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5.30.066

Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	April 3, 2020
Subject:	Isturisa	**Page:**	1 of 4

Last Review Date: June 15, 2023

Isturisa

Description

Isturisa (osilodrostat)

Background
Isturisa (osilodrostat) is a cortisol synthesis inhibitor. It inhibits 11β-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. Cushing's disease is caused by a tumor on the pituitary gland that results in high levels of the steroid hormone cortisol (1).

Regulatory Status
FDA-approved indication: 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 (1).

Correct hypokalemia and hypomagnesemia prior to starting Isturisa. Baseline electrocardiogram (ECG) should be obtained. Repeat ECG should be done one week after initiation of treatment, and as clinically indicated thereafter (1).

Isturisa lowers cortisol levels and can lead to hypocortisolism and sometimes life-threatening adrenal insufficiency. Patients should be educated on the symptoms associated with hypocortisolism. 24-hour urine free cortisol, serum or plasma cortisol, and patient's signs and symptoms should be monitored periodically during Isturisa treatment (1).

Isturisa is associated with a dose-dependent QT interval prolongation which may cause cardiac arrhythmias. It is recommended to obtain a baseline QTc interval measurement prior to initiating

therapy and monitoring periodically during treatment. If indicated, electrolyte abnormalities should be corrected (1).

The safety and effectiveness of Isturisa in pediatric patients less than 18 years of age have not been established (1).

Related policies
Korlym, Signifor, Signifor LAR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Isturisa may be considered **medically necessary** if the conditions indicated below are met.

Isturisa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Cushing's disease

AND ALL of the following**:**

a. Pituitary surgery was not curative, or patient is not a candidate for surgery
b. Baseline electrocardiogram (ECG) has been or will be obtained, and prescriber agrees to monitor for QTc prolongation
c. If indicated, hypokalemia and hypomagnesemia will be corrected prior to initiating therapy
d. Prescriber agrees to monitor cortisol levels
e. Prescriber agrees to monitor for hepatic impairment

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Cushing's disease

AND ALL of the following:

a. Prescriber agrees to monitor for QTc prolongation
b. Prescriber agrees to monitor cortisol levels
c. Prescriber agrees to monitor for hepatic impairment

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Isturisa (osilodrostat) is a cortisol synthesis inhibitor. Cushing's disease is caused by a pituitary tumor that causes the release of too much of a hormone called adrenocorticotropin, which stimulates the adrenal gland to produce an excessive amount of cortisol. The safety and effectiveness of Isturisa in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Isturisa while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
April 2020	Addition to PA
June 2020	Annual review
September 2020	Annual review
June 2021	Annual review
June 2022	Annual editorial review
December 2022	Annual review. Changed policy number to 5.30.066
June 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.