



## Injectable Drugs and Biologics Step Therapy Requirement for Medicare Advantage Plans

**Effective Date: Jan. 1, 2025**

**Revision Date: Mar. 26, 2025**

In August 2018, the Centers for Medicare & Medicaid Services (CMS) rescinded its September 2012 memo “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services,” which provided Medicare Advantage (MA) plans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.<sup>1</sup> 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.<sup>2</sup> 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](https://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](https://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](https://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](https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f).

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<b>Drug class</b>	<b>Drug name</b>	<b>Status</b>	<b>Billing code</b>
Atypical Hemolytic Uremic Syndrome (aHUS)	<b>Ultomiris</b>	<b>Preferred</b>	<b>J1303</b>
	Bkemv IV	Nonpreferred	Q5139, Q5152
	Epysqli IV	Nonpreferred	Q5151
	Soliris	Nonpreferred	J1300
Alpha-1s	<b>Zemaira</b>	<b>Preferred</b>	J0256
	Aralast	Nonpreferred	J0256
	Glassia	Nonpreferred	J0257
	Prolastin-C	Nonpreferred	J0256
Bevacizumab (oncology)	<b>Mvasi</b>	<b>Preferred</b>	Q5107
	<b>Zirabev</b>	<b>Preferred</b>	Q5118
	Avastin	Nonpreferred	J9035
	Alymsys	Nonpreferred	Q5126
	Vegzelma	Nonpreferred	Q5129
Bone resorption inhibitors	<b>pamidronate</b>	<b>Preferred</b>	J2430
	<b>zoledronic acid</b>	<b>Preferred</b>	J3489
	Xgeva	Nonpreferred	J0897
Cervical cancer	<b>Keytruda</b>	<b>Preferred</b>	J9271
	Tivdak	Nonpreferred	J9273
Colony-stimulating factors – Leukocyte Growth factors (long-acting)	<b>Fulphila</b>	<b>Preferred</b>	Q5108
	<b>Neulasta/Neulasta Onpro</b>	<b>Preferred</b>	J2506
	<b>Udenyca</b>	<b>Preferred</b>	Q5111
	<b>Udenyca autoinjector</b>	<b>Preferred</b>	Q5111
	Udenyca Onbody	<b>Preferred</b>	Q5111

	Flynetra	Nonpreferred	Q5130
	Nyvepria	Nonpreferred	Q5122
	Rolvedon	Nonpreferred	J1449
	Stimufend	Nonpreferred	Q5127
	Ziextenzo	Nonpreferred	Q5120
Colony-stimulating factors – Leukocyte Growth factors (short-acting)	<b>Nivestym</b>	<b>Preferred</b>	Q5110
	<b>Zarxio</b>	<b>Preferred</b>	Q5101
	Granix	Nonpreferred	J1447
	Neupogen	Nonpreferred	J1442
	Nypozi	Nonpreferred	C9173, J3490, J3590, J9999
	Releuko	Nonpreferred	Q5125
Erythropoiesis-stimulating agents	<b>Retacrit</b>	<b>Preferred</b>	Q5106
	<b>Procrit</b>	<b>Preferred</b>	J0885
	Aranesp	Nonpreferred	J0881
	Epogen	Nonpreferred	J0885
Gaucher's disease	<b>Elelyso</b>	<b>Preferred</b>	J3060
	Vpriv	Nonpreferred	J3385
	Cerezyme	Nonpreferred	J1786
Hemophilia A	<b>Advate</b>	<b>Preferred</b>	J7192
	<b>Adynovate</b>	<b>Preferred</b>	J7207
	<b>Afstyla</b>	<b>Preferred</b>	J7210
	<b>Altuviio</b>	<b>Preferred</b>	J7214

	<b>Eloctate</b>	<b>Preferred</b>	J7205
	<b>Esperoct</b>	<b>Preferred</b>	J7204
	<b>Hemofil M</b>	<b>Preferred</b>	J7190
	<b>Jivi</b>	<b>Preferred</b>	J7208
	<b>Koate-DVI</b>	<b>Preferred</b>	J7190
	<b>Kogenate FS</b>	<b>Preferred</b>	J7192
	<b>Kovaltry</b>	<b>Preferred</b>	J7211
	<b>NovoEight</b>	<b>Preferred</b>	J7182
	<b>Nuwiq</b>	<b>Preferred</b>	J7209
	<b>Recombinate</b>	<b>Preferred</b>	J7192
	<b>Xyntha</b>	<b>Preferred</b>	J7185
	Hemlibra	Nonpreferred	J7170
	Hympazvi	Nonpreferred	C9399, J3490, J3590, J7199
Hereditary angioedema – acute use	<b>icatibant</b>	<b>Preferred</b>	J1744
	Berinert	Nonpreferred	J0597
	Firazyr	Nonpreferred	J1744
	Kalbitor	Nonpreferred	J1290
	Ruconest	Nonpreferred	J0596
Hereditary angioedema – prophylaxis	<b>Haegarda</b>	<b>Preferred</b>	J0599
	Cinryze	Nonpreferred	J0598
	Takhzyro	Nonpreferred	J0593
	Takhzyro subcutaneous	Nonpreferred	C9399, J3490, J3590
	<b>Repatha</b>	<b>Preferred</b>	C9399, J3590

Homozygous familial hypercholesterolemia (HoFH)	Evkeeza	Nonpreferred	J1305
Immune globulin	<b>Flebogamma DIF</b>	<b>Preferred</b>	J1572
	<b>Gammagard</b>	<b>Preferred</b>	J1569
	<b>Gammagard S/D</b>	<b>Preferred</b>	J1566
	<b>Gammaked</b>	<b>Preferred</b>	J1561
	<b>Gamunex-C</b>	<b>Preferred</b>	J1561
	<b>Hizentra</b>	<b>Preferred</b>	J1559
	<b>Octagam</b>	<b>Preferred</b>	J1568
	<b>Privigen</b>	<b>Preferred</b>	J1459
	<b>Xembify</b>	<b>Preferred</b>	J1558
	Alyglo	Nonpreferred	J1552
	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)	<b>Inflectra</b>	<b>Preferred</b>	Q5103
	<b>Infliximab</b>	<b>Preferred</b>	J1745
	<b>Remicade</b>	<b>Preferred</b>	J1745
	<b>Simponi Aria</b>	<b>Preferred</b>	J1602

	<b>Stelara</b>	<b>Preferred</b>	J3358
	<b>Tremfya IV</b>	<b>Preferred</b>	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
	Otulfy IV	Nonpreferred	C9399, J3490, J3590
	Pyzchiva IV	Nonpreferred	Q9997
	Renflexis	Nonpreferred	Q5104
	Riabni	Nonpreferred	Q5123
	Rituxan IV	Nonpreferred	J9312
	Ruxience	Nonpreferred	Q5119
	Steqeyma IV	Nonpreferred	C9399, J3490, J3590
	Tofidence IV	Nonpreferred	Q5133
	Truxima	Nonpreferred	Q5115
	Tyenne IV	Nonpreferred	Q5135
	Tysabri	Nonpreferred	J2323
	Wezlana IV	Nonpreferred	Q5138

	Yesintek IV	Nonpreferred	C9399, J3490, J3590
IV Iron	<b>Infed</b>	<b>Preferred</b>	J1750
	<b>Venofer</b>	<b>Preferred</b>	J1756
	Feraheme	Nonpreferred	Q0138
	Injectafer	Nonpreferred	J1439
	Monoferric	Nonpreferred	J1437
Melanoma	<b>Opdivo</b>	<b>Preferred</b>	J9299
	<b>Keytruda</b>	<b>Preferred</b>	J9271
	<b>Opdivo plus Yervoy</b>	<b>Preferred</b>	J9299, J9228
	Opdualag	Nonpreferred	J9298
Multiple sclerosis	<b>Ocrevus</b>	<b>Preferred</b>	J2350
	Ocrevus Zunovo	Preferred	C9399, J3490, J3590
	Briumvi	Nonpreferred	J2329
	Tysabri	Nonpreferred	J2323
	Lemtrada	Nonpreferred	J0202
Myasthenia gravis	<b>Soliris</b>	<b>Preferred</b>	J1300
	<b>Ultomiris</b>	<b>Preferred</b>	J1303
	<b>Vyvgart</b>	<b>Preferred</b>	J9332
	<b>Vyvgart Hytrulo</b>	<b>Preferred</b>	J9334
	Bkemv IV	Nonpreferred	Q5139, Q5152
	Epysqli IV	Nonpreferred	Q5151
	Rystiggo	Nonpreferred	J9333



Neoplasms (excluding pancreatic)	<b>docetaxel</b>	<b>Preferred</b>	J9171
	<b>paclitaxel</b>	<b>Preferred</b>	J9267
	Abraxane	Nonpreferred	J9264
	paclitaxel protein-bound	Nonpreferred	J9258
Neuromyelitis Optica Spectrum Disorder (NMOSD)	<b>Ultomiris</b>	<b>Preferred</b>	<b>J1303</b>
	Bkemv IV	Nonpreferred	Q5139, Q5152
	Epysqli IV	Nonpreferred	Q5151
	Soliris	Nonpreferred	J1300
Onivyde (liposomal irinotecan)	<b>Irinotecan</b>	<b>Preferred</b>	J9206
	Onivyde	Nonpreferred	J9205
Ophthalmic disorders - VEGF inhibitors	<b>Avastin</b>	<b>Preferred</b>	C9257, J9035
	<b>Byooviz</b>	<b>Preferred</b>	Q5124
	<b>Cimerli</b>	<b>Preferred</b>	Q5128
	<b>Eylea</b>	<b>Preferred</b>	J0178
	<b>Eylea HD</b>	<b>Preferred</b>	J0177
	<b>Vabysmo</b>	<b>Preferred</b>	J2777
	Beovu	Nonpreferred	J0179
	Lucentis	Nonpreferred	J2778
	Pavblu	Nonpreferred	C9399, J3490, J3590
	Susvimo	Nonpreferred	J2779
Osteoarthritis of the knee (intra-articular steroids)	<b>triamcinolone</b>	<b>Preferred</b>	J3301, J3302, J3303

	<b>methylprednisolone</b>	<b>Preferred</b>	J1020, J1030, J1040, J2920, J2930
	<b>betamethasone</b>	<b>Preferred</b>	J0702
	<b>dexamethasone</b>	<b>Preferred</b>	J1094, J1100
	Zilretta	Nonpreferred	J3304
Osteoporosis	<b>Prolia</b>	<b>Preferred</b>	J0897
	<b>zoledronic acid</b>	<b>Preferred</b>	J3489
	Evenity	Nonpreferred	J3111
Paroxysmal nocturnal hemoglobinuria (PNH)	<b>Ultomiris</b>	<b>Preferred</b>	J1303
	Bkemv IV	Nonpreferred	Q5139, Q5152
	Epysqli IV	Nonpreferred	Q5151
	PiaSky	Nonpreferred	J0870
	Soliris	Nonpreferred	J1300
PD-1/PD-L1 NSCLC	<b>Libtayo</b>	<b>Preferred</b>	J9119
	Imfinzi	Nonpreferred	J9173
	Imjudo	Nonpreferred	J9347
	Keytruda	Nonpreferred	J9271
	Opdivo	Nonpreferred	J9299
	Tecentriq Hybreza SQ	Nonpreferred	C9399, J3490, J3590, J9999
	Tecentriq IV	Nonpreferred	J9022
	Yervoy	Nonpreferred	J9228
Reblozyl	<b>Retacrit</b>	<b>Preferred</b>	Q5106
	<b>Procrit</b>	<b>Preferred</b>	J0885

	Reblozyl	Nonpreferred	J0896
Rituximab and hyaluronidase	<b>Ruxience</b>	<b>Preferred</b>	Q5119
	<b>Riabni</b>	<b>Preferred</b>	Q5123
	Rituxan IV	Nonpreferred	J9312
	Rituxan Hycela	Nonpreferred	J9311
	Truxima	Nonpreferred	Q5115
Somatostatin analogs (Lutathera)	<b>Sandostatin LAR</b>	<b>Preferred</b>	J2353
	<b>Somatuline Depot</b>	<b>Preferred</b>	J1930
	Lutathera	Nonpreferred	A9513
Trastuzumab and hyaluronidase-oysk	<b>Kanjinti</b>	<b>Preferred</b>	Q5117
	<b>Trazimera</b>	<b>Preferred</b>	Q5116
	Herceptin (IV)	Nonpreferred	J9355
	Herceptin Hylecta	Nonpreferred	J9356
	Hercessi IV	Nonpreferred	Q5146
	Herzuma	Nonpreferred	Q5113
	Ogivri	Nonpreferred	Q5114
	Ontruzant	Nonpreferred	Q5112
Viscosupplements	<b>Durolane</b>	<b>Preferred</b>	J7318
	<b>Monovisc</b>	<b>Preferred</b>	J7327
	<b>Orthovisc</b>	<b>Preferred</b>	J7324
	<b>Supartz FX</b>	<b>Preferred</b>	J7321
	<b>Synvisc-One</b>	<b>Preferred</b>	J7325
	Euflexxa	Nonpreferred	J7323

	Gel-One	Nonpreferred	J7326
	Gelsyn-3	Nonpreferred	J7328
	GenVisc 850	Nonpreferred	J7320
	Hyalgan	Nonpreferred	J7321
	Hymovis	Nonpreferred	J7322
	Synvisc	Nonpreferred	J7325
	SynoJoynt	Nonpreferred	J7331
	Triluron	Nonpreferred	J7332
	TriVisc	Nonpreferred	J7329
	Visco-3	Nonpreferred	J7321