BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.30.066

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	April 3, 2020
Subject:	Isturisa	**Page:**	1 of 4

Last Review Date: March 6, 2026

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 syndrome is caused by prolonged exposure to high levels of the steroid hormone cortisol (1).

Regulatory Status
FDA-approved indication: Isturisa is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom 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, Recorlev, 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:

Endogenous hypercortisolemia in Cushing's syndrome

AND ALL of the following**:**

a. 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:

Endogenous hypercortisolemia in Cushing's syndrome

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 syndrome is caused by prolonged exposure to 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.; July 2025.

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	April 3, 2020
Subject:	Isturisa	**Page:**	4 of 4

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
June 2024	Annual review and reference update
September 2024	Annual review
May 2025	Per PI update, changed indication to “endogenous hypercortisolemia in Cushing’s syndrome”
June 2025	Annual review
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.