SmartPA Criteria Proposal

Drug/Drug Class:	Isturisa Clinical Edit
First Implementation Date:	TBD
Proposed Date:	December 17, 2020
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 10-01-2019 to 9-30-2020			
Drug	**Claims**	**Cost per tablet**	**Cost per month (MAC)**
ISTURISA 1 MG TAB	0	$110.00 MAC	Initial dose (2 mg BID): $13,200
ISTURISA 5 MG TAB	0	$400.00 MAC	Avg maint dose (7 mg BID): $37,200
ISTURISA 10 MG TAB	0	$475.00 MAC	Max dose (30 mg BID): $85,500

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

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.