

Injectable Drugs and Biologics Step Therapy Requirement for Medicare Advantage Plans

Effective Date: Jan. 1, 2022 Revision Date: Dec. 28, 2022

In August 2018, the Centers for Medicare & Medicaid Services (CMS) rescinded its September 2012 memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," which provided Medicare Advantage plans the option of applying step therapy for physician-administered and other Part B drugs.¹ Due to this change, Humana added step therapy requirements in 2019 for some drugs on our preauthorization list.

CMS issued a final ruling on May 16, 2019, that modernizes and improves the Medicare Advantage program.² These changes finalized CMS requirements for the Part B Step Therapy program, enabling Medicare Advantage plans to negotiate better prices for physician-administered medicines in Part C. The changes as a result of this final ruling will be implemented Jan. 1, 2020.

Affected drugs are noted with a step therapy indicator on the Medicare preauthorization list posted at http://Humana.com/PAL.

If providers do not stock our preferred drug in their office, they may be able to obtain the preferred drug from a pharmacy (i.e., a pharmacy can ship the medication to the office). Visit our list of specialty and mail-order pharmacies at www.humana.com/mail-order to select a pharmacy that can provide the drug. A full list of pharmacies also is available via the Pharmacy Finder Tool at https://www.humana.com/finder/pharmacy/, or by calling customer care at 1-800-457-4708 (TTY: 711) for a full list of in-network pharmacies. During annual election period (or AEP, Oct. 15 through Dec. 7) and open enrollment period (or OEP, Jan. 1 through March 31), our hours of operation are 8 a.m. to 8 p.m. local time seven days a week. Otherwise, hours of operation are Monday through Friday, 8 a.m. to 8 p.m. local time.

This step therapy requirement will not apply to patients who already are actively receiving treatment with a nonpreferred drug (have a paid drug claim within the past 365 days).

Medicare Advantage patients subject to the step therapy requirement may:

- Request expedited exception reviews for step therapy prior authorization requests.
- Appeal a denied request for a nonpreferred drug due to step therapy requirements.

Effective Jan. 1, 2020, Humana no longer will offer a Drug Management Care Coordination Program (DM-CCP) for patients subject to step therapy and/or taking a preferred drug on the Part B Step Therapy Drug List. Per CMS guidance, in 2020, health plans will not be required to couple step therapy with a rewards and incentives program. Instead, MA plans must incorporate anticipated savings from implementing Part B step therapy into their bid amounts for each plan, which, in turn, may be used to provide supplemental benefits and/or lower premiums to the plans' enrollees.

¹https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs

²https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f

Important note:

Humana MA health maintenance organization (HMO): HMO members serviced by Intermountain
Healthcare (previously known as Healthcare Partners of Nevada) should refer to their primary care
physician (PCP), and might have different Part B step therapy requirements than those listed below.
HCP's current Part B step therapy policy is at
https://hcpnv.com/patient-information/biosimilar-medication-policy/.

If you have questions, please call 1-800-457-4708. During annual election period (or AEP, Oct. 15 through Dec. 7) and open enrollment period (or OEP, Jan. 1 through March 31), our hours of operation are 8 a.m. to 8 p.m. local time seven days a week. Otherwise, hours of operation are Monday through Friday, 8 a.m. to 8 p.m. local time.

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| Drug Class | Drug Name | Status | Billing Code |
|--|---------------------------|--------------|-------------------------------|
| Alpha-1s | Prolastin-C | Preferred | J0256 |
| | Aralast | Nonpreferred | J0256 |
| | Glassia | Nonpreferred | J0257 |
| | Zemaira | Nonpreferred | J0256 |
| Bevacizumab (oncology) | Avastin | Preferred | J9035 |
| | Mvazi | Preferred | Q5107 |
| | Zirabev | Preferred | Q5118 |
| | Alymsys | Nonpreferred | C9142, J3490, J3590, J9999 |
| Bone resorption inhibitors | pamidronate | Preferred | J2430 |
| | zoledronic acid | Preferred | J3489 |
| | Xgeva | Nonpreferred | J0897 |
| Cervical Cancer | Keytruda | Preferred | J9271 |
| | Tivdak | Nonpreferred | J9273 |
| Colony Stimulating Factors -Leukocyte Growth Factors (long-acting) | Fulphila | Preferred | Q5108 |
| | Neulasta / Neulasta Onpro | Preferred | J2506 |
| | Udenyca | Preferred | Q5111 |
| | Fylnetra | Nonpreferred | C9399, J3590, J3490, J9999 |
| | Nyvepria | Nonpreferred | Q5122 |
| | Rolvedon | Nonpreferred | C9399, J3590, J3490, J9999 |
| | Stimufend | Nonpreferred | C9399, J3590, J3490, J9999 |

| | Ziextenzo | Nonpreferred | Q5120 |
|--|--------------------------|--------------|-------|
| Colony-stimulating factors – leukocyte growth factors (short-acting) | Nivestym | Preferred | Q5110 |
| g c c c c c c c c c c c c c c c c c c c | Zarxio | Preferred | Q5101 |
| | Granix | Nonpreferred | J1447 |
| | Neupogen | Nonpreferred | J1442 |
| | Releuko | Nonpreferred | Q5125 |
| COPD | Perforomist | Preferred | J7606 |
| | Brovana | Nonpreferred | J7605 |
| Doxorubicin (liposomal) | doxorubicin conventional | Preferred | J9000 |
| | epirubicin | Preferred | J9178 |
| | Doxil | Nonpreferred | Q2050 |
| Erythropoiesis-stimulating agents | Retacrit | Preferred | Q5106 |
| | Procrit | Preferred | J0885 |
| | Aranesp | Nonpreferred | J0881 |
| | Epogen | Nonpreferred | J0885 |
| Gaucher's disease | Cerdelga | Preferred | J8499 |
| | Cerezyme | Preferred | J1786 |
| | Elelyso | Preferred | J3060 |
| | Vpriv | Nonpreferred | J3385 |
| | Zavesca | Nonpreferred | J8499 |
| Hemophilia A | Advate | Preferred | J7192 |
| | Adynovate | Preferred | J7207 |

| | Afstyla | Preferred | J7210 |
|-------------------------------------|-------------|--------------|--------------|
| | Eloctate | Preferred | J7205 |
| | Esperoct | Preferred | J7204 |
| | Helixate FS | Preferred | J7192 |
| | Hemofil-M | Preferred | J7190 |
| | Jivi | Preferred | J7208 |
| | Koate-DVI | Preferred | J7190 |
| | Kogenate FS | Preferred | J7192 |
| | Kovaltry | Preferred | J7211 |
| | Monoclate-P | Preferred | J7190 |
| | NovoEight | Preferred | J7182 |
| | Nuwiq | Preferred | J7209 |
| | Recombinate | Preferred | J7192 |
| | Xyntha | Preferred | J7185 |
| | Hemlibra | Nonpreferred | J7170 |
| Hereditary angioedema – acute use | icatibant | Preferred | J1744 |
| | Berinert | Nonpreferred | J0597 |
| | Firazyr | Nonpreferred | J1744 |
| | Kalbitor | Nonpreferred | J1290 |
| | Ruconest | Nonpreferred | J0596 |
| Hereditary angioedema – prophylaxis | Haegarda | Preferred | J0599 |
| | Cinryze | Nonpreferred | J0598 |
| | Takhzyro | Nonpreferred | J0593 |
| | Repatha | Preferred | C9399, J3590 |

| Homozygous familial | | | |
|--|----------------|--------------|-------|
| hypercholesterolemia (HoFH) | Evkeeza | Nonpreferred | J1305 |
| Immunologic drugs – autoimmune | Inflectra | Preferred | Q5103 |
| disorders (arthritis, psoriasis, inflammatory bowel disease) | Infliximab | Preferred | J1745 |
| | Remicade | Preferred | J1745 |
| | Simponi Aria | Preferred | J1602 |
| | Stelara | Preferred | J3358 |
| | Actemra IV | Nonpreferred | J3262 |
| | Avsola | Nonpreferred | Q5121 |
| | Entyvio | Nonpreferred | J3380 |
| | llumya | Nonpreferred | J3245 |
| | Orencia IV | Nonpreferred | J0129 |
| | Renflexis | Nonpreferred | Q5104 |
| | Rituxan IV | Nonpreferred | J9312 |
| | Truxima | Nonpreferred | Q5115 |
| | Tysabri | Nonpreferred | J2323 |
| IV Iron | Infed | Preferred | J1750 |
| | Venofer | Preferred | J1756 |
| | Feraheme | Nonpreferred | Q0138 |
| | Injectafer | Nonpreferred | J1439 |
| | Monoferric | Nonpreferred | J1437 |
| IVIG | Flebogamma DIF | Preferred | J1572 |

| | Gammagard | Preferred | J1569 |
|--------------------------|--------------------|--------------|--------------|
| | Gammagard S/D | Preferred | J1566 |
| | Gammaked | Preferred | J1561 |
| | Gamunex-C | Preferred | J1561 |
| | Hizentra | Preferred | J1559 |
| | Octagam | Preferred | J1568 |
| | Privigen | Preferred | J1459 |
| | Xembify | Preferred | J1558 |
| | Asceniv | Nonpreferred | J1554 |
| | Bivigam | Nonpreferred | J1556 |
| | Cutaquig | Nonpreferred | J1551 |
| | Cuvitru | Nonpreferred | J1555 |
| | Gammaplex | Nonpreferred | J1557 |
| | Hyqvia | Nonpreferred | J1575 |
| | Panzyga | Nonpreferred | J1599 |
| Melanoma | Opdivo | Preferred | J9299 |
| | Keytruda | Preferred | J9271 |
| | Opdivo Plus Yervoy | Preferred | J9299, J9228 |
| | Opdualag | Nonpreferred | J9298 |
| Multiple sclerosis | Ocrevus | Preferred | J2350 |
| | Tysabri | Nonpreferred | J2323 |
| | Lemtrada | Nonpreferred | J0202 |
| Myelodysplastic syndrome | azacitidine | Preferred | J9025 |
| | Dacogen | Nonpreferred | J0894 |

| | decitabine | Nonpreferred | J0894 |
|---|--------------------------|--------------|---|
| Neoplasms (excluding pancreatic) | docetaxel | Preferred | J9171 |
| | paclitaxel | Preferred | J9267 |
| | Abraxane | Nonpreferred | J9264 |
| | paclitaxel protein-bound | Nonpreferred | J9264 |
| Ophthalmic disorders - photodynamic therapy | Avastin | Preferred | C9257, J9035 |
| | Visudyne | Nonpreferred | J3396 |
| Ophthalmic disorders - VEGF inhibitors | Avastin | Preferred | C9257, J9035 |
| | Beovu | Nonpreferred | J0179 |
| | Byooviz | Nonpreferred | Q5124 |
| | Cimerli | Nonpreferred | C9399, J3590, J3490 |
| | Eylea | Nonpreferred | J0178 |
| | Lucentis | Nonpreferred | J2778 |
| | Macugen | Nonpreferred | J2503 |
| | Susvimo | Nonpreferred | J2779 |
| | Vabysmo | Nonpreferred | J2777 |
| Osteoarthritis of the knee (intra- articular steroids) | triamcinolone | Preferred | J3301, J3302, J3303 |
| | methylprednisolone | Preferred | J1020, J1030, J1040, J2920, J2930 |
| | betamethasone | Preferred | J0702 |
| | dexamethasone | Preferred | J1094, J1100 |

| | Zilretta | Nonpreferred | J3304 |
|-------------------------------------|--------------------|--------------|-------|
| Osteoporosis | zoledronic acid | Preferred | J3489 |
| | Prolia | Nonpreferred | J0897 |
| PD-1/PD-L1 | Keytruda | Preferred | J9271 |
| | Jemperli | Nonpreferred | J9272 |
| Rituximab and hyaluronidase | Rituxan IV | Preferred | J9312 |
| | Ruxience | Preferred | Q5119 |
| | Riabni | Preferred | Q5123 |
| | Truxima | Nonpreferred | Q5155 |
| | Rituxan Hycela | Nonpreferred | J9311 |
| Somatostatin analogs (Lutathera) | Sandostatin LAR | Preferred | J2353 |
| | Somatuline Depot | Preferred | J1930 |
| | Lutathera | Nonpreferred | A9513 |
| Somatostatin analogs (Signifor LAR) | octreotide acetate | Preferred | J2354 |
| | Sandostatin | Preferred | J2354 |
| | Signifor LAR | Nonpreferred | J2502 |
| Trastuzumab and hyaluronidase-oysk | Herceptin (IV) | Preferred | J9355 |
| | Kanjinti | Preferred | Q5117 |
| | Trazimera | Preferred | Q5116 |
| | Herceptin Hylecta | Nonpreferred | J9356 |
| | Herzuma | Nonpreferred | Q5113 |
| | Ogivri | Nonpreferred | Q5114 |
| | Ontruzant | Nonpreferred | Q5112 |

| Velcade | Bortezomib (505(b)(2)) | Preferred | J9044 |
|-------------------------|------------------------|--------------|--------------|
| | Velcade | Nonpreferred | J9041 |
| | bortezomib | Nonpreferred | J9041 |
| Vincristine (liposomal) | vincristine sulfate | Preferred | J9370 |
| | Marqibo | Nonpreferred | J9371 |
| Viscosupplements | Durolane | Preferred | J7318 |
| | Monovisc | Preferred | J7327 |
| | Orthovisc | Preferred | J7324 |
| | Supartz FX | Preferred | J7321 |
| | Synvisc One | Preferred | J7325 |
| | Euflexxa | Nonpreferred | J7323 |
| | Gel-One | Nonpreferred | J7326 |
| | Gelsyn-3 | Nonpreferred | J7328 |
| | GenVisc 850 | Nonpreferred | J7320 |
| | Hyalgan | Nonpreferred | J7321 |
| | Hymovis | Nonpreferred | J7322 |
| | Sodium Hyaluronate | Nonpreferred | C9399, J3490 |
| | Synvisc | Nonpreferred | J7325 |
| | SynoJoynt | Nonpreferred | J7331 |
| | Triluron | Nonpreferred | J7332 |
| | TriVisc | Nonpreferred | J7329 |
| | Visco-3 | Nonpreferred | J7333 |