HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Isturisa (osilodrostat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Isturisa is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative It inhibits 11beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland.
Cushing's syndrome is a disorder of excess cortisol which can be of an exogenous cause, for example from taking glucocorticoids, or it can be endogenous. Endogenous Cushing's syndrome is rare, with the most common type being Cushing's disease.

Isturisa (osilodrostat) will be considered for coverage when the following criteria are met:

Cushing's Syndrome

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 documented diagnosis of Cushing's syndrome, with an elevated urinary free cortisol (UFC) level; AND
4. Documentation that pituitary surgery was not curative, or surgery is not an option; AND
5. Member has tried and failed a preferred adrenal steroidogenesis inhibitor for at least 2 months at the maximum tolerated dose.
6. **Dosage allowed/Quantity limit:** Initiate 2 mg orally twice daily then titrate per package insert. Maximum recommended dose is 30 mg (as three 10 mg tablets) orally twice daily. Quantity limit: 180 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Labs must show an improved UFC level compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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HAP CareSource considers Isturisa (osilodrostat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/30/2020	New policy for Isturisa created.
03/28/2022	Transferred to new template. Added new references. Elaborated on dosing information. Added metyrapone as a trial option. In renewal, changed UFC normal range to improved UFC.
04/02/2025	Updated references; removed note about clinical trial dosage allowed; removed improved signs and symptoms from reauthorization criteria per variable result in clinical trial; changed trial length from three-months to two-months at the maximum tolerated dose for steroidogenesis inhibitor per Fleseriu M (2021) et al; replaced trial of ketoconazole or metyrapone with trial of a preferred adrenal steroidogenesis inhibitor; replaced Cushing's disease with Cushing's syndrome as indication per label update; updated summary.

References:

1. Isturisa [package insert]. Recordati Rare Diseases Inc.; 2025.
2. 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
3. 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
4. Fleseriu M, Auchus R, Bancos I, et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. *Lancet Diabetes Endocrinol*. 2021;9(12):847-875. doi:10.1016/S2213-8587(21)00235-7
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

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