BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICARE ADVANTAGE PART B DRUGS

NEXT REVIEW DATE: 3RD QTR 2026

ORIGINAL EFFECTIVE DATE: 01/01/23
LAST REVIEW DATE: 08/21/25
CURRENT EFFECTIVE DATE: 04/01/26
LAST CRITERIA REVISION DATE: 02/19/26
ARCHIVE DATE:

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

You can find our Non-Discrimination Statement (including multi-language interpreter services information) at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This evidence-based criteria must be read in its entirety to determine coverage eligibility, if any.

This evidence-based criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide AZ Blue complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary, experimental, or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-based criteria are subject to change as new information becomes available.

For purposes of this evidence-based criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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This policy provides the requirements and application of step therapy for covered Medicare Part B medications. Before using this policy, all reviewers must first identify and confirm the following: member's eligibility; any applicable federal or state regulatory requirements; any applicable policies from the Centers for Medicare and Medicaid Services (CMS); coverage provisions of the member's specific evidence of coverage; and any applicable network contract provisions of the treating provider

This policy supplements Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) for the purpose of determining coverage under Medicare Part B benefits by applying step therapy for the drugs/products in the table below.

We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.

This step therapy policy is not used to determine medical necessity for a drug. The purpose of this policy is to determine eligibility to receive a non-preferred drug for a health condition.

CRITERIA

Refer to FDA website for current indications and dosage.

- A Step 2 Medication will be approved when **ANY** of the following criteria are met:
  1. Individual has failure, contraindication or intolerance to drug(s)/product(s) listed in the **Step 1 Drug/Product** column, **O**
  2. Individual has been on the drug/product in the **Step 2 Drug/Product** column in the last 365 days

This policy applies step therapy for the following drugs/products:

Drug Class/Indication(s)	Step 2 Drug/Product	Applicable Diagnosis	Step 1 Drug(s)/Product(s)	Effective Date
Bevacizumab (oncology)	**Avastin**	Oncology	Mvasi **OR** Zirabev	01/01/2025
	Alymsys			01/01/2025
	Jobevne			01/01/2026
	Vegzelma			01/01/2025
Bone Density Agents (Non-Cancer diagnoses)	**Conexxence**		Zoledronic Acid **OR** Inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial **AND** Bildyos	01/01/2026
	Enoby			04/01/2026
	Evenity	**Excludes patients at very high risk for fracture:** •T-score ≥ - 3.0 even in the absence of fractures •T-score ≥ - 2.5 plus a fragility fracture, severe or multiple vertebral fractures		01/01/2026

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	Jubbonti			01/01/2026
	Ospomyv			01/01/2026
	Prolia			01/01/2026
	Stoboclo			01/01/2026
Botulinum Toxins	**Botox**	Cervical Dystonia	Dysport **OR** Xeomin	01/01/2024
	Daxxify			01/01/2024
	Myobloc			01/01/2024
Botulinum Toxins	**Botox**	Upper Limb Spasticity	Dysport **OR** Xeomin	01/01/2024
	Myobloc			01/01/2024
Botulinum Toxins	**Botox**	Lower Limb Spasticity	Dysport	01/01/2024
Botulinum Toxins	**Botox**	Chronic Sialorrhea	Xeomin	01/01/2026
	Myobloc			01/01/2026
Botulinum Toxins	**Botox**	Blepharospasm	Dysport **OR** Xeomin	01/01/2024
	Myobloc			01/01/2024
Botulinum Toxins	**Botox**	Hemifacial spasm	Dysport	01/01/2024
Colony-stimulating growth factors (long-acting)	**Fylnetra**		Fulphila **OR** Neulasta **OR** Udenyca	01/01/2026
	Nyvepria			01/01/2026
	Rolvedon			01/01/2026
	Stimufend			01/01/2026
	Ziextenzo			01/01/2026
Colony-stimulating growth factors (short-acting)	**Granix**		Nivestym **OR** Zarxio	01/01/2025
	Leukine			01/01/2025
	Neupogen			01/01/2025
	Nypozi			03/01/2025
	Releuko			01/01/2025
Denosumab (Xgeva) products	**Bomyntra**		Bilprevda	01/01/2026
	Osenvelt			01/01/2026
	Wyost			01/01/2026
	Xgeva			01/01/2026
	Xtrenbo			04/01/2026
Denosumab (Prolia) products	**Conexxence**		Bildyos	01/01/2026
	Enoby			04/01/2026
	Jubbonti			01/01/2026
	Ospomyv			01/01/2026
	Prolia			01/01/2026
	Stoboclo			01/01/2026

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Eculizumab products	**Bkemv**		Epysqli	01/01/2026
	Soliris			01/01/2026
Erythropoiesis-Stimulating Agents	**Epogen**	Cancer AND Non-cancer related diagnoses	Aranesp **OR** Procrit **OR** Retacrit	01/01/2025
	Mircera			01/01/2025
Gout	**Krystexxa**		Allopurinol **AND** Febuxostat	01/01/2024
Hemolytic uremic syndrome, atypical (Ahus)	**Bkemv**		Ultomiris **AND** Epysqli	01/01/2026
	Soliris			01/01/2026
Hereditary Angioedema - Acute Use	**Berinert**		Icatibant	01/01/2024
	Kalbitor			01/01/2024
	Ruconest			01/01/2024
Hereditary Angioedema - Prophylaxis	**Cinryze**		Haegarda	01/01/2024
	Takhzyro			01/01/2024
Hypercholesterolemia	**Evkeeza**		High-Intensity Statin* **AND** Praluent **OR** Repatha	01/01/2024
Immunoglobulin	**Alyglo**		Gammagard **OR** Gammaked **OR** Gamunex-C **OR** Hizentra **OR** Octagam **OR** Privigen **OR** Xembify	01/01/2026
	Asceniv			01/01/2026
	Bivigam			01/01/2026
	Carimune NF			01/01/2026
	Cutaquig			01/01/2026
	Cuvitru			01/01/2026
	Flebogamma			01/01/2026
	Gammagard S/D			01/01/2026
	Gammaplex			01/01/2026
	HyQvia			01/01/2026
	Panzyga			01/01/2026
	Yimmugo			01/01/2026
Immunologics	**Cimzia**	Ankylosing spondylitis	Avsola **OR** Renflexis	01/01/2026
	Cosentyx			01/01/2026
	Inflectra			01/01/2026

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	Infliximab		**OR**	01/01/2026
	Remicade		Simponi Aria	01/01/2026
Immunologics	**Cimzia**	Crohn's Disease	Avsola	01/01/2026
	Entyvio		**OR**	01/01/2026
	Imuldosa		Renflexis	01/01/2026
	Inflectra		**OR**	01/01/2026
	Infliximab		Starjemza	01/01/2026
	Omvoh		**OR**	01/01/2026
	Otulfi		Steqeyma	01/01/2026
	Pyzchiva			01/01/2026
	Remicade			01/01/2026
	Selarsdi			01/01/2026
	Skyrizi			01/01/2026
	Stelara			01/01/2026
	Tremfya			01/01/2026
	Tyruko			01/01/2026
	Tysabri			01/01/2026
	Ustekinumab			01/01/2026
	Wezlana			01/01/2026
	Yesintek			01/01/2026
Immunologics	**Cimzia**	Psoriasis	Avsola	01/01/2026
	Cosentyx		**OR**	01/01/2026
	Ilumya		Renflexis	01/01/2026
	Imuldosa		**OR**	01/01/2026
	Inflectra		Starjemza	01/01/2026
	Infliximab		**OR**	01/01/2026
	Otulfi		Steqeyma	01/01/2026
	Pyzchiva			01/01/2026
	Remicade			01/01/2026
	Selarsdi			01/01/2026
	Skyrizi			01/01/2026
	Stelara			01/01/2026
	Tremfya			01/01/2026
	Ustekinumab			01/01/2026
	Wezlana			01/01/2026
	Yesintek			01/01/2026
Immunologics	**Cimzia**	Psoriatic arthritis	Avsola	01/01/2026
	Cosentyx		**OR**	01/01/2026
	Imuldosa		Renflexis	01/01/2026
	Inflectra		**OR**	01/01/2026
	Infliximab		Simponi Aria	01/01/2026
	Orencia		**OR**	01/01/2026
	Otulfi		Starjemza	01/01/2026
	Pyzchiva		**OR**	01/01/2026
	Remicade		Steqeyma	01/01/2026

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	Selarsdi			01/01/2026
	Skyrizi			01/01/2026
	Stelara			01/01/2026
	Tremfya			01/01/2026
	Ustekinumab			01/01/2026
	Wezlana			01/01/2026
	Yesintek			01/01/2026
Immunologics	**Actemra**	Rheumatoid Arthritis	Avsola **OR** Renflexis **OR** Simponi Aria **AND** Tyenne	01/01/2026
	Avtozma			01/01/2026
	Cimzia		Avsola **OR** Renflexis **OR** Simponi Aria	01/01/2026
	Cosentyx			01/01/2026
	Inflectra			01/01/2026
	Infliximab			01/01/2026
	Orencia			01/01/2026
	Remicade			01/01/2026
	Tofidence		Avsola **OR** Renflexis **OR** Simponi Aria **AND** Tyenne	01/01/2026
	Tyenne		Avsola **OR** Renflexis **OR** Simponi Aria	01/01/2026
Immunologics	**Entyvio**	Ulcerative Colitis	Avsola **OR** Renflexis **OR** Starjemza **OR** Steqeyma	01/01/2026
	Imuldosa			01/01/2026
	Inflectra			01/01/2026
	Infliximab			01/01/2026
	Omvoh			01/01/2026
	Otulfi			01/01/2026
	Pyzchiva			01/01/2026
	Remicade			01/01/2026
	Selarsdi			01/01/2026
	Skyrizi			01/01/2026
	Stelara			01/01/2026
	Tremfya			01/01/2026
	Ustekinumab			01/01/2026
	Wezlana			01/01/2026
	Yesintek			01/01/2026

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Infliximab	**Inflectra**		Avsola **OR** Renflexis	01/01/2026
	Infliximab			01/01/2026
	Remicade			01/01/2026
IV Iron	**Feraheme**		Ferrlecit **OR** INFeD **OR** Venofer	01/01/2024
	Injectafer			01/01/2024
	Monoferric			01/01/2024
Leqvio	**Leqvio**		High-Intensity Statin* **AND** Praluent **OR** Repatha	01/01/2024 01/01/2024
Multiple Sclerosis	**Lemtrada**		Briumvi **OR** Ocrevus	01/01/2024
	Tyruko			01/01/2024
	Tysabri			01/01/2024
Myasthenia gravis	**Bkemv**		Epysqli **AND** Ultomiris **AND** Vyvgart **OR** Vyvgart Hytrulo	01/01/2026
	Epysqli		Ultomiris **AND** Vyvgart **OR** Vyvgart Hytrulo	01/01/2026
	Imaavy	**Excludes patients with:** • Anti-muscle-specific tyrosine kinase (MuSK) antibody positive	Vyvgart **OR** Vyvgart Hytrulo	04/01/2026
	Rystiggo			
	Soliris		Epysqli **AND** Ultomiris **AND** Vyvgart **OR** Vyvgart Hytrulo	01/01/2026
Neuromyelitis optica spectrum disorder	**Bkemv**		Epysqli **AND**	01/01/2026

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			Riabni **OR** Truxima **AND** Uplizna **AND** Ultomiris	
	Epysqli		Riabni **OR** Truxima **AND** Uplizna **AND** Ultomiris	01/01/2026
	Soliris		Epysqli **AND** Riabni **OR** Truxima **AND** Uplizna **AND** Ultomiris	01/01/2026
	Uplizna		Riabni **OR** Truxima	01/01/2026
Ophthalmic Disorders - VEGF Inhibitors	**Beovu**		Avastin **AND** Byooviz **OR** Lucentis	01/01/2026
	Byooviz		Avastin	01/01/2025
	Cimerli		Avastin **AND** Byooviz **OR** Lucentis	01/01/2025
	Eylea		Avastin **AND** Byooviz **OR** Lucentis	01/01/2025
	Eylea HD		Avastin **AND** Byooviz **OR** Lucentis	01/01/2025
	Lucentis		Avastin	01/01/2025

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	Pavblu		Avastin **AND** Byooviz **OR** Lucentis	03/01/2025
	Susvimo		Avastin **AND** Byooviz **OR** Lucentis	01/01/2025
	Vabysmo		Avastin **AND** Byooviz **OR** Lucentis **AND** Eylea	01/01/2025
Osteoarthritis of the Knee (Intra-articular steroids)	**Zilretta**		Betamethasone **OR** Dexamethasone **OR** Methylprednisolone **OR** Triamcinolone	01/01/2024
Paroxysmal Nocturnal Hemoglobinuria	**Bkemv**		Ultomiris **AND** Epysqli	01/01/2026
	Epysqli		Ultomiris	01/01/2026
	PiaSky			01/01/2026
	Soliris		Ultomiris **AND** Epysqli	01/01/2026
Rituximabs	**Rituxan**	Cancer AND non-cancer indications	Riabni **OR** Truxima	01/01/2026
	Rituxan Hycela			01/01/2026
	Ruxience			01/01/2026
Severe Asthma	**Cinqair**		Fasenra **OR** Xolair	01/01/2025
	Nucala			01/01/2025
	Tezspire			01/01/2025
Systemic Lupus Erythematosus	**Saphnelo**		Benlysta	01/01/2024
Thyroid Eye Disease	**Tepezza**		Inadequate response to at least 6 weeks of therapy with a	01/01/2026

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			glucocorticosteroid (IV or oral)	
Tocilizumab products	**Actemra**		Tyenne	01/01/2026
	Avtozma			01/01/2026
	Tofidence			01/01/2026
Trastuzumab	**Herceptin**		Kanjinti **OR** Ogivri	01/01/2026
	Herceptin Hylecta			01/01/2026
	Hercessi			03/01/2026
	Herzuma			01/01/2026
	Ontruzant			01/01/2026
	Trazimera			01/01/2026
Ustekinumab products	**Imuldosa**		Starjemza **OR** Steqeyma	01/01/2026
	Otulfi			01/01/2026
	Pyzchiva			01/01/2026
	Selarsdi			01/01/2026
	Stelara			01/01/2026
	Ustekinumab			01/01/2026
	Wezlana			01/01/2026
	Yesintek			01/01/2026

History:	**Date**:	**Activity**:
Pharmacy and Therapeutics Committee	02/19/26	Revisions to guideline (eff 04/01/2026)
Pharmacy and Therapeutics Committee	11/20/25	Revisions to guideline (eff 01/01/2026)
Pharmacy and Therapeutics Committee	09/19/25	Revisions to guideline (eff 01/01/2026)
Pharmacy and Therapeutics Committee	08/21/25	Reviewed and approved policy with revisions (eff 01/01/26)
Pharmacy and Therapeutics Committee	08/21/25	Revisions to guideline (eff 11/01/25)
Pharmacy and Therapeutics Committee	05/15/25	Revisions to guideline (eff 06/01/25)
Pharmacy and Therapeutics Committee	02/20/25	Revisions to guideline (eff 03/01/25)
Pharmacy and Therapeutics Committee	08/15/24	Reviewed and approved policy with revisions (eff 01/01/25)
Pharmacy and Therapeutics Committee	08/15/24	Revisions to guideline (eff 08/15/24)
Pharmacy and Therapeutics Committee	05/16/24	Revisions to guideline
Pharmacy and Therapeutics Committee	02/15/24	Reviewed and approved policy with revisions
Pharmacy and Therapeutics Committee	11/16/23	Reviewed and approved policy with revisions
Medicare Advantage Clinical Pharmacist	11/13/23	Reviewed with revision
Pharmacy and Therapeutics Committee	09/27/23	Reviewed and approved policy with revisions by Ad Hoc
Medicare Advantage Clinical Pharmacist	09/11/23	Reviewed with revision

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Pharmacy and Therapeutics Committee	08/17/23	Reviewed and approved policy with revisions
Medicare Advantage Clinical Pharmacist	06/16/23	Reviewed with revision
Pharmacy and Therapeutics Committee	05/18/23	Reviewed and approved policy with revisions
Medicare Advantage Clinical Pharmacist	04/25/23	Reviewed with revision
Pharmacy and Therapeutics Committee	08/18/22	Approved policy
Medicare Advantage Clinical Pharmacist	08/01/22	Development

DESCRIPTION

Step therapy is the practice of beginning a drug for a health condition with a preferred drug before progressing to another therapy. It requires trying a preferred drug/product (Step 1) before getting a non-preferred drug/product (Step 2). Step therapy only applies to new prescriptions or administration of Part B drugs you have not used in the last 365 days. This means that if you are currently and actively receiving the medication you will not be required to change your medication.

You may be required to use a Part D drug before you can use a Part B drug. CMS does allow Part B step therapy programs to include drugs supported only by an off-label indication if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

Step therapy guidelines are developed and reviewed by a panel of practicing physicians and pharmacists.

DEFINITIONS

*High-intensity statins: Treatment guidelines recommend treating patients with familial hypercholesterolemia and pre-existing cardiovascular disease with high doses of high-intensity statins or maximally tolerated if high-intensity statins are not tolerated.

RESOURCES

We do not include marketing materials, poster boards and non-published literature in our review.

1. CMS Chapter 15 – Covered Medical and Other Health Services. Chapter 15- Drugs and Biologicals, last accessed June 9, 2023, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

2. CMS Memorandum titled Off-label Use of Drugs in Medicare Advantage Step Therapy Programs, dated November 5, 2021, last accessed June 9, 2023, https://www.cms.gov/files/document/hpmsstepherapymemo.pdf

3. CMS Memorandum titled Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, dated August 7, 2018, last accessed June 9, 2023,

https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf?source=your_stories_page

4. Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F),” Centers for Medicare & Medicaid Services, last accessed June. 9, 2023, https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f

5. Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs, Centers for Medicare & Medicaid Services, last accessed June 9, 2023, https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs

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NON-DISCRIMINATION STATEMENT

Blue Cross Blue Shield of Arizona (AZ Blue) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. AZ Blue provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. AZ Blue also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call 602-864-4884 for Spanish and 877-475-4799 for all other languages and other aids and services.

If you believe that AZ Blue has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: AZ Blue's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, 602-864-2288, TTY/TDD 602-864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance, AZ Blue's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800–537–7697 (TDD). Complaint forms are available at hhs.gov/ocr/office/file/index.html