BCBSMN 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	Preferred Alternatives	Effective Date	Special Comment
Bosaya Q5161 Conexxence Q5158 Enoby J3590 Ospomyv Q5159 Prolia J0897	Bildyos Q5162 Jubbonti Q5136 Stoboclo Q5157	1/1/26	
Aukelso Q5161 Bomyntra Q5158 Xgeva J0897 Xbryk Q5159 Xtrenbo J3590	Bilprevda Q5162 Osenvelt Q5157 Wyost Q5136	1/1/26	
Ryoncil J3402	Jakafi	1/1/26	

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Requested Product	Preferred Alternatives	Effective Date	Special Comment
Bkemv Q5152 Soliris J1299	Epysqli Q5151	1/1/26	For shared FDA approved indications only *See row below for gMG
Bkemv Q5152 Imaavy J9256 Soliris J1299	Epysqli Q5151, OR Ultomiris J1303, AND Rystiggo J9333, OR Vyvgart J9332, OR Vyvgart Hytrulo J9334	8/1/24	Applies to gMG diagnosis only
Alyglo J1552 Asceniv J1554	BivigamJ1556 Cutaquig J1551 Cuvitru J1555 Flebogamma J1572 Gammagard Liquid J1569 Gammagard Liquid ERC J1569 Gammagard S/D J1566 Gammaked J1561 Gammaplex J1557 Gamunex-C J1561 Hizentra J1559 Hyqvia J1575 intravenous immune globulin J1599; J1566 Octagam J1568 Panzyga J1576 Privigen J1459 Qivigy J1599 Xembify J1558 Yimmugo J1599	1/1/26	
Signifor LAR J2502	Lanreotide J1932 Sandostatin LAR J2353 Somatuline Depot J1930	7/1/25	Applies to acromegaly diagnosis only
Saphnelo J0491	Benlysta IV J0490	7/1/25	
Vyepti J3032	Aimovig Emgality Nurtec ODT	7/1/25	
Evkeeza J1305	Repatha	7/1/25	
Leqvio J1306	Repatha	7/1/25	

Requested Product	Preferred Alternatives	Effective Date	Special Comment
Cinryze J0598	Haegarda	7/1/25	
Krystexxa J2507	Probenecid, AND Allopurinol	7/1/25	
Vyvgart Hytrulo J9334	Asceniv J1554 Alyglo J1552 BivigamJ1556 Cutaquig J1551 Cuvitru J1555 Flebogamma J1572 Gammagard Liquid J1569 Gammagard Liquid ERC J1569 Gammagard S/D J1566 Gammaked J1561 Gammaplex J1557 Gamunex-C J1561 Hizentra J1559 Hyqvia J1575 intravenous immune globulin J1599; J1566 Octagam J1568 Panzyga J1576 Privigen J1459 Qivigy J1599 Xembify J1558 Yimmugo J1553	7/1/25	Applies to CIDP diagnosis only
Rytelo J0870	Reblozyl J0896, AND Procrit J0885, OR Epogen J0885, OR Retacrit Q5106, OR Aranesp J0881	7/1/25	Applies to only MDS diagnosis with all of the following: EPO ≤ 500 mU/mL, no del(5q), ring sideroblasts <15% (or <5% with SF3B1 mutation)
Injectafer J1439	Feraheme Q0138 Ferrlecit J2916 InFed J1750 Venofer J1756	7/1/25	Does not apply to iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity

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Requested Product	Preferred Alternatives	Effective Date	Special Comment
Monoferric J1437	Feraheme Q0138 Ferrlecit J2916 InFed J1750 Venofer J1756	7/1/25	
Zilretta J3304	Triamcinolone J3301	7/1/25	
Piasky J1307	Ultomiris J1303	7/1/25	
Boruzu J9054	Bortezomib (dr. reddy's) J9046 Bortezomib (fresenius kabi) J9048 Bortezomib (hospira) J9049 Bortezomib (maia) J9051 Velcade J9041	7/1/25	
Pemfexy J9304 Pemrydi RTU J9324 Axtle J9292	Alimta J9305 Pemetrexed (hospira) J9294 Pemetrexed (accord) J9296 Pemetrexed (sandoz) J9297 Pemetrexed (teva) J9314 Pemetrexed (bluepoint) J9322 Pemetrexed ditromethamine J9323	7/1/25	
Ahzantive Q5150 Beovu J0179 Byooviz Q5124 Cimerli Q5128 Enzeevu Q5149 Eydenzelt J3590 Eylea J0178 Eylea HD J0177 Lucentis J2778 Opuviz Q5153 Pavblu Q5147 Susvimo J2779 Vabysmo J2777 Yesafili Q5155	Avastin C9257	2/1/25	
Imuldosa IV Q5098 Otulfi IV Q9999 Pyzchiva IV Q9997 Starjemza IV J3590 Stelara IV J3358 Wezlana IV Q5138 Ustekinumab IV J3358	Selarsdi IV Q9998 Steqeyma IV Q5099 Yesintek IV Q5100	2/1/25	

Requested Product	Preferred Alternatives	Effective Date	Special Comment
Alymsys Q5126 Avastin J9035 Avzivi J9999 Jobevne Q5160 Vegzelma Q5129	Mvasi Q5107 Zirabev Q5118	8/1/24	
Rituxan J9312 Rituxan Hycela J9311	Riabni Q5123 Ruxience Q5119 Truxima Q5115	8/1/24	
Herceptin J9355 Herceptin Hylecta J9356 Hercessi Q5146 Herzuma Q5113 Kanjinti Q5117	Ontruzant Q5112 Ogivri Q5114 Trazimera Q5116	8/1/24	
Durolane J7318 Gel-One J7326 Gelsyn-3 J7328 Genvisc - 850 J7320 Hyalgan J7328 Hymovis J7322 Monovisc J7327 Orthovisc J7324 Supartx FX J7321 Synojoynt J7331 Triluron J7332 Trivisc J7329 Visco-3 J7321	Euflexxa J7323, AND Synvisc J7325, OR Synvisc One J7325	8/1/24	
Avsola Q5121	Inflectra Q5103 Remicade J1745 Infliximab unbranded J1745 Renflexis Q5104	8/1/24	
Nyvepria Q5122 Rolvedon J1449 Ryzneuta J9361 Stimufend Q5127 Udenyca/Udenyca OnBody Q5111 Ziextenzo Q5120	Fulphila Q5108 Fylnetra Q5130 Neulasta J2506 Neulasta Onpro J2506	8/1/24	

Summary of Evidence:

This Medicare Part B Step Therapy policy allows use of the nonpreferred agent(s) in the case of a previous trial, documented intolerance, ineffective treatment response, FDA labeled contraindication or hypersensitivity to the cost-effective preferred agent(s). This policy applies to Medicare Advantage and Minnesota Senior Health Options (MSHO) lines of business only and requires a separate review of medical necessity criteria outlined in the appropriate Centers for Medicare and Medicaid Services (CMS) NCD, LCD, Article, and/or BCSMN medical drug policy.

Rationale:

Step therapy is a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self- administered and physician-administered drugs, are medically appropriate for a particular enrollee and are eligible for coverage under a health plan. Step therapy is a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost-effective drug therapy and progresses to other drug therapies if medically necessary. This Medicare Part B Step Therapy policy will allow use of the nonpreferred agent(s) in the case of a previous trial, documented intolerance, ineffective treatment response, FDA labeled contraindication or hypersensitivity to the cost-effective preferred agent(s).

In a memorandum titled “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage,” the Centers for Medicare and Medicaid Services (CMS) provides an overview of the utilization of step therapy for part B drugs. This new guidance recognizes that Medicare Advantage (MA) plans may apply step therapy to control the utilization of services in a manner that does not create an undue access barrier for beneficiaries. Specifically, CMS believes that appropriate patient engagement and care coordination services support appropriate pathways to access to Part B drugs such as step therapy. CMS strongly encourages that MA plans use their qualified pharmacy and therapeutics (P&T) committees to determine when it is medically appropriate to use step therapy for selected drugs in Part B.

42 CFR § 422.136 outlines the following rules/ regulations related to Medicare Advantage (MA) and step therapy for part B drugs:

(a) General. If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must -

(1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;

(2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.

(3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.

(b) Step therapy and pharmacy and therapeutic committee requirements. A MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, an MA-PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA-PD plan operated under the same contract as the MA plan. The P&T committee must -

(1) Include a majority of members who are practicing physicians or practicing pharmacists.

(2) Include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to -

(i) The MA organization and MA plan; and

(ii) Pharmaceutical manufacturers.

If a product is added as preferred agents to the policy. The clinical guidelines addressing the applicable products generally do not recommend any one agent over another. Given the noninferiority of these products, Blue Cross and Blue Shield of Minnesota will prefer the use of preferred products over other products. It must be noted that biosimilar products are equally effective and used for the same treatment as the FDA approved originator products.

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 August 31, 2018 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
- 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).
- Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
- National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
- U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/
- DHHS HPMS memo dated 11/5/2021, Subject: Off-Label use of Drugs in Medicare Advantage Step Therapy Programs
- CMS Memorandum titled “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage,” dated August 7, 2018. Available at https://www.cms.gov/Medicare/

HealthPlans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

Drug/Therapy Class	Change or update	Effective Date of Change
Document created on: 8/1/2024 Date of last document revision: 4/1/2026		
Trastuzumab IV	Update: added Hercessi to non-preferred category	11/1/24
Ophthalmic VEGF	Category added to document. Avastin preferred.	2/1/25
LA-GCSF	Added Rolvedon and Ryzneuta to non-preferred category	2/1/25
Ustekinumab	Added category with Stelara IV as preferred	2/1/25
Yesintek IV	Added to Ustekinumab non-preferred category	5/1/25
Steqeyma IV	Added to Ustekinumab non-preferred category	5/1/25
Alzheimer's disease	Added category with Leqembi preferred	5/1/25
Somatostatin	Added category with Signifor non-preferred	7/1/25
Gout	Added category with Krystexxa non-preferred	7/1/25
Lupus	Added category with Benlysta preferred	7/1/25
Chronic Migraine CGRP	Added category with Vyepti non-preferred	7/1/25
Hyperlipidemia	Added category with Repatha preferred	7/1/25
Hereditary Angioedema Prophylaxis	Added category with Cinryze non-preferred	7/1/25
Anemia MDS	Added category with Reblozyl preferred	7/1/25
Ustekinumab	Updated preferred IV products to: Stelara, Selarsdi, Yesintek, Steqeyma, and generics.	7/1/25
PNH	Prefer Ultomiris, non-preferred PiaSky	7/1/25
Pemetrexed	Non-preferred drugs are Pemfexy, Pemrydi RTU and Axtle	7/1/25
Bortezomib	Non-preferred product is Boruzu	7/1/25
Opuviz	New HCPCS Q5153	7/1/25
Steqeyma IV	New HCPCS Q5099	7/1/25
Imuldosa IV	New HCPCS Q5098	7/1/25
Yesintek IV	New HCPCS Q5100	7/1/25
IV Iron	Injectafer and Monoferric are non-preferred	7/1/25
Bevacizumab	Added Jobevne J9999 as non-preferred	8/1/25
Yesafili	New HCPCS Q5155	10/1/25
Ustekinumab	Added non-preferred product: Starjemza IV Move Stelara and unbranded Stelara to non-preferred.	1/1/26
IVIG	Category added: Asceniv/Alyglo non-preferred	1/1/26
Ryoncil	Ryoncil is non-preferred. Prefer Jakafi	1/1/26
Eculizumab	Soliris J1299 & Bkemv are non-preferred. Epysqli Q5151 is preferred. For all FDA-	1/1/26

	labeled shared indications. *see row below for gMG	
Rituximab	Riabni moved from non-preferred to preferred	1/1/26
Trastuzumab	Ogivri and Ontruzant moved from non-preferred to preferred. Kanjinti moved from preferred to non-preferred.	1/1/26
Denosumab	Added category with Jubbonti, Osenvelt, Stoboclo, and Wyost as preferred. Bomyntra, Conexxence, Ospomyv, Prolia, Xbryk and Xgeva as non-preferred.	1/1/26
gMG category	Place Imaavy and Bkemv as non-preferred with other non-preferred Soliris. Epysqli added as preferred option with Ultomiris.	1/1/26
Pegfilgrastim	Nyvepria moved to non-preferred. Fulphila and Fylnetra moved to preferred.	1/1/26
IV Iron	Added step exception – heart failure as defined in special comment column.	1/1/26
Imaavy	Update HCPCS to J9256 from J3590	1/1/26
Jobevne	Update HCPCS to Q5160 from J9999	1/1/26
Denosumab	Add Bilprevda and Bildyos to preferred. Add Aukelso J3590, Bosaya J3590, Enoby J3590, and Xtrenbo J3590 to non-preferred.	4/1/26
IVIG	Add Gammagard Liquid ERC J1599 & Qivigy J1599 to preferred.	4/1/26
Bevacizumab/Ocular	Add Eydenzelt J3590 to non-preferred	4/1/26
Aukelso	CMS HCPCS update to Q5161	4/1/26
Bosaya	CMS HCPCS update to Q5161	4/1/26
Bilprevda	CMS HCPCS update to Q5162	4/1/26
Bildyos	CMS HCPCS update to Q5162	4/1/26
Yimmugo	CMS HCPCS update to J1553	4/1/26
Denosumab	Separated Xgeva and biosimilars/Prolia and biosimilars	3/16/26
Alzheimer's	Removed category from document: Leqembi step no longer required.	3/16/26
Gammagard ERC	CMS HCPCS Update to J1569	4/1/26