# 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 a Medicare outpatient (Part B) 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**
- The requested product is necessary for treating the enrollee's condition as the preferred drug(s) has(have) been or is(are) likely to be less effective or have adverse effects. **AND**
- When there are multiple preferred drugs, unless otherwise specified, only one is required prior to approval of the non-preferred drug;

| Requested Product (Non-Preferred) | Preferred Alternative Agent(s) | Effective Date | Special Comments |
|---|---|---|---|
| **Eylea (J0178)**<br>**Lucentis (J2778)**<br>**Beovu (J0179)**<br>**Byooviz (Q5124)**<br>**Susvimo (J2779)**<br>**Vabysmo (J2777)**<br>**Cimerli (Q5128)**<br>**Eylea HD (J0177)**<br>**Yesafili (J3590)**<br>**Opuviz (Q5153)**<br>**Ahzantive (Q5150)**<br>**Pavblu (Q5147)**<br>**Enzeevu (Q5149)** | Avastin – *ophthalmic use only*<br>(C9257) | 5/1/2019 | Patient must try and have an inadequate response (defined as 3 injections in either eye with minimal to no improvement), clinically significant adverse effects, or contraindication to Avastin (bevacizumab) prior to consideration of a non-preferred product. Documentation of contraindication, adverse events, or date(s) of failed therapy to Avastin (bevacizumab) required. |

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| **Nufymco (Q5168)** | | | |
| **Avastin (J9035)**<br>**Alymsys (Q5126)**<br>**Vegzelma (Q5129)**<br>**Avzivi (J9999)**<br>**Jobevne (Q5160)**<br>***for oncology indications only** | Mvasi (Q5107)<br>Zirabev (Q5118) | 4/1/2020 | N/A |
| **Fusilev (J0641)**<br>**Khapzory (J0642)** | Leucovorin (J0640) | 4/1/2020 | N/A |
| **Herceptin (J9355)**<br>**Ontruzant (Q5112)**<br>**Herzuma (Q5113)**<br>**Trazimera (Q5116)**<br>**Hercessi (Q5146)** | Ogivri (Q5114)<br>Kanjinti (Q5117) | 4/1/2020 | N/A |
| **Herceptin Hylecta (J9356)** | Ogivri (Q5114)<br>Kanjinti (Q5117) | 4/1/2020 | N/A |
| **Sustol (J1627)** | Aloxi (J2469)<br>Kytril (J1626)<br>Zofran (J2405) | 4/1/2020 | N/A |
| **Vivimusta (J9056)**<br>**Belrapzo/bendamustine (J9036)**<br>**Bendeka (J9034)** | Treanda (J9033) | 4/1/2020 | Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications:<br>Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen. |
| **Zilretta (J3304)** | Kenalog (J3301) | 4/1/2020 | N/A |
| **Rituxan (J9312)**<br>**Ruxience (Q5119)** | Truxima (Q5115)<br>Riabni (Q5123) | 6/1/2021 | Step therapy requirements **DO NOT APPLY** to pemphigus diagnosis. |
| **Rituxan Hycela (J9311)** | Truxima (Q5115)<br>Riabni (Q5123) | 6/1/2021 | Step therapy requirements **DO NOT APPLY** to pemphigus diagnosis. |
| **Remicade (J1745)**<br>**Infliximab (J1745)**<br>**Inflectra (Q5103)** | Renflexis (Q5104)<br>Avsola (Q5121) | 8/1/2021 | N/A |
| **Abraxane (J9264)**<br>**Paclitaxel Protein-Bound (J9264)** | Taxol (J9267) | 1/1/2022 | Step therapy requirements **DO NOT APPLY** to the following FDA-approved indications:<br>• Pancreatic Adenocarcinoma<br>• Non-small cell lung cancer (NSCLC) when used as first-line treatment in combination with carboplatin for locally advanced or metastatic |



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| | | | disease in patients who are not candidates for curative surgery or radiation therapy<br>• 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)<br>Carimune NF (J1566)<br>Flebogamma (J1572)<br>Gamunex-C (J1561)<br>Gammagard Liquid (J1569)<br>Gammagard S/D (J1566)<br>Gammaked (J1561)<br>Gammaplex (J1557)<br>Octagam (J1568)<br>Privigen (J1459)<br>Panzyga (J1576)<br>IV immune globulin (J1599)<br>Alyglo (J1552)<br>Yimmugo (J1599) | 1/1/2022 | N/A |
| **Durolane (J7318)**<br>**Euflexxa (J7323)**<br>**Gelsyn-3 (J7328)**<br>**Genvisc 850 (J7320)**<br>**Hymovis (J7322)**<br>**Monovisc (J7327)**<br>**Orthovisc (J7324)**<br>**Supartz /Supartz FX(J7321)**<br>**Synojoynt (J7331)**<br>**Synvisc/Synvisc-One (J7325)**<br>**Triluron (J7332)**<br>**Trivisc (J7329)**<br>**Visco-3 (J7321)** | Gel-One (J7326)<br>Hyalgan (J7321) | 1/1/2023 | N/A |
| **Omvoh (J2267)** | Preferred adalimumab product (Humira® or biosimilar*), tofacitinib (Xeljanz® IR/XR), upadacitinib (Rinvoq®), ustekinumab (Stelara®)<br>*Preferred Humira biosimilar(s) are subject to change | 7/1/2024 | Patient has had a clinical trial, inadequate response, or valid contraindication to TWO preferred agents. |
| **Cinqair (J2786)** | Fasenra (J0517)<br>Nucala (J2182) | 1/1/2025 | N/A |
| **Exdensur (J2361)** | Fasenra (J0517)<br>Nucala (J2182)<br>Cinqair (J2786) | 8/1/2026 | Patient has had a clinical trial, inadequate response, or valid contraindication to ALL three preferred agents. |



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| **Vyepti (J3032)** | Aimovig (erenumab)<br>Ajovy (fremanezumab)<br>Emgality (galcanezumab)<br>Qulipta (atogepant)<br>Nurtec ODT (rimegepant) | 7/1/2025 | N/A |
| **Evkeeza (J1305)**<br>**Leqvio (J1306)** | Praluent (alirocumab)<br>Repatha (evolocumab) | 7/1/2025 | N/A |
| **Krystexxa (J2507)** | allopurinol AND febuxostat | 7/1/2025 | N/A |
| **Benlysta IV (J0490)**<br>**Saphnelo (J0491)** | Benlysta (belimumab) subQ | 7/1/2025 | N/A |
| **Axtle (J9292)**<br>**Pemfexy (J9304)**<br>**Pemrydi RTU (J9324)** | Alimta (J9305)<br>Pemetrexed - accord (J9296)<br>Pemetrexed - bluepoint(J9322)<br>Pemetrexed - hospira (J9294)<br>Pemetrexed - sandoz (J9297)<br>Pemetrexed - teva (J9314)<br>Pemetrexed ditromethamine (J9323)<br>Pemetrexed (J9999) | 7/1/2025 | N/A |
| **Soliris (J1299)**<br>**Bkemv (Q5152)** | Epysqli (Q5151) AND Ultomiris (J1303) | 10/1/2025 | For Neuromyelitis Optica Spectrum Disorder patient has had a clinical trial, inadequate response, or valid contraindication to Ultomiris only. For all other indications Ultomiris and Epysqli steps are required |
| **Prolia (J0897)**<br>**Conexxence/denosumab-bnht (Q5158)**<br>**Ospomyv/denosumab-dssb (Q5159)**<br>**Bildyos (Q5162)**<br>**Denosumab-bmwo (Q5157)**<br>**Boncresa (Q5171)**<br>**Bosaya (Q5161)**<br>**Enoby (Q5167)**<br>**Denosumab-bbdz (Q5136)**<br>**Osvyrti (Q5166)** | Jubbonti (Q5136)<br>Stoboclo (Q5157) | 4/1/2026 | Patient has had a clinical trial, inadequate response, or valid contraindication to TWO preferred agents |
| **Xgeva (J0897)**<br>**Bilprevda (Q5162)**<br>**Bomyntra/denosumab-bnht (Q5158)**<br>**Xbryk/denosumab-dssb (Q5159)**<br>**Denosumab-bmwo (Q5157)**<br>**Aukelso (Q5161)**<br>**Denosumab-bbdz (Q5136)**<br>**Jubereq (Q5166)**<br>**Oziltus (Q5165)**<br>Xtrenbo (Q5167) | Wyost (Q5153)<br>Osenvelt (Q5157) | 4/1/2026 | Patient has had a clinical trial, inadequate response, or valid contraindication to TWO preferred agents |
| **Actemra (J3262)**<br>**tocilizumab-anoh (Q5156)**<br>**Tofidence (Q5135)**<br>**Tocilizumab-aazg (Q5133)** | Tyenne (Q5133)<br>Avtozma (Q5156) | 5/1/2026 | Patient has had a clinical trial, inadequate response, or valid contraindication to TWO preferred agents |



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## References


1. 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.
2. 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).
3. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
4. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
5. U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/


| Drug/Therapy Class | Change or Update | Effective Date |
|---|---|---|
| **Exdensur (J2361)** | Require T/F of Nucala (J2182), Fasenra (J0517), and Cinqair (J2786) | **8/1/2026** |
| **Tocilizumab** | Add Avtozma as preferred product | **8/1/2026** |
| **Xgeva (J0897)** | Remove T/F of Zoledronic Acid | **8/1/2026** |
| **Prolia (J0897)** | Add Boncresa (Q5171), Bosaya (Q5161), Enoby (Q5167), denosumab-bbdz (Q5136), Osvyrti (Q5166) as non-preferred | **8/1/2026** |
| **Xgeva (J0897)** | Add Aukelso (Q5161), Denosumab-bbdz (Q5136), Jubereq (Q5166), Oziltus (Q5165), Xtrenbo (Q5167) as non-preferred | **8/1/2026** |
| **IV Irons** | Injectafer (J1439), Feraheme (Q0138), and Monoferric (J1437) were removed from PA and ST requirements | **6/1/2026** |
| **Posfrea (J2468)** | Removed from PA & ST requirements | **6/1/2026** |
| **Actemra (J3262) & biosimilars** | Require T/F of Tyenne | **5/1/2026** |
| **Prolia (J0897) & biosimilars** | Require T/f of Stoboclo (Q5137) and Jubbonti (Q5136) | **4/1/2026** |
| **Xgeva (J0897) & biosimilars** | Require T/F of Osenvelt (Q5137) and Wyost (Q5136) | **4/1/2026** |
| **Aloxi (J2469)** | Remove requirement of T/F Kytril (J1626) and/or Zofran (J2405) | **3/10/2026** |
| **Filgrastim** | Remove Step Therapy from class | **1/1/2026** |
| **Pegfilgrastim** | Remove Step Therapy from class | **1/1/2026** |
| **Soliris (J1299)**<br>**Bkemv (Q5152)** | Require T/F of Epysqli (Q5151) AND Ultomiris (J1303). For NMOSD only step through Ultomiris required | **10/1/2025** |
| **Jobevne (J9999)** | Add to non-preferred bevacizumab products. Require T/F of Mvasi (Q5107) or Zirabev (Q5118) | **10/1/2025** |



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| **Vyepti (J3032)** | Require T/F of any of the preferred products Aimovig (erenumab) Ajovy (fremanezumab) Emgality (galcanezumab) Qulipta (atogepant) Nurtec ODT (rimegepant) | **7/1/2025** |
| **Evkeeza (J1305)**<br>**Leqvio (J1306)** | Require T/F of Repatha (evolocumab) or Praluent (alirocumab) | **7/1/2025** |
| **Krystexxa (J2507)** | Require T/F of allopurinol and febuxostat | **7/1/2025** |
| **Benlysta IV (J0490)**<br>**Saphnelo (J0491)** | Require T/F of Benlysta (belimumab) subQ | **7/1/2025** |
| **Bendamustine products** | Require a trial of Treanda (J9033) | **7/1/2025** |
| **Axtle (J9292)**<br>**Pemfexy (J9304)**<br>**Pemrydi RTU (J9324)** | Require a trial of preferred pemetrexed products | **7/1/2025** |
| **Posfrea (J2468)** | Requires a trial of Aloxi (J2469) | **7/1/2025** |
| **GCSF-SA** | Added Nypozi (Q5148) to non-preferred products | **7/1/2025** |
| **IVIG** | Added Yimmugo (J1599) to preferred products | **7/1/2025** |
| **Epogen/Procrit (J0885)** | Remove ST requirement | **4/1/2025** |
| **Cinqair (J2786)** | Require T/F of Fasenra (J0517) or Nucala (J2182) | **1/1/25** |
| **Ahzantive (J3590)**<br>**Pavblu (3590)**<br>**Enzeevu (J3590)** | Require T/F of Avastin ophthalmic | **1/1/25** |
| **Yesafil (J3590)**<br>**Opuviz (J3590)** | Require T/F of Avastin ophthalmic | **10/1/24** |
| **Hercessi (J9999)** | Require T/F of Ogivri (Q5114) or Kanjinti (Q5117) | **10/1/24** |
| **Sandostatin LAR (J2353)**<br>**Signifor LAR (J2502)**<br>**Lanreotide (J1932)** | Remove requirement of T/F Somatuline Depot (J1930) | **9/1/24** |
| **Palonosetron (J2468)** | Require T/F Kytril (J1626) or Zofran (J2405) | **7/1/24** |
| **Ryzneuta (J9361)** | Require T/F Neulasta (J2506) or Udenyca (Q5111) | **7/1/24** |
| **Lanreotide (J1932)** | Require T/F of Somatuline Depot (J1930) | **7/1/24** |
| **Omvoh (J2267)** | Require T/F of two of preferred adalimumab product, tofacitinib, Upadacitinib, or ustekinumab | **7/1/24** |
| **Avzivi (J9999)** | Require T/F of Mvasi (Q5107) or Zirabev (Q5118) | **4/1/24** |
| **Sandostatin LAR (J2353)**<br>**Signifor LAR (J2502)** | Require T/F of Somatuline Depot (J1930) | **4/1/24** |
| **IVIG** | Add Alyglo (J1599) to a preferred product ahead of Asceniv (J1554) | **4/1/24** |
| **Eylea (J0178)**<br>**Lucentis (J2778)**<br>**Macugen (J2503)**<br>**Beovu (J0179)**<br>**Byooviz (Q5124)**<br>**Susvimo (J2779)**<br>**Vabysmo (J2777)**<br>**Cimerli (Q5128)**<br>**Eylea HD (J0177)** | Update T/F language to: Patient must try and have an inadequate response (defined as 3 injections in either eye with minimal to no improvement), clinically significant adverse effects, or contraindication to Avastin (bevacizumab) prior to consideration of a non-preferred product. Documentation of contraindication, adverse events, or date(s) of failed therapy to Avastin (bevacizumab) required. | **4/1/24** |



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