

**ISTURISA  
(osilodrostat)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Isturisa (osilodrostat) is a cortisol synthesis inhibitor. It inhibits 11 $\beta$ -hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. Cushing's syndrome is caused by prolonged exposure to high levels of the steroid hormone cortisol (1).

**Regulatory Status**

FDA-approved indication: Isturisa is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative (1).

Correct hypokalemia and hypomagnesemia prior to starting Isturisa. Baseline electrocardiogram (ECG) should be obtained. Repeat ECG should be done one week after initiation of treatment, and as clinically indicated thereafter (1).

Isturisa lowers cortisol levels and can lead to hypocortisolism and sometimes life-threatening adrenal insufficiency. Patients should be educated on the symptoms associated with hypocortisolism. 24-hour urine free cortisol, serum or plasma cortisol, and patient's signs and symptoms should be monitored periodically during Isturisa treatment (1).

Isturisa is associated with a dose-dependent QT interval prolongation which may cause cardiac arrhythmias. It is recommended to obtain a baseline QTc interval measurement prior to initiating therapy and monitoring periodically during treatment. If indicated, electrolyte abnormalities should be corrected (1).

The safety and effectiveness of Isturisa in pediatric patients less than 18 years of age have not been established (1).

**Summary**

Isturisa (osilodrostat) is a cortisol synthesis inhibitor. Cushing's syndrome is caused by prolonged exposure to an excessive amount of cortisol. The safety and effectiveness of Isturisa in pediatric patients less than 18 years of age have not been established (1).



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Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Isturisa while maintaining optimal therapeutic outcomes.

### **References**

1. Isturisa [package insert]. Lebanon, NJ: Recordati Rare Disease, Inc.; April 2025.