CareSource

PHARMACY POLICY STATEMENT **Arkansas PASSE**	
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 **NOT** MEDICALLY NECESSARY	Click Here

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. Member has a diagnosis of Cushing's disease, with an elevated urinary free cortisol (UFC) level (lab report required); AND
3. Member had pituitary surgery and it was not curative OR member is not a candidate for surgery (documentation required); AND
4. Member has tried ketoconazole for at least 3 months with inadequate response.
5. **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.
12/21/2021	Removed prescriber specialty requirement.

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 En*docrinol 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 11β-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).

Effective date: 01/01/2022
Revised date: 12/21/2021