Tarpeyo (budesonide delayed release) capsules

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tarpeyo drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies.

FDA-Approved Indication

Tarpeyo (budesonide delayed release [DR]) is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).

Laboratory report and/or chart note(s) indicating that the member is at risk for disease progression defined by proteinuria greater than or equal to 0.5 g/day

Prescriber Specialties

Tarpeyo must be prescribed by or in consultation with a nephrologist

Criteria for Approval

Authorization of 10 months may be granted when all of the following criteria are met:

A. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy
B. Member is 18 years of age or older
C. Member is at risk of rapid disease progression defined by proteinuria greater than or equal to 0.5 g/day
D. Member's eGFR must be equal to or greater than 35 mL/min per 1.73 m^2

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E. Member is currently receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin II receptor blockers [ARBs]) for at least 3 months and will continue RAS inhibitor therapy or member has an intolerance or contraindication to RAS inhibitors
F. Dose does not exceed 16 mg (4 capsules) per day for 9 months, followed by 8 mg (2 capsules) per day for two weeks
G. The requested medication will not be used in combination with Filspari (sparsentan), Vanrafia (atrasentan), Voyxact (sibeprenlimab-szsi), or Fabhalta (iptacopan)
H. Member has not received more than 40 weeks* of treatment with Tarpeyo

**Safety and efficacy of subsequent treatment courses beyond 40 weeks have not been established.*

Tarpeyo is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the Criteria for Approval above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

120 capsules per 30 days (4 capsules per day). Duration limit: 40 weeks per lifetime.

CLINICAL RATIONALE

Tarpeyo (budesonide DR) is an oral targeted-release formulation that was designed to release budesonide, a glucocorticoid, in the ileocecal region where Peyer's patches are located. Mucosal B lymphocytes localized within Peyer's patches are thought to be a source for the production of immunoglobulin (Ig)A1 that is galactose deficient (GdIgA1), which has been thought to contribute to the pathogenesis of IgAN. GdIgA1 can form large immune complexes with anti-glycan IgG antibodies in circulation that can bind to glomerular mesangial cells resulting in stimulation of cell proliferation, release of inflammatory mediators that promote proteinuria, and fibrotic remodeling, ultimately leading to loss of renal function. Tarpeyo (budesonide DR) is the first medication FDA approved to reduce the loss of kidney function in adults with primary IgAN.

Efficacy

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The efficacy and safety of Tarpeyo (budesonide DR) were evaluated in an unpublished, randomized, double-blind, multicenter, phase III clinical trial (Nef-301) in 199 patients (68% male; 86% White; 12% Asian; 16% from the U.S.; median age 44 years) with biopsy-proven IgAN, estimated GFR ≥ 35 mL/min/1.73 m2 and proteinuria (i.e., ≥ 1 g/day or UPCR ≥ 0.8 g/g) who were receiving a stable dose of maximally tolerated RAS inhibitor therapy (Barratt, 2021; Tarpeyo prescribing information, 2021). At baseline, the mean estimated GFR was approximately 58 mL/min/1.73 m2, with 62% of patients having an estimated GFR < 60 mL/min/1.73 m2. The mean baseline UPCR was 1.6 g/g, and 25% of patients had proteinuria > 3.5 g/24 hours. Approximately 73% of patients had a history of hypertension, and 5% had a history of type 2 diabetes mellitus. At baseline, 98% were treated with an ACE inhibitor or ARB, and < 1% of patients were receiving a sodium-glucose cotransporter-2 (SGLT2) inhibitor.

Patients treated with Tarpeyo (budesonide DR) had a 34% reduction in UPCR at 9 months compared with a 5% reduction for patients treated with placebo (treatment difference 31%; 95% confidence interval 16 to 42; p = 0.0001) (Tarpeyo prescribing information, 2021). No significant differences were seen between subgroups, including key demographic and baseline disease. In the final analysis of 364 patients, the trial met the prespecified Part B primary endpoint (p<0.0001) and at Year 2, there was a 5.9 mL/min/1.73 m^2 difference in the mean change from baseline in eGFR between Tarpeyo and placebo (95% CI: 3.3 to 8.5 mL/min/1.73 m^2; p<0.0001).

Safety

Tarpeyo (budesonide DR) is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients in Tarpeyo (budesonide DR) (Tarpeyo prescribing information, 2021). Serious hypersensitivity reactions, including anaphylaxis have occurred with other budesonide formulations. Warnings and precautions for Tarpeyo (budesonide DR) include hypercorticism and adrenal axis suppression and risks of immunosuppression. In addition, patients with conditions where corticosteroids have unwanted effects (e.g., hypertension and diabetes mellitus) should be monitored. The most common adverse events associated with Tarpeyo (budesonide DR) include hypertension (16%), peripheral edema (14%), muscle spasms (13%), acne (11%), dermatitis (7%), increased weight (7%), dyspnea (6%), face edema (6%), dyspepsia (5%), fatigue (5%), and hirsutism (5%). Budesonide is a substrate for cytochrome P450 (CYP) 3A4, and therefore use with potent CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, saquinavir, erythromycin, cyclosporine) can cause increased systemic budesonide concentrations. Grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide, and therefore intake of grapefruit juice should be avoided. Use of Tarpeyo (budesonide DR) should be avoided in patients with severe hepatic impairment, and patients with moderate hepatic impairment should be monitored for increased signs and symptoms of hypercorticism. Tarpeyo (budesonide DR) may have a more favorable adverse event profile than other systemic corticosteroids since it undergoes extensive first-pass metabolism; less than 10% of budesonide enters the systemic circulation.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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*Some content reprinted from CVS Health

POLICY HISTORY

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