ALASKA MEDICAID
Prior Authorization Criteria

Isturisa®
(osilodrostat)

FDA INDICATIONS AND USAGE[1]

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.

APPROVAL CRITERIA[1,2,3,4,5,6]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a physician specializing in the patients' diagnosis or is in consultation with an endocrinologist **AND**;
3. Patient has a diagnosis of persistent or recurring Cushing's disease for whom pituitary surgery is not an option or pituitary surgery or repeat surgeries, with or without radiation therapy, has not been curative for the patient, and the patient still requires a cortisol synthesis inhibitor **AND**;
4. Documented failure, contraindication, or intolerance to TWO of the following for a period of at least 30 days:
    a. Oral ketoconazole
    b. Oral cabergoline
    c. Oral Metopirone (metyrapone)
    d. Oral Lysodren (mitotane) **AND**;
5. Urine free cortisol levels have been obtained (normal is <150nmol/24 hours OR 3.5-45mcg/24 hours) **AND**;
5. A baseline ECG has been obtained and will be monitored periodically **AND**;
6. A baseline serum potassium and magnesium has been obtained and corrected, if abnormal before starting therapy and monitored periodically during treatment.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient is female and currently lactating **OR**;
3. Patient is showing symptoms of adrenal insufficiency.

CAUTIONS[1]

- Monitor patients closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary.
- Dosages may need to be adjusted for hepatic impairment.
- Use with caution in patients with risk factors for QTc prolongation.
- Monitor for hypokalemia, worsening of hypertension, edema, and hirsutism.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if the prescriber documents the patient has achieved and maintains THREE of the following: a urinary free cortisol (UFC) less than or equal to the upper limit of normal (ULN), cortisol levels is within normal limits, no symptoms consistent with Cushing's disease, no evidence or symptoms of hypocortisolism, no evidence of disease progression

QUANTITY LIMIT

- 30 days supply (not to exceed 60 mg per day)

REFERENCES / FOOTNOTES:

1. Isturisa [package insert], Lebanon, NJ: Recordati Rare Diseases Inc.; March 2020.
2. Nieman LK, Biller BMK, Findling JW, et al. Treatment of Cushing's syndrome: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015;100: 2807-2831.
3. Baudry C, Coste J, Khalil RB, et al. Efficiency and tolerance of mitotane in Cushing's disease in 76 patients from a single center. Eur J Endocrinol. 2012;167:473-481.
4. Castinetti F, Guignat L, Giraud P, et al. Ketoconazole in Cushing's disease: is it worth a try? J Endrocrin Metab. 2014;99(5):1623-1630.
5. Feelders RA, Newell-Price J, Pivonello R, Nieman LK, Hofland LJ, Lacroix A. Advances in the medical treatment of Cushing's syndrome. Lancet Diabetes Endocrinol. 2019;7:300-312.
6. Nieman LK. Overview of the treatment of Cushing's syndrome. In: UpToDate, Lacroix A, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on July 6, 2021.