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RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	pyridostigmine
Policy Number:	RxA.227
Drug(s) Applied:	Mestinon®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Pyridostigmine (Mestinon®) is a cholinesterase inhibitor. Prior authorization is required for the oral syrup. Mestinon® is indicated for the treatment of myasthenia gravis.

Dosing Information

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

Dosage Forms

- Oral syrup: 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.

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously 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

B. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

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

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Mechanical intestinal or urinary obstruction, and bronchial asthma
- Boxed Warning(s):
  - None reported
  -

APPENDIX D: General Information
None

References

1. Mestinon® Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; April 2020. Available at: www.mestinon.com. Accessed August 01, 2020.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed August 01, 2020.
3. Pyridostigmine, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed August 01, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date

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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

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