AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Recorlev® (levoketoconazole)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limits: 240 tablets per 30 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with an endocrinologist or neurosurgeon
- ❑ Member has a diagnosis of persistent or recurrent Cushing's disease
- ❑ Member must meet at least **ONE** of the following **(chart notes must be submitted to document diagnosis and surgical history or contraindication to surgery)**:
  - ❑ Member has undergone pituitary surgery and must be at least 6 weeks post-surgery
  - ❑ Member has undergone irradiation and must be at least 4 years post-pituitary irradiation
  - ❑ Member is contraindicated to surgery **AND** irradiation

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- ❑ Member must have failed **90 days** of therapy with **ketoconazole** tablets **(verified by chart notes or pharmacy paid claims)**. Please provide documentation to support failure of oral ketoconazole along with rationale for use of requested medication
- ❑ Member must have current mean urine free cortisol levels (mUFC) >1.5 times the upper limit of normal (ULN)
- ❑ Member will **NOT** use concurrent Cushing's disease treatment with Recorlev (e.g., Isturisa, ketoconazole, metyrapone, mifepristone, mitotane)
- ❑ Member has been assessed for QTc prolongation/Torsade de Pointes
- ❑ Member has been assessed for hypokalemia, hypomagnesemia and treatment, as needed, prior to initiating therapy
- ❑ Member is **NOT** taking any CYP3A4 and/or P-gp substrate medications (e.g., lovastatin, simvastatin, tacrolimus)
- ❑ Provider attests member has been counseled to avoid excessive alcohol consumption
- ❑ Member does **NOT** have a history of any of the following:
  - Cirrhosis
  - Liver disease
  - Cholelithiasis
  - Baseline QTc prolongation
  - Ventricular tachycardia/fibrillation

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member's current 24-hour urinary free cortisol level is below the upper limit of normal **(labs must be submitted)**
- ❑ Improvements in quality of life have been maintained while on Recorlev therapy
- ❑ Member will continue to be monitored for QTc prolongation, electrolyte imbalances and hepatic impairment

Medication being provided by Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: 3/17/2022
REVISED/UPDATED: ~~4/26/2022; 6/15/2022; 6/16/2022;~~ **10/30/2023**