JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS125
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	Subject **Isturisa**	*Revision Date*	12/08/2021
		Page	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Isturisa

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	2
V.	REFERENCES	2
VI.	APPROVALS	2

I. POLICY

Isturisa (osilodrostat) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Isturisa may be approved for patients meeting All the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing a diagnosis of Cushing's Disease
   3. Documentation has been submitted showing one of the following:
      a. Persistent or recurrent disease despite pituitary surgery
      b. New diagnosis of disease, and patient is not a candidate for surgery
   4. Documentation has been submitted showing the mean of three 24-hour urinary free cortisol (UFC) levels as at least 1.5x the upper limit of normal measured
   5. Documentation has been submitted showing the patient has clinical symptoms of Cushing's Disease (diabetes, moon face, buffalo hump, central obesity, muscle wasting, hypertension, depression, anxiety, etc)
   6. Prescriber is, or has consulted with, an endocrinologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing beneficial response to treatment as evidenced by both of the following:
   1. A recent UFC level within normal limits
   2. Improvement in the clinical symptoms of Cushing’s Disease

IV. EXCLUSIONS

A. Isturisa will not be approved for the following:
   1. Pediatric patients
   2. Patient that are pregnant or breast-feeding
   3. Patients with clinical symptoms and profile due to ectopic ACTH secretion, or ACTH-independent Cushing's syndrome (adrenal adenoma)
   4. Any indications or usage that is not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Disease Inc; March 2020.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/15/2020	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

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