Paramount 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.

Non-Preferred Product	Preferred Alternative Agent(s)	Effective Date	Special Comments
Avastin (J9035) Alymsys (Q5126) Avzivi (J9999) Vegzelma (Q5129)	Mvasi (Q5107) Zirabev (Q5118)	7/1/2020 8/1/2021 1/22/24	Step Therapy does not apply to ophthalmic indications
Durolane (J7318) Gel-One (J7326) Gelsyn-3 (J7328) Genvisc 850 (J7320) Hyalgan (J7321) Hymovis (J7322) Monovisc (J7327) Orthovisc (J7324) Supartz (J7321) Sodium hyaluronate/ Synojoynt(J7331) Triluron (J7332) Trivisc (J7329) Visco-3 (J7321)	Synvisc/Synvisc-One (J7325) Euflexxa (J7323)	3/1/2020	
Herceptin (J9355) Ontruzant (Q5112) Herzuma (Q5113) Ogivri (Q5114) Herceptin Hylecta (J9356) Hercessi (J9999)	Trazimera (Q5116) Kanjinti (Q5117)	7/1/2020 8/1/2021	

Non-Preferred Product	Preferred Alternative Agent(s)	Effective Date	Special Comments
Neupogen (J1442) Granix (J1447) Nivestym (Q5110) Leukine (J2820) Releuko (Q5125) Nypozi (J3590)	Zarxio(Q5101)	11/1/2020	
Procrit/Epogen (J0885)	Retacrit (Q5106)	11/1/2020	
Udenyca (Q5111) Nyvepria (Q5122) Ziextenzo (Q5120) Stimufend (Q5127) Fylnetra (Q5130) Ryzneuta (J9361) Rolvedon (J1449)	Fulphila (Q5108) Neulasta (J2506)	7/1/2020 4/15/24	
Rituxan (J9312) Truxima (Q5115) Rituxan Hycela (J9311)	Ruxience (Q5119) Riabni (Q5123)	7/1/2020 8/1/2021	Step therapy does not apply to pemphigus diagnosis
Beovu (J0179) Eylea (J0178) Lucentis (J2778) Opuviz (J3590) Yesafili (J3590) Eylea HD (J0177) Ahzantive (J3590) Enzeevu (J3590) Susvimo (J2779) Vabysmo (J2777)	Avastin (J9035/C9257)	7/1/2021 8/1/2022 8/1/2023	
Cimerli (Q5128) Byooviz (Q5124)	Avastin (J9035/C9257)		

Non-Preferred Product	Preferred Alternative Agent(s)	Effective Date	Special Comments
Prolia / Xgeva (J0897) Evenity (J3111) Jubbonti/Wyost (Q5136)	Zoledronic acid (J3489)	10/1/2021 4/15/24	***Evenity Step***: Therapy does not apply to patients with extremely low BMD (T<-3.5) or a T<-2.5 with a history of fragility fractures. ***Xgeva/Wyost only***: Does not apply to patients with metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC)
Zilretta (J3304)	Triamcinolone inj. (J3301)	10/1/2021	
Fusilev (J0641) Khapzory (J0642)	Leucovorin (J0640)	10/1/2021	
Sustol (J1627)	Granisetron (J1626) Ondansetron (J2405) Aloxi (J2469)	10/1/2021	Does not apply to Highly Emetogenic Chemotherapy Regimens
Abraxane (J9264)	Taxol (J9267)	10/1/2021	Does not apply to pancreatic adenocarcinoma

Non-Preferred Product	Preferred Alternative Agent(s)	Effective Date	Special Comments
Remicade (J1745) Infliximab (J1745) Inflectra (Q5103) Avsola (Q5121) Ixifi (Q5109) Entyvio (J3380) *Simponi Aria (J1602)		10/1/2021	*Does not apply to Polyarticular Juvenile Idiopathic Arthritis
**Cimzia (J0717)		1/1/2022	**Does not apply for non-radiographic axial spondylarthritis
Actemra (J3262) Ilumya (J3245) Orencia (J0129) Stelara (J3358)	Renflexis (Q5104)	8/1/2022	
Wezlana (Q5137)		12/1/2023	
Otulfi IV (J3590)			
Tyenne (Q5135) Tofidence (Q5133) Selarsdi (Q9998) Pyzchiva (Q9996/Q9997)		4/15/2024 5/23/2024	
Treanda (J9033)	Bendeka (J9034) OR Belrapzo (J9036)	1/1/2022	
Ocrevus (J2350) Ocrevus Zunovo (J3590)	Generic glatiramer acetate (Part D)	1/1/2022	For relapsing multiple sclerosis: Step through generic glatiramer acetate

Non-Preferred Product	Preferred Alternative Agent(s)	Effective Date	Special Comments
Pemfexy (J9304) Pemrydi RTU (J9324)	Alimta (J9305) Pemetrexed (J9314, J9294, J9296, J9297, J9322, J9323, J9292)	9/1/2023	
Soliris (J1300) Bkemv (Q5139) Epysqli (J3590)	Ultomiris (J1303)	1/1/2022	***Atypical Hemolytic Uremic Syndrome (aHUS) & Paroxysmal Nocturnal Hemoglobinuria (PNH):*** Step through Ultomiris
	Ruxience (Q5119) or Riabni (Q5123) or Uplizna (J1823) or Enspryng (J3590)		***Neuromyelitis Optica Spectrum Disorders (NMOSD):*** Step through Ruxience, Riabni, Uplinza, Enspryng
	Ultomiris (J1303) or Vyvgart (J9332) or Vyvgart Hytrulo (J9334) or Rystiggo (J9333), or Zilbrysq (J3490)	1/1/2025	***Myasthenia Gravis:*** Step through Ultomiris, Vyvgart, Vyvgart Hytrulo, Rystiggo or Zilbrysq

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/

Drug/Therapy Class	Change or Update	Effective Date
NA	Reformatted & Moved to Prime Template	**1/1/2025**
Cimerli, Selarsdi, Pyzchiva, Bkemv	Update HCPCS Codes	**1/9/2025**