



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICARE ADVANTAGE
PART B DRUGS

ORIGINAL EFFECTIVE DATE: 01/01/23
LAST REVIEW DATE: 08/15/24
CURRENT EFFECTIVE DATE: 01/01/25
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NEXT REVIEW DATE: 3RD QTR 2025

MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located 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 BCBSAZ 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 or 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 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 (paid claim within 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
	Vegzelma			01/01/2025
Bone Density Agents	Evenity	Osteoporosis	Zoledronic Acid OR Inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial AND Prolia	02/15/2024
	Prolia			Zoledronic Acid

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

			OR Inadequate efficacy with an oral bisphosphonate therapy after a 12- month trial	
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	Myobloc OR Xeomin	01/01/2024
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 OR Ziextenzo	01/01/2025
	Nyvepria			01/01/2025
	Rolvedon			01/01/2025
	Stimufend			01/01/2025
Colony-stimulating growth factors (short-acting)	Granix		Nivestym OR Zarxio	01/01/2025
	Leukine			01/01/2025
	Neupogen			01/01/2025
	Releuko			01/01/2025
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

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

Hemolytic uremic syndrome, atypical (Ahus)	Bkerv		Ultomiris	01/01/2025
	Epysqli			01/01/2025
	Soliris			01/01/2024
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
Homozygous familial hypercholesterolemia	Evkeeza		High-Intensity Statin* AND Praluent OR Repatha	01/01/2024
Immunoglobulin	Alyglo		Cutaquig OR Flebogamma OR Gammagard OR Gammaked OR Gamunex-C OR Hizentra OR Octagam OR Privigen OR Xembify	01/01/2025
	Asceniv			01/01/2025
	Bivigam			01/01/2025
	Carimune NF			01/01/2025
	Cuvitru			01/01/2025
	Gammagard S/D			01/01/2025
	Gammaplex			01/01/2025
	HyQvia			01/01/2025
Panzyga	01/01/2025			
Immunologics	Avsola	Ankylosing spondylitis	Inflectra OR Infliximab OR Renflexis OR Simponi Aria	01/01/2024
	Cimzia			01/01/2024
	Cosentyx			01/01/2025
	Remicade			01/01/2025
Immunologics	Avsola	Crohn's Disease	Inflectra OR Infliximab OR Renflexis	01/01/2024
	Cimzia			01/01/2024
	Entyvio			01/01/2024
	Pyzchiva			01/01/2025
	Remicade			01/01/2025
	Skyrizi			01/01/2024

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

	Stelara			01/01/2024
	Tyruko			01/01/2024
	Tysabri			01/01/2024
	Wezlana			01/01/2025
Immunologics	Avsola	Psoriasis	Inflectra	01/01/2024
	Cimzia		OR	01/01/2024
	Cosentyx		Infliximab	01/01/2025
	Ilumya		OR	01/01/2024
	Pyzchiva		Renflexis	01/01/2025
	Remicade			01/01/2025
	Selarsdi			01/01/2025
	Skyrizi			01/01/2024
	Stelara			01/01/2024
	Tremfya			01/01/2024
	Wezlana			01/01/2025
Immunologics	Avsola	Psoriatic arthritis	Inflectra	01/01/2024
	Cimzia		OR	01/01/2024
	Cosentyx		Infliximab	01/01/2025
	Orencia		OR	01/01/2024
	Pyzchiva		Renflexis	01/01/2025
	Remicade		OR	01/01/2025
	Selarsdi		Simponi Aria	01/01/2025
	Skyrizi			01/01/2024
	Stelara			01/01/2024
	Tremfya			01/01/2024
	Wezlana			01/01/2025
Immunologics	Actemra	Rheumatoid Arthritis	Inflectra	01/01/2024
	Avsola		OR	01/01/2024
	Cimzia		Infliximab	01/01/2024
	Cosentyx		OR	01/01/2025
	Orencia		Renflexis	01/01/2024
	Remicade		OR	01/01/2025
	Tofidence		Simponi Aria	01/01/2025
	Tyenne			01/01/2025
Immunologics	Avsola	Ulcerative Colitis	Inflectra	01/01/2024
	Entyvio		OR	01/01/2024
	OmvoH		Infliximab	01/01/2024
	Remicade		OR	01/01/2025
	Stelara		Renflexis	01/01/2024
	Wezlana			01/01/2025
Infliximab	Avsola		Inflectra	01/01/2024

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	Remicade		OR Infliximab OR Renflexis	01/01/2025
IV Iron	Feraheme Injectafer Monoferric		Ferrlecit OR INFeD OR Venofer	01/01/2024 01/01/2024 01/01/2024
Leqvio	Leqvio	Heterozygous familial hypercholesterolemia Primary hyperlipidemia	High-Intensity Statin* AND Praluent OR Repatha	01/01/2024 01/01/2024
Multiple Sclerosis	Lemtrada Tyruko Tysabri		Briumvi OR Ocrevus	01/01/2024 01/01/2024 01/01/2024
Myasthenia gravis	Soliris		Rystiggo AND Ultomiris AND Vyvgart OR Vyvgart Hytrulo	01/01/2025
Neuromyelitis optica spectrum disorder	Soliris Uplizna		Ruxience OR Truxima AND Enspryng OR Uplizna AND Ultomiris Ruxience OR Truxima AND Enspryng	01/01/2025 01/01/2024
Ophthalmic Disorders - VEGF Inhibitors	Beovu	Diabetic Macular Edema (DME) Neovascular (Wet) Age-related Macular Degeneration (AMD)	Avastin AND Byooviz OR Cimerli	01/01/2025

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

*Previous trial and failure of Lucentis will not require a trial and failure of either Byooviz or Cimerli			OR Lucentis	
	Byooviz	Macular Edema Following Retinal Vein Occlusion (RVO)	Avastin	01/01/2025
		Myopic Choroidal Neovascularization (mCNV)	N/A	
		Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Avastin	
	Cimerli	Diabetic Macular Edema (DME)	Avastin	01/01/2025
		Diabetic Retinopathy (DR)		
		Macular Edema Following Retinal Vein Occlusion (RVO)		
		Myopic Choroidal Neovascularization (mCNV)	N/A	
		Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Avastin	
	Eylea	Diabetic Macular Edema (DME)	Avastin AND Byooviz OR Cimerli OR Lucentis	01/01/2025
		Diabetic Retinopathy (DR)		
		Macular Edema following Retinal Vein Occlusion (RVO)		
		Wet Age-related Macular Degeneration (AMD)		
	Eylea HD	Diabetic Macular Edema (DME)	Avastin AND Byooviz OR Cimerli OR Lucentis	01/01/2025
		Diabetic Retinopathy (DR)		
		Wet Age-related Macular Degeneration (AMD)		
Lucentis	Diabetic Macular Edema (DME)	Avastin	01/01/2025	
	Diabetic Retinopathy (DR)			
	Macular Edema Following Retinal Vein Occlusion (RVO)			

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

		Myopic Choroidal Neovascularization (mCNV)	N/A	
		Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Avastin	
	Susvimo	Neovascular (wet) Age-related Macular Degeneration (AMD)	Avastin AND Byooviz OR Cimerli OR Lucentis	01/01/2025
	Vabysmo	Diabetic Macular Edema (DME)	Avastin AND Byooviz OR Cimerli OR Lucentis AND Eylea	01/01/2025
		Macular Edema Following Retinal Vein Occlusion (RVO)		
		Wet Age-related Macular Degeneration (AMD)		
Osteoarthritis of the Knee (Intra-articular steroids)	Zilretta		Betamethasone OR Dexamethasone OR Methylprednisolone OR Triamcinolone	01/01/2024
Paroxysmal Nocturnal Hemoglobinuria	Bkemv		Ultomiris	01/01/2025
	Epysqli			01/01/2025
	Soliris			01/01/2024
Rituximabs	Riabni	Cancer AND non-cancer indications	Ruxience OR Truxima	01/01/2025
	Rituxan			01/01/2025
	Rituxan Hycela			01/01/2025
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 high-dose	01/01/2024

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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

			intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly), or maximally tolerated dose	
Trastuzumab	Herceptin		Kanjinti OR Trazimera	01/01/2025
	Herceptin Hylecta			01/01/2025
	Herzuma			01/01/2025
	Ogivri			01/01/2025
	Ontruzant			01/01/2025

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
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
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



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MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

B drugs you have not used in the last 365 days. This means that if you are currently and actively receiving the medication (paid claim within the last 365 days) 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.



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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/factsheets/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/factsheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ 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. BCBSAZ 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 BCBSAZ 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: BCBSAZ'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 BCBSAZ'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 <https://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 <http://www.hhs.gov/ocr/office/file/index.html>