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

**Effective date: Jan. 1, 2025**
**Revision date: Jan. 1, 2026**

In August 2018, the Centers for Medicare & Medicaid Services (CMS) rescinded its September 2012 memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," which provided Medicare Advantage (MA) plans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

CMS issued a final ruling on May 16, 2019, that modernizes and improves the MA 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 Humana.com/CoveragePolicies. Affected drugs are noted with a step therapy indicator on the Medicare preauthorization list at Humana.com/PAL.

If prescribers do not stock Humana's preferred drug in their office, they may be able to obtain the preferred drug from a pharmacy (i.e., pharmacy can ship prescription drugs to the office). Please visit our list of specialty and mail-order pharmacies at Humana.com/Mail-Order to select a pharmacy that can provide the drug. You can access a full list of pharmacies with the Pharmacy Finder Tool at Humana.com/Finder/Pharmacy/ or by calling 800-457-4708 (TTY: 711).

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

MA-covered patients subject to the step therapy requirement can:

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

As of Jan. 1, 2020, Humana no longer offers a Drug Management Care Coordination Program for patients subject to step therapy or who take a preferred drug on the Part B Step Therapy Drug List. According to CMS guidance, health plans do not have 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 can be used to provide supplemental benefits and/or lower premiums to the plans' enrollees.

If you have questions, please call 800-457-4708. During Annual Election Period (Oct. 15–Dec. 7) and Open Enrollment Period (Jan. 1–March 31), our hours of operation are daily, 8 a.m. – 8 p.m., Eastern time. Normal hours of operation are Monday – Friday, 8 a.m. – 8 p.m., Eastern time.

**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 |
|---|---|---|---|
| Atypical Hemolytic Uremic Syndrome (aHUS) | **Ultomiris** | **Preferred** | **J1303** |
| | Bkemv IV | Nonpreferred | Q5152 |
| | Epysqli IV | Nonpreferred | Q5151 |
| | Soliris | Nonpreferred | J1300, J1299 |
| 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 |
| | Jobevne | Nonpreferred | Q5160 |
| | Vegzelma | Nonpreferred | Q5129 |
| Bone resorption inhibitors | **pamidronate** | **Preferred** | J2430 |
| | **Wyost** | **Preferred** | Q5136 |
| | **Xgeva** | **Preferred** | J0897 |
| | **zoledronic acid** | **Preferred** | J3489 |
| | Bilprevda | Nonpreferred | C9399, J3490, J3590, J9999 |
| | Bomyntra | Nonpreferred | Q5158 |
| | Osenvelt | Nonpreferred | Q5157 |
| Cervical cancer | **Keytruda** | **Preferred** | J9271 |
| | Tivdak | Nonpreferred | J9273 |

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| CGRPs - applies to MAPD plans only | **Emgality** | **Preferred** | Part D benefit |
| | **Qulipta** | **Preferred** | Part D benefit |
| | Vyepti | Nonpreferred | J3032 |
| 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 |
| | Ryzneuta | Nonpreferred | C9399, J3490, J3590, J9999 |
| | 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 |
| | Nypozi | Nonpreferred | Q5148 |
| | Releuko | Nonpreferred | Q5125 |

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| Erythropoiesis-stimulating agents | **Retacrit** | **Preferred** | Q5106 |
| | **Procrit** | **Preferred** | J0885 |
| | Aranesp | Nonpreferred | J0881 |
| | Epogen | Nonpreferred | J0885 |
| Gaucher's disease | **Elelyso** | **Preferred** | J3060 |
| | Vpriv | Nonpreferred | J3385 |
| | Cerezyme | Nonpreferred | J1786 |
| Hemophilia A without inhibitors | **Advate** | **Preferred** | J7192 |
| | **Adynovate** | **Preferred** | J7207 |
| | **Afstyla** | **Preferred** | J7210 |
| | **Altuviiio** | **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 |
| | **NovoEight** | **Preferred** | J7182 |
| | **Nuwiq** | **Preferred** | J7209 |
| | **Recombinate** | **Preferred** | J7192 |
| | **Xyntha** | **Preferred** | J7185 |
| | Alhemo | Nonpreferred | J7173 |
| | Hemlibra | Nonpreferred | J7170 |

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| | Hympazvi | Nonpreferred | J7172 |
| | Qfitlia | Nonpreferred | J7174 |
| 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 |
| | Dawnzera | Nonpreferred | C9399, J3490 |
| | Takhzyro | Nonpreferred | J0593 |
| 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 | J1552 |
| | Asceniv | Nonpreferred | J1554 |

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| | Bivigam | Nonpreferred | J1556 |
| | Cutaquig | Nonpreferred | J1551 |
| | Cuvitru | Nonpreferred | J1555 |
| | Gammaplex | Nonpreferred | J1557 |
| | Hyqvia | Nonpreferred | J1575 |
| | Panzyga | Nonpreferred | J1576 |
| | Yimmugo | Nonpreferred | C9399, J3490, J3590 |
| Immunologic drugs – autoimmune disorders (arthritis, psoriasis, inflammatory bowel disease) | **Inflectra** | **Preferred** | Q5103 |
| | **Infliximab** | **Preferred** | J1745 |
| | **Otulfi IV** | **Preferred** | Q9999 |
| | **Remicade** | **Preferred** | J1745 |
| | **Simponi Aria** | **Preferred** | J1602 |
| | **Stelara** | **Preferred** | J3358 |
| | **Tremfya IV** | **Preferred** | J1628 |
| | **Yesintek IV** | **Preferred** | Q5100 |
| | Actemra IV | Nonpreferred | J3262 |
| | Avtozma IV | Nonpreferred | Q5156 |
| | Avsola | Nonpreferred | Q5121 |
| | Cimzia | Nonpreferred | J0717 |
| | Cosentyx | Nonpreferred | J3247 |
| | Entyvio IV | Nonpreferred | J3380 |
| | Ilumya | Nonpreferred | J3245 |

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| | Imuldosa IV | Nonpreferred | Q5098 |
| | Omvoh IV | Nonpreferred | J2267 |
| | Orencia IV | Nonpreferred | J0129 |
| | Pyzchiva IV | Nonpreferred | Q9997 |
| | Renflexis | Nonpreferred | Q5104 |
| | Riabni | Nonpreferred | Q5123 |
| | Rituxan IV | Nonpreferred | J9312 |
| | Ruxience | Nonpreferred | Q5119 |
| | Selarsdi IV | Nonpreferred | Q9998 |
| | Starjemza IV | Nonpreferred | C9399, J3490, J3590 |
| | Steqeyma IV | Nonpreferred | Q5099 |
| | Tofidence IV | Nonpreferred | Q5133 |
| | Truxima | Nonpreferred | Q5115 |
| | Tyenne IV | Nonpreferred | Q5135 |
| | Tysabri | Nonpreferred | J2323 |
| | Ustekinumab IV | Nonpreferred | J3358 |
| | Wezlana IV | Nonpreferred | Q5138 |
| IV Iron | **Infed** | **Preferred** | J1750 |
| | **Venofer** | **Preferred** | J1756 |
| | Feraheme | Nonpreferred | Q0138 |
| | Injectafer | Nonpreferred | J1439 |
| | Monoferric | Nonpreferred | J1437 |

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| 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, J1299 |
| | **Ultomiris** | **Preferred** | J1303 |
| | **Vyvgart** | **Preferred** | J9332 |
| | **Vyvgart Hytrulo** | **Preferred** | J9334 |
| | Bkemv IV | Nonpreferred | Q5152 |
| | Epysqli IV | Nonpreferred | Q5151 |
| | Imaavy | Nonpreferred | J9256 |
| | Rystiggo | Nonpreferred | J9333 |
| Neoplasms (excluding pancreatic) | **docetaxel** | **Preferred** | J9171 |
| | **paclitaxel** | **Preferred** | J9267 |
| | Abraxane | Nonpreferred | J9264 |
| | paclitaxel protein-bound | Nonpreferred | J9258 |
| Neuromyelitis Optica Spectrum Disorder (NMOSD) | **Ultomiris** | **Preferred** | **J1303** |
| | Bkemv IV | Nonpreferred | Q5152 |
| | Epysqli IV | Nonpreferred | Q5151 |
| | Soliris | Nonpreferred | J1300, J1299 |

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| Ophthalmic disorders - VEGF inhibitors | **Avastin** | **Preferred** | C9257, J9035 |
| | **Byooviz** | **Preferred** | Q5124 |
| | **Eylea** | **Preferred** | J0178 |
| | **Eylea HD** | **Preferred** | J0177 |
| | **Lucentis** | **Preferred** | J2778 |
| | **Pavblu** | **Preferred** | Q5147 |
| | **Vabysmo** | **Preferred** | J2777 |
| | Beovu | Nonpreferred | J0179 |
| | 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 |
| | **Jubbonti** | **Preferred** | Q5136 |
| | **zoledronic acid** | **Preferred** | J3489 |
| | Bildyos | Nonpreferred | C9399, J3490, J3590, J9999 |
| | Conexxence | Nonpreferred | Q5158 |
| | Evenity | Nonpreferred | J3111 |
| | Ospomyv | Nonpreferred | Q5159 |
| | Stoboclo | Nonpreferred | Q5157 |

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| Paroxysmal nocturnal hemoglobinuria (PNH) | **Ultomiris** | **Preferred** | J1303 |
| | Bkemv IV | Nonpreferred | Q5152 |
| | Epysqli IV | Nonpreferred | Q5151 |
| | PiaSky | Nonpreferred | J0870 |
| | Soliris | Nonpreferred | J1300, J1299 |
| PCSK9s - applies to MAPD plans only | **Repatha** | **Preferred** | Part D benefit |
| | Leqvio | Nonpreferred | J1306 |
| PD-1/PD-L1 NSCLC | **Libtayo** | **Preferred** | J9119 |
| | Imfinzi | Nonpreferred | J9173 |
| | Imjudo | Nonpreferred | J9347 |
| | Keytruda | Nonpreferred | J9271 |
| | Keytruda Qlex | Nonpreferred | C9399, J3490, J3590, J9999 |
| | Opdivo | Nonpreferred | J9299 |
| | Tecentriq Hybreza SQ | Nonpreferred | J9024 |
| | Tecentriq IV | Nonpreferred | J9022 |
| | Yervoy | Nonpreferred | J9228 |
| 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 |

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| Trastuzumab and hyaluronidase-oysk | **Kanjinti** | **Preferred** | Q5117 |
| | **Trazimera** | **Preferred** | Q5116 |
| | Herceptin (IV) | Nonpreferred | J9355 |
| | Herceptin Hylecta | Nonpreferred | J9356 |
| | Hercessi IV | Nonpreferred | Q5146 |
| | 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 |
| | Hymovis ONE | Nonpreferred | C9399, J3490 |
| | Synvisc | Nonpreferred | J7325 |
| | SynoJoynt | Nonpreferred | J7331 |
| | Triluron | Nonpreferred | J7332 |
| | TriVisc | Nonpreferred | J7329 |

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| | Visco-3 | Nonpreferred | J7321 |