

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** Cushing’s Disease – Isturisa Drug Quantity Management Policy – Per Rx

- Isturisa® (osilodrostat tablets – Recordati Rare Disease)

**REVIEW DATE:** 05/16/2022

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### 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.<sup>1</sup>

### Dosing

The recommended initial dose of Isturisa is 2 mg orally twice daily (BID).<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> The tablets are supplied in cartons containing 3 blister packs (60 tablets) or 1 blister pack (20 tablets); each blister pack contains 20 tablets.

### POLICY STATEMENT

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.

**Automation:** None.

### 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.

05/16/2022

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## **CRITERIA**

### Isturisa 1 mg tablets

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

### Isturisa 5 mg tablets

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

### Isturisa 10 mg tablets

No overrides recommended.

## **REFERENCES**

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