Drug and Biologic Coverage Policy

Effective Date..... 6/1/2023
Next Review Date..... 6/1/2024
Coverage Policy Number IP0413

Tarpeyo

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Related Coverage Resources

Quantity Limitations – (1201)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for budesonide (**Tarpeyo**™) delayed-release capsules.

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Budesonide (**Tarpeyo**) **is considered medically necessary when the following are met:**

Primary Immunoglobulin A Nephropathy (IgAN). Individual meets **ALL** of the following criteria:
A. Age 18 years or older
B. Documentation primary IgAN is confirmed by biopsy
C. Documentation of an estimated glomerular filtration rate of at least 30 mL/min/1.73 m^2

D. Documentation of **ONE** of the following:
    i. Proteinuria greater than 0.75 g/day
    ii. Urine protein-to-creatinine ratio greater than or equal to 1.5 g/g
E. Documentation the maximum or maximally tolerated dose of either an angiotension converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) has been received for at least 90 days
F. Has received at least 3 months of supportive care, including blood pressure management, cardiovascular risk modification and lifestyle modification
G. Medication is prescribed by, or in consultation with, a nephrologist
H. Non-Covered Product Criteria is met, refer to below table

Employer Group, Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Tarpeyo (budesonide delayed-release capsules)	Documentation of failure, contraindication or intolerance to **ONE** systemic corticosteroid.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of Budesonide (Tarpeyo) is considered medically necessary for primary IgAN when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 10 months
Reauthorization approval duration: up to 10 months (if initial approval was for less than 10 months, then total initial approval plus reauthorization duration is up to 10 months total)

Approval is **NOT** to exceed 10 consecutive months; for example, if an individual has received 3 consecutive months, then approve 7 months to complete 10 consecutive months of therapy.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

The use of Tarpeyo beyond a 10 month course of therapy: The recommended duration of therapy is 9 months. The safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.[1]

Background

OVERVIEW
*Tarpeyo, a corticosteroid, 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.[1] This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.*

The recommended dose is 16 mg orally once daily (QD) at least 1 hour before a meal for 9 months.[1] When discontinuing therapy, the dose is reduced to 8 mg QD for the last 2 weeks of therapy. Safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.

Clinical Efficacy
The efficacy of Tarpeyo was evaluated in one pivotal, 9-month trial in patients ≥ 18 years of age with IgAN.[1] Eligible patients had biopsy-proven IgAN, proteinuria (defined as either ≥ 1 g/day or UPCR ≥ 0.8 g/g despite optimized supportive care), and estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m^2 and ≤ 90 mL/min/1.73 m^2.[2] Optimized supportive care required that patients receive the maximum tolerated or maximum allowed dose of an angiotensin-converting enzyme inhibitor and/or angiotensin II type I receptor blocker for ≥ 3 months prior to randomization and continued throughout the trial. Tarpeyo resulted in statistically greater reduction in UPCR and less eGFR decline relative to placebo after 9 months of treatment. As part of a prespecified analysis, it was observed that in the subgroup of patients who entered the trial with baseline UPCR ≥ 1.5 g/g, the eGFR benefit was greater in the Tarpeyo-treated patients vs. the overall population, further supporting the approved indication.

Guidelines
Tarpeyo is recognized as new therapy "in development" for high-risk IgAN patients by the Kidney Diseases Improving Global Outcomes (KDIGO) guidelines for the management of glomerular diseases (2021).[3] According to the guidelines, a number of new therapies for high-risk IgAN patients are being evaluated that may augment the supportive care approach or more specific approaches (e.g., Tarpeyo, various complement inhibitors, and therapies targeting B-cell development).

Following biopsy-confirmed diagnosis of IgAN, the guidelines recommend assessment of disease progression.[3] The primary focus of IgAN treatment should include multiple modalities such as renin angiotensin system blockage (maximum dose or maximum tolerated dose), blood pressure control, cardiovascular risk minimization, and adherence to lifestyle advice (i.e., dietary counseling, smoking cessation, weight control, and exercise as appropriate). When proteinuria remains > 0.75 to 1.0 g/day despite ≥ 90 days of optimized supportive care, the patient has a high risk of progressive loss of kidney function and may be considered for a 6-month course of steroid therapy (recently cited trials include prednisone or methylprednisolone), or preferably the opportunity to take part in a clinical trial.[4] Guidelines point out that the clinical benefit of steroids in IgAN is not established, and should be used with extreme caution or avoided in patients with eGFR < 30 mL/min/1.73 m^2, diabetes, obesity (body mass index > 30 kg/m^2), latent infections (e.g., tuberculosis, viral hepatitis), secondary disease (e.g., cirrhosis), active peptic ulceration, uncontrolled psychiatric illness, and severe osteoporosis. There are no data to support the efficacy or reduced toxicity of alternate day steroid regimens or dose-reduced protocols.

References

1. Tarpeyo capsules [prescribing information]. Stockholm, Sweden: Calliditas; December 2021.
2. Barratt J, Lafayette R, Kristensen J, et al; for the NefIgArd Trial Investigators. Results from part A of the Multicenter, double-blind, randomized, placebo-controlled NefIgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy. *Kidney International.* 2022 Oct 19 [Epub ahead of print].
3. KDIGO 2021 clinical practice guidelines for the management of glomerular diseases. *Kidney International.* 2021;100:S1-S276. Available at: https://www.kidney-international.org/action/showPdf?pii=S0085-2538%2821%2900562-7. Accessed on: January 10, 2023.