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: Wakix® (pitolisant)

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

Maximum Daily Dose:

- Weight < 40 kg: 17.8 mg (one 17.8 mg tablet) once daily
- Weight ≥ 40 kg: 35.6 mg (two 17.8 mg tablets) once daily

Wakix for narcolepsy with or without cataplexy will NOT be approved in conjunction with Sunosi or Xyrem/Xywav. The Health Plan considers the use of concomitant therapy with Wakix and Sunosi or Xyrem/Xywav to be experimental and investigational. Safety and efficacy of these combinations has NOT been established and will NOT be permitted. In the event a member has an active Sunosi or Xyrem/Xywav authorization on file, all subsequent requests for Wakix will not be approved.

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.

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- ❑ Member does **NOT** have a history of any of the following: substance abuse, serious CV disorder, history of QT prolongation, current use of medications that cause QT prolongation, hepatic or renal abnormalities or a psychiatric disorder

AND

- ❑ Member does **NOT** have a sleep-related breathing disorder or periodic limb movement disorder **(polysomnography results must be submitted for documentation)**

DIAGNOSIS: Please check one of the applicable diagnoses below

❑ **Excessive Daytime Sleepiness associated with Narcolepsy.** 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 is 6 years of age or older

AND

- ❑ Member has a diagnosis of excessive daytime sleepiness (EDS) associated with narcolepsy **(MSLT confirming diagnosis of narcolepsy must be submitted)**

AND

- ❑ Provider must submit the member's baseline Epworth Sleepiness Scale score **(rating scale must be attached)**

AND

- ❑ Member has failed a 30-day trial of modafinil or armodafinil **(verified by paid pharmacy claims)**

AND

- ❑ Member has failed a 30-day trial of Sunosi* **(*Sunosi requires prior authorization; trial will be verified by paid pharmacy claims)**

❑ **Narcolepsy with Cataplexy.** 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 is 18 years of age or older

AND

- ❑ Member has a diagnosis of narcolepsy with cataplexy **(MSLT confirming diagnosis of narcolepsy and chart notes documenting the occurrence of more than one episode of cataplexy at baseline prior to treatment with Wakix must be submitted. If polysomnography required, please submit with MSLT)**

AND

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- ❑ Provider must submit the member's baseline Epworth Sleepiness Scale score **(rating scale must be attached)**

AND

- ❑ Member must have a **2-month trial** and failure of **ONE** of the following anti-cataplectic therapies **(verified by pharmacy paid claims; documentation of intolerance or treatment failure must be submitted, unless use is contraindicated. Please attach clinical documentation citing contraindication)**:
  - ❑ SSRI (i.e., fluoxetine)
  - ❑ TCA (i.e., clomipramine, imipramine, desipramine or protriptyline)
  - ❑ SNRI (i.e., venlafaxine or duloxetine)

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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**: ~~1/16/2021;~~ 7/25/2024
REVISED/UPDATED/REFORMATTED: ~~2/24/2021; 6/30/2021; 10/27/2023;~~ **8/21/2024**;