Pharmacy Policy Bulletin

Title:	Budesonide (Tarpeyo™)
Policy #:	Rx.01.262

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Budesonide (Tarpeyo™)** as provided under the member's prescription drug benefit.

Description:

Immunoglobulin A nephropathy (IgAN) or Berger's disease is a condition that damages the glomeruli inside the kidneys and can cause kidney disease. The kidney gets inflamed and can cause the kidneys to leak blood and protein which leads to loss of kidney function and kidney failure.

Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Mucosal B-cells present in the ileum, including the Peyer's patches, express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity. It has not been established to what extent TARPEYO's efficacy is mediated via local effects in the ileum vs systemic effects.

TARPEYO is 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.

Policy:

Budesonide (Tarpeyo™) is approved when ALL of the following are met:

1. Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy; and
2. Member is 18 years of age or older; and
3. Member is at risk of rapid disease progression (e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool); and
4. Used to reduce proteinuria; and
5. Estimated glomerular filtration rate (eGFR) greater than or equal to 35 ml/min/1.73 m2; and
6. One of the following:
    a. Member has been on a minimum 90-day trial of maximally tolerated dose and will continue to receive therapy with one of the following:
        i. An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril); or
        ii. An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan); or
    b. Member is unable to tolerate BOTH ACE inhibitors and ARBs; and
7. Inadequate response or inability to tolerate another glucocorticoid (e.g., prednisone, methylprednisolone); and
8. Prescribed by or in consultation with a nephrologist

Authorization duration: 9 months

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Tarpeyo (budesonide) [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB. December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=938cada4-d6bf-4252-836f-dd40f9eadb4d. Accessed April 18, 2023.

Cattran DC. IgA nephropathy: Treatment and prognosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed April 18, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Tarpeyo™	Budesonide

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	2.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024