Effective Date: 4/20
Reviewed: 1/20 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

RUZURGI (amifampridine)

POLICY

I. INDICATIONS

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

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

Compendial Uses:
Ruzurgi can be used for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adult patients.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of either of the following diagnostic tests is necessary to initiate prior authorization review:
A. Electromyography (EMG)
B. Anti-P/Q type voltage-gated calcium channel antibody test

III. EXCLUSIONS

Coverage will not be provided for members with a history of seizures.

IV. CRITERIA FOR INITIAL APPROVAL

Lambert-Eaton Myasthenic Syndrome (LEMS)
Authorization of 6 months may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) when all of the following criteria are met:
A. Prescriber is a neurologist
B. Diagnosis is confirmed by either of the following:
    1. EMG showing compound muscle action potential (CMAP) that increased at least 2-fold after maximum voluntary contraction of the tested muscle
    2. A positive anti- P/Q type voltage-gated calcium channel antibody test
C. Member has proximal muscle weakness
D. For treatment-naïve members, the Quantitative Myasthenia Gravis (QMG) score is at least 5

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for LEMS who are responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

VI. REFERENCES

1. Ruzurgi [package insert]. Princeton, NJ: Jacobus Pharmaceutical Co, Inc.; May 2019.
2. A Phase 3 Study of Amifampridine Phosphate in Patients With Lambert Eaton Myasthenic Syndrome (LEMS). (2018). Retrieved from https://clinicaltrials.gov/ct2 (Identification No. NCT01377922)