

Pharmacy Policy Bulletin

Title: Amifampridine (Firdapse®, Ruzurgi®)

Policy #: Rx.01.216

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **amifampridine (Firdapse®, Ruzurgi®)** as provided under the member's prescription drug benefit.

Description:

Lambert-Eaton myasthenic syndrome (LEMS) is a rare autoimmune disorder of the neuromuscular junction. LEMS is associated with reduced acetylcholine (ACh) release from the presynaptic nerve terminals. Antibodies directed against the voltage-gated calcium channel (VGCC) interfere with the normal calcium flux required for the release of ACh from the presynaptic nerve terminal. The most common symptoms of LEMS include proximal muscle weakness, fatigue, autonomic symptoms such as dry mouth, sluggish pupillary light response, erectile dysfunction in men, and reduced tendon reflexes. LEMS patients can be divided into two groups: patients with LEMS associated with underlying malignancy (paraneoplastic LEMS) and those without malignancy (non-paraneoplastic LEMS). For patients with paraneoplastic LEMS, treatment of malignancy may be the only intervention necessary to produce improvement in neurologic symptoms of LEMS.

Amifampridine (Firdapse®, Ruzurgi®) is broad spectrum potassium channel blocker indicated for the treatment of LEMS in adults. It blocks presynaptic voltage-gated potassium channels, prolonging the duration of the presynaptic action potential, lengthening the opening time of the VGCC, and increasing the presynaptic calcium levels. The increased calcium levels lead to an increase in the amount of ACh released. ACh then binds to muscle receptors and results in improved muscle function.

Policy:

INITIAL CRITERIA: Amifampridine (Firdapse®) or amifampridine (Ruzurgi®) is approved when ALL of the following are met:

1. Member has a diagnosis of Lambert-Eaton myasthenic syndrome; and
2. One of the following:
 - a. Member is 18 years of age or older (Firdapse only); or
 - b. Member is 6 to less than 17 years of age (Ruzurgi only); and
3. Neurological symptoms persist after treatment of malignancy, when malignancy is present; and
4. Member has moderate to severe weakness that interferes with function; and
5. Prescribed by or in consultation with a neurologist; and
6. Member does not have history of seizures

Initial authorization: 3 months

REAUTHORIZATION CRITERIA: Amifampridine (Firdapse®) or amifampridine (Ruzurgi®) is approved when there is documentation of positive clinical response to therapy.

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Firdapse® (amifampridine) [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc. November 2018. Available at: <https://www.firdapse.com/pdfs/firdapse-pi.pdf>. Accessed April 1, 2021.

Ruzurgi® (amifampridine) [prescribing information]. Plainsboro, NJ: Jacobus Pharmaceutical Company, Inc. May 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2731310a-c060-4d3e-ba41-763d791f63a9&type=display>. Accessed April 1, 2021.

Titulaer MJ, Lang B, Verschuuren JJGM. Lambert-Eaton myasthenic syndrome: from clinical characteristics to therapeutic strategies. *Lancet Neurol*. 2011[a]; 10:1098-1107

Weinberg DH. Lambert-Eaton myasthenic syndrome: Clinical features and diagnosis. UpToDate Web site. Updated April 6, 2018September 23, 2019. www.uptodate.com. Accessed April 1, 2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Firdapse®	amifampridine phosphate
Ruzurgi®	amifampridine phosphate

Cross References:

Rx.01.33 Off-Label Use

Policy Version Number:	4.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

