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ISTURISA® (osilodrostat)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

ISTURISA® (osilodrostat)

Criteria:

- **Criteria for initial therapy:** Isturisa (osilodrostat) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patients' diagnosis or is in consultation with an Endocrinologist

  2. Individuals 18 years of age or older

  3. A confirmed diagnosis of persistent or recurring Cushing's disease for whom pituitary surgery is not an option or has not been curative

  4. Documented failure, contraindication per FDA label, intolerance to **TWO** of the following:
     a. Oral ketoconazole
     b. Oral cabergoline
     c. Oral Metopirone (metyrapone)
     d. Oral Lysodren (mitotane)

  5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Serum potassium and magnesium with correction if abnormal before starting therapy
     b. Electrocardiogram (ECG)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Isturisa (osilodrostat) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. Achieved and maintains **THREE** of the following:
           1. A urinary free cortisol (UFC) less than or equal to the upper limit of normal (ULN)
           2. Cortisol levels is within normal limits
           3. No symptoms consistent with Cushing's disease
           4. No evidence or symptoms of hypocorticolism
           5. No evidence of disease progression

  3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Adrenal insufficiency
        ii. QTc prolongation
        iii. Hypokalemia that is uncontrolled with supplementation and use of mineralocorticoid antagonist
        iv. Severe hypocortisolism

5. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of a Non-Cancer Medications**

    2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Isturisa (osilodrostat) is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Osilodrostat is a cortisol synthesis inhibitor. It inhibits 11beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland, thereby lowering cortisol levels.

Resources:

Isturisa (osilodrostat) product information, revised by Recordati Rare Diseases, Inc. 03-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 06, 2021.

Nieman LK. Overview of the treatment of Cushing's syndrome. In: UpToDate, Lacroix A, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on April 6, 2021.

Nieman LK. Medical therapy of hypercortisolism (Cushing's syndrome). In: UpToDate, Lacroix A, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on April 6, 2021.