BlueCross BlueShield Federal Employee Program

TARPEYO
(budesonide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tarpeyo (budesonide) is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Mucosal B-cells present in the ileum, including the Peyer's patches, express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity (1).

Regulatory Status

FDA-approved indication: Tarpeyo is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression (1).

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 (1).

Tarpeyo contains warnings regarding hypercorticism and adrenal axis suppression, risks of immunosuppression, and other corticosteroid effects (1).

The clinical trials for Tarpeyo had inclusion criteria for patients to be on a maximum recommended or maximum tolerated dose of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB). Patients also had an estimated glomerular filtration rate (eGFR) of ≥ 35 mL/min/1.73 m2. The trial also had exclusion criteria for patients who had undergone a kidney transplant; patients with severe liver disease; patients with type 1 or type 2 diabetes mellitus; and patients with uncontrolled cardiovascular disease (2).

The safety and efficacy of Tarpeyo in pediatric patients less than 18 years of age have not been established (1).

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Summary

Tarpeyo (budesonide) is a corticosteroid used to treat adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. The recommended treatment duration is one treatment course of 9 months. Tarpeyo contains warnings regarding hypercorticism and adrenal axis suppression, risks of immunosuppression, and other corticosteroid effects. The safety and efficacy of Tarpeyo in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tarpeyo while maintaining optimal therapeutic outcomes.

References

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; December 2023.
2. Fellstrom BC, Barratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. Lancet. May 27, 2017;389(10084):2117-2127.