment of Oropharyngeal or Esophageal Candidiasis.The member must have a diagnosis for oropharyngeal or esophageal candidiasis and The member has a documented inadequate response/refractory or intolerant to itraconazole and fluconazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## POTELIGEO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression while on or following Poteligeo (mogamulizumab-kpkc).
Required Medical Information	Mycosis fungoides or Sézary syndrome: The member has a diagnosis of mycosis fungoides or Sézary syndrome AND The member has relapsed or refractory disease AND The member will be using Poteligeo (mogamulizumab-kpkc) as the sole systemic therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## PREVYMIS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Severe hepatic impairment (Child-Pugh C). End stage renal disease (Crcl less than 10mL/min). Members currently on dialysis.
Required Medical Information	Prophylaxis of CMV Infection and Disease in Adult CMV Seropositive Recipients [R+] of an Allogenic Hematopoietic Stem Cell Transplant (HSCT). Member must have received an allogeneic hematopoietic stem cell transplant. Member must be CMV-seropositive [R+]. Prevymis (letermovir) must be initiated within 28 days post-transplant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 Months Duration
Other Criteria	



# PROCRIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Anemia of CKD: Diagnosis of anemia associated with chronic kidney disease. Hgb level less than 10.0 g/dL or HCT less than 30- within last 4 weeks. Continue Therapy: Current- within last 4 weeks Hgb level less than 11 g/dL OR documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy.</p> <p>Anemia in Zidovudine-treated HIV-infected: Diagnosed with HIV (and AZT induced anemia) and receiving zidovudine treatment corresponding with HAART. Endogenous serum erythropoietin levels less than or equal to 500 mUnits/mL. The total zidovudine dose must not exceed 4200mg/wk. Must have Hgb level less than or equal to 10.0 g/dL or HCT less than 30-within the last four weeks. Continue Therapy: Zidovudine dose must not exceed 4200mg/wk. Must meet one of the following criteria: Current-within last 4 weeks Hgb level less than 12.0 g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL.</p> <p>Anemia in Chemotherapy Treated Cancer - first 4 weeks. Diagnosis with a non-myeloid, non-erythroid malignancy. Must be receiving concurrent chemotherapy treatment for incurable disease with palliative intent. Must have Hgb level less than 10.0 g/dL or HCT less than 30-within last 4 weeks. Maint. Phase after first 4 weeks: Member has responded to therapy, defined as one or more of the following: increase in hemoglobin of at least 1 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements OR member has experienced symptom improvement and prescriber determines to continue therapy. Continued dosing is needed to maintain the lowest hemoglobin level sufficient to avoid RBC transfusion.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 months for chemo induced anemia,HIV,HCV,MDS,RA,surgery. 6 months for CKD, CKD reauth: Plan Year

## PROCRIT

Other Criteria	<p>Anemia in Surgery Members: Must be scheduled to undergo elective, noncardiac, nonvascular surgery. Must have Hgb level of greater than 10 g/dL and less than or equal 13 g/dL (within last 4 weeks). Anemia in Myelodysplastic Syndromes: symptomatic anemia associated with MDS. Must have a serum erythropoietin level less than or equal to 500 mUnits/mL (unlikely to respond to ESA therapy if erythropoietin level greater than 500mUnits/ml). Must have Hgb level less than or equal to 10.0 g/dL or HCT less than 30 (within last 4 weeks). Cont. Therapy: has responded to therapy, defined as one or more of the following: An increase in hemoglobin of at least 1.5 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements, OR has experienced symptom improvement and prescriber determines to continue therapy. Cont. dosing is needed to maintain the lowest hemoglobin level (not to exceed 12 g/dL) sufficient to avoid RBC transfusion. Anemia associated with Management of Hepatitis C: anemia in management of chronic Hepatitis C. Receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV. Must have Hgb level less than or equal to 12.0 gm/dL or HCT less than 30 during combination therapy as defined above(within the last 4 weeks).Continue Therapy: Must be receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV.Must have been able to maintain previous ribavirin dosing without dose reduction due to symptomatic anemia. Must meet one of the following criteria: Current (within the last 4 weeks) Hgb level less than 12.0g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL. Anemia associated with Rheumatoid Arthritis (RA) Treatment. Diagnosis of anemia associated with pharmaceutical treatment of RA. Receiving active therapy known to cause anemia. Must have Hgb level less than 10 g/dL or HCT less than 30(within the last 4 weeks).Cont. Therapy: Receiving active RA pharmaceutical treatment. Current (within the last 4 weeks) Hgb less than 11 g/dL. For listed indications: Prior to initiation of therapy, other causes of anemia including iron, B-12, folate deficiencies, hemolysis, and bleeding have been ruled out. Prior to initiation of therapy, the member's iron scores should be evaluated. Transferrin saturation should be at least 20% OR ferritin at least 100 ng/mL within the last 4 months (applies to most recent result). Cont. of therapy requires documented Transferrin saturation of at least 20% OR ferritin of at least 100 ng/mL within the last 4 months for all indications (applies to most recent result).</p>
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## PROLASTIN-C

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	IgA deficient members or presence of antibodies against IgA.
Required Medical Information	Congenital Alpha1-antitrypsin Deficiency: The member has a diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema and chronic replacement therapy is needed. The member has an alpha1-antitrypsin phenotype of PiZZ, PiZ(null), or Pi (null, null) or phenotypes associated with serum alpha 1-antitrypsin concentrations of less than 50mg/dL if/when measured by laboratories using nephelometry instead of radial immunodiffusion. Otherwise, a deficiency is shown at 80mg/dL. (These products should not be used in individuals with the PiMZ or PiMS phenotypes of alpha1-antitrypsin deficiency because these individuals appear to be at small risk of developing clinically evident emphysema).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## PROMACTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	ITP members with previous documented failure of eltrombopag.
Required Medical Information	<p>Chronic Idiopathic Thrombocytopenic Purpura. Initial Approval: The member has a diagnosis of relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) AND The member has a platelet count of less than <math>50 \times 10^9/L</math>. The member has had an insufficient response or is intolerant to corticosteroids OR The member has had a splenectomy with an inadequate response AND had an insufficient response or is intolerant to post-splenectomy corticosteroids. Reauthorizations. The member has a platelet count of less than <math>400 \times 10^9/L</math> AND The member remains at risk for bleeding complications AND The member is responding to therapy as evidenced by increased platelet counts. Thrombocytopenia in Patients with Hepatitis C Infection: Initial Approval: The member has a diagnosis of chronic hepatitis C. The member has a platelet count of less than <math>75 \times 10^9/L</math>. The degree of thrombocytopenia is preventing the initiation of interferon therapy OR limits the ability to maintain optimal interferon based therapy. Reauthorization: The member has a platelet count of less than <math>400 \times 10^9/L</math> AND The member is responding to therapy as evidenced by increased platelet counts AND The member continues to receive interferon based therapy. Aplastic Anemia: Initial Approval: The member has a diagnosis of aplastic anemia AND The member will receive Promacta (eltrombopag) in combination with immunosuppressive therapy (e.g. cyclosporine, antithymocyte immune globulin) for first-line treatment of severe aplastic anemia OR Promacta (eltrombopag) is being used for the treatment of refractory severe aplastic anemia in members with an insufficient response to immunosuppressive therapy (e.g. cyclosporine, antithymocyte immune globulin). Reauthorization: The member has a platelet count of less than <math>400 \times 10^9/L</math> AND The member is responding to therapy as evidenced by increased platelet counts.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

# PYRUKYND

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hemolytic Anemia: the member has a diagnosis of pyruvate kinase deficiency with at least two mutant alleles in the PKLR gene, of which at least one is missense mutation. The member is not homozygous for the R479H mutation or had two non-missense, variants, without the presence of another missense variant in the PKLR gene. The member had a hemoglobin level less than or equal to 10g/dL. Continuation of therapy: member must meet the following criteria: efficacy of Pyrukynd (nitapivat) therapy as defined as: increase in hemoglobin by 1.5 g/dL or more from baseline hemoglobin OR decrease in transfusion requirements.
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	Licensed Practitioner

## QINLOCK

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Qinlock (ripretinib).
Required Medical Information	Gastrointestinal Stromal Tumor (GIST): The member has a diagnosis of advanced GIST AND The member has received prior therapy with three or more kinase inhibitors, including imatinib AND Qinlock (ripretinib) is being used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## quinine sulfate

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prolongation of QT interval. Glucose-6-phosphate dehydrogenase (G6PD) deficiency. Myasthenia gravis. Optic neuritis.
Required Medical Information	Plasmodium Falciparum Malaria: Diagnosis of uncomplicated chloroquine-resistant Plasmodium falciparum malaria. Brand Qualaquin request only: Members must have had previous treatment with generic Qualaquin(Quinine) or who have had contraindications or intolerance with generic Qualaquin(Quinine).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## rasagiline

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member has a diagnosis of Parkinson's disease AND has had prior therapy with, contraindication, or intolerance to selegiline.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## REGRANEX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Known neoplasm at the site of application.
Required Medical Information	Member must be using for the treatment of lower extremity diabetic ulcers AND the ulcer extends into the subcutaneous tissue or beyond AND the ulcer has an adequate blood supply AND Regranex will be used in combination with good ulcer care practices including debridement, pressure relief and prevention and treatment of infection.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## REPATHA PUSHTRONEX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Initial Authorization. Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Reauthorization: maintenance of a reduction in LDL-C from baseline.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Primary Hyperlipidemia and ACSVD: Initial Auth 6 months. Reauth: Plan Year. HOFH: Plan Year.

## REPATHA PUSHTRONEX

Other Criteria	<p>Clinical Atherosclerotic Cardiovascular Disease (ASCVD): Initial Authorization. The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin). Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.</p> <p>Reauthorization: Maintenance of a reduction in LDL-C from baseline.</p> <p>Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 500 mg/dL ( 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HeFH in both parents [untreated total cholesterol greater than 290 mg/dL (7.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)].</p> <p>Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.</p>
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# REPATHA SURECLICK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Initial Authorization. Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Reauthorization: maintenance of a reduction in LDL-C from baseline.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Primary Hyperlipidemia and ACSVD: Initial Auth 6 months. Reauth: Plan Year. HOFH: Plan Year.

## REPATHA SURECLICK

Other Criteria	<p>Clinical Atherosclerotic Cardiovascular Disease (ASCVD): Initial Authorization. The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin). Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.</p> <p>Reauthorization: Maintenance of a reduction in LDL-C from baseline.</p> <p>Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 500 mg/dL ( 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HeFH in both parents [untreated total cholesterol greater than 290 mg/dL (7.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)].</p> <p>Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.</p>
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## REPATHA SYRINGE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Initial Authorization. Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Reauthorization: maintenance of a reduction in LDL-C from baseline.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Primary Hyperlipidemia and ACSVD: Initial Auth 6 months. Reauth: Plan Year. HOFH: Plan Year.

## REPATHA SYRINGE

Other Criteria	<p>Clinical Atherosclerotic Cardiovascular Disease (ASCVD): Initial Authorization. The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin). Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMS) and SAMS symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMS despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.</p> <p>Reauthorization: Maintenance of a reduction in LDL-C from baseline.</p> <p>Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 500 mg/dL ( 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HeFH in both parents [untreated total cholesterol greater than 290 mg/dL (7.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)].</p> <p>Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.</p>
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# RETACRIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Anemia of CKD: Diagnosis of anemia associated with chronic kidney disease. Hgb level less than 10.0 g/dL or HCT less than 30- within last 4 weeks. Continue Therapy: Current- within last 4 weeks Hgb level less than 11 g/dL OR documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy.</p> <p>Anemia in Zidovudine-treated HIV-infected: Diagnosed with HIV (and AZT induced anemia) and receiving zidovudine treatment corresponding with HAART. Endogenous serum erythropoietin levels less than or equal to 500 mUnits/mL. The total zidovudine dose must not exceed 4200mg/wk. Must have Hgb level less than or equal to 10.0 g/dL or HCT less than 30-within the last four weeks. Continue Therapy: Zidovudine dose must not exceed 4200mg/wk. Must meet one of the following criteria: Current-within last 4 weeks Hgb level less than 12.0 g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL.</p> <p>Anemia in Chemotherapy Treated Cancer - first 4 weeks. Diagnosis with a non-myeloid, non-erythroid malignancy. Must be receiving concurrent chemotherapy treatment for incurable disease with palliative intent. Must have Hgb level less than 10.0 g/dL or HCT less than 30-within last 4 weeks. Maint. Phase after first 4 weeks: Member has responded to therapy, defined as one or more of the following: increase in hemoglobin of at least 1 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements OR member has experienced symptom improvement and prescriber determines to continue therapy. Continued dosing is needed to maintain the lowest hemoglobin level sufficient to avoid RBC transfusion. Must meet ALL of the following criteria: Current-within the last 4 weeks Hgb level is low enough to necessitate transfusion (and Hgb is less than 10 g/dL).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 months for chemo induced anemia,HIV,HCV,RA,MDS,surgery. 6 months for CKD, CKD reauth: Plan Year.



## RETACRIT

Other Criteria	<p>Anemia in Surgery Members: Must be scheduled to undergo elective, noncardiac, nonvascular surgery. Must have Hgb level of greater than 10 g/dL and less than or equal 13 g/dL (within last 4 weeks). Anemia in Myelodysplastic Syndromes: Diagnosis of symptomatic anemia associated with MDS. Must have a serum erythropoietin level less than or equal to 500 mUnits/mL (unlikely to respond to ESA therapy if erythropoietin level greater than 500mUnits/ml). Must have Hgb level less than or equal to 10.0 g/dL or HCT less than 30 (within last 4 weeks). Continue Therapy: The member has responded to therapy, defined as one or more of the following: An increase in hemoglobin of at least 1.5 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements, OR member has experienced symptom improvement and prescriber determines to continue therapy. Continued dosing is needed to maintain the lowest hemoglobin level (not to exceed 12 g/dL) sufficient to avoid RBC transfusion. Anemia associated with Management of Hepatitis C. Diagnosis of anemia in management of chronic Hepatitis C. Receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV. Must have Hgb level less than or equal to 12.0 gm/dL or HCT less than 30 during combination therapy as defined above (within the last 4 weeks).Continue Therapy: Must be receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV. Must have been able to maintain previous ribavirin dosing without dose reduction due to symptomatic anemia. Must meet one of the following criteria: Current (within the last 4 weeks) Hgb level less than 12.0g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL. Anemia associated with Rheumatoid Arthritis (RA) Treatment. Diagnosis of anemia associated with pharmaceutical treatment of RA. Receiving active therapy known to cause anemia. Must have Hgb level less than 10 g/dL or HCT less than 30(within the last 4 weeks).Continue Therapy: Receiving active RA pharmaceutical treatment. Current (within the last 4 weeks) Hgb less than 11 g/dL. For listed indications: Prior to initiation of therapy, other causes of anemia including iron, B-12, folate deficiencies, hemolysis, and bleeding have been ruled out. Prior to initiation of therapy, the member's iron scores should be evaluated. Transferrin saturation should be at least 20% OR ferritin at least 100 ng/mL within the last 4 months (applies to most recent result). Continuation of therapy requires documented Transferrin saturation of at least 20% OR ferritin of at least 100 ng/ mL within the last 4 months for all indications (applies to most recent result).</p>
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## RETEVMO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Retevmo
Required Medical Information	Non-small cell lung cancer. The member has a diagnosis of metastatic non-small lung cancer AND The disease is documented RET fusion positive AND Retevmo is being used as monotherapy. Medullary Thyroid cancer. The member has a diagnosis of metastatic or advanced medullary thyroid cancer AND The disease is documented RET mutant AND Retevmo is being used as a single agent for systemic therapy. Thyroid cancer. The member has a diagnosis of metastatic or advanced thyroid cancer AND The disease is documented RET fusion positive AND The disease is radioactive iodine refractory AND Retevmo is being used as a single agent for systemic therapy.
Age Restriction	For medullary thyroid cancer and thyroid cancer only: the member is 12 years and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## REVLIMID

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant Thalomid (thalidomide) or Pomalyst (pomalidomide). Members that have experienced disease progression while on Revlimid (lenalidomide).
Required Medical Information	Myelodysplastic Syndromes (MDS) with 5Q deletion. The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has a documented deletion 5q chromosomal abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent. Myelodysplastic Syndromes (MDS) without 5Q deletion (non-5Q deletion). The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has no documented 5q deletion abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent. Multiple Myeloma. Diagnosis of active Multiple Myeloma or Systemic Light Chain Amyloidosis. Primary induction OR for relapsed/refractory disease, Revlimid (lenalidomide) therapy should be utilized in conjunction with dexamethasone if no contraindication. As maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplantation. For Reauthorizations: The approval duration may be continued for six additional months if benefit is shown via no evidence of disease progression/treatment failure. Chronic Lymphoid Leukemia. Diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia (CLL). For Reauthorizations: The approval duration may be continued for six additional months if benefit is shown via no evidence of disease progression.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## REVLIMID

Other Criteria	<p>Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND The member has relapsed or refractory disease AND The member will be using for third line or subsequent systemic therapy.</p> <p>Non-Hodgkin Lymphoma: The member has one of the following diagnoses: AIDS-related B-cell lymphoma, diffuse large B-cell lymphoma, mucosa-associated lymphoid tissue (MALT) lymphoma [either gastric or nongastric], primary cutaneous B-cell lymphoma, marginal zone lymphoma, or mantle cell lymphoma AND The member has relapsed or refractory disease OR The member has a diagnosis of follicular lymphoma AND The member will use as first line therapy or for relapsed or refractory disease.</p>
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## REXULTI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Major depressive disorder: The member must have clinically diagnosed major depressive disorder AND The member must have documentation of prior therapy, intolerance, or contraindication to a generic oral atypical antipsychotic therapy AND at least one antidepressant therapy (ADT) AND Rexulti must be used as adjunctive or add-on treatment to ADT and not as monotherapy. Schizophrenia: The member must have clinically diagnosed schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to two generic oral atypical antipsychotic therapies.
Age Restriction	The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## REZUROCK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Rezurock (belumosudil).
Required Medical Information	Chronic Graft Versus Host Disease (cGVHD): The member has a diagnosis of chronic graft vs host disease (cGVHD) AND the member has been unable to achieve treatment goals with at least two prior lines of system therapy AND the member has a medical reason as to why Jakafi (ruxolitinib) cannot be started or continued. Reauthorization Criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g. resolution of skin rash, reduction of GI symptoms, symptom improvement).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

# RIABNI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	High dose CLL therapies (doses greater than 500mg/m <sup>2</sup> ). The member will be using rituximab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Required Medical Information	For requests for Truxima: member must have intolerance or contraindication with Rituxan or Ruxience or Riabni and meet the criteria below. Truxima requests are only for NHL, CLL, RA, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Ruxience and Riabni requests are only for NHL, CLL, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Chronic Lymphocytic Leukemia. The member has a diagnosis of CLL. Non-Hodgkin's Lymphoma (CD-20 positive/B-Cell). The member has a diagnosis of CD-20 positive/B-cell Non-Hodgkin's lymphoma. Hodgkin's Disease (Hodgkin's Lymphoma). The member has a diagnosis of Hodgkin's Disease. The member will be using rituximab for primary treatment or for relapsed or progressive disease AND disease has confirmed CD20 positivity. Rheumatoid Arthritis. The member has a diagnosis of moderately- to severely-active rheumatoid arthritis. The member has had previous treatment with, contraindication, or intolerance with one of the following: Remicade, Inflectra, infliximab, or Simponi Aria* (previous treatment with Simponi Aria applies to medical benefit requests only). The member must be on concomitant treatment with methotrexate during rituximab therapy, unless contraindicated or intolerant to methotrexate.
Age Restriction	Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## RIABNI

Other Criteria	<p>The member must have a diagnosis of Waldenstrom's macroglobulinemia. Post-transplant lymphoproliferative disorder. The member has a diagnosis of Post-transplant Lymphoproliferative disease. Immune or Idiopathic Thrombocytopenic Purpura. The member must have a diagnosis of refractory primary immune or idiopathic thrombocytopenic purpura. Member has not had a splenectomy, but has had an insufficient response or is intolerant to corticosteroids, AND immunoglobulins (IVIG), OR has had a splenectomy with an inadequate response or is intolerant to procedure AND had an insufficient response or is intolerant to post-splenectomy corticosteroids. Refractory response is characterized as EITHER: Platelet count less than 25,000/<math>\mu</math>L OR Active bleeding due to inadequate platelet function. The member must have had an inadequate response to post-splenectomy corticosteroid therapy for four consecutive weeks within the last three months. Diagnosis of Wegeners Granulomatosis OR Microscopic Polyangiitis. Must be taking rituximab in combination with glucocorticoids. Pemphigus Vulgaris (PV). The member must have a diagnosis of moderate to severe Pemphigus Vulgaris.</p>
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# RINVOQ

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis: The member has a diagnosis of moderate to severely active rheumatoid arthritis AND the member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide), or contraindication to all DMARDs. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, Enbrel). Atopic Dermatitis: The member has a diagnosis of moderate to severe atopic dermatitis AND the member has had prior therapy, contraindication or intolerance with at least one other systemic therapy (e.g. azathioprine, mycophenolate mofetil). Ulcerative Colitis: the member has a diagnosis of moderately to severely active ulcerative colitis AND the member has had prior therapy, contraindication, or intolerance with one or more TNF blockers (e.g. Humira). Ankylosing Spondylitis: the member has a diagnosis of ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with one or more TNF blockers (e.g. Humira, Enbrel).
Age Restriction	RA, Psoriatic Arthritis, UC, and ankylosing spondylitis: The member is 18 years of age or older. Atopic Dermatitis: the member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# RITUXAN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	High dose CLL therapies (doses greater than 500mg/m <sup>2</sup> ). The member will be using rituximab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Required Medical Information	For requests for Truxima: member must have intolerance or contraindication with Rituxan or Ruxience or Riabni and meet the criteria below. Truxima requests are only for NHL, CLL, RA, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Ruxience and Riabni requests are only for NHL, CLL, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Chronic Lymphocytic Leukemia. The member has a diagnosis of CLL. Non-Hodgkin's Lymphoma (CD-20 positive/B-Cell). The member has a diagnosis of CD-20 positive/B-cell Non-Hodgkin's lymphoma. Hodgkin's Disease (Hodgkin's Lymphoma). The member has a diagnosis of Hodgkin's Disease. The member will be using rituximab for primary treatment or for relapsed or progressive disease AND disease has confirmed CD20 positivity. Rheumatoid Arthritis. The member has a diagnosis of moderately- to severely-active rheumatoid arthritis. The member has had previous treatment with, contraindication, or intolerance with one of the following: Remicade, Inflectra, infliximab, or Simponi Aria* (previous treatment with Simponi Aria applies to medical benefit requests only). The member must be on concomitant treatment with methotrexate during rituximab therapy, unless contraindicated or intolerant to methotrexate.
Age Restriction	Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## RITUXAN

Other Criteria	<p>The member must have a diagnosis of Waldenstrom's macroglobulinemia. Post-transplant lymphoproliferative disorder. The member has a diagnosis of Post-transplant Lymphoproliferative disease. Immune or Idiopathic Thrombocytopenic Purpura. The member must have a diagnosis of refractory primary immune or idiopathic thrombocytopenic purpura. Member has not had a splenectomy, but has had an insufficient response or is intolerant to corticosteroids, AND immunoglobulins (IVIG), OR has had a splenectomy with an inadequate response or is intolerant to procedure AND had an insufficient response or is intolerant to post-splenectomy corticosteroids. Refractory response is characterized as EITHER: Platelet count less than 25,000/<math>\mu</math>L OR Active bleeding due to inadequate platelet function. The member must have had an inadequate response to post-splenectomy corticosteroid therapy for four consecutive weeks within the last three months. Diagnosis of Wegeners Granulomatosis OR Microscopic Polyangiitis. Must be taking rituximab in combination with glucocorticoids. Pemphigus Vulgaris (PV). The member must have a diagnosis of moderate to severe Pemphigus Vulgaris.</p>
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# RITUXAN HYCELA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member will be using Rituxan Hycela (rituximab/hyaluronidase) for the treatment of a non-malignant condition (e.g. rheumatoid arthritis). The member will be using Rituxan Hycela (rituximab/hyaluronidase) as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The member will be using Rituxan Hycela (rituximab/hyaluronidase) as a single agent for first-line therapy in follicular lymphoma (FL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). o The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Required Medical Information	For requests for Rituxan Hycela: member is unable to achieve treatment goals with Rituxan, Ruxience, or Riabni and meets the criteria below. Chronic Lymphocytic Leukemia: The member must have a diagnosis of chronic lymphocytic leukemia AND The member will be using Rituxan Hycela as monotherapy or in combination with fludarabine and cyclophosphamide. Follicular lymphoma: The member has a diagnosis of follicular lymphoma AND One of the following applies: Previously untreated disease and will be using Rituxan Hycela in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan Hycela in combination with chemotherapy, as single-agent maintenance therapy OR Non-progressing (including stable disease) disease, as a single agent after first line cyclophosphamide, vincristine, and prednisone chemotherapy OR Relapsed or refractory disease, as a single agent. Diffuse large B cell lymphoma: The member has a diagnosis of diffuse large B cell lymphoma AND The member has previously untreated disease and will be using Rituxan Hycela in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone or with another anthracycline-based chemotherapy regimen.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ROMIDEPSIN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on romidepsin. Members on concomitant hypomethylator (e.g. vorinostat) therapy.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Istodax (romidepsin) is being used to treat cutaneous T-cell lymphoma AND one of the following applies: the member will be using Istodax (romidepsin) as primary biologic systemic therapy OR the member has received at least one prior therapy. Peripheral T-cell Lymphoma (PTCL). Istodax (romidepsin) is being used to treat relapsed or refractory peripheral T-cell lymphoma. The member has received at least one prior therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## ROZLYTREK

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) AND the member has disease which is ROS1-positive. Solid Tumors: the member has a diagnosis of solid tumors which are metastatic AND The member has a documented neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND The member is not a candidate for surgical resection AND The member's disease has progressed following treatment or does not have satisfactory alternative therapy options. Reauthorization: The member has not developed a known resistance to Rozlytrek (entrectinib) AND Physician attestation that the member has continued to receive a clinical benefit (e.g., complete response, partial response, stable disease) and has not experienced disease progression.
Age Restriction	Solid tumors: member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## RUBRACA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on PARP inhibitor therapy [e.g., Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)].
Required Medical Information	Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer Maintenance Therapy: The member has a diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member has been treated with at least two prior lines of platinum based chemotherapy AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Rubraca (rucaparib) as monotherapy. *Discontinue Avastin before initiating maintenance therapy with Rubraca. BRCA-Mutated Advanced Ovarian Cancer: The member has a diagnosis of advanced ovarian cancer AND The member has deleterious BRCA mutation (germline and/or somatic) AND The member has been treated with two or more prior lines of chemotherapy AND The member will utilize Rubraca (rucaparib) as a monotherapy. Metastatic Castration-Resistant Prostate Cancer: The member has a diagnosis metastatic castration-resistant prostate cancer (mCRPC) AND The member has documented deleterious BRCA mutation (germline and/or somatic) AND The member has had prior treatment with androgen receptor-directed therapy (e.g. abiraterone, Xtandi, Erleada, or Nubeqa) and a taxane-based chemotherapy (e.g. docetaxel) AND The member will use Rubraca (rucaparib) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## rufinamide

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients with familial short QT syndrome.
Required Medical Information	Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) AND the member has prior therapy with, contraindication or intolerance to at least one other drug indicated for LGS (e.g., topiramate, lamotrogine).
Age Restriction	Member is one year of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



# RUXIENCE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	High dose CLL therapies (doses greater than 500mg/m <sup>2</sup> ). The member will be using rituximab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Required Medical Information	For requests for Truxima: member must have intolerance or contraindication with Rituxan or Ruxience or Riabni and meet the criteria below. Truxima requests are only for NHL, CLL, RA, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Ruxience and Riabni requests are only for NHL, CLL, granulomatosis with polyangitis (GPA) (Wegener's Granulomatosis), and microscopic polyangitis (MPA). Chronic Lymphocytic Leukemia. The member has a diagnosis of CLL. Non-Hodgkin's Lymphoma (CD-20 positive/B-Cell). The member has a diagnosis of CD-20 positive/B-cell Non-Hodgkin's lymphoma. Hodgkin's Disease (Hodgkin's Lymphoma). The member has a diagnosis of Hodgkin's Disease. The member will be using rituximab for primary treatment or for relapsed or progressive disease AND disease has confirmed CD20 positivity. Rheumatoid Arthritis. The member has a diagnosis of moderately- to severely-active rheumatoid arthritis. The member has had previous treatment with, contraindication, or intolerance with one of the following: Remicade, Inflectra, infliximab, or Simponi Aria* (previous treatment with Simponi Aria applies to medical benefit requests only). The member must be on concomitant treatment with methotrexate during rituximab therapy, unless contraindicated or intolerant to methotrexate.
Age Restriction	Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## RUXIENCE

Other Criteria	<p>The member must have a diagnosis of Waldenstrom's macroglobulinemia. Post-transplant lymphoproliferative disorder. The member has a diagnosis of Post-transplant Lymphoproliferative disease. Immune or Idiopathic Thrombocytopenic Purpura. The member must have a diagnosis of refractory primary immune or idiopathic thrombocytopenic purpura. Member has not had a splenectomy, but has had an insufficient response or is intolerant to corticosteroids, AND immunoglobulins (IVIG), OR has had a splenectomy with an inadequate response or is intolerant to procedure AND had an insufficient response or is intolerant to post-splenectomy corticosteroids. Refractory response is characterized as EITHER: Platelet count less than 25,000/<math>\mu</math>L OR Active bleeding due to inadequate platelet function. The member must have had an inadequate response to post-splenectomy corticosteroid therapy for four consecutive weeks within the last three months. Diagnosis of Wegeners Granulomatosis OR Microscopic Polyangiitis. Must be taking rituximab in combination with glucocorticoids. Pemphigus Vulgaris (PV). The member must have a diagnosis of moderate to severe Pemphigus Vulgaris.</p>
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## RUZURGI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	History of seizures.
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS): The member has a confirmed diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) by a specialist (e.g. neurologist) AND The diagnosis is supported by results from a clinical evaluation (e.g. electromyography or the presence of autoantibodies directed against VGCC [voltage gated calcium channels]).
Age Restriction	The member is 6 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## RYBREVANT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who have disease progression on Rybrevant (amivantamab).
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and all the following criteria applies: The NSCLC has documented epidermal growth factor receptor (EGFR) exon 20 insertion mutations (e.g. as detected by a FDA-approved test) AND the member has documented disease progression on prior platinum-based chemotherapy AND Rybrevant (amivantamab) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

# RYDAPT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on or following Rydapt (midostaurin), Members with a diagnosis of therapy-related acute myeloid leukemia (defined as acute myeloid leukemia due to prior radiation therapy or prior chemotherapy used as therapy for a prior disorder or malignancy), Members with a diagnosis of acute promyelocytic leukemia (APL), Members that are using Rydapt (midostaurin) for post-consolidation therapy, Members that are using Rydapt (midostaurin) as a single agent induction therapy for acute myeloid leukemia
Required Medical Information	Acute Myeloid Leukemia-Newly diagnosed: The member has newly diagnosed acute myeloid leukemia (AML) AND The member has documented FLT3 mutation-positive disease AND The member will be using Rydapt (midostaurin) in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. Systemic Mastocytosis: The member has a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematologic neoplasm (SM-AHN), or mast cell leukemia (MCL). Acute Myeloid Leukemia - Relapsed/Refractory: The member has relapsed or refractory acute myeloid leukemia (AML) AND The member has documented FLT3 mutation-positive disease AND The member will be using Rydapt (midostaurin) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## RYLAZE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with a history of serious pancreatitis with prior asparaginase based therapy. Members with a history of serious thrombosis with prior asparaginase based therapy. Members with a history of serious hemorrhagic events with prior asparaginase based therapy. Members that have experienced disease progression while on asparaginase based therapy.
Required Medical Information	Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL): The member has a diagnosis of acute lymphoblastic leukemia (ALL) or Lymphoblastic lymphoma (LBL) AND The member has documented, Grade 2 - 4 hypersensitivity (based on Common Terminology Toxicity Criteria) as a result of prior treatment with Oncaspar (pegaspargase) AND The member is using Rylaze (asparaginase Erwinia chrysanthemi-rywn) as a component of a multi-agent chemotherapeutic regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## sajazir

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use for prophylaxis of HAE attack. Evidence of autoantibodies against the C1INH protein. Evidence of underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks. Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest).
Required Medical Information	Hereditary Angioedema (HAE): The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Low evidence of C4 level (i.e. C4 level below lower limit of normal laboratory reference range) AND Low C1 inhibitor (i.e. C1INH level below lower limit of normal laboratory reference range) antigenic level (C1INH less than 19 mg/dL) OR Low C1INH functional level (i.e. functional C1INH less than 50% or below lower limit of normal laboratory reference range) OR Known HAE-causing C1INH mutation. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level. The member is using icatibant for treatment of acute attacks of HAE.
Age Restriction	The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## SANDOSTATIN LAR DEPOT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	<p>Acromegaly: The member must have a diagnosis of Acromegaly. Must have had an inadequate response to surgery/radiation or for whom surgical resection/radiation is not an option. Treatment of metastatic carcinoid tumors. Must have a diagnosis of a carcinoid tumor. Patient must have severe diarrhea and flushing resulting from carcinoid tumor. Treatment of vasoactive intestinal peptide tumors (VIPomas). Patient must be diagnosed with a vasoactive intestinal peptide tumor. Patient must have diagnosis of profuse watery diarrhea associated with VIP-secreting tumor. Treatment of chemotherapy or radiation induced diarrhea. Patient must have grade 3 or above diarrhea according to NCI common toxicity. Patient must have NCI grade 1 or 2 diarrhea and have failed treatment with loperamide or diphenoxylate and atropine. Treatment of severe secretory diarrhea in acquired immune deficiency syndrome (AIDS) patients. Patient must have diagnosis of severe diarrhea resulting from acquired immune deficiency syndrome (AIDS). Patient must have tried and failed antimicrobial agents (eg. ciprofloxacin or metronidazole) and/or anti-motility agents (eg. loperamide or diphenoxylate and atropine). Reversal of life-threatening hypotension due to carcinoid crisis during induction of anesthesia. Patient must have life-threatening hypotension due to carcinoid crisis.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## sapropterin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Initial: The member has a diagnosis of PKU. Reauth - The member has tetrahydrobiopterin -(BH4) responsive PKU defined by: The member has achieved a greater than or equal to a 20% reduction in blood phenylalanine concentration from pre-treatment baseline OR the member has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescriber.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	First approval: three months. if response is positive extended for plan year duration.
Other Criteria	NA

# SARCLISA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following an anti-CD38 inhibitor (e.g. daratumumab, isatuximab-irfc).
Required Medical Information	Multiple myeloma (third line). The member has a diagnosis of multiple myeloma AND The member will be using Sarclisa (isatuximab-irfc) in combination with Pomalyst (pomalidomide) and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The member has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g. bortezomib, carfilzomib). Multiple Myeloma (relapsed or refractory): The member has a diagnosis of relapsed or refractory multiple myeloma AND The member will be using Sarclisa (isatuximab-irfc) in combination with carfilzomib and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The member has received at least one prior therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## SCSEMBLIX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Scemblix (asciminib).
Required Medical Information	Chronic Myeloid Leukemia (chronic phase): The member has a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase AND One of the following applies: The member has had intolerance, resistance, or contraindication to at least two available tyrosine kinase inhibitors OR The member has T315I mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## SECUADO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Dementia related psychosis(in the absence of an approvable diagnosis)for members 65 years of age or older.
Required Medical Information	Schizophrenia: The member has diagnosis of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least two of the following: risperidone or olanzapine or quetiapine or ziprasidone or aripiprazole.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## SIGNIFOR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Cushing's disease: Diagnosis of Cushing's disease AND Pituitary surgery is not an option or has not been curative AND No severe hepatic impairment (Child-Pugh C).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months for initial approval.
Other Criteria	Reauthorization criteria for additional 180 days are as follows: No severe hepatic impairment (Child-Pugh C AND Urinary Free Cortisol (UFC) level has decreased from baseline at start of Signifor (pasireotide) treatment.

## sildenafil (pulm.hypertension)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH).The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization. The member has had prior therapy, contraindication, or intolerance to a phosphodiesterase type 5 (PDE-5) inhibitor approved for use in PAH (e.g., sildenafil or tadalafil).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## SIRTURO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Multidrug-resistant tuberculosis (MDR-TB). The member must have a diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) confirmed by drug susceptibility testing (DST). Bedaquiline will be used as part of a multidrug regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	24 weeks duration
Other Criteria	

# SKYRIZI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Plaque Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member has had prior therapy or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide), or contraindication with all DMARDS. Moderately to severely active Crohn's disease: member has a diagnosis of moderately to severely active Crohn's disease AND the member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g., prednisone, methylprednisolone) or an immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate).</p>
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



## SOMATULINE DEPOT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Diagnosis of acromegaly. The patient has a diagnosis of acromegaly. The patient has had an inadequate response to or cannot be treated with surgical resection OR The patient has had an inadequate response to or cannot be treated with radiation therapy. Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs): The member has a diagnosis of unresectable, well- or moderately-differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors. Carcinoid Syndrome: The member has a diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## SOMAVERT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acromegaly. The member must have a diagnosis of acromegaly. The member had inadequate response to surgery or radiation therapy, AND one dopamine agonists (i.e. bromocriptine) or one somatostatin analogues (i.e. octreotide, lanreotide).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## sorafenib

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Nexavar (sorafenib).
Required Medical Information	Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma (stage IV) AND the member has experienced intolerance, contraindication, or unable to achieve treatment goals with Cabometyx (cabozantinib) as second line therapy (e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome). Liver Carcinoma: Diagnosis of unresectable hepatocellular (liver) carcinoma. Thyroid Carcinoma: Diagnosis of advanced metastatic medullary carcinoma (thyroid carcinoma) OR The member has a diagnosis of advanced, clinically progressive and/or symptomatic papillary carcinoma, follicular carcinoma or Hürthle cell carcinoma AND Tumors are not responsive to radio-iodine treatment. Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST) AND The member experienced disease progression with imatinib or Sutent (sunitinib) or Stivarga (regorafenib).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## SPRYCEL

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors, Members that have experienced disease progression while on dasatinib. For ALL and CML: The member has one of the following mutations: T315I/A, F317L/V/I/C or V299L.
Required Medical Information	Chronic Myelogenous Leukemia (CML): The member has a diagnosis of Ph+ chronic myeloid leukemia (CML) and one of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated and one of the following applies: Intermediate- or high-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with Bosulif (bosutinib) OR Low risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib and Bosulif (bosutinib) OR The member has a diagnosis of chronic phase CML that has received previous treatment AND Low, intermediate-, or high-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with Bosulif (bosutinib). Acute Lymphoblastic Leukemia (ALL): The member has ALL (Philadelphia Chromosome positive) and Sprycel is being used for induction or consolidation treatment in combination with chemotherapy or corticosteroids OR treatment is for maintenance therapy or the treatment of members with resistance or intolerance to prior therapy. Advanced Gastrointestinal Stromal Tumor (GIST): The member has a diagnosis of advanced unresectable GIST. The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib) or Sutent (sunitinib) or Stivarga. [Pediatric] Chronic Myelogenous Leukemia (CML). The member has a diagnosis of chronic myeloid leukemia (CML) that is Philadelphia chromosome positive (Ph+) AND the member is in chronic phase. [Pediatric] Acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL) AND the member has Philadelphia chromosome positive (Ph+) disease AND the member has newly-diagnosed disease AND The member will be using Sprycel in combination with chemotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# STELARA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis (SC formulation only): The member must have a diagnosis of moderate to severe chronic plaque psoriasis AND The member has had prior therapy or intolerance to one or more oral systemic treatments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic arthritis (SC formulation only): The member must have a diagnosis of active psoriatic arthritis AND the member has had prior therapy or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide), or contraindication with all DMARDS. Moderately to severely active Crohn's disease (IV and SC formulations). The member must have a diagnosis of moderately to severely active Crohn's disease AND the member has had prior therapy, contraindication, or intolerance to a corticosteroid (e.g. prednisone, methylprednisolone) or an immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate). The member must have a diagnosis of moderately to severely active ulcerative colitis AND the member has had prior therapy, contraindication, or intolerance to one or more of the following conventional therapies: 5-aminosalicylic acids (5-ASAs) (e.g. mesalamine, balsalazide) OR Corticosteroids (e.g. prednisone, methylprednisolone) PR immunomodulators (e.g. azathioprine, 6-mercaptopurine).
Age Restriction	Moderate to severe chronic plaque psoriasis and psoriatic arthritis: The member must be 6 years of age or older. For all other indications: Must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# STIVARGA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Stivarga (regorafenib).Members on concomitant tyrosine kinase inhibitors.
Required Medical Information	Metastatic Colorectal Cancer.The member has a diagnosis of metastatic colorectal cancer AND The member is using Stivarga (regorafenib) as monotherapy AND The member has documented intolerance, contraindication or has failed previous treatment with ALL of the following therapies: fluoropyrimidine (regimens include 5-FU/capecitabine),oxaliplatin-based chemotherapy,irinotecan-based chemotherapy, and anti-VEGF therapy (e.g., bevacizumab, ziv-aflibercept) AND If the member is RAS wild-type and has documented intolerance, contraindication or has failed previous treatment with anti-EGFR therapy (e.g., cetuximab, panitumumab).Gastrointestinal Stromal Tumor.The member has a diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor AND The member has experienced disease progression, intolerance, or contraindication with imatinib mesylate and sunitinib malate. Hepatobiliary Cancers: The member has a diagnosis of hepatocellular carcinoma AND Stivarga (regorafenib) is being given as monotherapy AND The member has experienced progression after first line theapy (e.g., sorafenib). Soft Tissue sarcoma. Diagnosis of advanced or metastatic soft tisuse sarcoma (i.e., angiosarcoma, solitary fibrous tumor, non-adipocytic sarcoma, pleomorphic rhabdomyosarcoma) AND Stivarga (regorafenib) is being given as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Month Duration
Other Criteria	

## STRENSIQ

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Hypophosphatasia (HPP):The member must have a diagnosis of perinatal-onset, infantile-onset, or juvenile onset hypophosphatasia. Hypophosphatasia (HPP):The member must have a diagnosis of perinatal-onset, infantile-onset, or juvenile-onset hypophosphatasia defined by:Low total serum alkaline phosphatase (ALP) activity determined by the gender- and age-specific reference range, AND Elevated urine concentration of phosphoethanolamine (PEA) determined by age-specific reference range, OR Elevated serum pyridoxal 5'-phosphate (PLP) level (normal range 5 - 50 mcg/L), OR Documented gene mutation of tissue-nonspecific alkaline phosphatase (TNSALP).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial Auth: 6 months. Reauth: Plan Year Duration.
Other Criteria	Continuation of Therapy: The member is experiencing clinical benefit from Strensiq therapy (e.g. improvement in skeletal manifestations, gait/mobility, growth, etc).

## sunitinib

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Sutent. Member not to exceed a total treatment of 54 weeks (applicable to adjuvant therapy for renal cell carcinoma).
Required Medical Information	Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST) AND the member has disease progression on or intolerance to imatinib mesylate. Advanced renal cell carcinoma (RCC). Diagnosis of advanced renal cell carcinoma (stage IV). Renal Cell Carcinoma (RCC) Adjuvant Therapy. The member has high risk (i.e. tumor stage T3 or higher, regional lymph node metastases, or both) of recurrent RCC following nephrectomy AND Sutent (sunitinib) will be used as a single agent as adjuvant treatment. Pancreatic neuroendocrine tumors (PNET). Diagnosis of Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) AND The member has unresectable locally advanced or metastatic disease. Advanced Thyroid Carcinoma. Diagnosis of advanced/metastatic follicular carcinoma, Hurthle cell carcinoma, papillary (types of thyroid carcinoma) and are not responsive to radio-iodine treatment and clinical trials are not available or appropriate. OR The member has a diagnosis of advanced medullary carcinoma-disseminated symptomatic disease (type of thyroid carcinoma) and has disease progression or has an intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). Soft Tissue sarcoma. Diagnosis of soft tissue sarcoma (Angiosarcoma or Solitary Fibrous Tumor or Alveolar soft part sarcoma) AND Sutent (sunitinib) is being utilized as a single agent/monotherapy (without concomitant chemotherapy or biologics). Thymomas/thymic carcinoma: The member will be using as monotherapy in the second line.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



## SYLVANT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	NA
<b>Required Medical Information</b>	Multicentric Castleman's Disease: The member has a diagnosis of multicentric Castleman's disease. The member is human immunodeficiency (HIV) and human herpes virus (HHV-8) negative. The member has an absolute neutrophil count greater than or equal to $1.0 \times 10^9/L$ , a platelet count of greater than or equal to $75 \times 10^9$ , and hemoglobin level less than 17 g/dL. Reauthorization Criteria: The approval duration may be continued for 6 additional months if benefit is shown via no evidence of disease progression/treatment failure and the following laboratory parameters are met: The member has an absolute neutrophil count greater than or equal $1.0 \times 10^9/L$ , a platelet count of greater than or equal $50 \times 10^9$ , and hemoglobin level less than 17 g/dL.
<b>Age Restriction</b>	NA
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 month duration
<b>Other Criteria</b>	NA

## SYMDEKO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Cystic Fibrosis: The member has a diagnosis of Cystic Fibrosis AND member has documentation of a mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on clinical literature and/or in vitro assay data.
Age Restriction	The member is aged 6 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## SYMPAZAN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Lennox-Gastaut Syndrome: The member has a diagnosis of Lennox-Gastaut Syndrome AND the member will be taking at least one concomitant anti-epileptic medication therapy AND the member has had prior therapy AND has a documented contraindication (e.g. dysphagia) to BOTH a generic clobazam tablet AND oral suspension formulation.
Age Restriction	The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA

## SYNRIBO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Synribo (omacetaxine mepesuccinate).
Required Medical Information	Chronic Myelogenous Leukemia. The member has a diagnosis chronic or accelerated phase chronic myeloid leukemia AND one of the following applies: The member has had prior therapy, intolerance, or resistance to at least two of the following tyrosine kinase inhibitors: imatinib, Sprycel, Tasigna, or Bosulif OR The member has a documented T315I mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	

## TABRECTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Tabrecta (capmatinib).
Required Medical Information	Non-Small Lung Cell Cancer (NSCLC): The member has a diagnosis of metastatic NSCLC AND the disease is documented MET exon 14 skipping positive AND Tabrecta (capmatinib) is being used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## tadalafil (pulm. hypertension)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## TAFINLAR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	<p>Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab) Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Tafinlar (dabrafenib).</p> <p>Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib)].</p> <p>Adjuvant melanoma only: member is taking Tafinlar (dabrafenib) total treatment for more than one year.</p>
Required Medical Information	<p>Melanoma-Unresectable or Metastatic: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Tafinlar (dabrafenib) as monotherapy OR in combination with Mekinist (trametinib). Non-small cell lung cancer: The member has a diagnosis of recurrent or metastatic non-small cell lung cancer (NSCLC) AND The member has a documented BRAF V600E mutation AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Melanoma - Adjuvant. The member has a diagnosis of stage III melanoma AND The member has undergone lymph node resection of involved lymph nodes AND The member has a documented BRAF V600 activating mutation AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib) for adjuvant treatment.</p> <p>Anaplastic Thyroid Cancer. The member has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND The member has a documented V600E mutation AND The member has no satisfactory locoregional treatment options AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Metastatic Solid Tumors: the member has a diagnosis of unresectable or metastatic solid tumors with documented BRAF V600E mutation AND the member has disease that has progressed on prior therapy and has no satisfactory alternative treatments AND Tafinlar is given in combination with Mekinist.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

# TAGRISSO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members who have disease progression on Tagrisso (osimertinib). Total treatment exceeds three years (applicable to adjuvant therapy in NSCLC).
Required Medical Information	Non small cell lung cancer NSCLC: The member has a diagnosis of metastatic non small cell lung cancer (NSCLC) and the following criteria applies: The member has documented sensitizing EGFR mutations (exon 19 deletions or exon 21 L858R) AND Tagrisso (osimertinib) is being used as single agent for first line therapy OR The member has a documented epidermal growth factor receptor (EGFR) T790M mutation AND Tagrisso (osimertinib) is used as monotherapy after progression of EGFR inhibitors (e.g., erlotinib, gefitinib). Non-small cell lung cancer (NSCLC) [Adjuvant therapy]: The member has a diagnosis of NSCLC (i.e., Stage Ib- IIIA) AND The member has documented sensitizing EGFR mutations (exon 19 deletions or exon 21 L858R) AND The tumor has been resected AND Member will taking (osimertinib) as a single agent for adjuvant therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA



## TALZENNA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members have experienced disease progression while on or following PARP inhibitor therapy (eg, olaparib).
Required Medical Information	Breast Cancer. Member has a diagnosis of locally advanced or metastatic, HER-2 negative breast cancer AND Member has documented deleterious germline or suspected germline BRCA mutated disease AND if member has hormone receptor positive disease then is endocrine refractory AND Talzenna (talazoparib) will be used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## TARGRETIN

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that are pregnant. Members on concomitant retinoid therapy.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Targretin (bexarotene) capsules). The member will be using Targretin as primary treatment OR Member has experienced disease progression, contraindication, or intolerance to at least one prior systemic therapy for cutaneous manifestations of cutaneous T-cell lymphoma. Cutaneous T-cell Lymphoma. Targretin (bexarotene) 1% topical gel/jelly). The member will be using Targretin as primary treatment OR Member has experienced disease progression, contraindications, or intolerance to at least one prior CTCL therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# TASIGNA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Tasigna (nilotinib). For ALL and CML: The member has one of the following mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E.
Required Medical Information	Chronic Myelogenous Leukemia (CML). The member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (CML) AND One of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated, and one of the following applies: Intermediate- or high-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with Bosulif (bosutinib) OR Low-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib and Bosulif (bosutinib) OR The members has a diagnosis of chronic phase CML that has received previous treatment AND: Low, Intermediate-, or high-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with Bosulif (bosutinib). Advanced Gastrointestinal Stromal Tumor (GIST). Diagnosis of advanced unresectable GIST. The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib), Sutent (sunitinib), or Stivarga. Acute Lymphoblastic Leukemia (ALL). The member has diagnosis of Philadelphia positive acute lymphoblastic leukemia. Pediatric CML: Diagnosis of chronic phase Ph+ chronic myeloid leukemia (CML) OR diagnosis of accelerated phase Ph+ chronic myeloid leukemia (CML) AND resistance, intolerance, or contraindication to prior TKI therapy.
Age Restriction	Pediatric CML- member is greater than or equal to 1 year of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## tazarotene

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The treatment of acne vulgaris: The member must have a documented diagnosis of acne vulgaris AND The member must have had previous treatment, or intolerance to generic topical tretinoin (non-micro)*. The treatment of stable plaque psoriasis: The member must have a documented diagnosis of stable plaque psoriasis AND The member must have had previous treatment , intolerance, or contraindication with topical betamethasone dipropionate or triamcinolone 0.5%. *Generic topical tretinoin (non-micro) has additional prior authorization requirements.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## TAZVERIK

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member experiences disease progression on Tazverik
Required Medical Information	Epithelioid Sarcoma: The member has a diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection AND Tazverik will be given as monotherapy. Follicular lymphoma: The member has a diagnosis of relapsed/refractory follicular lymphoma AND one of the following applies: The member has a documented EZH2 mutation by an FDA approved test and the member has received at least two prior therapies and the member will be using Tazverik (tazemetostat) as monotherapy OR The member has no satisfactory alternative treatment options and The member will be using Tazverik (tazemetostat) as monotherapy.
Age Restriction	The member is 16 years of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## TECENTRIQ

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant setting for Non-Small Cell Lung Cancer: member is taking Tecentriq (atezolizumab) total treatment for more than one year.
Required Medical Information	<p>Urothelial cancer: The member has a diagnosis of locally advanced or metastatic urothelial cancer AND The member will be using Tecentriq (atezolizumab) as a single agent AND One of the following apply: Tecentriq is being used as initial therapy in members who are ineligible to receive cisplatin containing chemotherapy and disease expressing PD-L1 (i.e., PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) OR Tecentriq is being used as initial therapy in members who are ineligible to receive platinum containing chemotherapy regardless of PD-L1 status. Non-Small Cell Lung Cancer: metastatic NSCLC with non-squamous cell histology AND member has disease with no EGFR or ALK genomic tumor aberrations AND Tecentriq will be given as a component of one of the two combo regimens: in combination with carboplatin and paclitaxel and Avastin as first line therapy followed by maintenance therapy with combination Tecentriq and Avastin OR in combo with Abraxane (nabpaclitaxel) and carboplatin as first line therapy. OR The member must have a diagnosis of metastatic squamous or non-squamous nonsmall cell lung cancer AND has experienced disease progression on or after chemotherapy and EGFR inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib]), if EGFR mutation positive or ALK inhibitor (e.g., Xalkori (crizotinib)), if ALK positive AND the member will be using Tecentriq as monotherapy. OR metastatic NSCLC AND Disease has high PD-L1 expression [PD-L1 stained greater than or equal to 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering greater than or equal to 10% of the tumor area] AND PD-L1 tumor expression is determined by an FDA-approved test AND disease has no EGFR or ALK genomic tumor aberrations and will be given as 1st line therapy AND as monotherapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## TECENTRIQ

Other Criteria	<p>Small Cell Lung Cancer: The member has a diagnosis of extensive-stage small cell lung cancer AND Tecentriq will be given in combination with etoposide and carboplatin as first line therapy followed by maintenance therapy with Tecentriq. Hepatocellular Carcinoma: The member has a diagnosis of unresectable or metastatic hepatocellular carcinoma AND Tecentriq (atezolizumab) will be used as first line therapy in combination with bevacizumab. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND the member will use Tecentriq in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib). Non-Small Cell Lung Cancer (Adjuvant): The member must have a diagnosis of Stage II to IIIA non-small cell lung cancer AND The disease has expression of PD-L1 on greater than or equal to 1% of tumor cells as determined by an FDA-approved test AND The member is post complete surgical resection and adjuvant platinum-based chemotherapy AND The member will be using Tecentriq (atezolizumab) as monotherapy in the adjuvant setting.</p>
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## TECFIDERA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## TECVAYLI

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review

# TEMODAR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Temozolomide is contraindicated in member with a history of hypersensitivity to dacarbazine.
Required Medical Information	<p>Glioblastoma Multiforme/ Anaplastic Astrocytoma: The member is an adult with glioblastoma multiforme (GBM) or anaplastic astrocytoma and Temodar (temozolomide) is being used as the following: Newly diagnosed GBM or anaplastic astrocytoma as a single agent or in combination with radiotherapy OR Maintenance therapy for GBM or anaplastic astrocytoma or treatment of recurrent disease as a single agent or in combination with bevacizumab product for GBM or anaplastic astrocytoma. Low Grade Gliomas: The member is an adult with low grade infiltrative supratentorial astrocytoma or oligodendroglioma AND The member has disease progression on a regimen containing carmustine, lomustine, or procarbazine AND The member must use Temodar (temozolomide) as a single agent for recurrent or progressive disease OR The member must use Temodar (temozolomide) as a single agent as adjuvant therapy. Ewing's Sarcoma: The member has Ewing's sarcoma and Temodar (temozolomide) is being used in combination with irinotecan for one of the following: Relapse therapy. Progressive disease following primary treatment. Melanoma: The member has diagnosis of unresectable or recurrent melanoma and Temodar (temozolomide) is being used as a single agent for subsequent therapy. Neuroendocrine Tumors of the Pancreas: The member has diagnosis of unresectable locoregional and/or distant metastatic neuroendocrine tumors of the pancreas (islet cell tumors) and Temodar is being as single agent or in combo with Xeloda for the management of symptomatic disease, clinically significant tumor burden or clinically significant progression.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## TEMODAR

Other Criteria	Neuroendocrine Tumors of the Lung or Thymus: The member has locoregional or metastatic neuroendocrine carcinoma and Temodar (temozolomide) is being used as a single agent. Mycosis fungoides (MF)/Sezary syndrome(SS): The member has a diagnosis of MF/SS. Primary Central Nervous System (CNS) Lymphoma: The member has a diagnosis of primary CNS lymphoma and will be using Temodar (temozolomide) in combination with high-dose methotrexate and rituximab product OR The member has progressive or recurrent primary CNS lymphoma and Temodar (temozolomide) is being used as a single agent or in combination with rituximab product. Soft tissue sarcoma: The member has diagnosis of soft tissue sarcoma. Anaplastic Gliomas. The member has diagnosis of Anaplastic Gliomas and Temodar (temozolomide) will be used as monotherapy and one of the following applies: adjuvant treatment or recurrent disease OR Temodar (temozolomide) will be given in combination with bevacizumab product for treatment of recurrent disease.
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## temsirolimus

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients that have experienced disease progression while on temsirolimus.
Required Medical Information	The member has a diagnosis of advanced/metastatic renal cell carcinoma (stage IV). Endometrial cancer: The member has a diagnosis of endometrial cancer AND the member has been surgically staged and found to be stage IIIA-IVB and Torisel will be used as adjuvant therapy OR Torisel (temsirolimus) will be used as primary treatment. OR The member has a diagnosis of recurrent or metastatic endometrial cancer.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## TEPMETKO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member experiences disease progression on MET inhibitor (e.g., Tabrecta, Tepmetko).
Required Medical Information	Non-small cell lung cancer. The member has a diagnosis of metastatic NSCLC AND The disease is documented MET exon 14 skipping positive AND The member has a medical reason as to why Tabrecta (capmatinib) cannot be started or continued AND Tepmetko (tepotinib) is being used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	NA

## testosterone

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member has one of the following diagnoses: Primary hypogonadism: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals OR Hypogonadotropic hypogonadism: idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation AND Member has had one of the following: Documentation of two morning serum testosterone levels (total or free) that are less than the reference range for the lab, taken at separate times, prior to treatment OR Documentation of a serum testosterone level (total or free) that is less than or within the reference range for the lab, when already on treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## tetrabenazine

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Diagnosis of chorea associated with Huntington's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# THALOMID

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members on concomitant Revlimid (lenalidomide) or Pomalyst (pomalidomide). Members that have experienced disease progression while on thalidomide.
Required Medical Information	Thalomid (thalidomide) will require prior authorization and may be considered medically necessary when the following criteria are met for the following indication(s): Erythema Nodosum Leprosum (ENL). The member is currently having acute cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) OR Thalomid (thalidomide) is prescribed for maintenance therapy for prevention and suppression of the cutaneous manifestations of (ENL) recurrence. Multiple Myeloma. The member has a diagnosis of Multiple Myeloma. Waldenström's Macroglobulinemia. The member has a diagnosis of Waldenström's macroglobulinemia or lymphoplasmacytic lymphoma AND Thalomid (thalidomide) is being used for primary therapy, progressive or relapsed disease or salvage therapy for disease that does not respond to primary therapy AND Thalomid (thalidomide) is being used as monotherapy or in combination with a rituximab product.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



# TIBSOVO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Tibsovo (ivosedinib).
Required Medical Information	<p>Acute Myeloid Leukemia- Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member has a documented IDH1 mutation AND one of the following applies: The member will be using Tibsovo (ivosedinib) as monotherapy OR the member will be using Tibsovo as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months). Acute Myeloid Leukemia Newly diagnosed: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has newly diagnosed disease AND one of the following applies: the member is 60 years of age or older and is not a candidate for intensive induction therapy due to comorbidities OR the member is 60 years of age or older and the member declines intensive induction therapy OR the member is 75 years of age or older. The member has a documented IDH1 mutation as detected by an FDA-approved test AND the member will be using Tibsovo as monotherapy or in combination with azactidine.</p> <p>Cholangiocarcinoma: The member has locally advanced or metastatic cholangiocarcinoma AND the disease has documented isocitrate dehydrogenase-1 (IDH1) mutation AND Tibsovo (ivosedinib) will be a subsequent therapy and used as monotherapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## TIVDAK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Tivdak (tisotumab vedotin-tftv).
Required Medical Information	Recurrent/ Metastatic Cervical Cancer: The member has recurrent or metastatic cervical cancer AND The member experienced disease progression after chemotherapy AND If the disease expresses CPS score of greater than equal to 1 AND The member has a medical reason why Keytruda (pembrolizumab) cannot be initiated as subsequent therapy AND Tivdak (tisotumab vedotin-tftv) is administered as monotherapy as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## tobramycin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients with a forced expiratory volume in one second (FEV1) less than 25% or greater than 80% predicted. Patients colonized with Burkholderia cepacia.
Required Medical Information	Cystic Fibrosis or Bronchiectasis: The member has a diagnosis of cystic fibrosis (CF) or Bronchiectasis. The member is colonized with P.aeruginosa.
Age Restriction	Must be 6 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## tobramycin with nebulizer

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Patients with a forced expiratory volume in one second (FEV1) less than 25% or greater than 80% predicted. Patients colonized with Burkholderia cepacia.
Required Medical Information	Cystic Fibrosis or Bronchiectasis: The member has a diagnosis of cystic fibrosis (CF) or Bronchiectasis. The member is colonized with P.aeruginosa.
Age Restriction	Must be 6 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## TRAZIMERA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	For Ogivri, Herzuma or Ontruzant requests: member must have an intolerance or contraindication Herceptin (trastuzumab) OR Trazimera (trastuzumab-qyyp) OR Kanjinti (trastuzumab-anns) and meets below criteria: Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease. Gastric Cancer: The member has a diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma and HER2 positive disease AND trastuzumab is being used in combination with cisplatin and fluorouracil or capecitabine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## TREANDA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who experience disease progression on bendamustine containing regimens.
Required Medical Information	Chronic Lymphocytic Leukemia (CLL). The member has a diagnosis of CLL without del(17p)/TP53 mutation and with or without del(11q) AND bendamustine is being used for relapsed or refractory disease or as first line therapy. Multiple Myeloma (MM). The member has a diagnosis of MM AND bendamustine is being used for disease relapse or for progressive or refractory disease. Non-Hodgkin's Lymphoma: The member has a diagnosis of follicular lymphoma, gastric MALT lymphoma or nongastric MALT lymphoma and is using Bendamustine. The member has a diagnosis of mantle cell lymphoma and bendamustine is being used as one of the following: Less aggressive induction therapy OR Second-line therapy for relapsed, refractory or progressive disease. The member has a diagnosis of primary cutaneous B-cell lymphoma (primary cutaneous marginal zone or follicle center B-cell lymphoma) and bendamustine is being used as a single agent or in combination with rituximab in one of the following: Refractory generalized cutaneous disease OR generalized extracutaneous disease as initial therapy or for relapse. The member has a diagnosis of splenic marginal zone lymphoma and bendamustine is being used as one of the following: First-line therapy for disease progression following initial treatment for splenomegaly OR Second-line or subsequent therapy for progressive disease. The member has a diagnosis of diffuse large B-cell lymphoma and bendamustine is being used as second-line therapy or subsequent therapy .The member has a diagnosis of AIDS-related B-cell lymphoma and bendamustine is being used as second-line therapy or subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration.
Other Criteria	Waldenström's Macroglobulinemia:The member has Waldenström's macroglobulinemia or lymphoplasmacytic lymphoma and bendamustine is being used as one of the following: Primary therapy OR Progressive or relapsed disease. Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND bendamustine will be used as subsequent therapy for relapsed or refractory disease.

## TRELSTAR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agonists.
Required Medical Information	Prostate Cancer.The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## tretinoin

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Approval will be given to all members using this agent for medically necessary, FDA approved or compendia supported, non-cosmetic indications.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan Year Duration.
Other Criteria	NA



## TRIKAFTA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis: The member has a diagnosis of Cystic Fibrosis AND Member does not have severe liver impairment (Child-Pugh Class C) AND Submission of Lab testing to confirm at least one F508del mutation or a mutation in the CFTR gene that is responsive based on in vitro data.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## TRISENOX

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Acute Promyelocytic Leukemia (APL). The member has a diagnosis of acute promyelocytic leukemia AND the member will be using Trisenox (arsenic trioxide) for induction therapy, consolidation therapy, or relapsed disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## TRODELVY

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members experienced disease progression on Trodelvy (sacituzumab govitecan-hziy)
Required Medical Information	Breast Cancer. The member has unresectable locally advanced or metastatic triple negative breast cancer AND The member has received at least two prior therapies, where one was administered for metastatic disease AND Trodelvy (sacituzumab govitecan-hziy) is given as single agent as subsequent therapy. Urothelial cancer: The member has locally advanced or metastatic urothelial cancer AND The member has received prior platinum containing chemotherapy AND The member has received prior PD-1 or PD-L1 inhibitor AND Trodelvy (sacituzumab govitecan-hziy) is given as single agent as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## TRUSELTIQ

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experienced disease progression on FGFR2 inhibitors (e.g., infigratinib, pemigatinib).
Required Medical Information	Cholangiocarcinoma: The member has unresectable locally advanced or metastatic cholangiocarcinoma AND The cholangiocarcinoma is fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test AND The member has received prior treatment AND Truseltiq (infigratinib) is given as a single agent for subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

# TUKYSA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Tukysa (tucatinib)
Required Medical Information	Breast Cancer. The member has metastatic or advanced unresectable HER 2 positive breast cancer (inclusive of brain metastases) and all of the following apply: Member has received one or more prior anti-HER2 based regimen in the metastatic setting AND Tukysa is given in combination with trastuzumab product and capecitabine as subsequent therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## TURALIO

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Symptomatic Tenosynovial Giant Cell Tumor: The member has symptomatic tenosynovial giant cell tumor (TGCT) and the disease is associated with severe morbidity or functional limitations and the disease is not amenable to improvement with surgery and Turalio (pexidartinib) will be used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## TYKERB

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors. Members that have experienced disease progression while on Tykerb (lapatinib).
Required Medical Information	Breast Cancer. The member has a diagnosis of HER2(human epidermal growth factor receptor2) positive advanced or metastatic breast cancer AND The member had prior therapy, contraindication, or intolerance with an anthracycline (e.g. doxorubicin) and a taxane (e.g. paclitaxel) OR The member has a diagnosis of HER2 positive metastatic breast cancer AND Used as first line treatment in combination with an aromatase inhibitor (Femara/letrozole, Arimidex/anastrozole or Aromasin/exemestane) for hormone receptor positive disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA

## TYMLOS

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member is postmenopausal with a diagnosis of osteoporosis. The member is at high risk for osteoporotic fracture as evident by the following: The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment, contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



# UDENYCA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgastrim-sndz or filgastrim-aafi), tbo-filgratim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose). Same day administration with myelosuppressive chemotherapy or therapeutic (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis. The member must have a diagnosis of non-myeloid malignancy (e.g. solid tumors) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to pegfilgrastim injection AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy OR Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours) OR Bone marrow involvement by tumor OR Recent surgery and/or open wounds OR Liver dysfunction (bilirubin greater than 2.0 mg/dL) OR Renal dysfunction (creatinine clearance less than 50 mL/min) OR Age greater than 65 receiving full chemotherapy dose intensity Or Previous neutropenic fever complication from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 months duration
Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.

# UNITUXIN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members receiving Unituxin (dinutuximab) as monotherapy. Members that have experienced disease progression while on Unituxin (dinutuximab).
Required Medical Information	High-risk neuroblastoma: The member has a diagnosis of high-risk neuroblastoma AND Unituxin (dinutuximab) will be used in combination with isotretinoin AND Unituxin (dinutuximab) will be used in alternating cycles of Leukine (sargramostim) and Proleukin (aldesleukin) AND The member has achieved at least a partial response to the following: Induction combination chemotherapy AND Maximum feasible surgical resection The member has had the previous procedure/therapy: Myeloablative consolidation chemotherapy followed by autologous stem cell transplantation AND Radiation therapy to residual soft tissue disease.
Age Restriction	Member must be 18 years of age or younger.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

## VALCHLOR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Valchlor (mechlorethamine).
Required Medical Information	Cutaneous T-Cell Lymphoma: The member has a diagnosis of fungoides-type cutaneous T-cell lymphoma AND The member has had prior therapy with skin-directed therapy or using as primary treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## valrubicin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has an active urinary tract infection (UTI). The member has perforated bladder or compromised bladder mucosa. The member has small bladder capacity (unable to tolerate a 75 mL instillation).
Required Medical Information	Bladder Cancer: The member has recurrent or persistent carcinoma in situ of the urinary bladder(Cis). The member has experienced disease progression, intolerance or has a contraindication to BCG therapy. The member is not a candidate for immediate cystectomy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## VALSTAR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has an active urinary tract infection (UTI). The member has perforated bladder or compromised bladder mucosa. The member has small bladder capacity (unable to tolerate a 75 mL instillation).
Required Medical Information	Bladder Cancer: The member has recurrent or persistent carcinoma in situ of the urinary bladder(Cis). The member has experienced disease progression, intolerance or has a contraindication to BCG therapy. The member is not a candidate for immediate cystectomy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## vancomycin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	C. difficile-associated diarrhea: The member must have a diagnosis of C. difficile-associated diarrhea. Enterocolitis caused by staphylococcus aureus (including methicillin-resistant strains): The member must have a diagnosis of enterocolitis caused by staphylococcus aureus (including methicillin-resistant strains).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## VARIZIG

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Varicella Zoster: The member is using Varizig (varicella zoster immune globulin) for post-exposure prophylaxis of varicella zoster. The member is at high risk for the development of varicella zoster infection. High risk individuals include: Immunocompromised children and adults. Newborns of mothers with varicella shortly before or after delivery. Premature infants. Neonates and infants less than one year of age. Adults without evidence of immunity. Pregnant members.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# VECTIBIX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Metastatic colorectal cancer members with RAS-mutant mCRC or for whom RAS mutation status is unknown. Member has had disease progression on Vectibix (panitumumab) or Erbitux (cetuximab). Vectibix (panitumumab) may not be used in conjunction with Erbitux(cetuximab), Tarceva (erlotinib), or Iressa (gefitinib). Vectibix (panitumumab) may not be used in conjunction with bevacizumab product (based on the results from the PACCE trial).
Required Medical Information	Metastatic Colorectal Cancer. Diagnosis of Metastatic (stage IV) Colorectal Cancer AND the member has mCRC that expresses verified wild-type RAS (defined as KRAS and NRAS). RAS testing should be performed for all mCRC members that are potential candidates for panitumumab or cetuximab therapy. Applies to new starts only. And one of the following applies .The member had disease progression on or following fluoropyrimidine (generally Xeloda/capecitabine/5-FU/fluorouracil), oxaliplatin, and irinotecan containing chemotherapy regimens. OR Using Vectibix (panitumumab) in combination with FOLFOX or FOLFIRI as first-line treatment OR using Vectibix (panitumumab) concurrently with irinotecan-based therapy in mCRC members.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA



## VELCADE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on bortezomib.
Required Medical Information	Mantle Cell Lymphoma (MCL): The member has a diagnosis of Mantle Cell Lymphoma(MCL). Multiple Myeloma. The member has a diagnosis of Multiple Myeloma. Waldenström's Macroglobulinemia. The member has a diagnosis of Waldenström's macroglobulinemia AND Velcade (bortezomib) is being used for primary therapy, progressive or relapsed disease or salvage therapy for disease that does not respond to primary therapy AND Velcade (bortezomib) is being used as monotherapy, in combination with Dexamethasone, or in combination with a rituximab product. For brand Velcade intravenous requests, the member will need to have documented failure and/or intolerance to generic bortezomib intravenous (applies to Part B requests only).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## VENCLEXTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Venclexta (venetoclax).
Required Medical Information	<p>Chronic Lymphocytic Leukemia (CLL): The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL) and one of the following applies: has received at least one prior therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with rituximab OR the request is for first-line therapy AND the member is using Venclexta (venetoclax) in combination with Gazyva (obinutuzumab).</p> <p>Mantle Cell Lymphoma: The member has a diagnosis of MCL AND The member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product AND The member meets one of the following: relapsed, refractory, or progressive disease OR Stable disease or partial response after induction therapy.</p> <p>Acute Myeloid Leukemia - Newly Diagnosed: The member has a diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND one of the following applies: member is 75 years or older OR member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2-3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, or creatinine clearance less than 45 ml/min). The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.</p> <p>Acute Myeloid Leukemia - relapsed/refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed/refractory disease AND One of the following applies: As a component of repeating the initial successful induction regimen if late relapse (greater than or equal to 12 months since induction regimen) AND Venclexta (venetoclax) has not been administered continuously AND Venclexta (venetoclax) was not stopped due to the development of clinical resistance OR The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Venclexta (venetoclax).
Required Medical Information	<p>Chronic Lymphocytic Leukemia (CLL): The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL) and one of the following applies: has received at least one prior therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with rituximab OR the request is for first-line therapy AND the member is using Venclexta (venetoclax) in combination with Gazyva (obinutuzumab).</p> <p>Mantle Cell Lymphoma: The member has a diagnosis of MCL AND The member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product AND The member meets one of the following: relapsed, refractory, or progressive disease OR Stable disease or partial response after induction therapy.</p> <p>Acute Myeloid Leukemia - Newly Diagnosed: The member has a diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND one of the following applies: member is 75 years or older OR member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2-3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, or creatinine clearance less than 45 ml/min). The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.</p> <p>Acute Myeloid Leukemia - relapsed/refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed/refractory disease AND One of the following applies: As a component of repeating the initial successful induction regimen if late relapse (greater than or equal to 12 months since induction regimen) AND Venclexta (venetoclax) has not been administered continuously AND Venclexta (venetoclax) was not stopped due to the development of clinical resistance OR The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.</p>
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## VENTAVIS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (WHO GROUP I):The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization with WHO/NYHA Function Class IV symptoms OR the member must have had prior therapy, intolerance to, or contraindication to ONE Phosphodiesterase type 5 (PDE-5) inhibitor approved for use in PAH (e.g., sildenafil or tadalafil) or Adempas (riociguat) AND ONE Endothelin receptor antagonist [e.g., ambrisentan, bosentan, Opsumit (macitentan)) approved for use in PAH.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## VERSACLOZ

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	The member must be using clozapine orally disintegrating tablet for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## VERZENIO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member is on concomitant palbociclib or ribociclib. Member has experienced disease progression on Faslodex (fulvestrant) [applies to combination therapy with Faslodex (fulvestrant)]. Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, ribociclib). Member exceeds two years of total Verzenio (abemaciclib) based treatment (applicable only to early breast cancer).
Required Medical Information	Metastatic Breast cancer- initial endocrine based therapy. The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (Her2neu)-negative breast cancer AND Verzenio (abemaciclib) is given in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine based therapy. Metastatic breast cancer combination therapy with Faslodex (fulvestrant). The member has diagnosis of advanced or metastatic hormone receptor (HR) positive human epidermal growth factor receptor 2 (HER2) negative breast cancer AND The member has experienced disease progression on endocrine therapy (e.g., anastrozole) AND Verzenio (abemaciclib) is given in combination with Faslodex (fulvestrant). Metastatic breast cancer monotherapy: The member has diagnosis of advanced or metastatic HR positive, HER2 negative breast cancer AND the member has experienced disease progression on endocrine therapy (e.g., anastrozole) and chemotherapy in the metastatic setting AND Verzenio (abemaciclib) is being used as monotherapy. Early Breast cancer - combination therapy: The member has a diagnosis of HR positive, HER2 negative, node positive, early breast cancer at high risk of recurrence AND The breast cancer has documented Ki-67 score greater than or equal to 20% AND Verzenio (abemaciclib) is given in combination with tamoxifen or aromatase inhibitor.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## vigabatrin

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Complex Partial Seizure: Documented diagnosis of refractory complex partial seizure. Unsuccessful treatment with at least two concomitant antiepileptic drugs (AEDs) (e.g. carbamazepine, lamotrigine, levetiracetam, topiramate). Infantile Spasms: Documented diagnosis of infantile spasms.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## vigadrone

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Complex Partial Seizure: Documented diagnosis of refractory complex partial seizure. Unsuccessful treatment with at least two concomitant antiepileptic drugs (AEDs) (e.g. carbamazepine, lamotrigine, levetiracetam, topiramate). Infantile Spasms: Documented diagnosis of infantile spasms.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA



## VIIBRYD

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member must be utilizing Viibryd (vilazodone) for treatment of major depressive disorder. For new starts only: The member must have a documentation of prior therapy, intolerance, or contraindication to a selective serotonin reuptake inhibitor (SSRI) AND a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) or mirtazapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## vilazodone

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member must be utilizing Viibryd (vilazodone) for treatment of major depressive disorder. For new starts only: The member must have a documentation of prior therapy, intolerance, or contraindication to a selective serotonin reuptake inhibitor (SSRI) AND a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) or mirtazapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## VITRAKVI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Solid Tumors. Member has been diagnosed with advanced or metastatic solid tumor AND Member has a documented neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known resistance mutation AND Member is not a candidate for surgical resection AND Member is not a candidate for or does not have alternative systemic therapy treatment options. Reauthorization: Member has not developed a known resistance mutation to Vitrakvi (larotrectinib) AND Physician attestation that the member has continued to receive a clinical benefit (e.g., complete response, partial response, stable disease) and has not experienced disease progression.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 90 days. Reauthorization: Six month duration
Other Criteria	NA

## VIZIMPRO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant tyrosine kinase inhibitors.
Required Medical Information	Non-small cell lung cancer (NSCLC). The member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND the following criteria applies: The member has a documented epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation AND The member is using Vizimpro (dacomitinib) as a single agent for first line therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

# VONJO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Vonjo (pacritinib).
Required Medical Information	Myelofibrosis: The member has a diagnosis of primary myelofibrosis or secondary myelofibrosis (i.e. post-polycythemia vera or post-essential thrombocythemia) AND The member has one of the following risk categories, as defined by accepted risk stratification tools for myelofibrosis (e.g. International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or DIPSS-PLUS): Intermediate-risk disease OR High-risk disease AND The member will be using Vonjo (pacritinib) as monotherapy AND The member has a platelet count below 50 x 10 <sup>9</sup> /L. Reauthorization criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement) AND Physician attestation that the member has not experienced unacceptable toxicities.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial Authorization: 6 months duration. Reauthorization: 6 months duration
Other Criteria	

## voriconazole

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Antifungal Prophylaxis in members undergoing bone marrow transplants. Antifungal Prophylaxis in members who are intermediate or high risk of developing cancer-related fungal infections. Prophylaxis of Aspergillus species in post-heart transplantation patients should meet one of the following: CMV disease, Isolation of Aspergillus species in respiratory tract cultures, Post-transplant hemodialysis or Reoperation, Existence of an episode of invasive aspergillosis in heart transplant program two months before or after heart transplant. Prophylaxis of both Candida and Aspergillus species in high risk post-liver transplant patients should meet one of the following criteria: Local epidemiology, Renal failure needing hemodialysis or continuous venovenous dialysis pre- or post-transplantation, Reoperation involving thoracic or abdominal cavity (exploratory laparotomy, or intrathoracic surgery), Retransplantation OR Transplantation for fulminant hepatic failure. Prophylaxis of invasive aspergillosis in post-lung transplantation, Treatment of invasive aspergillosis, Treatment of chronic cavitory or necrotizing pulmonary aspergillosis and/or Serious fungal infections cause by Scedosporium apiospermum and Fusarium spp. including Fusarium solani, in patients intolerant of other therapy OR Empiric therapy of suspected invasive Candidiasis or Aspergillosis in high risk patients with febrile neutropenia despite receiving broad-spectrum antibiotic therapy. Diagnosis of one of the following fungal infections and failed to achieve clinical response or has contraindications to fluconazole or itraconazole for sensitive (non-krusei, non-glabrata) candida infections: Esophageal candidiasis, Oropharyngeal candidiasis, Candidemia in nonneutropenic patients and/or The following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and/or wounds.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year
Other Criteria	

## VOSEVI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Retreatment of Chronic Hepatitis C. The member must have a diagnosis of chronic hepatitis C (HCV). The member must have HCV genotype documented prior to therapy. Baseline HCV RNA must be documented. Member must be tested for the presence of HBV by screening for the surface antigen of HBV (HBsAg) and anti-hepatitis B core total antibodies (anti-HBc) prior to initiation of therapy. The member has relapsed after completing a full course of or has a contraindication to: Genotypes 1, 4, 5, and 6: Harvoni AND Epclusa. Genotypes 2 and 3: The member has relapsed after completing a full course of or has a contraindication to Epclusa.
Age Restriction	
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	12 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	

## VOTRIENT

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on previous pazopanib therapy.
Required Medical Information	Advanced Renal Cell Carcinoma RCC).The member has a diagnosis of advanced renal cell carcinoma (stage IV). First-line therapy as a single agent for relapsed or unresectable stage IV disease with predominant clear cell histology OR as subsequent therapy as a single agent for relapsed or unresectable stage IV disease with predominant clear cell histology in members who have progressed on prior first-line therapy.Soft Tissue Sarcoma. The member has a diagnosis of soft tissue sarcoma AND The member has progressed after prior chemotherapy. Thyroid Carcinoma: The member has a diagnosis of advanced or metastatic radio-iodine refractory follicular carcinoma, Hürthle cell carcinoma, papillary and disease is progressive OR The member has a diagnosis of advanced medullary carcinoma and has disease progression on or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). Ovarian Cancer. The member has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer. Uterine Neoplasms. The member has a diagnosis of stage II, III, IV, or advanced metastatic uterine neoplasm sarcoma and disease is not suitable for primary surgery AND Votrient (pazopanib) will be used as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA



## VRAYLAR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Dementia-related psychosis (in the absence of an approvable diagnosis), for member 65 years of age or older.
Required Medical Information	Schizophrenia/ Bipolar I Disorder, manic or mixed episode: The member must be utilizing Vraylar for the treatment of schizophrenia or bipolar I disorder AND The member must have documentation of prior therapy, intolerance, or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone or aripiprazole. Bipolar 1 Disorder (Bipolar Depression): The member must have a diagnosis of bipolar 1 disorder (bipolar depression) and the member must have documentation of prior treatment, intolerance, or contraindication to quetiapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

# VYNDAMAX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM): Member has a history of NYHA Class I through III Heart Failure AND Member has a diagnosis of ATTR-CM defined as: Significant cardiac involvement (e.g. substantial ventricular wall thickening or elevated intra-cardiac filling pressures) on echocardiography or cardiac MRI and one of the following: Medical records indicate presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry using Technescan PYP (PYP Screening) or Medical records indicate presence of amyloid deposits on analysis of biopsy specimens. The member does not have a history of any of the following: Liver Transplant, Heart Transplant without evidence of further amyloid deposits post-transplant, Left Ventricular Assist Device (LVAD), Current Pregnancy. Reauthorization: Member has evidence of slowing of clinical decline (e.g., decrease in number of hospitalizations, improvement or stabilization of the 6-minute walk test, stable or improvement in KCCQ-OS).</p>
<b>Age Restriction</b>	The member is 18 years of age or older.
<b>Prescriber Restriction</b>	The member is being treated by a specialist (e.g. cardiologist).
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	

## VYNDAQEL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM): Member has a history of NYHA Class I through III Heart Failure AND Member has a diagnosis of ATTR-CM defined as: Significant cardiac involvement (e.g. substantial ventricular wall thickening or elevated intra-cardiac filling pressures) on echocardiography or cardiac MRI and one of the following: Medical records indicate presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry using Technescan PYP (PYP Screening) or Medical records indicate presence of amyloid deposits on analysis of biopsy specimens. The member does not have a history of any of the following: Liver Transplant, Heart Transplant without evidence of further amyloid deposits post-transplant, Left Ventricular Assist Device (LVAD), Current Pregnancy. Reauthorization: Member has evidence of slowing of clinical decline (e.g., decrease in number of hospitalizations, improvement or stabilization of the 6-minute walk test, stable or improvement in KCCQ-OS).</p>
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	The member is being treated by a specialist (e.g. cardiologist).
Coverage Duration	Plan Year Duration
Other Criteria	

## VYXEOS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on Vyxeos (daunorubicin and cytarabine). Member has experienced disease progression on conventional daunorubicin and cytarabine regimen (e.g. "7+3")
Required Medical Information	Acute Myeloid Leukemia: The member has a diagnosis of therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) AND one of the following applies: The member has newly diagnosed disease OR the member is using Vyxeos (daunorubicin and cytarabine) as post-remission therapy (if given in induction) OR the member is using Vyxeos (daunorubicin and cytarabine) as re-induction (if given in induction).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## WELIREG

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Welireg (belzutifan).
Required Medical Information	von Hippel Lindau VHL disease: The member has von Hippel Lindau (VHL) disease and the member does not require immediate surgery and The member requires treatment for: associated renal cell carcinoma (RCC) OR associated central nervous system hemangioblastomas OR pancreatic neuroendocrine tumors and Welireg (belzutifan) is administered as monotherapy. Reauthorization criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g., response of lesions by imaging).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 6 months duration. Reauthorization: plan year duration.
Other Criteria	

## XALKORI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members using Xalkori (crizotinib) for adjuvant therapy.
Required Medical Information	Non-small Cell Lung Cancer (NSCLC). The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) and The member will be using Xalkori (crizotinib) as monotherapy and one of the following applies: The member has documented anaplastic lymphoma kinase (ALK)-positive NSCLC disease AND the member has a medical reason as to why Alecensa (alectinib) or Alunbrig (brigatinib) cannot be started or continued OR the member has disease which is ROS1 positive. Anaplastic large cell lymphoma (ALCL): The member has a diagnosis of relapsed or refractory, systemic ALCL AND the disease has documented ALK-positivity AND Xalkori (crizotinib) is given as monotherapy. Inflammatory myofibroblastic tumor (IMT): the member has a diagnosis of unresectable, recurrent, or refractory IMT AND the disease has documented ALK-positivity AND Xalkori (crizotinib) is given as monotherapy.
Age Restriction	ALCL: The member is greater than 1 year of age up to young adult (21 years of age). IMT: The member is greater than 1 year of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	

## XATMEP

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that are pregnant or nursing. Members with disease progression on Xatmep (methotrexate)(applies to acute lymphoblastic leukemia only).
Required Medical Information	Acute Lymphoblastic Leukemia (ALL): The member has a diagnosis of acute lymphoblastic leukemia AND The member will be using Xatmep (methotrexate) as part of a multi-phase, combination chemotherapy maintenance regimen AND The member has had previous treatment or intolerance to generic methotrexate. Polyarticular Juvenile Idiopathic Arthritis (pJIA): The member has a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) AND The member has had an insufficient therapeutic response to previous treatment, or is intolerant to, an adequate trial of first-line therapy including non-steroidal antiinflammatory agents (NSAIDs) AND The member has had previous treatment or intolerance to generic methotrexate.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## XCOPRI

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Familial short QT syndrome.
Required Medical Information	Partial-Onset Seizures. The member has a diagnosis of partial-onset seizures AND The member has been unable to achieve seizure control with at least TWO other antiepileptic medications indicated for partial-onset seizures.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	



## XCOPRI MAINTENANCE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Familial short QT syndrome.
Required Medical Information	Partial-Onset Seizures. The member has a diagnosis of partial-onset seizures AND The member has been unable to achieve seizure control with at least TWO other antiepileptic medications indicated for partial-onset seizures.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## XCOPRI TITRATION PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Familial short QT syndrome.
Required Medical Information	Partial-Onset Seizures. The member has a diagnosis of partial-onset seizures AND The member has been unable to achieve seizure control with at least TWO other antiepileptic medications indicated for partial-onset seizures.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

## XGEVA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Uncorrected Pre-existing hypocalcemia. Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Required Medical Information	Osteolytic Bone Metastases of Solid Tumors. The member has a diagnosis of solid tumor cancer (such as breast cancer, prostate cancer, or other solid tumor). The member must have documented bone metastases. The member has experienced disease progression, intolerance or contraindication following treatment with zoledronic acid or pamidronate (disease progression, intolerance or contraindication following treatment with pamidronate or zoledronic acid does not apply for prostate cancer). Multiple Myeloma: The member has a diagnosis of multiple myeloma AND the member has experienced disease progression, intolerance or contraindication following treatment with zoledronic acid or pamidronate. Giant Cell tumor of Bone: Diagnosis of giant cell tumor of bone. Hypercalcemia of malignancy: The member has hypercalcemia of malignancy, defined as an albumin-corrected calcium of greater than 12.5 mg/dL AND The member has had prior therapy with intravenous bisphosphonate therapy (e.g. pamidronate or zoledronic acid). Applies only to beneficiaries enrolled in an MA-PD plan. Part B before Part D Step therapy
Age Restriction	
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan Year Duration.
Other Criteria	

## XIFAXAN

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prevention of traveler's diarrhea. Treatment of traveler's diarrhea caused by pathogens other than E.Coli. Treatment of traveler's diarrhea complicated by fever or bloody stools.
Required Medical Information	Travelers diarrhea: Member must have traveler's diarrhea caused by non-invasive strains of Escherichia Coli. Member has previous treatment, intolerance or contraindication to ciprofloxacin, levofloxacin, or azithromycin. Hepatic encephalopathy prophylaxis: Member must have hepatic encephalopathy. Member has previous treatment, intolerance or contraindication to lactulose or neomycin. Irritable bowel syndrome with diarrhea (IBS-D): Diagnosis of Irritable bowel syndrome with diarrhea (IBS-D).
Age Restriction	Must be age 12 or older for Travelers Diarrhea, Age 18 or older for Hepatic encephalopathy prophylaxis and IBS-D.
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan year for Hepatic Encephalopathy, 30 days for traveler's diarrhea and 3 months for IBS-D.
Other Criteria	NA

## XOLAIR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Chronic Idiopathic Urticaria. Member has a diagnosis of chronic idiopathic urticaria. Member has remained symptomatic despite at least 2 weeks of H1 antihistamine therapy, unless contraindicated. Member will continue to receive H1 antihistamine therapy while on Xolair, unless contraindicated. Diagnosis of moderate or severe persistent asthma, FEV1, allergic sensitivity skin or blood test, baseline serum IgE. Omalizumab may be considered medically necessary when the following criteria are met for the following indication: Moderate or Severe persistent asthma. The patient has a diagnosis of moderate or severe persistent asthma. The patient has evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. RAST) for a specific IgE or in vitro reactivity to a perennial aeroallergen. For ages 12 and older, patient must have a baseline serum IgE between 30 IU/ml and 700 IU/ml. For ages 6 years old to less than 12 years old: must have baseline serum IgE between 30 IU/ml and 1300 IU/ml. The patient has inadequately controlled asthma despite the use of: Inhaled Corticosteroids.
Age Restriction	The patient is 12 years of age or older for diagnosis of chronic idiopathic urticaria. The patient is 6 years of age or older for moderate to severe persistent asthma. The patient is 18 years of age or older for nasal polyps.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## XOLAIR

Other Criteria	<p>Continuation of therapy: Member is currently stable on Xolair therapy. Member will continue on asthma controller inhalers: inhaled corticosteroids with or without a long-acting beta2-agonist (e.g. Flovent HFA/Diskus, Arnuity Ellipta, Serevent Diskus, Striverdi Respimat, Advair Diskus, Breo Ellipta, Symbicrt HFA, Dulera HFA, Asmanex HFA, Asmanex Twisthaler or available generic versions of these agents).</p> <p>Nasal Polyps - Initial Review: The member must meet all of the following criteria: have a diagnosis of nasal polyps (e.g., Chronic Rhinosinusitis with Nasal Polyposis [CRSwNP]) AND Xolair will be used in combination with a daily intranasal corticosteroid spray AND is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. Reauthorization: The member must meet ALL of the following criteria: Had a sustained improvement in symptoms (e.g., decrease in nasal congestion, decrease in polyp size, improvement in ability to smell) AND will continue intranasal corticosteroid spray therapy.</p>
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## XOSPATA

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on FLT3 inhibitors.
Required Medical Information	Acute Myeloid Leukemia. The member has a diagnosis of acute myeloid leukemia AND The member has relapsed or refractory disease AND The member has documented FLT3 mutation positive disease AND The member will be using Xospata (gilteritinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA

# XPOVIO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on Xpovio (selinexor).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has received at least one prior therapy AND The member will be using Xpovio in combination with dexamethasone and bortezomib (unless documented intolerance/contraindication to corticosteroid) OR The member has a diagnosis of multiple myeloma AND The member has received at least four prior therapies AND The member's disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents and an anti-CD38 monoclonal antibody AND The member will be using Xpovio (selinexor) in combination with dexamethasone (unless documented intolerance/contraindication to corticosteroid). Diffuse large B-cell lymphoma: The member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma AND The member has received at least two prior lines of systemic therapy AND The member will be using Xpovio (selinexor) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	



# XTANDI

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with Erleada (apalutamide), abiraterone acetate, Provenge (sipuleucel-T), Taxotere (docetaxel) or Jevtana (cabazitaxel) is not recommended at this time due to lack of evidence supporting safety and efficacy. Members that have experienced disease progression while on Xtandi (enzalutamide).
Required Medical Information	Prostate Cancer (metastatic castration-resistant). The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC). Prostate Cancer (non-metastatic castration-resistant). The member has a diagnosis of non-metastatic castration-resistant prostate cancer AND The member will use Xtandi (enzalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog). Prostate Cancer (metastatic castration-sensitive): the member has a diagnosis of metastatic castration-sensitive prostate cancer AND the member will use Xtandi (enzalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## XYREM

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Narcolepsy with Cataplexy: The member has a diagnosis of narcolepsy with cataplexy. Reauthorization: Documentation must be provided demonstrating a reduction in frequency of cataplexy attacks associated with Xyrem therapy. Narcolepsy with excessive daytime sleepiness: The member has a diagnosis of narcolepsy according to ICSD-3 or DSM-5 criteria AND the member has condition of excessive daytime sleepiness (EDS) associated with narcolepsy as confirmed by documented sleep testing (e.g. polysomnography, multiple sleep latency test) AND previous treatment, intolerance, or contraindication to at least one CNS stimulant (e.g. methylphenidate, amphetamine salt combination immediate release, or dextroamphetamine) and modafinil. Prerequisite therapy required only for diagnosis of narcolepsy with excessive daytime sleepiness. Reauthorization: Documentation must be provided demonstrating a reduction in symptoms of EDS associated with Xyrem therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial authorization: 3 months. Reauthorization: 6 months.
Other Criteria	NA

# YERVOY

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant Zelboraf (vemurafenib), Tafinlar (dabrafenib), Cotellic (cobimetnib) or Mekinist (trametinib) therapy. The member has had progression of disease on adjuvant therapy with Yervoy (ipilimumab).
Required Medical Information	<p>Melanoma. The member has a diagnosis of unresectable or metastatic melanoma OR Adjuvant treatment of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including total lymphadenectomy. The member is naive to Yervoy (ipilimumab). The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. Melanoma - Reauthorization Criteria</p> <p>Melanoma. The member had stable disease, partial response or complete response for greater than 3 months following the completion of initial induction (completion of four cycles within a 16 week period. Members who were unable to tolerate or receive the complete induction regimen within 16 weeks of initiation will not receive approval). AND The member has progressive disease, necessitating reinduction therapy with Yervoy (ipilimumab). AND The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. Reauth adjuvant treatment of cutaneous melanoma. The member has not had disease recurrence or unacceptable toxicity with Yervoy (ipilimumab) AND The total duration of treatment is less than 3 years AND The member has an ECOG performance status of 0-2. Renal Cell Carcinoma. The member has a diagnosis of advanced renal cell carcinoma (RCC) AND The member has intermediate or poor risk disease, based on International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) Criteria AND The member has predominant clear cell histology AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab) AND The member will be using for first line therapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 Months Duration

## YERVOY

Other Criteria	<p>Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer. The member has a diagnosis of unresectable or metastatic colorectal cancer with documented microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab) AND One of the following applies: The member has disease that has progressed following treatment with oxaliplatin-, irinotecan-, or fluoropyrimidine-based therapy OR The member has unresectable metachronous metastases and previously received adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months.</p> <p>Hepatocellular carcinoma: The member has a diagnosis of hepatocellular carcinoma AND The member has received prior treatment with a first line therapy (i.e., sorafenib) AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab).</p> <p>Non-small cell lung cancer (NSCLC) -- First Line Therapy: The member must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND one of the following applies: Disease with PD-L1 expression greater than or equal to 1% with no EGFR or ALK genomic tumor aberrations and given as first line therapy AND Tumor expresses PD-L1 as determined by an FDA-approved test AND Will be used in combination with Opdivo (nivolumab) OR Disease with no EGFR or ALK genomic tumor aberrations and given as first line therapy AND Will be used in combination with Opdivo (nivolumab) AND Will be used in combination with two cycles of platinum doublet chemotherapy.</p> <p>Malignant pleural mesothelioma: The member has a diagnosis of unresectable malignant pleural mesothelioma AND The member will be using for first-line or subsequent treatment, if not administered first-line AND Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab).</p> <p>Esophageal Cancer (squamous cell carcinoma): the member has unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus AND Yervoy will be given as first line treatment in combination with Opdivo.</p>
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## YONDELIS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Yondelis (trabectedin)
Required Medical Information	Liposarcoma/Leiomyosarcoma: The member has unresectable or metastatic liposarcoma or leiomyosarcoma AND The member has received prior anthracycline (e.g., doxorubicin) containing regimen. Soft Tissue Sarcoma. Yondelis (trabectedin) will be used as monotherapy for palliative treatment and one of the following applies: The member has a diagnosis of unresectable or progressive retroperitoneal or intraabdominal soft tissue sarcoma OR the member has a diagnosis of angiosarcoma or rhabdomyosarcoma OR the member has a diagnosis stage IV soft tissue sarcoma of the extremity/superficial trunk, head/neck, or recurrent disease with disseminated metastases.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six month duration
Other Criteria	NA

## ZALTRAP

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members receiving concomitant therapy with bevacizumab product. The member has experienced disease progression while on Zaltrap.
Required Medical Information	Metastatic Colorectal Cancer: The member has a diagnosis of metastatic colorectal cancer AND The member is using Zaltrap in combination with irinotecan or FOLFIRI (leucovorin, irinotecan, 5-fluorouracil) chemotherapy AND At least one of the following applies: Zaltrap is being used as second line therapy AND The member experienced disease progression or resistance with an Oxaliplatin containing regimen OR The member has unresectable metachronous metastases and has received previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX(capecitabine and oxaliplatin)
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	NA

# ZARXIO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim, biosimilar filgrastim (e.g. filgrastim-sndz or filgrastim-aafi), tbo-filgrastim, sargramostim (unless part of stem cell mobilization protocol), pegfilgrastim (within seven days of pegfilgrastim dose), or biosimilar pegfilgrastim (e.g. pegfilgrastim-jmbd or pegfilgastrim-cbqv, within seven days of pegfilgrastim dose).
Required Medical Information	Neutropenia in Myelodysplastic Syndromes. The member must have a diagnosis of neutropenia associated with myelodysplastic syndrome. Treatment of Febrile Neutropenia: The member must have a diagnosis of febrile neutropenia AND biosimilar filgrastim must be used in adjunct with appropriate antibiotics in high risk members. Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following myelosuppressive chemotherapy: The member must have a diagnosis of non-myeloid malignancy (e.g. breast cancer, lung cancer) AND The member has received or will receive myelosuppressive chemotherapy during the 24-72 hour time frame prior to starting biosimilar filgrastim injections AND The member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen and one or more of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 Months Duration

## ZARXIO

Other Criteria	<p>Febrile Neutropenia Prophylaxis, in members with acute myeloid leukemia receiving chemotherapy: The member must have a diagnosis Acute Myeloid Leukemia (AML). The member must be receiving either induction chemotherapy OR consolidation Chemotherapy AND the member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy.</p> <p>Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following Hematopoietic Stem Cell Transplant (HCST): The member must have had a Hematopoietic Stem Cell Transplant (HCST) (e.g. bone marrow transplant, peripheral-blood progenitor cell (PBPC) transplant) for a non-myeloid malignancy AND the member is not administering biosimilar filgrastim earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy. Harvesting of peripheral blood stem cells. The member must be scheduled for autologous peripheral-blood stem cell (PBSC) transplantation, storing cells for a possible future autologous transplant, or donating stem cells for an allogeneic or syngeneic PBSC transplant. Neutropenic disorder, chronic (Severe), Symptomatic: The member must have a diagnosis of congenital, cyclic, or idiopathic neutropenia. Neutropenia in AIDS patients. The member must have a diagnosis of AIDS with neutropenia. Treatment of Aplastic Anemia. The member must have a diagnosis of Aplastic Anemia. Treatment of Agranulocytosis. The member must have a diagnosis of congenital or drug induced agranulocytosis. Hematopoietic Syndrome of Acute radiation syndrome. The member has been acutely exposed to myelosuppressive doses of radiation.</p>
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## ZEJULA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g., Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)].
Required Medical Information	Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer : The member has a diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member has been treated with at least two prior lines of platinum based chemotherapy AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Zejula (niraparib) as a monotherapy. *Discontinue Avastin before initiating maintenance therapy with Zejula. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer - Fourth Line Treatment: The member has a diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer AND the member's disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability and progression more than six months after response to last platinum-based chemotherapy. AND the member has been treated with three or more prior lines of chemotherapy. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer - First line maintenance therapy: member has a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer AND member is in complete response or partial response to first line treatment with platinum based chemotherapy AND member will utilize Zejula (niraparib) capsules as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## ZELBORAF

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Tafinlar (dabrafenib), Mekinist (trametinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Zelboraf (vemurafenib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinst (trametinib)].
Required Medical Information	Melanoma: The member has a diagnosis of Unresectable or Stage IV Metastatic melanoma. The member has a documented BRAF V600 activating mutation. The member will be using Zelboraf (vemurafenib) as monotherapy OR in combination with Cotellic (cobimetinib). Erdheim-Chester Disease: The member has a diagnosis of Erdheim-Chester Disease AND The member has a documented BRAF V600 mutation AND The member will be using Zelboraf (vemurafenib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	

## ZEPZELCA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Zepzelca (lurbinectedin).
Required Medical Information	Small cell lung cancer: The member has a diagnosis of metastatic small cell lung cancer AND The member had progression on or after treatment with platinum-based chemotherapy AND Zepzelca (lurbinectedin) will be used as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA

## ZIRABEV

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Used in lung cancer members that have small cell or squamous cell disease, recent hemoptysis, history of bleeding, continuing anticoagulation, or as a single agent (unless maintenance as described in Coverage Determinations). Should not be initiated in members with recent hemoptysis. Should not be used in members who experience a severe arterial thromboembolic event. Should not be used in members with gastrointestinal perforation. Bevacizumab should not be used in members with fistula formation involving internal organs. Bevacizumab should not be used in members experiencing a hypertensive crisis or hypertensive encephalopathy. Bevacizumab should not be used for at least 28 days following major surgery or until surgical incision is fully healed. Bevacizumab may not be used in conjunction with Vectibix. Bevacizumab may not be used in conjunction with Erbitux. Bevacizumab may not be used in the adjuvant or neoadjuvant setting (except in epithelial ovarian, fallopian tube, or primary peritoneal cancer adjuvant setting). Bevacizumab should not be continued or restarted after disease progression with the exception of metastatic colorectal cancer.

## ZIRABEV

<b>Required Medical Information</b>	<p>Alymsys (bevacizumab-maly) oncology requests: must have an intolerance or contraindication with Avastin, Mvasi, or Zirabev and meet criteria below. Metastatic colorectal cancer: Diagnosis of metastatic colorectal cancer AND 1 of the following apply: bevacizumab in combo with fluoropyrimidine (e.g., 5-fluorouracil or capecitabine) based chemo for 1st or 2nd-line therapy OR combo with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemo for 2nd-line therapy in patients who have progressed on 1st-line bevacizumab-containing regimens. Non-small cell lung cancer (non-squamous cell histology). NSCLC with non-squamous cell histology AND using bevacizumab in combo with cisplatin or carboplatin based regimens for unresectable, locally advanced, recurrent, or metastatic NSCLC AND 1 of the following apply: using for 1st line therapy OR as subsequent therapy immediately after 1 of the following situations: EGFR mutation-positive tumors after prior therapy (e.g., erlotinib, afatinib) [if cytotoxic therapy not previously given] OR ALK-positive tumors after prior therapy (e.g., crizotinib, brigatinib) [if cytotoxic therapy not previously given] OR ROS-1 positive disease after prior therapy (e.g., crizotinib) [if cytotoxic therapy not previously given] OR Pembrolizumab (with PD-L1 expression of greater than 1%) administered as 1st line therapy and EGFR, ALK, BRAF V600E, and ROS1 negative tumors (if cytotoxic therapy not previously given) OR has BRAF V600E positive disease (if cytotoxic therapy not previously given) OR as single-agent continuation maintenance therapy if bevacizumab was used as 1st line treatment for recurrence or metastasis OR has disease with no EGFR or ALK genomic tumor aberrations AND will be given in combo with carboplatin and paclitaxel and Tecentriq as 1st line therapy followed by maintenance therapy with Tecentriq and bevacizumab. Hepatocellular carcinoma: unresectable or metastatic HCC AND used as 1st line therapy in combo with Tecentriq.</p>
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	6 Months Duration. Ocular indications: Plan Year Duration

## ZIRABEV

Other Criteria	<p>Metastatic breast cancer (Effectiveness based on improvement in progression-free survival. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab). Member has metastatic HER-2 negative breast cancer AND is using bevacizumab in combo with paclitaxel. Recurrent Ovarian Cancer. Bevacizumab is being used to treat recurrent or persistent ovarian cancer for 1 of the following situations: in combo with liposomal doxorubicin or weekly paclitaxel or topotecan for platinum resistant disease or as monotherapy or in combo with carboplatin and gemcitabine for platinum sensitive disease. Stage IV/Metastatic (Unresectable) RCC. Member has RCC and is using bevacizumab to treat stage IV unresectable kidney cancer in combo with interferon alpha OR is using bevacizumab as systemic therapy for non-clear cell histology. Recurrent Primary CNS Tumor (including Glioblastoma multiforme). Diagnosis of progressive or recurrent glioblastoma or anaplastic glioma AND Bevacizumab is being used as a single agent or in combo with irinotecan, carmustine, lomustine or temozolomide. Member does not have a CNS hemorrhage. Soft Tissue Sarcoma. Diagnosis of angiosarcoma and bevacizumab is being used as a single agent OR member has a diagnosis of solitary fibrous tumor and hemangiopericytoma and bevacizumab is being used in combo with temozolomide. Macular Retinal Edema. Avastin is being used to treat central or branch retinal vein occlusion with macular retinal edema. Cervical Cancer: member has recurrent, or metastatic cervical cancer AND Bevacizumab will be used in combo (if not previously used as first line therapy) with paclitaxel and cisplatin or carboplatin and paclitaxel or paclitaxel and topotecan as first line therapy. Endometrial Cancer: progressive endometrial cancer AND Bevacizumab will be used as a single-agent. Malignant Pleural Mesothelioma. Diagnosis of unresectable malignant pleural mesothelioma and bevacizumab will be used in combo with cisplatin and pemetrexed followed by bevacizumab monotherapy for maintenance therapy (for responders). Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer AND has Stage III or IV disease AND bevacizumab is initially being given in combo with carboplatin and paclitaxel after initial surgical resection followed by bevacizumab monotherapy OR advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability as defined by FDA approved test AND Member is in complete response or partial response to 1st line treatment with platinum-based chemo AND Bevacizumab is given in combo with Lynparza. Age Related Macular Degeneration (Avastin requests only). Diabetic Macular Edema (Avastin requests only).</p>
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## ZOKINVY

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Progeroid Laminopathies: Member must meet ALL of the following criteria: Diagnosis of one of the following: Hutchinson-Gilford Progeria syndrome OR Progeroid Laminopathies with either Heterozygous LMNA mutation with progerin-like protein accumulation OR Homozygous or Compound Heterozygous ZMPTSTE24 mutations. AND Body Surface Area of 0.39 meters squared or greater.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ZOLADEX

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Zoladex should not be continued or restarted after malignant disease progression(Exception is Prostate Cancer). Concomitant use with other LHRH agents. Abnormal vaginal bleeding of unknown etiology.
Required Medical Information	Prostate Cancer. The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Breast Cancer. The patient must be pre- or perimenopausal. The patient must have a diagnosis of hormone receptor (ER and/or PR +) positive breast cancer. Endometriosis. The patient must have a diagnosis of endometriosis. The patient has had an inadequate pain control response or intolerance to: Danazol,Combination Oral Contraceptives, Progesterone Only Products.Endometrial Thinning. The patient is scheduled for endometrial ablation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	2 months for endometrial hyperplasia
Other Criteria	Approval Durations. Advanced Prostate Cancer or Invasive Breast Cancer is 12 months. Endometriosis is six months. Endometrial Hyperplasia is two months



## zoledronic acid-mannitol-water

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Severe renal impairment (creatinine clearance less than 35 mL/min). Evidence of acute renal failure. Patients with Hypocalcemia.
Required Medical Information	Osteoporosis: The member has a diagnosis of osteoporosis. Has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance with an oral OR IV bisphosphonate (ALENDRONATE, IBANDRONATE, PAMIDRONATE). Osteoporosis Prophylaxis in postmenopausal members: The member is postmenopausal. Has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance with an oral OR IV bisphosphonate (ALENDRONATE, IBANDRONATE, PAMIDRONATE). Glucocorticoid induced Osteoporosis in men and women taking systemic glucocorticoids: Diagnosis of glucocorticoid induced osteoporosis or is either initiating or continuing systemic glucocorticoids with a daily dosage equivalent of 7.5 mg or greater of prednisone and is expected to remain on glucocorticoids for at least 12 months AND has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance with an oral OR IV bisphosphonate (ALENDRONATE, IBANDRONATE, PAMIDRONATE). Paget's Disease: Diagnosis of Paget's disease. The member has continued elevation(s) in serum alkaline phosphatase (SAP) of two times or higher than the upper limit of normal despite previous treatment, contraindication, or intolerance with an oral OR IV bisphosphonate (ALENDRONATE, PAMIDRONATE). And the member: Is symptomatic OR is at risk for complications from their disease, to induce remission, or to normalize serum alkaline phosphatase. Brand Reclast request only: Members must have previous treatment, contraindication, or intolerance to generic Zoledronic acid (generic Reclast).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ZOLINZA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Zolinza (vorinostat).
Required Medical Information	Cutaneous T-Cell Lymphoma (CTCL).The member has a diagnosis of progressive, persistent, or recurrent disease or The member hwill be using Zolinza as primary treatment or adjuvant therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ZONISADE

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review

## ZTALMY

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Seizures associated with Cyclin-dependent Kinase-Like 5 (CDKL5) Deficiency Disorder (CDD): the member has a diagnosis of cyclin-dependent kinase-like 5 CDKL5) deficiency disorder (CDD) AND the member continues to experience seizures while on current therapy AND the member has previous treatment, contraindication, or intolerance to at least one broad-spectrum antiepileptic medication.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

# ZULRESSO

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Post-Partum Depression: The member is an adult with a clinical diagnosis of major depressive disorder (MDD) in the third trimester of pregnancy or within 4 weeks of delivery as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. HAM-D, MADRS, PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item). The member has previous treatment, contraindication, or intolerance to at least one antidepressant from the following: generic SSRI (e.g., citalopram, fluoxetine, paroxetine, or sertraline), SNRI (e.g., venlafaxine or duloxetine), bupropion OR mirtazapine OR physician attests with documentation that the severity of the depression would place the health of the mother or infant at significant risk. The member is not pregnant and not more than 6 months post-partum at initiation of Zulresso (brexanolone) therapy. The member is not experiencing active psychosis and does not have a history of bipolar disorders, schizophrenia, and/or schizoaffective disorder. The member has not attempted suicide in the current episode of postpartum depression.</p>
Age Restriction	The member is at least 15 years of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	60 days duration
Other Criteria	

## ZYDELIG

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib).
Required Medical Information	Chronic Lymphocytic Leukemia (CLL): The member must have a diagnosis of relapsed OR refractory chronic lymphocytic leukemia (CLL) or relapsed OR refractory small lymphocytic lymphoma (SLL). Follicular Lymphoma (FL): The member must have a diagnosis of relapsed follicular lymphoma (FL) AND The member must have received at least one prior systemic therapy AND The member will be using Zydelig (idelalisib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA

## ZYKADIA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-small Cell Lung Cancer (NSCLC): The member has a diagnosis of metastatic and documented anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) AND the member has a medical reason as to why Alecensa (alectinib) OR Alunbrig (brigatinib) cannot be started or continued AND member will be using Zykadia (ceritinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA

## ZYNLONTA

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experienced disease progression on Zynlonta (loncastuximab tesirine-lpyl).
Required Medical Information	B-cell Lymphoma: The member has a diagnosis of one of the following: diffuse large B-cell lymphoma (DLBCL) otherwise not specified, DLBCL arising from a low grade lymphoma (e.g. follicular lymphoma) OR a diagnosis of high-grade B-cell lymphoma (HGBL) not otherwise specified or with translocations AND The member has relapsed or refractory disease AND The member has had two or more lines of systemic therapy AND The member will be using Zynlonta as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA



The following drugs are subject to a Medicare Part B or D authorization depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

## PART B VERSUS PART D

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### Products Affected

- Akynzeo (netupitant) 300 mg-0.5 mg capsule
- aprepitant 125 mg (1)-80 mg (2) capsules in a dose pack
- Astagraf XL 0.5 MG; 1 MG; 5 MG; capsule,extended release
- azathioprine 100 MG; 50 MG; 75 MG; tablet
- CellCept 200 MG/ML; 250 MG; 500 MG; oral suspension
- CellCept Intravenous 500 MG; intravenous solution
- Compazine 10 MG; 5 MG; tablet
- cyclosporine modified 100 MG; 100 MG/ML; 25 MG; 50 MG; capsule
- dronabinol 10 MG; 2.5 MG; 5 MG; capsule
- Emend 125 mg (1)-80 mg (2) capsules in a dose pack
- Envarsus XR 0.75 MG; 1 MG; 4 MG; tablet,extended release
- Gengraf 100 MG; 100 MG/ML; 25 MG; capsule
- granisetron HCl 1 MG; tablet
- Marinol 10 MG; 2.5 MG; 5 MG; capsule
- methotrexate sodium 2.5 MG; tablet
- Millipred 5 MG; tablet
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; capsule
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; tablet
- Anzemet 50 MG; tablet
- aprepitant 125 MG; 125 mg (1)- 80 MG (2); 40 MG; 80 MG; capsule
- Azasan 100 MG; 75 MG; tablet
- CellCept 200 MG/ML; 250 MG; 500 MG; capsule
- CellCept 200 MG/ML; 250 MG; 500 MG; tablet
- chlorpromazine 10 MG; 25 MG; tablet
- cyclosporine 100 MG; 25 MG; capsule
- cyclosporine modified 100 MG; 100 MG/ML; 25 MG; 50 MG; oral solution
- Emend 125 mg (1)- 80 MG (2); 125 mg (25 mg/ ML FINAL CONC.); 40 MG; 80 MG; capsule
- Emend 125 mg (25 mg/mL final conc.) oral suspension
- everolimus (immunosuppressive) 0.25 MG; 0.5 MG; 0.75 MG; 1 MG; tablet
- Gengraf 100 MG; 100 MG/ML; 25 MG; oral solution
- Imuran 50 MG; tablet
- Medrol 16 MG; 2 MG; 32 MG; 4 MG; 8 MG; tablet
- methylprednisolone 16 MG; 32 MG; 4 MG; 8 MG; tablet
- mycophenolate 500 MG; intravenous solution
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; oral suspension
- mycophenolate sodium 180 MG; 360 MG; tablet,delayed release

- Myfortic 180 MG; 360 MG; tablet,delayed release
- Neoral 100 MG; 100 MG/ML; 25 MG; oral solution
- ondansetron HCl 4 MG; 4 MG/5 ML; 8 MG; oral solution
- prednisone 1 MG; 10 MG; 2.5 MG; 20 MG; 5 MG; 5 MG/5 ML; 50 MG; oral solution
- Prednisone Intensol 5 MG/ML; oral concentrate
- Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; capsule
- Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; oral solution
- Rayos 1 MG; 2 MG; 5 MG; tablet,delayed release
- Sandimmune 100 MG; 100 MG/ML; 25 MG; oral solution
- sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; tablet
- tacrolimus 0.5 MG; 1 MG; 5 MG; capsule, immediate-release
- Trexall 10 MG; 15 MG; 5 MG; 7.5 MG; tablet
- Varubi 90 MG; tablet
- Zofran 4 MG; tablet
- Zuplenz 4 MG; 8 MG; oral soluble film
- Neoral 100 MG; 100 MG/ML; 25 MG; capsule
- ondansetron 4 MG; 8 MG; disintegrating tablet
- ondansetron HCl 4 MG; 4 MG/5 ML; 8 MG; tablet
- prednisone 1 MG; 10 MG; 2.5 MG; 20 MG; 5 MG; 5 MG/5 ML; 50 MG; tablet
- prochlorperazine maleate 10 MG; 5 MG; tablet
- Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; oral granules in packet
- Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; tablet
- Sandimmune 100 MG; 100 MG/ML; 25 MG; capsule
- sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; oral solution
- Syndros 5 MG/ML; oral solution
- Tigan 300 MG; capsule
- trimethobenzamide 300 MG; capsule
- Xatmep 2.5 MG/ML; oral solution
- Zortress 0.25 MG; 0.5 MG; 0.75 MG; 1 MG; tablet

# IMPORTANT!

## At CarePlus, it is important you are treated fairly.

CarePlus Health Plans, Inc. does not discriminate or exclude people because of their race, color, national origin, age, disability, sex, sexual orientation, gender, gender identity, ancestry, marital status, or religion. Discrimination is against the law. CarePlus complies with applicable Federal Civil Rights laws. If you believe that you have been discriminated against by CarePlus, there are ways to get help.

- You may file a complaint, also known as a grievance, with: **CarePlus Health Plans, Inc. Attention: Member Services Department.** 11430 NW 20th Street, Suite 300. Miami, FL 33172. If you need help filing a grievance, call **1-800-794-5907 (TTY: 711)**. From October 1 - March 31, we are open 7 days a week, 8 a.m. to 8 p.m. From April 1 - September 30, we are open Monday - Friday, 8 a.m. to 8 p.m. You may always leave a voicemail after hours, Saturdays, Sundays, and holidays and we will return your call within one business day.
- You can also file a civil rights complaint with the **U.S. Department of Health and Human Services**, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at **U.S. Department of Health and Human Services**, 200 Independence Avenue, SW, Room 509F, HHH Building, Washington, DC 20201, **1-800-368-1019, 800-537-7697 (TDD)**.

Complaint forms are available at <https://www.hhs.gov/ocr/office/file/index.html>.

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CarePlus provides free auxiliary aids and services, such as qualified sign language interpreters and written information in other formats to people with disabilities when such auxiliary aids and services are necessary to ensure an equal opportunity to participate.

### Language assistance services, free of charge, are available to you. 1-800-794-5907 (TTY: 711).

**Español (Spanish):** Llame al número arriba indicado para recibir servicios gratuitos de asistencia lingüística.

**繁體中文 (Chinese):** 撥打上面的電話號碼即可獲得免費語言援助服務。

**Tiếng Việt (Vietnamese):** Xin gọi số điện thoại trên đây để nhận được các dịch vụ hỗ trợ ngôn ngữ miễn phí.

**한국어 (Korean):** 무료 언어 지원 서비스를 받으려면 위의 번호로 전화하십시오.

**Tagalog (Tagalog – Filipino):** Tawagan ang numero sa itaas upang makatanggap ng mga serbisyo ng tulong sa wika nang walang bayad.

**Русский (Russian):** Позвоните по номеру, указанному выше, чтобы получить бесплатные услуги перевода.

**Kreyòl Ayisyen (French Creole):** Rele nimewo ki pi wo la a, pou resevwa sèvis èd pou lang ki gratis.

**Français (French):** Appelez le numéro ci-dessus pour recevoir gratuitement des services d'aide linguistique.

**Polski (Polish):** Aby skorzystać z bezpłatnej pomocy językowej, proszę zadzwonić pod wyżej podany numer.

**Português (Portuguese):** Ligue para o número acima indicado para receber serviços linguísticos, grátis.

**Italiano (Italian):** Chiamare il numero sopra per ricevere servizi di assistenza linguistica gratuiti.

**Deutsch (German):** Wählen Sie die oben angegebene Nummer, um kostenlose sprachliche Hilfsdienstleistungen zu erhalten.

**ગુજરાતી (Gujarati):** નિચીલેલું નંબર સહાય સેવાઓ પ્રાપ્ત કરવા માટે ઉપરોક્ત નંબર પર કોલ કરો.

**ภาษาไทย (Thai):** โทรติดต่อที่หมายเลขด้านบนนี้เพื่อรับบริการช่วยเหลือด้านภาษาโดยไม่เสียค่าใช้จ่าย.

**Diné Bizaad (Navajo):** Wóda'í beeésh bee hani'í bee wolta'ígíí bich'í' hódíílnih éí bee t'áá jiik'eh saad bee'áká'ánída'áwo'déé nika'adoowól.

**العربية (Arabic):**

الرجاء الاتصال بالرقم المبين أعلاه للحصول على خدمات مجانية للمساعدة بلغتك