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 and reduce inflammation (i.e., "supportive care"), as well as

dietary and lifestyle changes to help protect the kidneys. In high-risk patients (i.e, proteinuria >/= 1 g/day despite at least 3-6 months of optimized supportive care), immunosuppressive therapy is recommended (e.g., systemic glucocorticoids, targeted-release budesonide, 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 estimate 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.

"**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.

"**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.

"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.

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; ***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))**; *or*** the member is unable to use **ALL,** or has tried and/or failed **a maximally tolerated ACE inhibitor or ARB.**

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-month 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***
- Graft-versus-host disease; ***or***
- Microscopic (lymphocytic and collagenous) colitis; ***or***
- Pouchitis; ***or***
- Refractory celiac disease types 1 and 2; ***or***
- Ulcerative colitis.

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Clinical Guideline Revision / History Information

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