**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 2/17/2022**
**LAST REVIEW DATE:**
**LAST CRITERIA REVISION DATE:**
**ARCHIVE DATE:**

# TARPEYO™ (budesonide) oral

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline 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.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

# TARPEYO™ (budesonide) oral

**Criteria**:

- **Criteria for therapy:** Tarpeyo (budesonide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of primary immunoglobulin A nephropathy (IgAN) at risk for rapid disease progression

  4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring 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. Documented failure, contraindication per FDA label, intolerance, or not a candidate to **ALL** the following:
     a. Prednisone
     b. Methylprednisolone
     c. Mycophenolate mofetil

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

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

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

  10. There are no significant interacting drugs

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

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- 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.

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 contains 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.

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**Resources:**

Tarpeyo (budesonide) product information, revised by Calliditas Therapeutics AB 12-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 31, 2021.

Cheung CK, Barratt J. IgA nephropathy: Clinical features and diagnosis. In: UpToDate, Glassock RJ, Fervenza FC, Lam AQ (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated January 10, 2022. Accessed January 13, 2022.

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. Topic last updated January 03, 2022. Accessed January 13, 2022.