Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Isturisa (osilodrostat)

Policy Number: 5.01.722
Origination: 10/2020
Last Review: 10/2023
Next Review: 10/2024

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Isturisa (osilodrostat)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Isturisa (osilodrostat) may be considered **medically necessary** when the following criteria are met:

FDA Approved Indication:

1. **Cushing's Disease:** Approve for **6 months** if patient meets all of the following:
    a. Diagnosis of Cushing's disease
    b. One of the following:
        i. Patient is not a candidate for pituitary surgery
        ii. Pituitary surgery has not been curative for the patient
    c. Prescribed by or in consultation with an endocrinologist

Reauthorization: Approve for 1 year if:

    d. Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

When Policy Topic is not covered

Isturisa (osilodrostat) is considered **not medically necessary** when the above criteria is not met and **investigational** for all other uses.

Considerations

Isturisa (osilodrostat) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty

guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

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 pituitary tumor that releases too much of a hormone called adrenocorticotropin, which stimulated the adrenal gland to produce and excessive amount of cortisol. The safety and effectiveness of Isturisa in pediatric patients less than 18 years of age have not been established (1).

Rationale

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

Warnings and Precautions

- Hypercortisolism: Monitor patients closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary
- QTc Prolongation: Perform electrocardiogram in all patients Use with caution in patients with risk factors for QTc prolongation
- Elevations in Adrenal Hormone Precursors and Androgens: Monitor for hypokalemia, worsening of hypertension, edema, and hirsutism

References

1. Isturisa prescribing information. Recordati Rare Diseases Inc. Lebanon, NJ. May 2020.
2. Pivonello R, Fleseriu M, Newell-Price J, et al. Osilodrostat provides clinical benefit over 48 weeks in patients with Cushing disease: results from the LINC 3 study. Endocr Abstr. 2019. https://doi.org/10.1530/endoabs.63.OC3.1. Accessed May 16, 2020.

Billing Coding/Physician Documentation Information

N/A	Oral; Specialty pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/2020	New policy titled Isturisa (osilodrostat)
10/2021	Annual review – no changes made
10/2022	Annual review – added Warnings and Precautions
10/2023	Annual review – no changes made