MEDICAL MUTUAL®

Drug Policy

Policy:	Isturisa (osilodrostat)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

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. Isturisa blocks formation of cortisol by inhibiting 11-beta-hydroxylase and is the first agent with this mechanism of action to gain FDA approval.

POLICY STATEMENT

This policy involves the use of Isturisa. Prior authorization is recommended for pharmacy benefit coverage of Isturisa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Isturisa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Isturisa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Isturisa is recommended in those who meet the following criteria:

FDA-Approved Indication

1. <u>Cushing's Disease, Initial Therapy</u>
Criteria. *Patient must meet the following criteria (A, B, C, D, E, <u>and</u> F):*

- **A.** The patient is 18 years of age or older; AND
- **B.** The patient is not a candidate for pituitary surgery or surgery has not been curative; AND
- **C.** Isturisa is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndromes; AND
- **D.** Patient has tried ketoconazole tablets; AND
- **E.** Baseline urinary free cortisol is elevated [Documentation required]; AND
- **F.** Baseline laboratory testing, including serum potassium and serum magnesium, have been completed [Documentation required].

2. **Cushing's Disease, Currently Receiving Isturisa for at least 6 months**
Criteria. *Patient must meet the following criteria (A,B,C, D and E):*

   A. The patient is 18 years of age or older; AND
   B. The patient is not a candidate for pituitary surgery or surgery has not been curative; AND
   C. Isturisa is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome; AND
   D. Patient has tried ketoconazole tablets; AND
   E. Documentation of positive response to therapy, evidenced by a decrease in urinary free cortisol from baseline [Documentation required].

Other Uses with Supportive Evidence

1. **Endogenous Cushing's Syndrome.** Approve if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is 18 years of age or older; AND
   B) Baseline free cortisol is elevated [Documentation required]; AND
   C) Patient meets ONE of the following (i, ii, or iii)
      i. According to the prescriber, the patient is not a candidate for surgery or surgery has not been curative; OR
      ii. Patient is awaiting surgery for **endogenous Cushing's Syndrome**; OR
      iii. Patient is awaiting therapeutic response after radiotherapy for **endogenous Cushing's Syndrome**; AND
   D) Patient has tried ketoconazole tablets; AND
   E) The medication is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of endogenous Cushing's syndrome; AND
   F) Baseline laboratory testing, including serum potassium and serum magnesium, have been completed [Documentation required].

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Isturisa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Isturisa [prescribing information]. Lebanon, NJ: Recordati Rare Disease, Inc.; March 2020.
2. Osilodrostat. In: DRUGDEX [online database], Truven Health Analytics; Greenwood Village, CO. Last updated 11 May 2022. Accessed 17 May 2022.
3. Osilodrostat. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 4 May 2022. Accessed on 17 May 2022.
4. Osilodrostat. Micromedex (electronic version). IBM Watson Health; 2024. Accessed June 14, 2024. https://micromedexsolutions.com