



Step Therapy requirements for Medicare outpatient (Part B) medications

Step Therapy will be required for the medications listed in the table below provided the following are met:

- The requested product meets the definition of a Medicare outpatient (Part B) drug; **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**
- The requested product is necessary for treating the enrollee's condition as the preferred drug(s) has(have) been or is(are) likely to be less effective or have adverse effects. **AND**
- When there are multiple preferred drugs, unless otherwise specified, only one is required prior to approval of the non-preferred drug.

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date
Avastin (J9035) Avzivi (J9999) Vegzelma (Q5129) Zirabev (Q5118) Jobevne (Q5160)	Mvasi (Q5107) Allymsys (Q5126)	Oncology indications only	4/1/2026
Myobloc (J0587)	Botox (J0585) Xeomin (J0588) Dysport (J0586) Daxxify (J0589)	Shared indications only	4/1/2026
Epogen (J0885)	Retacrit (Q5106) Procrit (J0885) Aranesp (J0881)		4/1/2026
Trelstar (J3315) Lupron (J9217, J9218, J1950, J1954)	Camcevi (J1952) Firmagon (J9155) Eligard (J9217)	Shared indications only	4/1/2026
Orencia (J0129)	Simponi Aria (J1602) Cimzia (J0717) Ilumya (J3245) Tremfya (J1628)	Shared indications only	4/1/2026

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date
Actemra (J3262) Tofidence (Q5133) Avtozma (Q5156)	Tyenne (Q5135)		4/1/2026
Steqeyma (Q5099) Wezlana (Q5138, Q5137) Pyzchiva (Q9997, Q9996) Otulfi (Q9999) Imuldosa (Q0598)	Stelara/ustekinumab (J3358, J3357) Selarsdi (Q9998) Yesintek (Q5100)		4/1/2026
Remicade (J1745) Infliximab (J1745) Renflexis (Q5104)	Avsola (Q5121) Inflectra (Q5103)		4/1/2026
Feraheme (Q0138) Injectafer (J1439) Monoferric (J1437)	Ferrlecit (J2916) Infed (J1750) Venofer (J1756)		4/1/2026
Fylnetra (Q5130) Stimufend (Q5127) Nyvepria (Q5122) Ziextenzo (Q5120) Neulasta (J2506)	Udenyca (Q5111) Fulphila (Q5108)		4/1/2026
Ryzneuta (J9361)	Rolvedon (J1449)		4/1/2026
Vyepti (J3032)	Ajovy (J3031) Aimovig (J3590) Emgality (J3590)		4/1/2026
Piasky (J1307)	Soliris (J1299, J1300) Ultomiris (J1303) Vyvgart (J9332) Vyvgart Hytrulo (J9334) Rystiggo (J9333) Bkemv (Q5152) Epysqli (Q5151) Imaavy (J9256)	Shared indications only	4/1/2026
Keytruda (J9271) Opdivo (J9299)	Loqtorzi (J3263)	Shared indications only	4/1/2026
Leqvio (J1306)	Praluent (J3590) Repatha (J3590)		4/1/2026
Rituxan (J9312) Rituxan Hycela (J9311)	Ruxience (Q5119) Truxima (Q5115) Riabni (Q5123)		4/1/2026
Neupogen (J1442) Granix (J1447) Releuko (Q5125) Nypozi (Q5148)	Zarxio (Q5101) Nivestym (Q5110)		4/1/2026

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date
Saphnelo (J0491)	Benlysta (J0490)		4/1/2026
Cinqair (J2786) Exdensur (J3590)	Tezspire (J2356) Nucala (J2182) Fasenra (J0517)	Shared indications only	4/1/2026
Herceptin (J9355) Herceptin Hylecta (J9356) Herzuma (Q5113) Hercessi (Q5146) Trazimera (Q5116)	Kanjinti (Q5117) Ogivri (Q5114) Ontruzant (Q5112)		4/1/2026
Ahzantive (Q5150) Beovu (J0179) Byooviz (Q5124) Cimerli (Q5128) Enzeevu (Q5149) Eylea (J0178) Eylea HD (J0177) Lucentis (J2778) Opuviz (Q5153) Pavblu (Q5147) Susvimo (J2779) Vabysmo (J2777) Yesafili (Q5155)	Avastin – Ophthalmic (C9257)		4/1/2026
Briumvi (J2329) Ocrevus (J2350) Ocrevus Zunovo (J2351)	one generic disease-modifying agent (i.e., dimethyl fumarate, glatiramer, fingolimod, teriflunomide)		4/1/2026
Tyruko (Q5134) Tysabri (J2323)	MS: one generic disease-modifying agent (i.e., dimethyl fumarate, glatiramer, fingolimod, teriflunomide) CD: one TNF-inhibitor		4/1/2026
Lemtrada (J0202)	Any two disease-modifying agents for multiple-sclerosis		4/1/2026

References

- 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 June 13, 2025 and found under Medicare > Enrollment & renewal > Health plans - General Information > Downloads.
- Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02,; available at <http://www.cms.gov> - last checked June 13, 2025 and found under Medicare > Regulations & 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/>

Drug/Therapy Class	Change or Update	Effective Date
All Step Therapy Categories	Step Therapy Document Creation	4/1/2026