# MEDICAL COVERAGE POLICY

**SERVICE:** **Step Therapy Policy – Medicare Part B**

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| **Policy Number:** | **307** |
| **Effective Date:** | **05/01/2024** |
| **Last Review:** | **02/12/2024** |
| **Next Review:** | **02/12/2025** |

***Important note:** Unless otherwise indicated, medical policies will apply to all lines of business.*
*Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

**SERVICE:** Step Therapy Policy – Medicare Part B

**PRIOR AUTHORIZATION:** See specific policy for appropriate drug or device

**POLICY:**

Medicare coverage policies at CMS.gov (e.g. Local Coverage Determination (LCD) documents and Articles, National Coverage Determination (NCD) documents, etc.) will apply in addition to this policy. Baylor Scott & White Health plan medical policies as specified in the table below will be applied, in addition to this policy, if no applicable Medicare coverage policy exists. Thereafter, the step therapy requirement(s) in this supplemental policy should be applied.

This policy provides a list of drugs and devices that require step therapy. Step therapy is when a trial of a preferred therapeutic alternative is required prior to coverage of a non-preferred drug or device for a specific indication. Preferred and non-preferred drugs and products are evaluated for cost and clinical appropriateness. Where preferred agents are defined, it was determined per review of relevant clinical literature and compendia that it is clinically reasonable to require provider to address use of preferred drugs and products prior to coverage of non-preferred drugs and products.

Baylor Scott & White Health Plan, and its wholly owned subsidiaries (together, “Plan”) considers the use of medications with a non-preferred status medically necessary when used consistent with the member’s coverage document and based on all of the following criteria:

1) The member is a new start (i.e., has not received the requested medication for the past 365 days)
2) The member must have failure of an adequate trial of or clinically significant intolerance or contraindication to preferred drugs that can also be used for the requested indication.
3) The member meets additional clinical coverage criteria per CMS or Plan policy as specified in the table below.

| Class | Preferred | Non-Preferred | CMS or BSWHP policy |
|---|---|---|---|
| Bevacizumab – for oncology indications only | Mvasi<br>Zirabev | Avastin (J9035)<br>Alymsys<br>Avzivi | BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines |

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|---|---|---|---|
| | | Vegzelma<br>Other bevacizumab biosimilars | |
| Long-acting G-CSF | Udenyca<br>Neulasta | Fulphila<br>Fylnetra<br>Nyvepria<br>Stimufend<br>Ziextenzo<br>Other long-acting G-CSF | BSWHP policy 215 Medications Covered Under Medical Insurance Policy<br>OR<br>BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines |
| Short-acting G-CSF | Zarxio | Granix<br>Neupogen<br>Nivestym<br>Releuko<br>Other short-acting GCSF | BSWHP policy 215 Medications Covered Under Medical Insurance Policy<br>OR<br>BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines |
| Rituximab | Ruxience<br>Truxima | Riabni<br>Rituxan<br>Rituxan Hycela<br>Other rituximab containing agents | BSWHP policy 215 Medications Covered Under Medical Insurance Policy<br>OR<br>BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines |
| Trastuzumab | Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera<br>Other trastuzumab biosimilars | Herceptin<br>Herceptin Hylecta | BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines |
| VEGF inhibitors – for ophthalmic indications only | Cimerli | Beovu | BSWHP policy 215 Medications Covered |

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| | Compounded Avastin | Byooviz<br>Eylea (regular and HD)<br>Lucentis<br>Susvimo<br>Vabysmo<br>Other ophthalmic VEGF inhibitor containing agents | Under Medical Insurance Policy |

The Plan considers the use of devices with a non-preferred status medically necessary when used consistent with the member's coverage document and based on all of the following criteria:

1) The provider submits clinical rationale for why non-preferred devices are medically necessary and preferred agents are not appropriate.
2) The member meets additional clinical coverage criteria as specified in the table below.

| **Class** | **Preferred** | **Non-Preferred** | **CMS or BSWHP policy** |
|---|---|---|---|
| Continuous glucose monitors | Dexcom<br>Freestyle Libre | All other CGMs | LCD 33822 Glucose Monitors |

**POLICY HISTORY:**

| **Status** | **Date** | **Action** |
|---|---|---|
| New | 12/13/2023 | New policy – previously under medical policy 215 Medications Covered Under Medical Insurance Policy and 219 Cancer Chemotherapy/Therapy Guidelines |
| Updated | 02/12/2024 | Updated nonpreferred bevacizumab and VEGF inhibitors for new agents |

***Note**:*
*Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.*

*RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.*