Gateway Health℠ It's Wholecare.

Updated: 07/2020
PARP Approved: 08/2020

Prior Authorization Criteria
Isturisa (osilodrostat)

All requests for Isturisa (osilodrostat) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of Cushing's disease and the following criteria is met:

- Member must be 18 years of age or older
- Must be prescribed by or in association with an endocrinologist
- Member must have persistent or recurrent disease evidenced by ALL of the following:
    - mUFC > 1.3 x ULN [Mean of three 24-hour urine samples collected preferably on 3 consecutive days, during screening after washout of prior medical therapy for CD (if applicable)] with ≥ 2 of the individual UFC values being > 1.3 x ULN.
    - Morning plasma ACTH above Lower Limit of Normal.
    - Confirmation (based on medical history) of pituitary source of excess
- Member must have excessive secretion of adrenocorticotropin hormone (ACTH) by a pituitary tumor as evidenced by at least ONE of the following:
    - Histopathologic confirmation of an ACTH-staining adenoma in patients who have had prior pituitary surgery.
    - MRI confirmation of pituitary adenoma > 6 mm OR Bilateral inferior petrosal sinus sampling (BIPSS) with either CRH or DDAVP stimulation for patients with a tumor ≤ 6mm.
- Must provide documentation that pituitary surgery is not an option or has not been curative
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Member must have mUFC within normal limits (reference range must be provided).
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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ISTURISA (OSILODROSTAT) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

For Cushing's Disease:

- Does the member have mean UFC > 1.3 x ULN (mean of 3 24-hour urine samples after washout of prior medical therapy) with at least 2 of the individual UFC values > 1.3 x ULN? ☐ Yes ☐ No
- Is the morning plasma ACTH above the lower limit of normal? ☐ Yes ☐ No
- Is there confirmation (based on medical history) of pituitary sources of excess? ☐ Yes ☐ No
- Please indicate which of the following apply to this member:
  - ☐ Histopathologic confirmation of an ACTH-staining adenoma in patients who have had prior pituitary surgery
  - ☐ MRI confirmation of pituitary adenoma > 6 mm
  - ☐ Bilateral inferior petrosal sinus sampling (BIPSS) with either CRH or DDAVP stimulation for patients with a tumor ≤6 mm
- Has pituitary surgery been completed? ☐ Yes ☐ No, please explain below why surgery is not an option:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is the mean UFC level within normal limits? ☐ Yes ☐ No
Please provide value and reference range.

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date