



Injectable Drugs and Biologics Step Therapy Requirement for Medicare Advantage Plans

Effective date: Jan. 1, 2024

Revision date: Feb. 7, 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In August 2018, the Centers for Medicare & Medicaid Services (CMS) rescinded its September 2012 memo “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services,” which provided Medicare Advantage (MA) plans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 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](https://www.humana.com/CoveragePolicies). Affected drugs are noted with a step therapy indicator on the Medicare preauthorization list at [Humana.com/PAL](https://www.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](https://www.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/](https://www.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.

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| 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 |
| Botulinum toxins | Botox | Preferred | J0585 |
| | Dysport | Preferred | J0586 |
| | Myobloc | Preferred | J0587 |
| | Xeomin | Preferred | J0588 |
| | Daxxify | Nonpreferred | C9160 |
| 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 |

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| | 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 |

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| | Adynovate | Preferred | J7207 |
| | Afstyla | Preferred | J7210 |
| | Altuviio | Preferred | C9399, J3490, J3590, J7199 |
| | 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 |

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| | 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 |
| | Asceniv | Nonpreferred | J1554 |
| | Bivigam | Nonpreferred | J1556 |
| | Cutaquig | Nonpreferred | J1551 |
| | Cuvitru | Nonpreferred | J1555 |
| | Gammaplex | Nonpreferred | J1557 |
| | Hyqvia | Nonpreferred | J1575 |
| Panzyga | Nonpreferred | J1599, J1576 | |
| Immunologic drugs – autoimmune disorders (arthritis, psoriasis, inflammatory bowel disease) | Inflectra | Preferred | Q5103 |
| | Infliximab | Preferred | J1745 |
| | Remicade | Preferred | J1745 |
| | Simponi Aria | Preferred | J1602 |

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| | Stelara | Preferred | J3358 |
| | Actemra IV | Nonpreferred | J3262 |
| | Avsola | Nonpreferred | Q5121 |
| | Entyvio IV | Nonpreferred | J3380 |
| | Cosentyx | Nonpreferred | C9399, J3490, J3590 |
| | Ilumya | Nonpreferred | J3245 |
| | OmvoH IV | Nonpreferred | C9399, J3490, J3590 |
| | 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 |
| Melanoma | Opdivo | Preferred | J9299 |
| | Keytruda | Preferred | J9271 |
| | Opdivo plus Yervoy | Preferred | J9299, J9228 |
| | Opdualag | Nonpreferred | J9298 |
| Multiple sclerosis | Ocrevus | Preferred | J2350 |

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| | 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 |
| Ophthalmic disorders - photodynamic therapy | Avastin | Preferred | C9257, J9035 |
| | Visudyne | Nonpreferred | J3396 |
| Ophthalmic disorders - VEGF inhibitors | Avastin | Preferred | C9257, J9035 |
| | Cimerli | Preferred | Q5128 |
| | Eylea | Preferred | J0178 |
| | Eylea HD | Preferred | C9161, J3490, J3590 |
| | Lucentis | Preferred | J2778 |
| | Vabysmo | Preferred | J2777 |
| | Beovu | Nonpreferred | J0179 |

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| | Byooviz | Nonpreferred | Q5124 |
| | 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 | zoledronic acid | Preferred | J3489 |
| | Prolia | Nonpreferred | J0897 |
| 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 | Q5155 |
| Somatostatin analogs (Lutathera) | Sandostatin LAR | Preferred | J2353 |
| | Somatuline Depot | Preferred | J1930 |
| | Lutathera | Nonpreferred | A9513 |
| Somatostatin analogs (long acting) | Sandostatin Depot | Preferred | J1930 |

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| | Sandostatin LAR | Preferred | J2353 |
| | 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 |

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| | Triluron | Nonpreferred | J7332 |
| | TriVisc | Nonpreferred | J7329 |
| | Visco-3 | Nonpreferred | J7333 |