

MEDICAL COVERAGE POLICY
SERVICE: Step Therapy Policy –
Medicare Part B

Policy Number: 307

Effective Date: 09/01/2025

Last Review: 07/14/2025

Next Review: 07/14/2026

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)
- The member must have failure of an adequate trial of or clinically significant intolerance or contraindication to ALL 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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Preferred	Non-Preferred	CMS or BSWHP policy
Bendamustine (brand Treanda)		
Mvasi Zirabev Zoledronic Acid	Avastin (J9035) Alymsys Avzivi Vegzelma Other bevacizumab biosimilars Xgeva	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines BSWHP policy 219 Cancer Chemotherapy /
		Cancer Chemotherapy / Therapy Guidelines
For sickle cell disease: refer <u>BSWHP policy 310 Exagamglogene autotemcel</u> (Casgevy™) and <u>BSWHP policy 311 lovotibeglogene autotemcel</u> (Lyfgenia™)		
Refer to BSWHP policy 045 Immune Globulin Therapy		
Refer to BSWHP policy 2	39 Infliximab Products	
Udenyca Neulasta	Fulphila Fylnetra Nyvepria	BSWHP policy 215 Medications Covered Under Medical Insurance Policy
	Stimufend	OR
	Ziextenzo Other long-acting G-CSF	BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines
Refer to BSWHP policy 314 Nogapendekin alfa inbakicept (Anktiva)		
Ruxience Truxima	Riabni Rituxan Rituxan Hycela Other rituximab containing agents	BSWHP policy 215 Medications Covered Under Medical Insurance Policy OR BSWHP policy 219
	Bendamustine (brand Treanda) Mvasi Zirabev Zoledronic Acid For sickle cell disease: re (Casgevy™) and BSWHP Refer to BSWHP policy 2 Udenyca Neulasta Refer to BSWHP policy 3 Ruxience	Bendamustine (brand Treanda) Mvasi Avastin (J9035) Zirabev Alymsys Avzivi Vegzelma Other bevacizumab biosimilars Zoledronic Acid Xgeva For sickle cell disease: refer BSWHP policy 310 Exar (Casgevy™) and BSWHP policy 311 lovotibeglogene Refer to BSWHP policy 045 Immune Globulin Therap Refer to BSWHP policy 239 Infliximab Products Udenyca Fulphila Neulasta Fylnetra Nyvepria Stimufend Ziextenzo Other long-acting G- CSF Refer to BSWHP policy 314 Nogapendekin alfa inbak Ruxience Truxima Rituxan Rituxan











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











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DRUGS (NOT LISTED ABOVE)			<u>Under Medical</u> <u>Insurance Policy</u>
			OR
			BSWHP policy 219 Cancer Chemotherapy / Therapy Guidelines

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	All other CGMs	LCD 33822 Glucose
	Freestyle Libre		<u>Monitors</u>

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
Updated	06/09/2025	Added class and hyperlinks to sickle cell gene therapy policies. Added Pavblu to ophthalmic VEGF inhibitor class. Clarified step therapy applies to all preferred drugs.
Updated	07/14/2025	Added non-muscle invasive bladder cancer treatment class.

Note:











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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 MRSAs service areas; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.