



MEDICAL COVERAGE POLICY

SERVICE: Step Therapy Policy – Medicare Part B

Policy Number: 307

Effective Date: 05/01/2025

Last Review: 04/14/2025

Next Review: 04/14/2026

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.

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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
Bendamustine	Belrapzo Bendeka	Bendamustine 505b2 formulations Vivimusta	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines



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Class	Preferred	Non-Preferred	CMS or BSWHP policy
	Bendamustine (brand Treanda)		
Bevacizumab – for oncology indications only	Mvasi Zirabev	Avastin (J9035) Alymsys Avzivi Vegzelma Other bevacizumab biosimilars	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Bone antiresorptive therapy – for oncology indications only, does NOT apply to prostate or breast cancer	Zoledronic Acid	Xgeva	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Immune Globulins	Refer to BSWHP policy 045 Immune Globulin Therapy		
Infliximab	Refer to BSWHP policy 239 Infliximab Products		
Long-acting G-CSF	Udenyca Neulasta	Fulphila Fylmetra Nyvepria Stimufend Ziextenzo Other long-acting G-CSF	BSWHP policy 215 Medications Covered Under Medical Insurance Policy OR BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Short-acting G-CSF	Zarxio	Granix Neupogen Nivestym Releuko Other short-acting G-CSF	BSWHP policy 215 Medications Covered Under Medical Insurance Policy OR BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Rituximab	Ruxience Truxima	Riabni Rituxan Rituxan Hycela	BSWHP policy 215 Medications Covered Under Medical Insurance Policy OR



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Class	Preferred	Non-Preferred	CMS or BSWHP policy
		Other rituximab containing agents	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Taxanes – does NOT apply to pancreatic cancer, ampullary adenocarcinoma, biliary tract cancers	Paclitaxel (brand Taxol) Docetaxel (brand Taxotere)	Docetaxel 505b2 formulations Paclitaxel Protein-Bound (brand Abraxane) Paclitaxel Protein-Bound 505b2 formulations	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Trastuzumab	Herzuma Kanjinti Ogivri Ontruzant Trazimera Other trastuzumab biosimilars	Herceptin Herceptin Hylecta	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
VEGF inhibitors – for ophthalmic indications only	Avastin	Beovu Byooviz Eylea (regular and HD) Lucentis Susvimo Vabysmo Other ophthalmic VEGF inhibitor containing agents	BSWHP policy 215 Medications Covered Under Medical Insurance Policy
ALL OTHER MEDICARE OUTPATIENT (PART B) DRUGS (NOT LISTED ABOVE)	Not Applicable (Covered at Parity)	Not Applicable (Covered at Parity)	BSWHP policy 215 Medications Covered Under Medical Insurance Policy OR BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines



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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 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
Updated	10/14/2024	Added bendamustine, bone antiresorptive therapy, and taxane classes. Added BSWHP policy hyperlinks.
Updated	12/09/2024	Added hyperlinks for classes using other policies for completeness and transparency
Updated	04/14/2025	Removed Cimerli from preferred due to paused commercialization

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 is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA service areas; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.