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 effective **8/1/2021**, 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
- The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days)

Requested Product	Preferred Alternative Agent(s)	Go-live date	Special Comments
Epogen/Procrit (J0885)	Retacrit (Q5106)	5/1/2019	N/A
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 non-preferred 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 non-preferred product.
Neupogen (J1442), Nivestym (Q5110)	Granix (J1447), Zarxio (Q5101)	4/1/2020	N/A
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)	Mvasi (Q5107), Zirabev (Q5118)	4/1/2020	Step therapy requirements **DO NOT APPLY** to the follow FDA-approved indications: • Metastatic colorectal cancer: ○ In combo w/ intravenous fluorouracil-based chemo for 2nd-line treatment. ○ In combo w/ fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemo for 2nd-line treatment in patients who have progressed on a 1st-line Avastin-containing regimen.
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
Requested Product	**Preferred Alternative Agent(s)**	**Go-live date**	**Special Comments**
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)	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)	Neulasta (J2505), Udenyca (Q5111), Fulphila (Q5108)	7/17/2020	N/A
Nyvepria (Q5122)	Neulasta (J2505), Udenyca (Q5111), Fulphila (Q5108)	12/1/2020	N/A
Rituxan (J9312), Ruxience (Q5119)	Truxima (Q5115), Riabni (Q5123)	6/1/2021	Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications: • Non-Hodgkin's Lymphoma (NHL): ○ Follicular, CD-20 positive, B-cell NHL in patients achieving a complete or partial response to a rituximab product in combo w/ chemo, as single-agent maintenance therapy. ○ Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after 1st-line cyclophosphamide, vincristine, and prednisone (CVP) chemo. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately to severely-active RA who have inadequate response to one or more TNF antagonist therapies.
Rituxan Hycela (J9311), Ruxience (Q5119)	Truxima (Q5115), Riabni (Q5123)	6/1/2021	Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications: • Non-Hodgkin's Lymphoma (NHL): ○ Follicular, CD-20 positive, B-cell NHL in patients achieving a complete or partial response to a rituximab product in combo w/ chemo, as single-agent maintenance therapy. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after 1st-line cyclophosphamide, vincristine, and prednisone (CVP) chemo.
Remicade (J1745), Inflectra (J5103), Avsola (J5121)	Renflexis (J5104)	8/1/2021	N/A

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. 100-02, 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 > 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/