

budesonide delayed release (Tarpeyo™)

Policy # 00798

Original Effective Date: 07/11/2022

Current Effective Date: 07/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider budesonide delayed release capsules (Tarpeyo™)† for the treatment of primary immunoglobulin A nephropathy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for budesonide delayed release capsules (Tarpeyo) will be considered when the following criteria are met:

- Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN); AND
- Patient is greater than or equal to 18 years of age; AND
- Diagnosis has been confirmed by biopsy; AND
- According to the prescriber, the patient has received greater than or equal to 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient is at high risk of disease progression, defined by meeting the following criteria:
 - Patient meets ONE of the following:
 - Proteinuria greater than or equal to 1 g/day; OR
 - Urine protein to creatinine ratio greater than or equal to 0.8 g/g; AND

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has been receiving the maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) (e.g., lisinopril, enalapril, benazepril, captopril, fosinopril, moexipril, perindopril, quinapril, ramipril, trandolapril) or angiotensin receptor blocker (ARB) (e.g., candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan) for greater than or equal to 90 days; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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- Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73m²; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has not received a previous complete course of Tarpeyo (defined as 9 consecutive months of therapy).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of budesonide delayed release (Tarpeyo) when the patient has not received at least 90 days of optimized supportive care, the patient doesn't meet criteria defining a high risk of disease progression or the patient has an estimated glomerular filtration rate less than 30 mL/min/1.73m² to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of budesonide extended release when patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational**.*

Background/Overview

Tarpeyo contains the active ingredient budesonide in a delayed release formulation designed to release the drug in the ileocecal region where it is postulated that Mucosal B lymphocytes may be a source of abnormal immunoglobulin A₁. This immunoglobulin may be involved in the pathogenesis of immunoglobulin A nephropathy (IgAN). Tarpeyo is indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression. Tarpeyo is available in 4 mg capsules and should be dosed as 16 mg once daily for 9 months. For the last two weeks of therapy, the dose should be reduced to 8 mg once daily.

IgAN is the most common cause of primary glomerulonephritis in resource-abundant settings. Around 25% of patients with this condition have a slow progression to end-stage kidney disease (ESKD) within 25 years of presentation. The remaining patients enter a sustained remission or have persistent low-grade hematuria and/or proteinuria. There is no single universally accepted definition of 'high risk' for disease progression in IgAN. However, several clinical and pathological features are consistently associated with increased risk. These include persistent proteinuria (with risk increasing at levels ≥ 0.5 g/day and particularly ≥ 1 g/day despite optimized supportive care), hypertension, reduced estimated glomerular filtration rate (eGFR) at baseline, and adverse histopathologic findings (e.g., Oxford MEST-C classification features). The goal of treating IgAN is to prevent disease progression to ESKD by reducing proteinuria to less than 0.5 to 1 g/day and resolving microscopic hematuria. The first-line treatment options to achieve this goal are supportive care with blood pressure control, maximally tolerated renin-angiotensin system blockade, treatment

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with a sodium-glucose cotransporter-2 (SGLT2) inhibitor, and lifestyle modification. After 3-6 months of optimized supportive care, patients at high risk may require further therapy with immunosuppressive agents such as glucocorticoids to reduce risk.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tarpeyo was approved in December 2021 under accelerated approval to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥ 1.5 g/g. In December 2023, Tarpeyo gained full approval and the indication was broadened to remove the prescriptive risk criteria language.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The effect of Tarpeyo on proteinuria was assessed in a randomized, double-blind, multicenter study in patients with biopsy-proved IgAN, estimated glomerular filtration rate ≥ 35 mL/min/1.73m², and proteinuria (defined as either ≥ 1 g/day or UPCR ≥ 0.8 g/g) who were on a stable dose of maximally-tolerated renin-angiotensin inhibitor therapy. Patients with other glomerulopathies, nephrotic syndrome, or those who had been treated with systemic immunosuppressive medications were excluded. Patients were randomized 1:1 to either Tarpeyo 16 mg once daily or placebo and treated for 9 months followed by a 2-week taper of either Tarpeyo 8 mg once daily or placebo.

The primary endpoint was the percentage reduction in UPCR at 9 months compared to baseline and was evaluated in 199 patients who completed the Month 9 visit. In the Tarpeyo group, the percentage reduction in UPCR was 34% compared to 5% in the placebo group ($p = 0.0001$).

References

1. Tarpeyo [package insert]. Calliditas Therapeutics AB. Stockholm, Sweden. Updated January 2026.
2. IgA Nephropathy: Treatment and Prognosis. UpToDate. Updated January 2022.
3. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). *Kidney International*. 2025;108(4S):S1–S71.

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06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. New policy.

06/01/2023 Medical Policy Committee review

06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/06/2024 Medical Policy Committee review

06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/05/2025 Medical Policy Committee review

06/11/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/04/2026 Medical Policy Committee review

06/10/2026 Medical Policy Implementation Committee approval. Updated criteria and background information to reflect label update to risk factors for high risk of progression.

Next Scheduled Review Date: 06/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.