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: 05/15/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 three blister packs (60 tablets) or one 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.

Drug Quantity Limits

Product	Strength and Dose Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity Per Rx
Isturisa® (osilodrostat tablets)	1 mg tablets	240 tablets	720 tablets
	5 mg tablets	60 tablets	180 tablets
	10 mg tablets	180 tablets	540 tablets

Cushing's Disease – Isturisa Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Isturisa 1 mg tablets

1. If the patient is taking 6 mg twice daily, approve 360 tablets per dispensing at retail or 1,080 tablets per dispensing at home delivery.
2. If the patient is taking 7 mg twice daily, approve 420 tablets per dispensing at retail or 1,260 tablets per dispensing at home delivery.
3. If the patient is taking 8 mg twice daily, approve 480 tablets per dispensing at retail or 1,440 tablets per dispensing at home delivery.
4. If the patient is taking 9 mg twice daily, approve 540 tablets per dispensing at retail or 1,620 tablets per dispensing at home delivery.

Isturisa 5 mg tablets

1. If the patient is taking 15 mg twice daily, approve 180 tablets per dispensing at retail or 540 per dispensing at home delivery.

2. If the patient is taking 25 mg twice daily, approve 300 tablets per dispensing at retail or 900 tablets per dispensing at home delivery.

Isturisa 10 mg tablets
No overrides recommended.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	05/16/2023
Annual Revision	No criteria changes.	05/15/2024