Osilodrostat (Isturisa) and levoketoconazole (Recorlev)

Coverage Criteria:

1. Prescribed by an endocrinologist; AND,
2. Patient has a diagnosis of Cushing's disease; AND,
3. Patient meets ONE of the following:
    a. Patient has had an inadequate response to pituitary surgery; OR,
    b. Patient is not a candidate for pituitary surgery; AND,
4. The patient's disease is persistent or recurrent as evidenced by ONE of the following:
    a. Patient has a mean of three 24-hour urine free cortisol (UFC) >1.3 times the upper limit of normal; OR,
    b. Morning plasma adrenocorticotropic hormone (ACTH) above the lower limit of normal; AND,
5. Patient has had an inadequate response to two of the following conventional agents (note: one agent must be ketoconazole if requesting coverage of Recorlev):
    a. Ketoconazole; AND,
    b. Cabergoline; AND,
    c. Pasireotide; AND,
6. For Recorlev, patient has a documented allergic reaction to generic ketoconazole; and,
7. Patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy; AND,
8. Prescribed within the FDA approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by the prescriber in the previous 12 months; AND,
2. Patient has had a clinically meaningful response to the medication per medical chart documentation confirming a reduction in 24-hour urinary free cortisol from baseline; AND,
3. Prescribed within the FDA approved dosing regimen.

Coverage Duration:

Initial authorizations will be provided for 6 months.
Re-authorizations will be provided for 12 months.

P&T Date: October 2020
Effective Date: 1/1/2021; Revised 1/1/2024, 10/1/2025