BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 01/01/23**
SECTION: MEDICARE ADVANTAGE PART B DRUGS	**LAST REVIEW DATE: 09/10/26**
	CURRENT EFFECTIVE DATE: 01/01/27
	LAST CRITERIA REVISION DATE: 09/10/26
NEXT REVIEW DATE: 3RD QTR 2027	**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, **OR**

  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 1 Preferred Drug(s)/Product(s)	Applicable Diagnosis	Step 2 Non-preferred Drug(s)/Product(s)	Effective Date
Bevacizumab (oncology)	Mvasi **OR** Vegzelma		Alymsys	01/01/2027
			Avastin	01/01/2027
			Avzivi	01/01/2027
			Jobevne	01/01/2027
			Zirabev	01/01/2027
Bone Density Agents - Osteoporosis (Non-Cancer diagnoses)	Zoledronic Acid **OR** Inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial **AND**		Bosaya	01/01/2027
			Conexxence	01/01/2027
		Excludes patients at very high risk for fracture: •T-score ≥ - 3.0 even in the	Evenity	01/01/2027

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	Bildyos **OR** Enoby	absence of fractures •T-score ≥ - 2.5 plus a fragility fracture, severe or multiple vertebral fractures		
			Jubbonti	01/01/2027
			Ospomyv	01/01/2027
			Osvyrti	01/01/2027
			Prolia	01/01/2027
			Stoboclo	01/01/2027
Botulinum Toxins	Botox **OR** Daxxify **OR** Dysport		Myobloc	01/01/2027
			Xeomin	01/01/2027
Colony-stimulating growth factors (long-acting)	Fulphila **OR** Udenyca		Armlupeg	01/01/2027
			Fylnetra	01/01/2027
			Neulasta	01/01/2027
			Neulasta Onpro	01/01/2027
			Nyvepria	01/01/2027
			Rolvedon	01/01/2027
			Ryzneuta	01/01/2027
			Stimufend	01/01/2027
			Ziextenzo	01/01/2027
Colony-stimulating growth factors (short-acting)	Granix **OR** Zarxio		Filkri	01/01/2027
			Leukine	01/01/2027
			Neupogen	01/01/2027
			Nivestym	01/01/2027
			Nypozi	01/01/2027
			Releuko	01/01/2027
Denosumab (Xgeva) products	Bilprevda **OR** Xtrenbo		Aukelso	01/01/2027
			Bomyntra	01/01/2027
			Jubereq	01/01/2027
			Osenvelt	01/01/2027
			Wyost	01/01/2027
			Xbryk	01/01/2027
			Xgeva	01/01/2027
Denosumab (Prolia) products	Bildyos **OR** Enoby		Bosaya	01/01/2027
			Conexxence	01/01/2027
			Jubbonti	01/01/2027
			Ospomyv	01/01/2027

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			Osvyrti	01/01/2027
			Prolia	01/01/2027
			Stoboclo	01/01/2027
Eculizumab products	Epysqli		Bkemv	01/01/2026
			Soliris	01/01/2026
Erythropoiesis-Stimulating Agents	Aranesp **OR** Procrit **OR** Retacrit		Epogen	01/01/2025
			Mircera	01/01/2025
Gout	Allopurinol **AND** Febuxostat		Krystexxa	01/01/2024
Hemolytic uremic syndrome, atypical (Ahus)	Ultomiris **OR** Epysqli		Bkemv	01/01/2027
			Soliris	01/01/2027
Hereditary Angioedema - Acute Use	Icatibant		Berinert	01/01/2024
			Kalbitor	01/01/2024
			Ruconest	01/01/2024
Hereditary Angioedema - Prophylaxis	Haegarda		Cinryze	01/01/2024
			Takhzyro	01/01/2024
Hypercholesterolemia	High-Intensity Statin* **AND** Praluent **OR** Repatha		Evkeeza	01/01/2024
Immunoglobulin	Cutaquig **OR** Flebogamma **OR** Gammagard ERC **OR** Gammagard Liquid **OR** Gammaked **OR** Gamunex-C **OR** HyQvia		Alyglo	01/01/2027
			Asceniv	01/01/2027
			Bivigam	01/01/2027
			Carimune NF	01/01/2027
			Cuvitru	01/01/2027
			Gammagard S/D	01/01/2027
			Gammaplex	01/01/2027
			Hizentra	01/01/2027
			Panzyga	01/01/2027
			Qivigy	01/01/2027
			Xembify	01/01/2027
			Yimmugo	01/01/2027

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	OR Octagam **OR** Privigen			
Immunologics	Avsola **OR** Renflexis **OR** Simponi Aria	Ankylosing spondylitis	Cimzia	01/01/2026
			Cosentyx	01/01/2026
			Inflectra	01/01/2026
			Infliximab	01/01/2026
			Remicade	01/01/2026
Immunologics	Avsola **OR** Renflexis **OR** Starjemza **OR** Steqeyma **OR** Yesintek	Crohn's Disease	Cimzia	01/01/2027
			Entyvio	01/01/2027
			Imuldosa	01/01/2027
			Inflectra	01/01/2027
			Infliximab	01/01/2027
			Omvoh	01/01/2027
			Otulfi	01/01/2027
			Pyzchiva	01/01/2027
			Remicade	01/01/2027
			Selarsdi	01/01/2027
			Skyrizi	01/01/2027
			Stelara	01/01/2027
			Tremfya	01/01/2027
			Tyruko	01/01/2027
			Tysabri	01/01/2027
			Ustekinumab	01/01/2027
			Wezlana	01/01/2027
Immunologics	Avsola **OR** Renflexis **OR** Starjemza **OR** Steqeyma **OR** Yesintek	Psoriasis	Cimzia	01/01/2027
			Cosentyx	01/01/2027
			Ilumya	01/01/2027
			Imuldosa	01/01/2027
			Inflectra	01/01/2027
			Infliximab	01/01/2027
			Otulfi	01/01/2027
			Pyzchiva	01/01/2027
			Remicade	01/01/2027
			Selarsdi	01/01/2027
			Skyrizi	01/01/2027
			Stelara	01/01/2027
			Tremfya	01/01/2027
			Ustekinumab	01/01/2027
			Wezlana	01/01/2027
Immunologics	Avsola **OR** Renflexis	Psoriatic arthritis	Cimzia	01/01/2027
			Cosentyx	01/01/2027
			Imuldosa	01/01/2027

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	OR Simponi Aria **OR** Starjemza **OR** Steqeyma **OR** Yesintek		Inflectra	01/01/2027
			Infliximab	01/01/2027
			Orencia	01/01/2027
			Otulfi	01/01/2027
			Pyzchiva	01/01/2027
			Remicade	01/01/2027
			Selarsdi	01/01/2027
			Skyrizi	01/01/2027
			Stelara	01/01/2027
			Tremfya	01/01/2027
			Ustekinumab	01/01/2027
			Wezlana	01/01/2027
Immunologics	Avsola **OR** Renflexis **OR** Simponi Aria **AND** Avtozma **OR** Tyenne	Rheumatoid Arthritis	Actemra	01/01/2027
	Avsola **OR** Renflexis **OR** Simponi Aria		Avtozma	01/01/2027
	Avsola **OR** Renflexis **OR** Simponi Aria		Cimzia	01/01/2027
			Cosentyx	01/01/2027
			Inflectra	01/01/2027
			Infliximab	01/01/2027
			Orencia	01/01/2027
			Remicade	01/01/2027
	Avsola **OR** Renflexis **OR** Simponi Aria **AND** Avtozma **OR** Tyenne		Tofidence	01/01/2027
	Avsola **OR** Renflexis **OR**		Tyenne	01/01/2027

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	Simponi Aria			
Immunologics	Avsola **OR** Renflexis **OR** Starjemza **OR** Steqeyma **OR** Yesintek	Ulcerative Colitis	Entyvio	01/01/2027
			Imuldosa	01/01/2027
			Inflectra	01/01/2027
			Infliximab	01/01/2027
			Omvoh	01/01/2027
			Otulfi	01/01/2027
			Pyzchiva	01/01/2027
			Remicade	01/01/2027
			Selarsdi	01/01/2027
			Skyrizi	01/01/2027
			Stelara	01/01/2027
			Tremfya	01/01/2027
			Ustekinumab	01/01/2027
			Wezlana	01/01/2027
			Yesintek	01/01/2027
Infliximab	Avsola **OR** Renflexis		Inflectra	01/01/2026
			Infliximab	01/01/2026
			Remicade	01/01/2026
IV Iron	Ferrlecit **OR** INFeD **OR** Venofer		Feraheme	01/01/2024
			Injectafer	01/01/2024
			Monoferric	01/01/2024
Leqvio	High-Intensity Statin* **AND** Praluent **OR** Repatha		Leqvio	01/01/2024
Multiple Sclerosis	Briumvi **OR** Ocrevus		Lemtrada	01/01/2024
			Tyruko	01/01/2024
			Tysabri	01/01/2024
Myasthenia gravis	Epysqli **OR** Ultomiris **AND** Vyvgart **OR** Vyvgart Hytrulo		Bkemv	01/01/2027
			Soliris	01/01/2027

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

	OR Rystiggo **OR** Imaavy **AND** Uplizna			
Neuromyelitis optica spectrum disorder	Epysqli **OR** Ultomiris **AND** Riabni **OR** Ruxience **AND** Uplizna		Bkemv	01/01/2027
	Riabni **OR** Ruxience		Epysqli	01/01/2027
	Epysqli **OR** Ultomiris **AND** Riabni **OR** Ruxience **AND** Uplizna		Soliris	01/01/2027
	Riabni **OR** Ruxience		Ultomiris	01/01/2027
			Uplizna	01/01/2027
Ophthalmic Disorders - VEGF Inhibitors	Bevacizumab **AND** Lucentis **OR** Yesafili		Beovu	01/01/2027
	Bevacizumab		Byooviz	01/01/2027

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

	AND Lucentis			
	Bevacizumab **AND** Lucentis		Cimerli	01/01/2027
	Bevacizumab **AND** Lucentis **AND** Yesafili		Eylea	01/01/2027
	Bevacizumab **AND** Lucentis **AND** Yesafili		Eylea HD	01/01/2027
	Bevacizumab		Lucentis	01/01/2025
	Bevacizumab **AND** Lucentis		Nufymco	01/01/2027
	Bevacizumab **AND** Lucentis **AND** Yesafili		Pavblu	01/01/2027
	Bevacizumab **AND** Lucentis **OR** Yesafili		Susvimo	01/01/2027

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	Bevacizumab **AND** Lucentis **AND** Yesafili		Vabysmo	01/01/2027
	Bevacizumab		Yesafili	01/01/2027
Osteoarthritis of the Knee (Intra-articular steroids)	Betamethasone **OR** Dexamethasone **OR** Methylprednisolone **OR** Triamcinolone		Zilretta	01/01/2024
Paroxysmal Nocturnal Hemoglobinuria	Ultomiris **OR** Epysqli		Bkemv	01/01/2027
			PiaSky	01/01/2027
			Soliris	01/01/2027
Rituximabs	Riabni **OR** Ruxience		Rituxan	01/01/2027
			Rituxan Hycela	01/01/2027
			Truxima	01/01/2027
Severe Asthma	Fasenra **OR** Omlyclo		Cinqair	01/01/2027
			Exdensur	01/01/2027
			Nucala	01/01/2027
			Tezspire	01/01/2027
	Omlyclo		Xolair	01/01/2027
Systemic Lupus Erythematosus	Benlysta		Saphnelo	01/01/2024
Thyroid Eye Disease	Inadequate response to at least 6 weeks of therapy with a glucocorticosteroid (IV or oral)		Tepezza	01/01/2026
Tocilizumab products	Avtozma **OR** Tyenne		Actemra	01/01/2027
			Tofidence	01/01/2027
Trastuzumab	Ogivri **OR** Ontruzant		Herceptin	01/01/2027
			Herceptin Hylecta	01/01/2027
			Hercessi	01/01/2027

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

	OR Trazimera		Herzuma	01/01/2027
			Kanjinti	01/01/2027
Ustekinumab products	Starjemza **OR** Steqeyma **OR** Yesintek		Imuldosa	01/01/2027
			Otulfi	01/01/2027
			Pyzchiva	01/01/2027
			Selarsdi	01/01/2027
			Stelara	01/01/2027
			Ustekinumab	01/01/2027
			Wezlana	01/01/2027

History:	**Date**:	**Activity**:
Pharmacy and Therapeutics Committee	09/10/26	Reviewed ad hoc and approved policy with revisions (eff 01/01/27)
Pharmacy and Therapeutics Committee	08/20/26	Revisions to guideline (eff 10/01/26)
Pharmacy and Therapeutics Committee	05/21/26	Revisions to guideline (eff 07/01/26)
Pharmacy and Therapeutics Committee	02/19/26	Revisions to guideline (eff 04/01/26)
Pharmacy and Therapeutics Committee	11/20/25	Revisions to guideline (eff 01/01/26)
Pharmacy and Therapeutics Committee	09/19/25	Revisions to guideline (eff 01/01/26)
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
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

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

Medicare Advantage Clinical Pharmacist	08/01/22	Development

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

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.

AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

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/hpmssteptherapymemo.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