Security Health Plan 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 an outpatient 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
- Step therapy does not apply to patients using a non-preferred product if an indication is not shared by the preferred product or is not supported by treatment guidelines or clinical literature

Requested Product	Preferred Alternative Agent(s)	Go-live date	Special Comments
Epogen/Procrit (J0885)	Retacrit (Q5106)	5/1/2019	This requirement is waived if the preferred agent is in shortage
Eylea(J0178), Lucentis (J2778), Macugen (J2503)	Avastin – *ophthalmic use only* (C9257)	5/1/2019	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.
Beovu (J0179)	Avastin – *ophthalmic use only* (C9257)	4/1/2020	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.
Neupogen (J1442), Nivestym (Q5110), Releuko (Q5125)	Granix (J1447), Zarxio (Q5101)	4/1/2020	Granix is not indicated for treatment of severe chronic symptomatic neutropenia (cyclic, congenital, or idiopathic) for a patient not on chemotherapy

Aloxi (J2469)	Kytril (J1626), Zofran (J2405)	4/1/2020	Step therapy requirements **DO NOT APPLY** to chemotherapy regimens considered highly emetogenic.

Avastin – *for oncology indications only* (J9035), Alymsys (Q5126), Vegzelma (Q5129)	Mvasi (Q5107), Zirabev (Q5118)	4/1/2020	N/A
Fusilev (J0641), Khapzory (J0642)	Leucovorin (J0640)	4/1/2020	N/A
Herceptin (J9355)	Ontruzant (Q5112), Herzuma (Q5113), Ogivri (Q5114), Trazimera (Q5116), Kanjinti (Q5117)	4/1/2020	N/A
Herceptin Hylecta (J9356)	Ontruzant (Q5112), Herzuma (Q5113), Ogivri (Q5114), Trazimera (Q5116), Kanjinti (Q5117)	4/1/2020	N/A
Sustol (J1627)	Aloxi (J2469), Kytril (J1626), Zofran (J2405)	4/1/2020	N/A
Treanda (J9033); Vivimusta (J9056); Bendamustine (J9058), Bendamustine (J9059), Bendamustine (J9999)	Belrapzo (J9036), Bendeka (J9034)	4/1/2020	Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications: Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen.
Xgeva (J0897)	Zoledronic acid (J3489)	4/1/2020	Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications: • Hypercalcemia of malignancy • Skeletal-related events in patients with bone metastases from metastatic breast and metastatic castration-resistant prostate cancers
Zilretta (J3304)	Kenalog (J3301)	4/1/2020	N/A
Ziextenzo (Q5120) Nyvepria (Q5122) Fylnetra (Q5130) Stimufend(Q5127) Rolvedon (J1449)	Neulasta (J2506), Udenyca (Q5111), Fulphila (Q5108)	2020	N/A

Rituxan (J9312), Ruxience (Q5119)	Truxima (Q5115), Riabni (Q5123)	6/1/2021	Step therapy requirements **DO NOT APPLY** to pemphigus diagnosis
Rituxan Hycela (J9311)	Truxima (Q5115), Riabni (Q5123)	6/1/2021	Step therapy requirements **DO NOT APPLY** to pemphigus diagnosis
Remicade (J1745), Infliximab (J1745), Inflectra (Q5103), Avsola (Q5121)	Renflexis (Q5104)	8/1/2021	N/A

Abraxane (J9264)	Taxol (J9267)	1/1/2022	Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications : • Pancreatic Adenocarcinoma • Non-small cell lung cancer (NSCLC) when used as first-line treatment in combination with
			carboplatin for locally advanced or metastatic disease in patients who are not candidates for curative surgery or radiation therapy • Breast Cancer when used after failure of combination chemotherapy (which should have included an anthracycline) for metastatic disease or relapse within 6 months of adjuvant chemotherapy
Asceniv (J1554)	Bivigam(J1556) Carimune NF (J1566) Flebogamma (J1572) Gamunex-C (J1561) Gammagard Liquid(J1569) Gammagard S/D (J1566) Gammaked (J1561) Gammaplex (J1557) Octagam (J1568) Privigen (J1459) Panzyga (J1599) IV, immune globulin (J1599)	1/1/2022	N/A
Byooviz (Q5124)	Avastin- *ophthalmic use only* (C9257)	4/1/2022	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.
Susvimo (J2779)	Avastin- *ophthalmic use only* (C9257)	4/1/2022	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.

Vabysmo (J2777)	Avastin- *ophthalmic use only* (C9257)	7/1/2022	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.
Injectafer (J1439) Feraheme (Q0138) Monoferric (J1437)	Venofer (J1756) Infed (J1750) Ferrlecit (J2916)	10/1/2022	
Durolane (J7318) Euflexxa (J7323) Gelsyn-3 (J7328) Genvisc 850 (J7320) Hymovis (J7322) Monovisc (J7327) Orthovisc (J7324) Supartz (J7321) Sodium hyaluronate/ Synojoynt (J7331) Synvisc/Synvisc-One (J7325) Triluron (J7332) Trivisc (J7329) Visco-3 (J7321)	Gel-One (J7326) Hyalgan (J7321)	1/1/2023	
Cimerli (Q5128)	Avastin – ophthalmic use only (C9257)	1/1/2023	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in **EITHER EYE** prior to consideration of a nonpreferred product.

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 May 1, 2020 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
- Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 10002, Chapter 15, Sec. 50 (Rev. 241, Feb. 2, 2018); available at http://www.cms.gov - last checked May 1, 2020 and found under Medicare > Regulations and Guidance > Manuals > InternetOnly 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/