Step Therapy Requirements for Medicare Outpatient (Part B) Medications

The medications in the table below need step therapy. But, they'll need to meet the following criteria:

- The medication is a Medicare Part B drug.
- The medication is a new drug for the member, meaning they haven't used it in the last 365 days.
- The drug is being used to treat a medically accepted indication under Medicare rules.
- The dose, frequency and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication.

Requested Product	Codes	Preferred Alternative Agent(s)	Codes
Bendamustine Products			
Vivimusta®	J9056	Bendeka® or Belrapzo® or Treanda®	J9034 J9036 J9033
Retinal Disorder Agents - Age Related Macular Degeneration (AMD)		**» For Age Related Macular Degeneration (AMD) -**	
Beovu®	J0179		
Byooviz®	Q5124		
Cimerli®	Q5128		
Eylea®	J0178	Avastin®	J9035/C9257
Eylea® HD	J0177		
Lucentis®	J2778		
Vabysmo®	J2777		
Visudyne®	J3396		
Retinal Disorder Agents - Diabetic Macular Edema (DME) / Diabetic Retinopathy (DR)			
Eylea®	J0178	Avastin® or	J9035/C9257
Eylea® HD	J0177	Lucentis®	J2778

Requested Product	Codes	Preferred Alternative Agent(s)	Codes
Bevacizumab Products		**» For oncology Indications only -**	
Alymsys®	Q5126	Mvasi® or	Q5107
Avastin®	J9035	Zirabev™	Q5118
Vegzelma®	Q5129		
Lysosomal Storage Disorder Agents			
VPRIV®	J3385	Cerezyme™ or Elelyso®	J1786 J3060
Hemlibra®	J7170	Xyntha® or Feiba®	J7185 J7198
HP Acthar Cortrophin Gel	J0801 J0802	**» For all indications except infantile spasms -** corticosteroids	 various
Hyaluronic Acid Derivatives			
Durolane®	J7318		
Gel-One®	J7326		
Gelsyn™	J7328		
GenVisc® 850	J7320		
Hyalgan®	J7321		
Hymovis®	J7322		
Monovisc®	J7327	Synvisc®/Synvisc One® or Euflexxa®	J7325
Orthovisc®	J7324		J7323
Supartz FX®	J7321		
Synojoynt™	J7331		
Triluron®	J7332		
TriVisc®	J7329		
Visco-3®	J7321		
Infliximab Products			
Avsola®	Q5121	Remicade®/infliximab or	J1745
Renflexis®	Q5104	Inflectra®	Q5103
Long-acting Growth Colony Stimulating Products		**» Does not apply for patients using a pegfilgrastim biosimilar or Rolvedon™ for any indication not shared with Fulphila® or Neulasta®**	
Fylnetra®	Q5130	Fulphila® or	Q5108
Nyvepria™	Q5122	Neulasta®/Neulasta® Onpro®	J2506
Rolvedon™	J1449		
Stimufend®	Q5127		
Udenyca®/Udenyca® ONBODY™	Q5111		
Ziextenzo®	Q5120		

Requested Product	Codes	Preferred Alternative Agent(s)	Codes
Evenity™	J3111	Prolia® or zoledronic acid 5 mg	J0897 J3489
Xgeva™	J0897	**» For hypercalcemia of malignancy** pamidronate or zoledronic acid 4mg	 J2430 J3489
Rituximab Products		**» For Rituxan®, step therapy does not apply for Pemphigus Vulgaris -**	
Riabni™	Q5123		
Rituxan®	J9312	Truxima® or Ruxience®	Q5115 Q5119
Rituxan Hycela®	J9311		
PiaSky®	J1307	Ultomiris®	J1303
Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical hemolytic-uremic syndrome (aHUS)			
Soliris®	J1299	Ultomiris®	J1303
Generalized Myasthenia Gravis			
Soliris®	J1299	Vyvgart® or Vyvgart® Hytrulo	J9332 J9334
Neuromyelitis optica spectrum disorder (NMOSD)			
Soliris®	J1299	Rituximab products or Uplizna™	J9312/ Q5115/ Q5119/ Q5123 J1823
Somatostatin Analogues		**» For all indications except Cushing's Disease -**	
Signifor® LAR	J2502	Somatuline Depot® or	J1930
Lanreotide Acetate	J1932	Sandostatin LAR®	J2353
Trastuzumab Products			
Herceptin®	J9355		
Herceptin Hylecta™	J9356		
Hercessi™	Q5146	Trazimera® or Kanjinti®	Q5116 Q5117
Herzuma®	Q5113		
Ogivri®	Q5114		
Ontruzant®	Q5112		

Exceptions

Members (enrollees) may request an exception from the plan's step therapy requirement to access a Part B covered drug, which is reviewed through our organization's determination process.

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, Health Plan Management System (HPMS), Off-Label use of Drugs in Medicare Advantage Step Therapy Programs; available at http://www.cms.gov - last checked November 5, 2021 and found under Medicare > Research, Statistics, Data & Systems > Health Plan Management System (HPMS) > HPMS Memos Archive – Weekly.
- 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. https://www.cms.gov/medicare-coverage-database/search.aspx.
- National Coverage Determination (NCD). Centers for Medicare & Medicare Services. https://www.cms.gov/medicare-coverage-database/search.aspx.
- U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/