

# 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)

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 – <i>ophthalmic use only</i> (C9257)	5/1/2019	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in <b>EITHER EYE</b> prior to consideration of a nonpreferred product.
Beovu (J0179)	Avastin – <i>ophthalmic use only</i> (C9257)	4/1/2020	Patient must try and have an inadequate response, contraindication, or intolerance to an adequate trial of bevacizumab in <b>EITHER EYE</b> prior to consideration of a nonpreferred 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 <b>DO NOT APPLY</b> to chemotherapy regimens considered highly emetogenic.

Avastin – <i>for oncology indications only</i> (J9035)	Mvasi (Q5107), Zirabev (Q5118)	4/1/2020	Step therapy requirements <b><u>DO NOT APPLY</u></b> to the following FDA approved indications: Metastatic colorectal cancer: <ul style="list-style-type: none"> <li>In combo w/ intravenous fluorouracil-based chemo for 2<sup>nd</sup>-line treatment.</li> <li>In combo w/ fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemo for 2<sup>nd</sup>line treatment in patients who have progressed on a 1<sup>st</sup>-line Avastin-containing regimen.</li> </ul>
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)	Belrapzo (J9036), Bendeka (J9034)	4/1/2020	Step therapy requirements <b><u>DO NOT APPLY</u></b> to the following FDA-approved indications: <ul style="list-style-type: none"> <li>Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen.</li> </ul>
Xgeva (J0897)	Zoledronic acid (J3489)	4/1/2020	Step therapy requirements <b><u>DO NOT APPLY</u></b> to the following FDA-approved indications: <ul style="list-style-type: none"> <li>Hypercalcemia of malignancy</li> <li>Skeletal-related events in patients with bone metastases from metastatic breast and metastatic castration-resistant prostate cancers</li> </ul>
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 <b><u>DO NOT APPLY</u></b> to the following FDA-approved indications: Non-Hodgkin’s Lymphoma (NHL): <ul style="list-style-type: none"> <li>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.</li> </ul>

			<ul style="list-style-type: none"> <li>Non-progressing (including stable disease), low grade, CD20-positive, B-cell NHL as a single agent after 1<sup>st</sup>-line cyclophosphamide, vincristine, and prednisone (CVP) chemo.</li> </ul> <p>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.</p>
Rituxan Hycela (J9311), Ruxience (Q5119)	Truxima (Q5115), Riabni (Q5123)	6/1/2021	<p>Step therapy requirements <b>DO NOT APPLY</b> to the following FDA-approved indications:</p> <p>Non-Hodgkin’s Lymphoma (NHL):</p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p>Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after 1<sup>st</sup>-line cyclophosphamide, vincristine, and prednisone (CVP) chemo.</p>
Remicade (J1745), Inflectra (J5103), Avsola (J5121)	Renflexis (J5104)	8/1/2021	N/A
Abraxane (J9264)	Taxol (J9267)	1/1/2022	<p>Step therapy requirements <b>DO NOT APPLY</b> to the following FDA-approved indications :</p> <ul style="list-style-type: none"> <li>Pancreatic Adenocarcinoma</li> <li>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</li> <li>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</li> </ul>
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

## 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/>

