RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	osilodrostat
Policy Number:	RxA.633
Drug(s) Applied:	Isturisa®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All line of business

Background

Isturisa® is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
osilodrostat (Isturisa®)	Cushing's disease	Initial dosing: 2 mg orally twice daily, with or without food. Dosage is titrated by 1 to 2 mg twice daily, no more frequently than every 2 weeks based on rate of cortisol changes, individual tolerability and improvement in signs and symptoms.	Maximum recommended dosage is 30 mg twice daily.

Dosage Forms

- Tablets: 1 mg, 5 mg, and 10 mg

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. Cushing's Disease (must meet all):

1. Patient must be 18 years of age or older
2. Prescriber must be an endocrinologist
3. Documented diagnosis of Cushing's disease
4. Documentation of failed pituitary surgery or contraindication to pituitary surgery
5. dose does not exceed 30 mg twice daily

Approval Duration

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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Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Cushing's Disease (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 30 mg twice daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
Not applicable

APPENDIX B: Therapeutic Alternatives

Drug	Daily Dose (mid-range)	Dose Limit/Maximum Dose
Korlym	600 mg/day	1200 mg/ day
Signifor	0.6 mg twice daily	1.8 mg/day
Signifor LAR	10 mg – 60 mg every 28 days	60 mg / 28 days

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
Not applicable

References

1. Product Information: ISTURISA (osilodrostat) oral tablets. Recordati S.p.A (per FDA), Lebanon, NJ, 2020. Accessed June 29, 2020
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Accessed June 29, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	09/14/2020	09/14/2020

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