



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Isturisa Clinical Edit
<b>First Implementation Date:</b>	April 22, 2021
<b>Revised Date:</b>	December 14, 2023
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Isturisa® (osilodrostat)

**Why Issue Selected:** Isturisa® (osilodrostat) was FDA approved in March 2020 for the treatment of adult patients with Cushing’s disease (CD) for whom pituitary surgery is not an option or has not been curative. CD occurs in the presence of pituitary adenomas that produce high levels of adrenocorticotropin hormone (ACTH); this over secretion of ACTH leads to an overproduction of cortisol by the adrenal glands. CD can be life-threatening if not treated, and may cause significant health issues such as obesity, type 2 diabetes, high blood pressure, blood clots, bone loss, immunosuppression, and neuropsychiatric symptoms. Isturisa is a twice-daily oral cortisol synthesis inhibitor that inhibits 11-beta-hydroxylase (CYP11B1), which is responsible for the final step of cortisol biosynthesis in the adrenal gland. Isturisa represents the first agent with this mechanism of action to be approved by the FDA for the treatment of CD.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Isturisa.

Program-Specific Information:	Date Range FFS 1-1-2022 to 12-31-2022			
	Drug	Claims	Spend	Avg Spend per Claim
	ISTURISA 1 MG TAB	9	\$260,682.37	\$28,964.71
	ISTURISA 5 MG TAB	3	\$82,770.38	\$27,590.13
	ISTURISA 10 MG TAB	0	-	-

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Isturisa® (osilodrostat)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

### Initial Therapy:

- Participant aged 18 years or older **AND**
- Prescribed by or in consultation with an endocrinologist or other appropriate specialist for the treated disease state **AND**
- Documented diagnosis of Cushing's disease **AND**
- Documentation of failed pituitary surgery or reason pituitary surgery is not an option **AND**
- Documentation of baseline electrocardiogram **AND**
- Documentation of baseline potassium, magnesium, and cortisol levels

### Continuation of Therapy:

- Initial approval is for 3 months, renewal of prior authorization may be given for up to 12 months following documentation of the following along with an expectation of monitoring of potassium and magnesium levels:
  - Recent (within the past 3 months) cortisol levels demonstrating mean urine free cortisol (mUFC) ≤ ULN **AND**
  - Recent (within the past 3 months) electrocardiogram

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
ISTURISA 1 MG TABLET	OSILODROSTAT	8 tablets per day
ISTURISA 5 MG TABLET	OSILODROSTAT	<b>2 12 tablets per day</b>
ISTURISA 10 MG TABLET	OSILODROSTAT	6 tablets per day

## Required Documentation

Laboratory Results:

Progress Notes:

MedWatch Form:

Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

3 months

## References

- Isturisa (osilodrostat) [package insert]. Lebanon, NJ: Recordati Rare Disease Inc; March 2020.
- IPD Analytics. New Drug Review: Isturisa (osilodrostat). March 2020.
- Nieman L., Biller B., Findling J., et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism; 2015;100(8):2807-283.

SmartPA Clinical Proposal Form

© 2023 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.