BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

TARPEYO™ (budesonide) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **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.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for therapy:** Tarpeyo (budesonide) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Nephrologist or Immunologist

  2. Individual is 18 years of age or older

  3. Individual has a confirmed diagnosis of primary immunoglobulin A nephropathy (IgAN) and is at risk for rapid disease progression

  4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:

a. Biopsy proven IgAN
b. Proteinuria of at least 1 g/day **or** UPCR of at least 1.5 g/g
c. Estimated glomerular filtration rate is at least 35 mL/min/1.73m^2

5. Individual is on stable doses of maximally tolerated angiotensin converting enzyme inhibitor (such as lisinopril, enalapril, etc.) **or** angiotensin receptor blocker (such as losartan, irbesartan, etc.) therapy

6. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
   a. Prednisone (or methylprednisolone)
   b. Mycophenolate mofetil

8. There are **NO** FDA-label contraindications, such as: Hypersensitivity to budesonide

9. Agent will not be used in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex

10. Individual does not have severe hepatic impairment (Child-Pugh Class C)

11. Individual is not currently taking any other drugs which cause any significant drug interactions requiring discontinuation such as strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine)

Approval duration: 9 months plus 2-weeks
- safety and efficacy of subsequent treatment courses have not been established

➢ Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Tarpeyo (budesonide) is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo (budesonide) slows kidney function decline in patients with IgAN. The recommended duration of therapy is 9-months. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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Most patients with IgAN present with either gross hematuria (single or recurrent), usually accompanying an upper respiratory infection, or microscopic hematuria with or without mild proteinuria detected on a routine examination. Less commonly, patients may present with either nephrotic syndrome or an acute, rapidly progressive glomerulonephritis.

The diagnosis of IgAN should be suspected in any patient who presents with one or more episodes of gross hematuria (especially if accompanied by an upper respiratory infection), persistent microscopic hematuria with or without proteinuria, or slowly progressive kidney function impairment. The diagnosis is confirmed by kidney biopsy. However, a kidney biopsy is usually performed only if there are signs suggestive of more severe or progressive disease, such as persistent proteinuria of at least 500 mg per day or an elevated serum creatinine concentration.

Budesonide reduces the activity of endogenous chemical mediators of inflammation (e.g., kinins, prostaglandins). Budesonide is available in the following dosage forms: capsule, delayed release (e.g., Tarpeyo); capsule, delayed release particles (e.g., Entocort EC, others); capsule, extended release (e.g., Ortikos); and tablet, extended release (e.g., Uceris, others).

Oral budesonide formulations allow for targeted, pH-dependent budesonide release in the treatment of IBD (e.g., Crohn disease, ulcerative colitis). The capsule, delayed release form is designed to release the drug in the ileocecal region where Peyer patches are located. Mucosal B lymphocytes localized within Peyer patches are postulated to be a source of aberrant production of galactosylated IgA, which has been implicated in the pathogenesis of IgAN. The capsule, controlled release particles contain enteric coated granules that dissolve at a pH ≥ 5.5, delivering budesonide to the ileum and ascending colon. The multi-matrix enteric coated tablet dissolves at a pH ≥ 7, delivering budesonide to the entire colon.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Tarpeyo (budesonide) delayed release cap product information, revised by Calliditas Therapeutics AB 06-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 26, 2025.

Cheung CK, Barratt J. IgA nephropathy: Clinical features and diagnosis. In: UpToDate, Glassock RJ, Fervenza FC, Cappo R, Lam AQ (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through December 2024. Topic last updated January 05, 2024. Accessed January 08, 2025.

Cattran DC, Appel GB, Coppo R. IgA nephropathy: Treatment and prognosis. In: UpToDate, Glassock RJ, Fervenza FC, Lam AQ (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through December 2024. Topic last updated March 21, 2024. Accessed January 08, 2025.

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