Antimyasthenic/Cholinergic Agents
Firdapse (amifampridine)
pyridostigmine bromide 30 mg tablet
Effective 02/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

No PA	Drugs that require PA
Mestinon® # (pyridostigmine bromide)	Firdapse® (amifampridine)
	pyridostigmine bromide 30 mg tablet

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent

Ruzurgi® (amifampridine) is no longer FDA-approved in LEMS.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Firdapse

Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of symptomatic Lambert-Eaton myasthenic syndrome (LEMS)
2. The member is ≥ 18 years of age
3. Prescriber is a neurologist or consult notes from a neurologist are provided

4. The member meets **ONE** of the following laboratory results confirming the diagnosis:
    a. neurophysiology study tests
    b. positive anti-P/Q type voltage-gated calcium channel antibody test
5. Appropriate dosing *(See appendix for pediatric dosing requests)*

pyridostigmine bromide 30 mg tablet
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of myasthenia gravis
2. Clinical rationale why pyridostigmine bromide 60 mg tablets may not be appropriate (e.g. use of dose that is not optimal to obtain from 60 mg formulation)

Continuation of Therapy
Firdapse: Reauthorizations requires physician documentation of positive response to therapy.

Pyridostigmine 30 mg tablet: Reauthorizations requires physician documentation of continued necessity of dosage form.

Limitations
1. Initial approvals will be for 6 months.
2. Reauthorizations will be for:
    a. Firdapse: 6 months
    b. Pyridostigmine 30 mg tablet: 12 months

Appendix
Requests for Firdapse in Pediatrics
Amifampridine has been studied in pediatric patients ≥6 years of age through the prior FDA-approval filing for Ruzurgi® (amifampridine), which no longer holds an FDA-approval for LEMS. Firdapse® (amifampridine) requests for members ≥6 years of age may be considered for approval if other criteria are met.
Appropriate dosing can be verified by considering the dosing previously approved for Ruzurgi® (amifampridine):

Lambert-Eaton myasthenic syndrome (LEMS):
Pediatric patients weighing less than 45 kg: 7.5 mg to 15 mg daily in divided doses, increase daily in 2.5 to 5 mg increments to a maximum single dose of 15 mg and maximum total daily maintenance dose of 50 mg

Pediatric patients weighing 45 kg or more: 15 mg to 30 mg daily in divided doses, increase daily in 5 mg to 10 mg increments to a maximum single dose of 30 mg and maximum total daily maintenance dose of 100 mg

References

1. Firdapse® [package insert] Coral Gables (FL): Catalyst Pharmaceutical Inc; 2021 Mar.
2. BioSpace. Catalyst Pharmaceuticals Reports that the FDA Marketing Approval Previously Granted for Ruzurgi® is No Longer Valid. San Francisco (CA); 2022 [cited 2022 Mar 11]. Available from: https://www.biospace.com/article/releases/catalyst-pharmaceuticals-reports-that-the-fda-marketing-approvalpreviously-granted-for-ruzurgi-is-no-longer-valid/.

3. FDA approves first treatment for Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder [press release on the Internet]. 2018 Nov 28 [cited 2019 Jan 11]. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm627093.htm.
4. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. Eur J Neurol. 2010 Jul;17(7):893-902.
5. Lambert-Eaton Myasthenic Syndrome [database on the Internet]: National Organization of Rare Diseases; 2019 [cited 2019 Jan 11]. Available from: https://rarediseases.org/rare-diseases/lambert-eaton-myasthenic-syndrome/.
6. Lambert-Eaton myasthenic syndrome [database on the Internet]: Orphanet; 2021 [cited 2021 Aug 12]. Available from: https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=en&Expert=43393.
7. BioMarin Launches Firdapse in the European Union [press release on the Internet]. 2010 Apr 19 [cited Jan 11, 2019]. Available from: https://investors.biomarin.com/2010-04-19-BioMarin-Launches-Firdapse-in-the-European-Union.
8. Weinberg DH. Lambert-Eaton myasthenic syndrome: Treatment and prognosis. In Shefner JM, Wen PY (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Aug 12]. Available from: http://www.utdol.com/utd/index.do.
9. Sanders D. David vs Goliath: Two Competing US Trials of 3,4-Diaminopyridine (3,4-DAP) in Lambert-Eaton Myasthenic Syndrome (LEMS) (P4.271). Neurology. 2015 Apr 8;82(10):supp.
10. Pyridostigmine bromide [package insert]. Fort Worth (TX): Method Pharmaceuticals; 2020 Apr.
11. Ruzurgi® [package insert] Plainsboro (NJ): Jacobus Pharmaceutical Company, Inc; 2020 Apr

Review History

09/16/2020 – Reviewed and approved Sept P&T Mtg. Effective 11/01/20.
11/16/2022 – Reviewed and updated for Nov P&T. Separated out MH vs Comm/Exch. Removed Ruzurgi as product is obsolete and no longer FDA approved for LEMS. Matched MH UPPL criteria. Effective 2/1/23.

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