Original Effective Date: 12/08/2022
Current Effective Date: 10/12/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 07/2026
Policy Number: C24199-A

Tarpeyo (budesonide)

PRODUCTS AFFECTED

Tarpeyo (budesonide) delayed release capsules

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Primary Immunoglobulin A Nephropathy (IgAN)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN):
   1. Documented diagnosis of Primary Immunoglobulin A Nephropathy (IgAN)
      AND
   2. Documentation diagnosis was confirmed by kidney biopsy

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AND

3. Documentation that member is receiving a stable dose of a Renin-angiotensin-system (RAS) inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose [3]
   AND
4. Documentation that member has had a trial and failure of ONE formulary preferred glucocorticoid for at least 2 months. [4]
   AND
5. Documentation that member's eGFR is ≥35 mL/min/1.73 m2
   AND
6. Member is not currently receiving dialysis or has not undergone kidney transplant.
   AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Tarpeyo (budesonide) delayed release capsules include: Hypersensitivity to budesonide or any of the ingredients in Tarpeyo, avoid use in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex, Avoid use in patients with severe hepatic impairment (Child-Pugh Class C), Avoid use with potent CYP3A4 inhibitors; e.g. ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine.]

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: 9 months; Continuation or therapy: NA
NOTE: The recommended duration of therapy is 9 months, with a dosage of 16 mg administered orally once daily. When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy. Safety and efficacy of treatment with subsequent courses of TARPEYO have not been established.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified Nephrologist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
16 mg once daily (4 capsules per day)

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Glucocorticosteroids

HIGH RISK ALERT

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FDA-APPROVED USES:
Indicated to reduce the loss of kidney functions in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Per the KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases, kidney biopsy is the "gold standard" for diagnostic evaluation of glomerular disease. The guideline further notes that IgAN can only be diagnosed with a kidney biopsy (Chapter 2, reference 3). Additionally, the use of an ACE inhibitor or ARB up to a maximally tolerated or allowed dose is considered first line therapy for the treatment of hypertension and proteinuria. The guideline defines a high risk for progressive disease as proteinuria greater than 0.75 to 1 gram despite the use of optimized supportive care, including an ACE inhibitor or ARB, for at least 90 days. For those patients who remain at high risk of progressive CKD despite the maximized supportive care, immunosuppressive drugs should be considered.

Tarpeyo was studied in the Nef-301 (NCT 03643965) randomized, double blind, clinical trial in patients with biopsy proven IgAN. Patients were required to have an eGFR greater than 35 mL/min/1.73 m2 and proteinuria. Patients were also required to be stable on a maximally tolerated RAS inhibitor. The primary end point was the percent reduction in UPCR at 9 months.

In December 2023, the FDA granted full approval to Tarpeyo (budesonide) and updated the approved indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. Recommendation duration of therapy is unchanged and remains 9 months.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Tarpeyo (budesonide) delayed release capsules are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tarpeyo (budesonide) delayed release capsules include: hypersensitivity to budesonide or any of the ingredients in Tarpeyo, avoid use in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex, Avoid use in patients with severe hepatic impairment (Child-Pugh Class C), Avoid use with potent CYP3A4 inhibitors; e.g. ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine.

OTHER SPECIAL CONSIDERATIONS:
Tarpeyo (budesonide) delayed release capsules must be swallowed whole and should not be opened or crushed. The recommended dose is 16 mg administered daily in the morning, at least 1 hour before a meal.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit*

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document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Tarpeyo CPDR 4MG

REFERENCES

1. Tarpeyo (budesonide) delayed release capsules [prescribing information]; Stockholm, Sweden: Calliditas Therapeutics AB, June 2024.
2. Fellström, B. C., Barratt, J., Cook, H., Coppo, R., Feehally, J., de Fijter, J. W., Floege, J., Hetzel, G., Jardine, A. G., Locatelli, F., Maes, B. D., Mercer, A., Ortiz, F., Praga, M., Sørensen, S. S., Tesar, V., Del Vecchio, L., & NEFIGAN Trial Investigators (2017). Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. Lancet (London, England), 389(10084), 2117–2127. https://doi.org/10.1016/S0140-6736(17)30550-0
3. 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.
4. Lv, J., Wong, M. G., Hladunewich, M. A., Jha, V., Hooi, L. S., Monaghan, H., Zhao, M., Barbour, S., Jardine, M. J., Reich, H. N., Cattran, D., Glassock, R., Levin, A., Wheeler, D. C., Woodward, M., Billot, L., Stepien, S., Rogers, K., Chan, T. M., Liu, Z. H., … TESTING Study Group (2022). Effect of Oral Methylprednisolone on Decline in Kidney Function or Kidney Failure in Patients With IgA Nephropathy: The TESTING Randomized Clinical Trial. *JAMA*, *327*(19), 1888–1898. https://doi.org/10.1001/jama.2022.5368

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements	Q3 2025
REVISION- Notable revisions: Required Medical Information Quantity FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q3 2024
REVISION- Notable revisions: Required Medical Information Duration of Approval Quantity FDA-Approved Uses Other Special Considerations	Q3 2023
Initial Policy	Q4 2022

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