

| Division: Pharmacy Policy | Subject: State of Florida's Agency for Health Care Administration's |
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| | Prior Authorization Criteria |
| Original Development Date: | June 9, 2021 |
| Original Effective Date: | |
| Revision Date: | |
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ISTURISA® (osilodrostat)

LENGTH OF AUTHORIZATION: Six months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
- Patient has a confirmed diagnosis of Cushing's Disease.
- Pituitary surgery is not an option or has not been curative.
- Baseline electrocardiogram (ECG) has been obtained and, if present, hypokalemia and/or hypomagnesemia have been corrected prior to initiating therapy.
- Documented baseline urinary free cortisol (UFC) test ≥ 1.5 upper limit of normal (UFC normal range = 3.5-45 mcg/24 hours (9.66-124.2 nmol/24 hours)).
- Patient has tried and failed previous treatments for Cushing's Disease.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Patient has responded to therapy as defined by a documented UFC test ≤ the upper limit of normal.

DOSING AND ADMINISTRATION:

- Initiate at 2 mg orally twice daily, titrate dose to 1 to 2 mg twice daily, no more frequently than every 2 weeks, maximum recommended dosage is 30 mg twice daily
- Available as 1 mg, 5 mg, and 10 mg tablets