

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 adrenocorticotrophic hormone (ACTH) above the lower limit of normal; AND,
5. Patient has had an inadequate response to all of the following conventional agents:
 - a. Ketoconazole; AND,
 - b. Cabergoline; AND,
 - c. Pasireotide; AND,
6. Patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy; AND,
7. 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.