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, blood tests, and kidney biopsy. Treatment options depend on the severity of the disease and may include medications to control

blood pressure and reduce inflammation, as well as dietary and lifestyle changes to help protect the kidneys.

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.

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.

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

"**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.

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

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

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

Medical Necessity Criteria for Authorization

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, defined as urine protein-to-creatinine (UPCR) ratio of greater than or equal to (≥)1.5 g/g; ***and***
    b. glomerular filtration rate (eGFR) is greater than 35 mL/min/1.73 m^2; ***and***
    c. proteinuria ≥1 g/day or UPCR ≥0.8 g/g despite at least three months of optimized supportive care consisting of **BOTH** of the following:
        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))**; *AND***
3. The member does **NOT** have documentation of ANY of the following:
    a. currently receiving dialysis or has undergone kidney transplant; ***or***
    b. presence of other glomerulopathies, such as C3 glomerulopathy or diabetic nephropathy; ***or***
    c. 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. prior treatment with systemic immunosuppressive medications within the last 12 months; ***or***
    e. previously received 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**; *AND***
5. Tarpeyo (budesonide delayed release capsules) will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature**; *AND***
6. 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 a single 9-months treatment course.

Experimental or Investigational / Not Medically Necessary

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, or unproven. Non-covered indications include, but are not limited to, the following:

- Autoimmune hepatitis; ***or***
- Crohn disease; ***or***
- Eosinophilic esophagitis; ***or***
- Microscopic (lymphocytic and collagenous) colitis.

References

1. Barratt J, Lafayette R, Kristensen J, Stone A, Cattran D, Floege J, Tesar V, Trimarchi H, Zhang H, Eren N, Paliege A, Rovin BH; NefIgArd Trial Investigators. Results from part A of the multi-center, double-blind, randomized, placebo-controlled NefIgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy. Kidney Int. 2023 Feb;103(2):391-402. doi: 10.1016/j.kint.2022.09.017. Epub 2022 Oct 19. PMID: 36270561.
2. Barratt J, Floege J. SGLT-2 inhibition in IgA nephropathy: the new standard of care? Kidney Int 2021;100:24-26.
3. Campbell KN. Oral Glucocorticoids for IgA Nephropathy. JAMA 2022; 327:1872.
4. Canney M, Barbour SJ, Zheng Y, et al. Quantifying Duration of Proteinuria Remission and Association with Clinical Outcome in IgA Nephropathy. J Am Soc Nephrol 2021; 32:436.
5. Cattran DC, Appel GB, Coppo R. IgA nephropathy: treatment and prognosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com.
6. Fellström 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 2017.
7. 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:S1.
8. Lv J, Wong MG, Hladunewich MA, et al. Effect of oral methylprednisolone on decline in kidney function or kidney failure in patients with IgA nephropathy: the TESTING randomized clinical trial. JAMA 2022;327:1888-1898.
9. National Organization for Rare Disorders (NORD) Rare Disease Database. IgA Nephropathy. Available at: https://rarediseases.org/rare-diseases/iga-nephropathy/. Updated July 19, 2018. Accessed February 24, 2022.

10. Tarpeyo (budesonide) [prescribing information]. Stockholm Sweden: Colliditas Therapeutics AB; December 2021.
11. Vaz de Castro PAS, Bitencourt L, Pereira BWS, et al. Efficacy and safety of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers for IgA nephropathy in children. Pediatr Nephrol 2022; 37:499.
12. Wheeler D.C., et al.: A pre-specified analysis of the DAPA-CKD trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy . Kidney Int 2021; 100 (1): pp. 215-224.

Clinical Guideline Revision / History Information

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