

Step Therapy requirements for Medicare outpatient (Part B) medications

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Articles may exist and compliance with these policies is required where applicable. Step Therapy will be required for the medications listed in the table below effective 1/1/2022, provided the following are met for the requested drug:

- Meets the definition of a Medicare Part B medication.
- New for the patient, as defined by no use in the last 365 days.
- Proposed use of the requested and alternative drug has been determined to be a medically accepted indication under Medicare rules.
- Dose, frequency and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication.

Non-Preferred Drug	HCPCS Code	Preferred Drug	HCPCS Code	Special Comment
Aloxi/palonosetron	J2469	Kytril/ ondansetron	J1626/J2405	Regimens of moderately emetogenicity or less
Avastin/Alymsys/ Vegzelma/Avzivi	J9035/Q5126/ Q5129/J9999	Mvasi/ Zirabev	Q5107/Q5118	Oncology use only
Fusilev	J0641	Leucovorin	J0640	
Khapzory	J0642	Leucovorin	J0640	
Herceptin/Herceptin Hylecta/Ontruzant/ Herzuma/Kanjinti/ Hercessi	J9355/J9356/ Q5112/Q5113/ Q5117/	Trazimera/ Ogivri	Q5116/Q5114	
HP Acthar	J0800	Corticosteroids	multiple	Exclude for patients with West Syndrome
Neulasta/Ziextenzo/ Udenyca/Flyneta/ Stimufend/Rolvedon /Ryzneuta	J2506/Q5120/ Q5111/Q5130/ Q5127/J1449/J3590	Nyvepria/ Fulphila	Q5122/Q5108	
Neupogen/Nivestym /Granix/Releuko	J1442/Q5110/J1447 /Q5125	Zarxio	Q5101	

Procrit/Epogen (non-ESRD)	J0885	Retacrit (non-ESRD)	Q5106	
Eylea/Ahzantive/Opuviz/Yesafili	J0178/J3590	Avastin - Ophthalmic	C9257/J9035	
Lucentis	J2778	Avastin - Ophthalmic	C9257/J9035	
Macugen	J2503	Avastin - Ophthalmic	C9257/J9035	
Beovu	J0179	Avastin - Ophthalmic	C9257/J9035	
Susvimo	J2779	Avastin - Ophthalmic	C9257/J9035	
Vabysmo	J2777	Avastin – Ophthalmic AND Eylea	C9257/J9035/J0178	
Byooviz	Q5124	Avastin – Ophthalmic	C9257/J9035	
Cimerli	Q5128	Avastin - Ophthalmic	C9257/J9035	
Eylea HD	J0177	Eylea	J0178	
Rituxan/Rituxan Hycela/Riabni	J9312/J9311/Q5123	Truxima/Ruxience	Q5115/Q5119	
Sustol	J1627	Kytril/ ondansetron/ Aloxi/ palonosetron	J2405/J1626/ J2469	Moderate emetogenicity or less
Vivimusta/ bendamustine (Apotex)/ bendamustine (Baxter)	J9056/J9058/J9059	Belrapzo/ Bendeka/ Treanda	J9036/J9034/J9033	
Prolia/Xgeva Wyost/Jubbonti	J0897/Q5136	Zoledronic acid	J3489	Exclude patients with metastatic breast and metastatic prostate per clinical data
Zilretta	J3304	Triamcinolone inj.	J3301	

Fereheme	Q0138	Venofer/Infed/ Ferrlecit	J1756/J1750/ J2916	
Injectafer	J1439	Venofer/Infed/ Ferrlecit	J1756/J1750/ J2916	
Infugem	J9199	Gemcitabine	J9201	
Marqibo	J9371	Vincristine	J9370	
Monoferric	J1437	Venofer/Infed/ Ferrlecit	J1756/J1750/ J2916	
Remicade/ infliximab/Renflexis	J1745/Q5104	Inflectra/Avsola	Q5103/Q5121	
Durolane/Gel- One/GelSyn3/ GenVisc 850/Hyalgan/ Hymovis/Monovisc/ Orthovisc/sodium hyaluronate/ Supartz/Supartz FX/ Synojoynt/Synvisc/ Synvisc-One/ Trivisc/VISCO- 3/Triluron	J7318/J7326/J7328/ J7320/J7321/J7322/ J7327/J7324/J3490/ J7331/J7325/J7329/ J7332	Euflexxa	J7323	
Soliris/Epysqli/ Bkemv	J1300/J3590	PNH/aHUS – Ultomiris NMOSD – Uplizna/Ruxience/ Truxima/Enspryng AChR+ gMG – Vyvgart HD/ Rystiggo/Vyvgart/	J1303/J1823/ Q5115/Q5119/ J9332/J3590	For shared FDA approved indications only
Ultomiris	J1303	AChR+ gMG – Vyvgart Hytrulo/ Rystiggo/Vyvgart/	J9334/J9333/ J9332	
Leqvio	J1306	Praluent/Repatha	Medicare Part D	
Saphnelo	J0491	Benlysta	J0490	
Tyruko	Q5134	Tysabri	J2323	
Pemfexy	J9304	Alimta/pemetrexe d	J9305/J9314/J92 94/J9296/J9297/J	

			9323/J9321/J932 2	
OmvoH	J2267	Xeljanz/Rinvoq/ Stelara/Pyzchiva/ Selarsdi/Humira/ Hadlima	Medicare Part D	

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/>