

<b>Clinical Policy Title:</b>	osilodrostat
<b>Policy Number:</b>	RxA.633
<b>Drug(s) Applied:</b>	Isturisa®
<b>Original Policy Date:</b>	09/14/2020
<b>Last Review Date:</b>	08/28/2024
<b>Line of Business Policy Applies to:</b>	All line of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Cushing's Disease (must meet all):

1. Diagnosis of Cushing's disease;
2. Member meets one of the following (a or b):
  - a. Pituitary surgery has not been curative;
  - b. Member is not eligible for pituitary surgery.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Cushing's Disease (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

Not applicable.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	09/14/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.4 was updated to include "Hypokalemia and hypomagnesemia levels are corrected, and baseline electrocardiogram is obtained prior to starting therapy...". 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".	07/02/2021	09/14/2021
Policy was reviewed.	04/06/2022	07/18/2022

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.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4: Updated to remove prior lab criteria "Hypokalemia and hypomagnesemia levels are corrected, and baseline electrocardiogram is obtained prior to starting therapy".</li> <li>2. Initial Approval Criteria, I.A.4: Updated surgery criteria from Documentation supporting failure of pituitary surgery or clinical inability of the patient to undergo pituitary surgery to Member meets one of the following (a or b):             <ol style="list-style-type: none"> <li>a. Pituitary surgery has not been curative;</li> <li>b. Member is not eligible for pituitary surgery;</li> </ol> </li> <li>3. Initial Approval Criteria, I.A: Updated Approval duration from 3 to 6 months for Commercial and Medicaid.</li> </ol>	<p>04/28/2023</p>	<p>07/13/2023</p>
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> </ol>	<p>8/28/2024</p>	<p>9/13/2024</p>