Clinical Policy Title:	pyridostigmine oral solution
Policy Number:	RxA.227
Drug(s) Applied:	Mestinon®
Original Policy Date:	02/07/2020
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Pyridostigmine (Mestinon®) is a cholinesterase inhibitor. It is indicated for the treatment of myasthenia gravis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pyridostigmine oral solution (Mestinon®)	Myasthenia gravis	60-1,500 mg/day (average 600 mg/day) orally divided into 5 to 6 doses, spaced to provide maximum relief	1,500 mg/day

Dosage Forms

- Oral solution: 60 mg/5 mL (473 mL bottle)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Myasthenia Gravis (must meet all)**:**

1. Diagnosis of myasthenia gravis;
2. Documentation supports inability to use generic pyridostigmine tablets (e.g, inability to swallow pill due to young age, disease with bulbar involvement);
3. Dose does not exceed 1,500 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Myasthenia Gravis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met

initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,500 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
pyridostigmine tablet (Mestinon®)	60-1,500 mg/day (average 600 mg/day) orally divided into 5 to 6 doses, spaced to provide maximum relief	1,500 mg/day

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Mechanical intestinal or urinary obstruction, and bronchial asthma;
  - Care should be observed in the use of atropine for counteracting side effects.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- The safety of Mestinon® during pregnancy or lactation in humans has not been established. Therefore, use of Mestinon® in women who may become pregnant requires weighing the drug's potential benefits against its possible hazards to mother and child.

References

1. Mestinon® Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; December 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a851795e-b7a8-40c3-9922-5e79d3eb4d92. Accessed February 04, 2022.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Available at: http://www.clinicalkey.com. Accessed February 04, 2022.
3. Pyridostigmine, Lexi-Drug. Lexicomp. Wolters Kluwer. Hudson, OH. Available at: http://online.lexi.com. Accessed February 04, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to "pyridostigmine"; Drug(s) Applied was updated to "Mestinon®"; Line of Business Policy Applies to was updated to "All". 2. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy". 3. Appendix C was updated: Contraindication has been updated to "Mechanical intestinal or urinary obstruction, and bronchial asthma". 4. References were updated.	08/01/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy Title was updated to include “oral solution”. 2. Background was updated to remove “Prior authorization is required for the oral syrup”. 3. Dosing Information drug name was updated from “syrup” to “solution”. 4. Dosage Forms was updated from “syrup” to “solution”. 5. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 6. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..".	07/12/2021	09/14/2021

8. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 9. Appendix C contraindications was updated to include “Care should be observed in the use of atropine for counteracting side effects.”. 10. Appendix D was updated to include “The safety of Mestinon® during pregnancy or lactation in humans has not been established. Therefore, use of Mestinon® in women…”. 11. References were reviewed and updated.		
Policy was reviewed: 1. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 2. References were reviewed and updated.	02/04/2022	04/18/2022