SmartPA Criteria Proposal

Drug/Drug Class:	Isturisa Clinical Edit
First Implementation Date:	April 22, 2021
Proposed Date:	March 17, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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 for whom pituitary surgery is not an option or has not been curative. Cushing's disease occurs in the presence of pituitary adenomas that produce high levels of adrenocorticotropin hormone (ACTH); this oversecretion of ACTH leads to an overproduction of cortisol by the adrenal glands. Cushing's disease 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 Cushing's disease.

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 1-1-2021 to 12-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ISTURISA 1 MG TAB	10	$122,977.15	$12,297.72
ISTURISA 5 MG TAB	0	-	-
ISTURISA 10 MG TAB	0	-	-

Type of Criteria:
- ☒ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **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	2 tablets per day
ISTURISA 10 MG TABLET	OSILODROSTAT	6 tablets per day

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

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.