Step Therapy Requirements for Outpatient (Part B) Medications Capital Blue

Refer to the Medicare Coverage Database (MCD) for a national coverage determination (NCD) or local coverage determination (LCD) from the Medicare Administrative Contractor (MAC) for the jurisdiction. If an NCD or LCD exists for the requested medication, the NCD/LCD must first be met before the Step Therapy criteria is followed. In the absence of a NCD or LCD for the requested medication, refer to Medicare Part B Prior Authorization to establish medical necessity before Step Therapy criteria will be followed.

Step Therapy will be required for the medications listed in the table below effective 1/1/2021, provided the following are met:

- The requested product meets the definition of a Medicare outpatient (Part B) drug[2]; **AND**
- The proposed use of the requested product has been determined to be a medically accepted indication; **AND**
- The proposed use of the preferred alternative agent has been determined to be a medically accepted indication; **AND**
- The dose, frequency, and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication; **AND**
- The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days); **AND**
- Step therapy does not apply to patients using a non-preferred product if an indication is not shared by the preferred product or is not supported by compendia or clinical literature.

Category	Requested Product(s)	Preferred Alternative Product(s)	Comments
Bevacizumab	ALYMSYS (Q5126) AVASTIN (J9035) VEGZELMA (Q5129)	MIRVASI (Q5107) **or** ZIRABEV (Q5118)	Non-oncology indications for Avastin will not require prerequisite agents
Blood Modifier/Colony Stimulating Factors - Filgrastim	NEUPOGEN (J1442) RELEUKO (Q5125)	GRANIX (J1447) **or** NIVESTYM (Q5110) **or** ZARXIO (Q5101)	Preferred alternative agents will not require Prior Authorization
Blood Modifier/Colony Stimulating Factors – Pegylated Filgrastim	FULPHILA (Q5108) FYLNETRA (Q5130) NYVEPRIA (Q5122) ROLVEDON (J1449) STIMUFEND (Q5127) ZIEXTENZO (Q5120)	NEULASTA (J2506) **or** UDENYCA (Q5111)	Preferred alternative agents will not require Prior Authorization
Bendamustine	TREANDA (J9033)	BELRAPZO (J9036) **or** BENDEKA (J9034)	Preferred alternative agents will not require Prior Authorization

Category	Requested Product(s)	Preferred Alternative Product(s)	Comments
Infliximab	AVSOLA (Q5121) RENFLEXIS (Q5104)	INFLECTRA (Q5103) **or** INFLIXIMAB MFGR: JANSSEN (J1745) **or** REMICADE (J1745)	Preferred alternative agents will not require Prior Authorization
IV Iron	FERAHEME (Q0138) FERUMOXYTOL (Q0138) INJECTAFER (J1439) MONOFERRIC (J1437)	FERRLECIT (J2916) **or** INFED (J1750) **or** VENOFER (J1756)	Preferred alternative agents will not require Prior Authorization
Levoleucovorin	FUSILEV (J0641) KHAPZORY (J0642)	LEUCOVORIN (J0640)	Preferred alternative agents will not require Prior Authorization
Ophthalmic VEGFs	BEOVU (J0179) BYOOVIZ (Q5124) CIMERLI (Q5128) EYLEA (J0178) LUCENTIS (J2778)	AVASTIN (J9035)	Oncology indications for Avastin will require Step Therapy
Rituximab	RITUXAN (J9312) RITUXAN HYCELA (J9311) RIABNI (Q5123)	RUXIENCE (Q5119) **or** TRUXIMA (Q5115)	Preferred alternative agents will not require Prior Authorization
Complement Inhibitors	SOLIRIS (J1300)	ULTOMIRIS (J1303)	For indications of PNH or aHUS Preferred alternative agents will not require Prior Authorization
Trastuzumab	HERCEPTIN (J9355) HERCEPTIN HYLECTA (J9356) HERZUMA (Q5113) OGIVRI (Q5114) ONTRUZANT (Q5112)	KANJINTI (Q5117) **or** TRAZIMERA (Q5116)	Preferred alternative agents will not require Prior Authorization
HA/Viscosupplements	DUROLANE (J7318) GENVISC 850 (J7320) GEL-ONE (J7326) GELSYN-3 (J7328) HYALGAN (J7321) HYMOVIS (J7322) MONOVISC (J7327) ORTHOVISC (J7324) SUPARTZ FX (J7321) SYNOJOYNT (J7331) TRILURON (J7332) TRIVISC (J7329) VISCO-3 (J7321)	EUFLEXXA (J7323) **or** SYNVISC (J7325) **or** SYNVISC-ONE (J7325)	Preferred alternative agents will not require Prior Authorization

References

1. Centers for Medicare and Medicaid Services, Health Plan Management System (HPMS), MA_Step_Therapy_HPMS_Memo_8_7_18; available at http://www.cms.gov - last checked August 31, 2018 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
2. Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, Sec. 50 (Rev. 241, Feb. 2, 2018); available at http://www.cms.gov - last checked August 31, 2018 and found under Medicare > Regulations and Guidance > Manuals > Internet-Only Manuals (IOMs).
3. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
4. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
5. U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/

Document History

Original Prime Standard Part B ST criteria, approved by P&T UM Committee 02/2023
Administrative Action (addition of Vegzelma and Alymsys to Monoclonal Antibodies as non-preferred) 8/2023
Administrative Action (addition of Rolvedon, Stimufend and Fylnetra to Blood Modifier/Colony Stimulating Factors) 08/2023
Administrative Action (addition of Byooviz to Ocular Angiogenesis Inhibitors) 08/2023
Mid-Year Review Prime Standard Part B PA criteria, with changes to criteria, approved by P&T UM Committee 08/2023
Administrative Action (Corrected IV Iron with addition of Ferumoxytol as non-preferred) 01/2024
Administrative Action (Removal of non-preferred Macugen from Ophthalmic VEGFs) 02/2024