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: 08/17/23**
	CURRENT EFFECTIVE DATE: 01/01/24
	LAST CRITERIA REVISION DATE: 11/16/23
NEXT REVIEW DATE: 3RD QTR 2024	**ARCHIVE DATE:**

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.

This policy will only manage non-oncology indications for drugs with both oncology and non-oncology indications.

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
Bone Density Agents	**Evenity**	Osteoporosis	Zoledronic Acid **AND** Prolia	01/01/2024
	Prolia		Zoledronic Acid	01/01/2024
Botulinum Toxins	**Botox**	Cervical Dystonia	Dysport **OR** Xeomin	01/01/2024
	Daxxify			01/01/2024
	Myobloc			01/01/2024

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Botulinum Toxins	**Botox** **Myobloc**	Upper Limb Spasticity	Dysport **OR** Xeomin	01/01/2024 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** **Myobloc**	Blepharospasm	Dysport **OR** Xeomin	01/01/2024 01/01/2024
Botulinum Toxins	**Botox**	Hemifacial spasm	Dysport	01/01/2024
Erythropoiesis-Stimulating Agents	**Epogen** **Mircera**	Non-cancer related diagnoses	Aranesp **OR** Procrit **OR** Retacrit	01/01/2024 01/01/2024
Gout	**Krystexxa**		Allopurinol **AND** Febuxostat	01/01/2024
Hemolytic uremic syndrome, atypical (Ahus)	**Soliris**		Ultomiris	01/01/2024
Hereditary Angioedema - Acute Use	**Berinert** **Firazyr** **Kalbitor** **Ruconest**		Icatibant	01/01/2024 01/01/2024 01/01/2024 01/01/2024
Hereditary Angioedema - Prophylaxis	**Cinryze** **Takhzyro**		Haegarda	01/01/2024 01/01/2024
Homozygous familial hypercholesterolemia	**Evkeeza**		High-Intensity Statin* **AND** Praluent **OR** Repatha	01/01/2024

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Immunoglobulin	**Asceniv**		Flebogamma **OR** Gammagard **OR** Gammaked **OR** Gamunex-C **OR** Hizentra **OR** Octagam **OR** Privigen **OR** Xembify	01/01/2024
	Bivigam			01/01/2024
	Carimune NF			01/01/2024
	Cutaquig			01/01/2024
	Cuvitru			01/01/2024
	Gammagard S/D			01/01/2024
	Gammaplex			01/01/2024
	HyQvia			01/01/2024
	Panzyga			01/01/2024
Immunologics	**Avsola**	Ankylosing spondylitis	Inflectra **OR** Infliximab **OR** Remicade **OR** Simponi Aria	01/01/2024
	Cimzia			01/01/2024
	Renflexis			01/01/2024
Immunologics	**Avsola**	Crohn's Disease	Inflectra **OR** Infliximab **OR** Remicade	01/01/2024
	Cimzia			01/01/2024
	Entyvio			01/01/2024
	Renflexis			01/01/2024
	Skyrizi			01/01/2024
	Stelara			01/01/2024
	Tyruko			01/01/2024
	Tysabri			01/01/2024
Immunologics	**Avsola**	Psoriasis	Inflectra **OR** Infliximab **OR** Remicade	01/01/2024
	Cimzia			01/01/2024
	Ilumya			01/01/2024
	Renflexis			01/01/2024
	Skyrizi			01/01/2024
	Stelara			01/01/2024
	Tremfya			01/01/2024
Immunologics	**Avsola**	Psoriatic arthritis	Inflectra **OR** Infliximab **OR** Remicade **OR** Simponi Aria	01/01/2024
	Cimzia			01/01/2024
	Orencia			01/01/2024
	Renflexis			01/01/2024
	Skyrizi			01/01/2024
	Stelara			01/01/2024
	Tremfya			01/01/2024

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Immunologics	**Actemra**	Rheumatoid Arthritis	Inflectra **OR** Infliximab **OR** Remicade **OR** Simponi Aria	01/01/2024
	Avsola			01/01/2024
	Cimzia			01/01/2024
	Orencia			01/01/2024
	Renflexis			01/01/2024
Immunologics	**Avsola**	Ulcerative Colitis	Inflectra **OR** Infliximab **OR** Remicade	01/01/2024
	Entyvio			01/01/2024
	Omvoh			01/01/2024
	Renflexis			01/01/2024
	Stelara			01/01/2024
Infliximab	**Avsola**		Inflectra **OR** Infliximab **OR** Remicade	01/01/2024
	Renflexis			01/01/2024
IV Iron	**Feraheme**		Ferrlecit **OR** INFeD **OR** Venofer	01/01/2024
	Injectafer			01/01/2024
	Monoferric			01/01/2024
Leqvio	**Leqvio**	Heterozygous familial hypercholesterolemia	High-Intensity Statin* **AND** Praluent **OR** Repatha	01/01/2024
		Primary hyperlipidemia		01/01/2024
Multiple Sclerosis	**Lemtrada**		Briumvi **OR** Ocrevus	01/01/2024
	Tyruko			01/01/2024
	Tysabri			01/01/2024
Myasthenia gravis	**Rystiggo**		Ultomiris **AND** Vyvgart **OR** Vyvgart Hytrulo	01/01/2024
	Soliris			01/01/2024
Neuromyelitis optica spectrum disorder	**Enspryng**		Ruxience **OR** Truxima	01/01/2024
	Soliris		Ruxience **OR** Truxima **AND**	01/01/2024

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			Enspryng **OR** Uplizna	
	Uplizna		Ruxience **OR** Truxima **AND** Enspryng	01/01/2024
Ophthalmic Disorders - VEGF Inhibitors	**Beovu**	Diabetic Macular Edema (DME)	Avastin **AND** Byooviz **OR** Cimerli	01/01/2024
		Neovascular (Wet) Age-related Macular Degeneration (AMD)		
	Byooviz	Macular Edema Following Retinal Vein Occlusion (RVO)	Avastin	01/01/2024
		Myopic Choroidal Neovascularization (mCNV)	N/A	
		Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Avastin	
	Cimerli	Diabetic Macular Edema (DME)	Avastin	01/01/2024
		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	01/01/2024
		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**	01/01/2024
		Diabetic Retinopathy (DR)		

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		Wet Age-related Macular Degeneration (AMD)	Cimerli	
	Lucentis	Diabetic Macular Edema (DME)	Avastin **AND** Byooviz **OR** Cimerli	01/01/2024
		Diabetic Retinopathy (DR)		
		Macular Edema Following Retinal Vein Occlusion (RVO)		
		Myopic Choroidal Neovascularization (mCNV)	Byooviz **OR** Cimerli	
		Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Avastin **AND** Byooviz **OR** Cimerli	
	Susvimo	Neovascular (wet) Age-related Macular Degeneration (AMD)	Avastin **AND** Byooviz **OR** Cimerli	01/01/2024
	Vabysmo	Diabetic Macular Edema (DME)	Avastin **AND** Byooviz **OR** Cimerli **AND** Eylea	01/01/2024
		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
Osteoarthritis (Viscosupplements)	**Durolane**		Orthovisc **OR** Synvisc **OR** Synvisc-One	01/01/2024
	Euflexxa			01/01/2024
	Gel-One			01/01/2024
	Gelsyn-3			01/01/2024
	Genvisc 850			01/01/2024
	Hyalgan			01/01/2024
	Hymovis			01/01/2024
	Monovisc			01/01/2024
	Supartz			01/01/2024
	Supartz Fx			01/01/2024

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	Synojoynt			01/01/2024
	Triluron			01/01/2024
	TriVisc			01/01/2024
	Visco-3			01/01/2024
Paroxysmal Nocturnal Hemoglobinuria	**Soliris**		Ultomiris	01/01/2024
Rituximabs	**Riabni**	Non-cancer diagnoses	Ruxience **OR** Truxima	01/01/2024
	Rituxan			01/01/2024
	Rituxan Hycela			01/01/2024
Severe Asthma	**Tezspire**		Cinqair **OR** Fasenra **OR** Nucala **OR** Xolair	01/01/2024
Systemic Lupus Erythematosus	**Saphnelo**		Benlysta	01/01/2024
Thyroid Eye Disease	**Tepezza**		Inadequate response to at least 6 weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly), or maximally tolerated dose	01/01/2024

History:	**Date**:	**Activity**:
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

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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 (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.

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 (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