Pharmacy Medical Necessity Guidelines:
Tarpeyo (budesonide)

Effective: August 11, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-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,.

COVERAGE GUIDELINES

The plan may authorize coverage of Tarpeyo (budesonide) 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 30 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.

CODES

None

REFERENCES

1. Tarpeyo (budesonide) [package insert]. Stockholm, Sweden: Calliditas Therapeutics; June 7, 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 HISTORY

June 13, 2023: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

- August 13, 2024: Effective November 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. Administrative change to fax number.

- August 12, 2025: Effective November 1, 2025: Updated coverage criteria to include proteinuria ≥ 1 g/day and 3-month trial of ACEi, ARB, SGLT2i, and supportive care.
- August 11, 2026: No changes.

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.

Provider Services