Tarpeyo (budesonide delayed release capsules)

Summary

IgA nephropathy, also known as Berger's disease, is a type of kidney disease that is caused by the accumulation of immunoglobulin A (IgA) in the kidneys. It is a chronic, progressive disease that can lead to kidney failure if left untreated.

The exact cause of IgA nephropathy is not fully understood, but it is believed to be related to an abnormal immune response that causes the body to produce aberrant galactose-deficient IgA1, which then accumulates in the kidneys. This accumulation can lead to inflammation and damage to the small blood vessels in the kidneys, leading to a decrease in kidney function over time.

The most common symptom of IgA nephropathy is blood in the urine, which may be visible or only detected through laboratory tests. Other symptoms may include proteinuria (excess protein in the urine), high blood pressure, swelling of the hands and feet, decreased kidney function and fatigue. However, some people with IgA nephropathy may have no symptoms at all.

Diagnosis of IgA nephropathy typically involves a combination of urine tests and blood tests and is confirmed via kidney biopsy. Treatment options depend on the severity of the disease and may include medications to control blood pressure (such a Angiotensin-converting enzyme [ACE] inhibitors and Angiotensin II receptor blockers [ARBs]), reduce or stop pathogenic forms of IgA and IgA-IC formation, and reduce or stop IgA-mediated kidney injury. Dietary and lifestyle changes to help protect the kidneys are also recommended. In addition to blood pressure-lowering agents, other therapeutic approaches include Tarpey (targeted budesonide delayed release capsules), systemic glucocorticoids, sodium-glucose cotransporter-2 inhibitors (SGLT2-is), and less frequently immunosuppressive therapy such mycophenolate mofetil, calcineurin inhibitors (cyclosporine, tacrolimus), rituximab, cyclophosphamide, azothiaprine, leflunomide, hydroxychloroquine.

In some cases, IgA nephropathy may progress to end-stage renal disease, which requires dialysis or kidney transplant. However, early diagnosis and treatment can help slow the progression of the disease and preserve kidney function.

Tarpeyo (budesonide delayed release capsules) is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. Tarpeyo (budesonide delayed release capsules) approval was based on the findings of the NefIgArd study, which found that in participants on a stable dose of maximally tolerated renin-angiotensin-System (RAS) inhibitor therapy in the Tarpeyo arm had a significant reduction in urine-protein-to-creatinine ratio (UPCR) and significantly lower decline in renal function (measured by estimated glomerular filtration rate[eGFR]). The recommended dose of Tarpeyo (budesonide delayed release capsules) is 16 mg administered orally once daily for a duration of 9 months; this is followed by a reduced dose of 8 mg once daily for the last 2 weeks of (whether discontinued before 9 months or after the 9-month course).

Definitions

"Angiotensin-converting enzyme (ACE) inhibitor" is a class of medications that lowers blood pressure by relaxing blood vessels.

"Angiotensin II receptor blocker (ARB)" is a class of medications similar to ACE inhibitors, that lowers blood pressure.

"C3 glomerular nephropathy" is a set of rare kidney diseases caused by a disorder of the complement system, part of the body's immune system.

"Diabetic nephropathy" is a long-term complication of diabetes, resulting in damage to the kidneys, reduction in kidney function and can lead to chronic kidney disease or end-stage renal disease.

"Dialysis" is a procedure that removes waste and fluid from the blood when the kidneys stop working properly.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Estimated Glomerular Filtration Rate (eGFR)" is a measure of how well the kidneys are working.

"Glomerulopathies" are a group of kidney diseases that affect the tiny blood vessels that filter blood in the kidney.

"Immunoglobulin A nephropathy (IgAN)" is a disease of the kidney that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidney.

"Immunosuppressives" are any agent aimed at reducing the body's immune response, which may be used to treat conditions characterized by overactive immune systems, or to avoid rejection of bone marrow or organ transplant.

"Nephrotic syndrome" is a kidney disorder that causes the body to pass too much protein in the urine.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Proteinuria" is when elevated levels of protein are found in the urine.

"Renin-angiotensin system (RAS)" refers to the system of hormones, proteins, enzymes adn reactions that help regulate blood pressure. RAS inhibitors include ACE inhibitors and ARBs, as well as direct renin inhibitors.

"[s]" indicates state mandates may apply.

"Supportive care" is care administered in an attempt to improve quality of life in a person with an illness/disease by preventing or treating the symptoms of the disease and/or the side effects associated with the treatment of the illness/disease.

"Urine-protein-to-creatinine ratio (UPCR)" is a test that measures the amount of protein found in urine.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Tarpeyo (budesonide delayed release capsules) medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a nephrologist; *AND*
2. The member has a diagnosis of Immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND documentation of ALL of the following:
    a. Is at risk of rapid disease progression; *and*
    b. Glomerular filtration rate (eGFR) is greater than 35 mL/min/1.73 m^2; *and*
    c. Proteinuria ≥0.5 g/day or UPCR ≥0.8 g/g despite at least three months of optimized supportive care consisting of ALL of the following:[s]
        i. Lifestyle modification (such as dietary sodium and protein restriction, smoking cessation, weight control, and exercise as appropriate); *and*
        ii. Maximally tolerated renin-angiotensin system blockade (either an angiotensin-converting enzyme [ACE] inhibitor [e.g., benazepril, enalapril, lisinopril] or angiotensin receptor blocker [ARB] [e.g., candesartan, losartan, valsartan]); *or* the member is unable to use ALL, or has tried and/or failed a maximally tolerated ACE inhibitor or ARB; *AND*
3. The member meets ALL of the following:
    a. No evidence of currently receiving dialysis or having undergone kidney transplant; *or*
    b. No evidence of presence of other glomerulopathies, such as C3 glomerulopathy or diabetic nephropathy; *or*
    c. No evidence of nephrotic syndrome, characterized by proteinuria greater than 3.5 g/day, serum albumin levels below 3.0 g/dL, and with or without edema. The only exception to this exclusion criteria is for patients diagnosed with IgA nephropathy accompanied by nephrotic syndrome. In such cases, coverage for the drug may be considered; *or*
    d. No evidence of previously receiving a treatment course of Tarpeyo (budesonide delayed release capsules); *AND*
4. Tarpeyo (budesonide delayed release capsules) will be used as an add-on treatment to optimized standard care including a maximally-tolerated, stable dose of an ACE inhibitor or ARB, unless the member is unable to use ALL ACE inhibitors or ARBs; *AND*
5. The member meets ONE (1) of the following:[s]

a. The member has tried and failed generic systemic methylprednisolone with or without prednisolone or prednisone, or prednisone, for 6 to 9 months (see Appendix A)*; or*
b. The member is unable to use methylprednisolone or prednisone due to an adverse event or contraindication that would NOT exist or be reasonably expected to occur with Tarpeyo (budesonide delayed release capsules); *AND*

6. Tarpeyo (budesonide delayed release capsules) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
7. Recent (within the last 3 months) chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Tarpeyo (budesonide delayed release capsules) will be approved for up to a single 42 weeks (9-months and 2-weeks) treatment course.[s]

Experimental or Investigational / Not Medically Necessary[s]

Tarpeyo (budesonide delayed release capsules) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Autoimmune hepatitis; *or*
- Crohn disease; *or*
- Eosinophilic esophagitis; *or*
- Graft-versus-host disease; *or*
- Microscopic (lymphocytic and collagenous) colitis; *or*
- Pouchitis; *or*
- Refractory celiac disease types 1 and 2; *or*
- Ulcerative colitis; *or*
- Subsequent courses of Tarpeyo after the initial treatment course as safety and efficacy of treatment with subsequent courses have not been established. The Kidney Disease: Improving Global Outcomes (KDIGO) 2025 guidelines explicitly state that safety and efficacy data of additional courses have not yet been made available.

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Appendix A

Table 1: Recommended Dosing and duration of glucocorticoid therapy for adult patients with IgA nephropathy

Glucocorticoid	Initial dose	Duration of initial dose	Taper	Total duration of glucocorticoid therapy
Methylprednisolone (IV) and Prednisolone/prednisone (oral)	Methylprednisolone 1 g IV for 3 days at the start of months 1, 3, and 5 and Prednisolone or prednisone 0.5 mg/kg orally every other day on remaining days	6 months	None	6 months
Prednisone	1 mg/kg orally per day (maximum dose: 75 mg/day)	2 months	Reduce daily dose by 0.2 mg/kg every month for 4 months	6 months
Prednisone	0.8 to 1 mg/kg orally per day	2 months	Reduce daily dose by 5 to 10	6 to 8 months

Glucocorticoid	Initial dose	Duration of initial dose	Taper	Total duration of glucocorticoid therapy
			mg every 2 weeks for ≥4 months	
Methylprednisolone	0.4 mg/kg orally once daily (rounded to nearest 4 mg; maximum dose: 32 mg/day)	2 months	Reduce daily dose by 4 mg every month for ≥4 months	6 to 9 months
Tarpeyo (budesonide) delayed release capsules	16 mg orally daily	9 months	Reduce dose to 8 mg once daily for 2 weeks, then discontinue	9 months and 2 weeks

Clinical Guideline Revision / History Information

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