Ruzurgi (amifampridine)

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 medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ruzurgi policy is to encourage appropriate use according to clinical guidelines and/or clinical trials in the treatment of Lambert-Eaton myasthenic syndrome (LEMS).

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Ruzurgi is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in pediatric patients 6 to less than 17 years of age.

Compendial Uses
Lambert-Eaton myasthenic syndrome (LEMS) in adults

POLICY

Documentation
Submission of either of the following diagnostic tests is necessary to initiate prior authorization review:

A. Neurophysiology studies (e.g., electromyography)
B. Anti-P/Q type voltage-gated calcium channel antibody test
C. Documenation of clinical benefit from Firdapse therapy

Criteria for Initial Approval

A. Lambert-Eaton Myasthenic Syndrome (LEMS)

Authorization of **6 months** may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) when the diagnosis is confirmed by either of the following:

1. Neurophysiology studies (e.g., electromyography)
2. A positive anti- P/Q type voltage-gated calcium channel antibody test

Initial approval will be for **6 months**

Continuation of Therapy

Continuation of therapy may be granted for members that meet all initial criteria and are experiencing a clinical benefit since intiating therapy (e.g., improved muscle strength, improvement in mobility).

Approval will be for **12 months**

Quantity Limits Apply

Ruzurgi 300 tablets/30days

CLINICAL RATIONALE

Lambert-Eaton myasthenic syndrome (LEMS) is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. In people with LEMS, the body's own immune system attacks the neuromuscular junction and disrupts the ability of nerve cells to send signals to muscle cells. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer. LEMS can occur at any age with an overall prevalence estimated to be three per one million individuals worldwide.

Ruzurgi (amifampridine) is a broad spectrum potassium channel blocker approved to treat LEMS in pediatric patients age 6 to less than 17. The use of Ruzurgi for the treatment of LEMS in patients 6 to less than 17 years of age is supported by evidence from adequate and well-controlled studies of Ruzurgi in adults with LEMS, pharmacokinetic data in adult patients, pharmacokinetic modeling and simulation to identify the dosing regimen in pediatric patients, and safety data from pediatric patients 6 to less than 17 years of age.

The efficacy of Ruzurgi was established in a randomized, double-blind, placebo-controlled withdrawal study of 32 adult patients with LEMS. After an initial open-label run-in phase, patients were randomized to Ruzurgi or a switch to placebo. The primary measure of efficacy was the categorization of the degree of change (e.g., greater than 30% deterioration) in the Triple Timed Up and Go test (3TUG) upon withdrawal of active medication, when compared with the time-matched average of the 3TUG assessments at baseline (higher 3TUG scores represent greater impairment). Of the patients randomized to continue Ruzurgi, none experienced > 30% deterioration in the final post-dose 3TUG test. In contrast, 72% (13/18) of those randomized to placebo experienced > 30% deterioration in the final 3TUG test ($p < 0.0001$). Patients who were randomized to placebo returned to baseline after restarting Ruzurgi.

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.

REFERENCES

- Ruzurgi [prescribing information]. Princeton, NJ: Jacobus Pharmaceutical Company Inc; May 2019.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.69
Reviewed: August 2020
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