STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT PHOSPHATE	ISTURISA	46396		GPI-10 (3002206060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Pituitary surgery is not an option or has not been curative for the patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
   E. You had a trial of or contraindication (harmful for) to oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

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OSILODROSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (a type hormone disorder)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

- Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
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