



Injectable Drugs and Biologics Step Therapy Requirement for Medicare Advantage Plans

Effective Date: Jan. 1, 2024

Revision Date: Nov. 6, 2024

In August 2018, the Centers for Medicare & Medicaid Services (CMS) rescinded its September 2012 memo “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services,” which provided Medicare Advantage (MA) plans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

CMS issued a final ruling on May 16, 2019, that improves the Medicare Advantage program.² These changes updated CMS requirements for the Part B Step Therapy Program, enabling MA plans to negotiate better prices for physician-administered drugs under Medicare Part C. The changes that resulted from this final ruling were implemented on Jan. 1, 2020.

Important note: The designation of preferred status does not mean a drug is always exempt from a step therapy requirement. Please refer to the specific criteria contained in our coverage criteria policies, which is posted at [CarePlusHealthPlans.com/PAL](https://www.careplushealthplans.com/PAL). Also on that page, you can find the Medicare Preauthorization list which displays step therapy indicators on the drugs that are impacted by a step therapy requirement.

If healthcare 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). A list of specialty and mail-order pharmacies can be found in the Provider Directories located on our website at www.careplushealthplans.com/members/pharmacy-directories. A full list of pharmacies is also available via the Pharmacy Finder Tool at www.careplushealthplans.com/pharmacy-finder.

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

MA 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, CarePlus does not 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, health plans will not be required to combine step therapy with 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 may be used to provide supplemental benefits and/or lower premiums to the plans' enrollees.

References:

1. "Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs," Centers for Medicare & Medicaid Services, last accessed Jan. 18, 2024, www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.
2. "Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)," Centers for Medicare & Medicaid Services, last accessed Jan. 18, 2024, www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f.

Continued on following page

Drug class	Drug name	Status	Billing code
Alpha-1s	Zemaira	Preferred	J0256
	Aralast	Nonpreferred	J0256
	Glassia	Nonpreferred	J0257
	Prolastin-C	Nonpreferred	J0256
Bevacizumab (oncology)	Mvasi	Preferred	Q5107
	Zirabev	Preferred	Q5118
	Avastin	Nonpreferred	J9035
	Alymsys	Nonpreferred	Q5126
	Vegzelma	Nonpreferred	Q5129
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
	Udenyca autoinjector	Preferred	Q5111
	Udenyca Onbody	Preferred	Q5111
	Fylnetra	Nonpreferred	Q5130
	Nyvepria	Nonpreferred	Q5122
	Rolvedon	Nonpreferred	J1449

	Stimufend	Nonpreferred	Q5127
	Ziextenzo	Nonpreferred	Q5120
Colony-stimulating factors – Leukocyte Growth factors (short-acting)	Nivestym	Preferred	Q5110
	Zarxio	Preferred	Q5101
	Granix	Nonpreferred	J1447
	Neupogen	Nonpreferred	J1442
	Releuko	Nonpreferred	Q5125
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
	Altuviio	Preferred	J7214
	Eloctate	Preferred	J7205
	Esperoct	Preferred	J7204
	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
	Takhzyro subcutaneous	Nonpreferred	C9399, J3490, J3590
Homozygous familial hypercholesterolemia (HoFH)	Repatha	Preferred	C9399, J3590
	Evkeeza	Nonpreferred	J1305
Immune globulin	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
	Alyglo	Nonpreferred	C9399, J1599
	Asceniv	Nonpreferred	J1554
	Bivigam	Nonpreferred	J1556
	Cutaquig	Nonpreferred	J1551
	Cuvitru	Nonpreferred	J1555
	Gammaplex	Nonpreferred	J1557
	Hyqvia	Nonpreferred	J1575
	Panzyga	Nonpreferred	J1576
Immunologic drugs – autoimmune disorders (arthritis, psoriasis, inflammatory bowel disease)	Inflectra	Preferred	Q5103
	Infliximab	Preferred	J1745
	Remicade	Preferred	J1745
	Simponi Aria	Preferred	J1602
	Stelara	Preferred	J3358
	Tremfya IV	Preferred	J1628
	Actemra IV	Nonpreferred	J3262
	Avsola	Nonpreferred	Q5121

	Entyvio IV	Nonpreferred	J3380
	Cosentyx	Nonpreferred	J3247
	Ilumya	Nonpreferred	J3245
	OmvoH IV	Nonpreferred	J2267
	Orencia IV	Nonpreferred	J0129
	Renflexis	Nonpreferred	Q5104
	Riabni	Nonpreferred	Q5123
	Rituxan IV	Nonpreferred	J9312
	Ruxience	Nonpreferred	Q5119
	Tofidence IV	Nonpreferred	Q5133
	Truxima	Nonpreferred	Q5115
	Tyenne IV	Nonpreferred	Q5135
	Tysabri	Nonpreferred	J2323
IV Iron	Infed	Preferred	J1750
	Venofer	Preferred	J1756
	Feraheme	Nonpreferred	Q0138
	Injectafer	Nonpreferred	J1439
	Monoferric	Nonpreferred	J1437
Melanoma	Opdivo	Preferred	J9299
	Keytruda	Preferred	J9271
	Opdivo plus Yervoy	Preferred	J9299, J9228
	Opdualag	Nonpreferred	J9298
Multiple sclerosis	Ocrevus	Preferred	J2350

	Ocrevus Zunovo	Preferred	C9399, J3490, J3590
	Briumvi	Nonpreferred	J2329
	Tysabri	Nonpreferred	J2323
	Lemtrada	Nonpreferred	J0202
Myasthenia gravis	Soliris	Preferred	J1300
	Ultomiris	Preferred	J1303
	Vyvgart	Preferred	J9332
	Vyvgart Hytrulo	Preferred	J9334
	Rystiggo	Nonpreferred	J9333
Neoplasms (excluding pancreatic)	docetaxel	Preferred	J9171
	paclitaxel	Preferred	J9267
	Abraxane	Nonpreferred	J9264
	paclitaxel protein-bound	Nonpreferred	J9258
Onivyde (liposomal irinotecan)	Irinotecan	Preferred	J9206
	Onivyde	Nonpreferred	J9205
Ophthalmic disorders - photodynamic therapy	Avastin	Preferred	C9257, J9035
	Visudyne	Nonpreferred	J3396
Ophthalmic disorders - VEGF inhibitors	Avastin	Preferred	C9257, J9035
	Byooviz	Preferred	Q5124
	Cimerli	Preferred	Q5128

	Eylea	Preferred	J0178
	Eylea HD	Preferred	J0177
	Lucentis	Preferred	J2778
	Vabysmo	Preferred	J2777
	Beovu	Nonpreferred	J0179
	Pavblu	Nonpreferred	C9399, J3490, J3590
	Susvimo	Nonpreferred	J2779
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	Prolia	Preferred	J0897
	zoledronic acid	Preferred	J3489
	Evenity	Nonpreferred	J3111
Reblozyl	Retacrit	Preferred	Q5106
	Procrit	Preferred	J0885
	Reblozyl	Nonpreferred	J0896
Rituximab and hyaluronidase	Ruxience	Preferred	Q5119
	Riabni	Preferred	Q5123
	Rituxan IV	Nonpreferred	J9312

	Rituxan Hycela	Nonpreferred	J9311
	Truxima	Nonpreferred	Q5115
Somatostatin analogs (Lutathera)	Sandostatin LAR	Preferred	J2353
	Somatuline Depot	Preferred	J1930
	Lutathera	Nonpreferred	A9513
Somatostatin analogs (long acting)	Sandostatin Depot	Preferred	J1930
	Somatuline Depot	Preferred	J1930
	Lanreotide (ciplā)	Nonpreferred	J1932
	Signifor LAR	Nonpreferred	J2502
Trastuzumab and hyaluronidase-oysk	Kanjinti	Preferred	Q5117
	Trazimera	Preferred	Q5116
	Herceptin (IV)	Nonpreferred	J9355
	Herceptin Hylecta	Nonpreferred	J9356
	Herzuma	Nonpreferred	Q5113
	Ogivri	Nonpreferred	Q5114
	Ontruzant	Nonpreferred	Q5112
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	J7321