Drug Quantity Management – Per Rx
Cushing's Disease – Isturisa® (osilodrostat tablets)

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108074

Effective 2/7/23: 82443

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Isturisa. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx*
Isturisa® (osilodrostat tablets)	1 mg tablets	240 tablets
	5 mg tablets	60 tablets
	10 mg tablets	180 tablets

* This is enough for a 30-day supply of each strength at a dose of 4 mg BID for the 1 mg tablets, 5 mg BID for the 5 mg tablets, and 30 mg BID for the 10 mg tablets.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Isturisa 1 mg tablets
1. If the individual is taking 6 mg twice daily, approve quantity of 360 tablets per dispensing.
2. If the individual is taking 7 mg twice daily, approve a quantity of 420 tablets per dispensing.
3. If the individual's is taking 8 mg twice daily, approve a quantity of 480 tablets per dispensing.
4. If the individual's is taking 9 mg twice daily, approve a quantity of 540 tablets per dispensing.

Isturisa 5 mg tablets
1. If the individual is taking 15 mg twice daily, approve a quantity of 180 tablets per dispensing.
2. If the individual is taking 25 mg twice daily, approve a quantity of 300 tablets per dispensing.

Isturisa 10 mg tablets
No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Isturisa is a cortisol synthesis inhibitor indicated for the treatment of adults with **Cushing's disease** for whom pituitary surgery is not an option or has not been curative.[1]

Dosing
The recommended initial dose of Isturisa is 2 mg orally twice daily (BID).[1] The dose is titrated by 1 mg to 2 mg BID no more frequently than every 2 weeks based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms of Cushing's disease. If a patient tolerates a dose of 10 mg BID and continues to have elevated 24-hour urine free cortisol levels above upper normal limit, the dose can be titrated further by 5 mg BID every 2 weeks. The maintenance dose of Isturisa is individualized and determined by titration based on cortisol levels and patient's signs and symptoms. In clinical trials, the maintenance dose varied between 2 mg and 7 mg BID. The maximum recommended maintenance dose of Isturisa is 30 mg BID.

Lower starting doses are recommended in patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.[1] Dose reductions are recommended when Isturisa is used with a strong cytochrome P450(CYP) 3A inhibitor. The dose of Isturisa may need to be increased if used with strong inducers of CYP3A4 and CYP2B6. Dose modifications of Isturisa are guided by cortisol concentration and the patient's signs and symptoms.

Availability
Isturisa is available as 1 mg, 5 mg, and 10 mg tablets.[1] The tablets are supplied in cartons containing 3 blister packs (60 tablets) or 1 blister pack (20 tablets); each blister pack contains 20 tablets.

References

1. Isturisa® tablets [prescribing information]. Lebanon, NJ: Recordati Rare Disease; March 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No changes to criteria.	05/16/2022