Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Tarpeyo (budesonide)

Effective: August 11, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Tarpeyo (budesonide) is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of **Tarpeyo** for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of immunoglobulin A nephropathy confirmed by kidney biopsy

AND

2. Documented urine protein-to-creatinine ratio (UPCR) of at least 1.5 g/g or proteinuria ≥ 1 g/day

AND

3. Documented estimated glomerular filtration rate of at least 35 mL/min/1.73 m^2

AND

4. Prescribed by or in consultation with a nephrologist

AND

5. Documentation the patient has not developed end stage renal disease by requiring either dialysis or a kidney transplant

AND

6. Documentation that the member has received or is currently receiving at least 3 months of therapy with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) (at up to maximally indicated doses), unless contraindicated or not tolerated

AND

7. Documentation that the member has received or is currently receiving at least 3 months of therapy with a sodium-glucose cotransporter-2 inhibitor (SGLT2i), unless contraindicated or not tolerated

AND

8. Documentation that the member has received optimized supportive care for at least 3 months, including blood pressure management, lifestyle modification, and cardiovascular risk modification

Limitations

1. Coverage authorization for Tarpeyo is limited to 9 months. Coverage past 9 months of therapy will not be authorized.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Tarpeyo (budesonide) [package insert]. Stockholm, Sweden: Calliditas Therapeutics; June 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1–S276.

Approval And Revision History

June 13, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 11, 2024: Effective September 1, 2024, updated that coverage for Tarpeyo is limited to 9 months, and coverage past 9 months of therapy will not be authorized. Reauthorization criteria removed. Administrative update to Tarpeyo's full FDA-approved indication within the overview section.
- June 10, 2025: No changes
- August 12, 2025: Effective November 1, 2025, updated coverage criteria to include proteinuria ≥ 1 g/day and 3-month trial of angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), sodium-glucose cotransporter-2 inhibitor (SGLT2i), and supportive care.
- August 11, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.