



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2218-2
Program	Prior Authorization/Medical Necessity- Custom Oxford SoNJ and SoNY
Medication	Diagnostic Agents*, Metopirone (metyrapone)*
P&T Approval Date	9/2020, 9/2021
Effective Date	12/1/2021; Oxford Only: 12/1/2021

1. Background:

Diagnostic agents are used to identify impairment in normal functioning of the body and include products such as medical imaging drugs and test collection kits. Diagnostic agents are generally governed by the same FDA regulations as other drugs, biologics and devices. Diagnostic agents are typically benefit exclusions. This program only applies when diagnostic agents are covered by the plan.

2. Coverage Criteria^a:

A. **Metopirone*** will be approved based on **one** of the following criteria:

1. For adrenocorticotrophic hormone (ACTH) function testing

-OR-

2. Diagnosis of **one** of the following:

- a. Cushing's syndrome after transsphenoidal selective adenectomy (TSS)
- b. Occult or metastatic ectopic ACTH secretions (EAS)
- c. Adrenocortical carcinoma

Authorization will be issued for 1 month for ACTH function testing.

Authorization will be issued for 12 months for other approved indications.

B. Any other **diagnostic agent*** will be approved based on the following criteria:

1. The intended use aligns with the labeling of the product

Authorization will be issued for 1 month

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Diagnostic agents are typically excluded from coverage.

4. References:

1. Metopirone [package insert]. Chatillon, France: HRA Pharma Rare Diseases; February 2020.
2. Nieman, Lynette K et. al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, August 2015, 100(8):2807–2831.

Program	Prior Authorization/Medical Necessity- Diagnostic Agents
Change Control	
9/2020	New program.
9/2021	Annual review. No changes.