

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Isturisa (osilodrostat)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 180 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Isturisa (osilodrostat) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### CUSHING'S DISEASE

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a diagnosis of Cushing's disease, with an elevated urinary free cortisol (UFC) level (lab report required); AND
4. Member had pituitary surgery and it was not curative OR member is not a candidate for surgery (documentation required); AND
5. Member has tried ketoconazole for at least 3 months with inadequate response.
6. **Dosage allowed:** Max recommended dose is 30mg (as three 10mg tablets), twice daily.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Labs must show UFC level within normal range; AND
2. Chart notes must show the member has improved signs and symptoms of disease (e.g. weight, fasting glucose, blood pressure, or tumor size).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Isturisa (osilodrostat) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
06/30/2020	New policy for Isturisa created.

References:

1. Isturisa [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc; 2020.
2. Recordati Rare Diseases: Isturisa(R) (osilodrostat) Phase III LINC-4 Trial Meets Its Primary Endpoint in Cushing's Disease. Barron's. <https://www.barrons.com/press-release/recordati-rare-diseases-isturisa-r-osilodrostat-phase-iii-linc-4-trial-meets-its-primary-endpoint-in-cushing-s-disease-01592380982?tesla=y>. Published June 17, 2020. Accessed June 30, 2020.
3. Nieman, LK. Medical therapy of hypercortisolism (Cushing's syndrome). *UpToDate*. <https://www.uptodate.com>. Updated 6/29/20. Accessed 6/30/20.
4. IPD analytics. Accessed 6/30/20.
5. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
6. Fleseriu M, Pivonello R, Young J, et al. Osilodrostat, a potent oral 11 $\beta$ -hydroxylase inhibitor: 22-week, prospective, Phase II study in Cushing's disease. *Pituitary*. 2015;19(2):138-148. doi:10.1007/s11102-015-0692-z
7. Biller BM, Newell-Price J, Fleseriu M, et al. OR16-2 Osilodrostat Treatment in Cushing's Disease (CD): Results from a Phase III, Multicenter, Double-Blind, Randomized Withdrawal Study (LINC 3). *Journal of the Endocrine Society*. 2019;3(Supplement\_1).

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