BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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|---|---|
| **EVIDENCE-BASED CRITERIA** | |
| **SECTION: MEDICARE ADVANTAGE PART B DRUGS** | |
| **ORIGINAL EFFECTIVE DATE:** | **01/01/23** |
| **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.**

**EVIDENCE-BASED CRITERIA**
**SECTION: MEDICARE ADVANTAGE PART B DRUGS**

**NEXT REVIEW DATE: 3RD QTR 2027**

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# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

**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 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | Bildyos<br>**OR**<br>Enoby | absence of fractures<br><br>•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<br>**OR**<br>Daxxify<br>**OR**<br>Dysport | | Myobloc | 01/01/2027 |
| | | | Xeomin | 01/01/2027 |
| | | | | |
| Colony-stimulating growth factors (long-acting) | Fulphila<br>**OR**<br>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<br>**OR**<br>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<br>**OR**<br>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<br>**OR**<br>Enoby | | Bosaya | 01/01/2027 |
| | | | Conexxence | 01/01/2027 |
| | | | Jubbonti | 01/01/2027 |
| | | | Ospomyv | 01/01/2027 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | | | 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<br>**OR**<br>Procrit<br>**OR**<br>Retacrit | | Epogen | 01/01/2025 |
| | | | Mircera | 01/01/2025 |
| | | | | |
| Gout | Allopurinol<br>**AND**<br>Febuxostat | | Krystexxa | 01/01/2024 |
| | | | | |
| Hemolytic uremic syndrome, atypical (Ahus) | Ultomiris<br>**OR**<br>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*<br><br>**AND**<br><br>Praluent<br>**OR**<br>Repatha | | Evkeeza | 01/01/2024 |
| | | | | |
| Immunoglobulin | Cutaquig<br>**OR**<br>Flebogamma<br>**OR**<br>Gammagard ERC<br>**OR**<br>Gammagard Liquid<br>**OR**<br>Gammaked<br>**OR**<br>Gamunex-C<br>**OR**<br>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 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | **OR**<br>Octagam<br>**OR**<br>Privigen | | | |
| | | | | |
| Immunologics | Avsola<br>**OR**<br>Renflexis<br>**OR**<br>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<br>**OR**<br>Renflexis<br>**OR**<br>Starjemza<br>**OR**<br>Steqeyma<br>**OR**<br>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<br>**OR**<br>Renflexis<br>**OR**<br>Starjemza<br>**OR**<br>Steqeyma<br>**OR**<br>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<br>**OR**<br>Renflexis | Psoriatic arthritis | Cimzia | 01/01/2027 |
| | | | Cosentyx | 01/01/2027 |
| | | | Imuldosa | 01/01/2027 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | **OR**<br>Simponi Aria<br>**OR**<br>Starjemza<br>**OR**<br>Steqeyma<br>**OR**<br>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<br>**OR**<br>Renflexis<br>**OR**<br>Simponi Aria<br><br>**AND**<br><br>Avtozma<br>**OR**<br>Tyenne | Rheumatoid Arthritis | Actemra | 01/01/2027 |
| | Avsola<br>**OR**<br>Renflexis<br>**OR**<br>Simponi Aria | | Avtozma | 01/01/2027 |
| | Avsola<br>**OR**<br>Renflexis<br>**OR**<br>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<br>**OR**<br>Renflexis<br>**OR**<br>Simponi Aria<br><br>**AND**<br><br>Avtozma<br>**OR**<br>Tyenne | | Tofidence | 01/01/2027 |
| | Avsola<br>**OR**<br>Renflexis<br>**OR** | | Tyenne | 01/01/2027 |

**EVIDENCE-BASED CRITERIA**
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# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | Simponi Aria | | | |
| | | | | |
| Immunologics | Avsola<br>**OR**<br>Renflexis<br>**OR**<br>Starjemza<br>**OR**<br>Steqeyma<br>**OR**<br>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<br>**OR**<br>Renflexis | | Inflectra | 01/01/2026 |
| | | | Infliximab | 01/01/2026 |
| | | | Remicade | 01/01/2026 |
| | | | | |
| IV Iron | Ferrlecit<br>**OR**<br>INFeD<br>**OR**<br>Venofer | | Feraheme | 01/01/2024 |
| | | | Injectafer | 01/01/2024 |
| | | | Monoferric | 01/01/2024 |
| | | | | |
| Leqvio | High-Intensity Statin*<br><br>**AND**<br><br>Praluent<br>**OR**<br>Repatha | | Leqvio | 01/01/2024 |
| | | | | |
| Multiple Sclerosis | Briumvi<br>**OR**<br>Ocrevus | | Lemtrada | 01/01/2024 |
| | | | Tyruko | 01/01/2024 |
| | | | Tysabri | 01/01/2024 |
| | | | | |
| Myasthenia gravis | Epysqli<br>**OR**<br>Ultomiris<br><br>**AND**<br><br>Vyvgart<br>**OR**<br>Vyvgart Hytrulo | | Bkemv | 01/01/2027 |
| | | | Soliris | 01/01/2027 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

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

## AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | **AND**<br>Lucentis | | | |
| | Bevacizumab<br>**AND**<br>Lucentis | | Cimerli | 01/01/2027 |
| | Bevacizumab<br>**AND**<br>Lucentis<br>**AND**<br>Yesafili | | Eylea | 01/01/2027 |
| | Bevacizumab<br>**AND**<br>Lucentis<br>**AND**<br>Yesafili | | Eylea HD | 01/01/2027 |
| | Bevacizumab | | Lucentis | 01/01/2025 |
| | Bevacizumab<br>**AND**<br>Lucentis | | Nufymco | 01/01/2027 |
| | Bevacizumab<br>**AND**<br>Lucentis<br>**AND**<br>Yesafili | | Pavblu | 01/01/2027 |
| | Bevacizumab<br>**AND**<br>Lucentis<br>**OR**<br>Yesafili | | Susvimo | 01/01/2027 |

# AZ BLUE MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

| | | | | |
|---|---|---|---|---|
| | Bevacizumab<br>**AND**<br>Lucentis<br>**AND**<br>Yesafili | | Vabysmo | 01/01/2027 |
| | Bevacizumab | | Yesafili | 01/01/2027 |
| | | | | |
| Osteoarthritis of the Knee (Intra-articular steroids) | Betamethasone<br>**OR**<br>Dexamethasone<br>**OR**<br>Methylprednisolone<br>**OR**<br>Triamcinolone | | Zilretta | 01/01/2024 |
| | | | | |
| Paroxysmal Nocturnal Hemoglobinuria | Ultomiris<br>**OR**<br>Epysqli | | Bkemv | 01/01/2027 |
| | | | PiaSky | 01/01/2027 |
| | | | Soliris | 01/01/2027 |
| | | | | |
| Rituximabs | Riabni<br>**OR**<br>Ruxience | | Rituxan | 01/01/2027 |
| | | | Rituxan Hycela | 01/01/2027 |
| | | | Truxima | 01/01/2027 |
| | | | | |
| Severe Asthma | Fasenra<br>**OR**<br>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<br>**OR**<br>Tyenne | | Actemra | 01/01/2027 |
| | | | Tofidence | 01/01/2027 |
| | | | | |
| Trastuzumab | Ogivri<br>**OR**<br>Ontruzant | | Herceptin | 01/01/2027 |
| | | | Herceptin Hylecta | 01/01/2027 |
| | | | Hercessi | 01/01/2027 |

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| | | | | |
|---|---|---|---|---|
| | **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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| **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

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