AvMed

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Nulibry™ (fosdenopterin) **IV (Medical) (J3490)**

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:** _____

Quantity Limit: Maximum approval of 0.9mg/kg/day (actual body weight)

Recommended Dosage: Initial dose for infants will be 0.55mg/kg/dose once daily for 1 month, then increase to 0.75mg/kg/dose once daily for 2 months, then increase to target dose of 0.9mg/kg once daily

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 Approval: 6 months

- ❑ Provider is a metabolic geneticist, neurologist, or other specialist in treatment of molybdenum cofactor deficiency (MoCD) Type A

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- ❑ Member has a diagnosis of molybdenum cofactor deficiency (MoCD) Type A as diagnosed by an FDA-approved test documenting a mutation in the MOCS1 gene **(must submit genetic test results)**
- ❑ Member has confirmation of all of the following **(must submit lab test results)**:
  - ❑ Elevated S-sulfocysteine or sulfite urinary levels
  - ❑ Low serum or urinary uric acid levels
  - ❑ Elevated xanthine or hypoxanthine urinary levels
- ❑ Member has clinical presentation of MoCD including at least two (2) of the following **(submit current chart documentation)**:
  - ❑ intractable seizures
  - ❑ encephalopathy
  - ❑ hyper/hypotonia,feeding difficulties
  - ❑ developmental delay
  - ❑ exaggerated startle reaction
- ❑ Member's current weight must be noted: _____ **(submit current chart notes documenting weight)**
- ❑ Was member already initiated on fosdenopterin (Nulibry) or on recombinant cPMP (rcPMP)?
  - ❑ Yes **(must submit chart note documentation)**
  - ❑ No
- ❑ Member will not use fosdenopterin in combination with other substrate replacement therapy (e.g., recombinant cyclic pyranopterin monophosphate, etc.)
- ❑ Member does not have clinically significant intracranial hemorrhage, cortical or subcortical encephalomalacia, or abnormalities on brain imaging not attributable to MoCD Type A
- ❑ Member does not have a Modified Glasgow Coma Scale (mGCS) for infants and children score of less than 7 for more than 24 hours **(must submit mGCS scale with results)**

Reauthorization Approval – 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.

- ❑ If established on Nulibry but not previously approved by AvMed **ALL** of the initial authorization criteria must be met
- ❑ Member has confirmation of both of the following **(must submit lab test results)**:
  - ❑ Reduction of S-sulfocysteine (SSC) urinary levels to ≤11 µmol/mmol
  - ❑ Serum or urinary uric acid levels have increased from baseline or have been maintained above baseline level since last approval
- ❑ Member has had stabilization or improvement in one or more signs and symptoms of disease including, but not limited to, seizure frequency/duration, growth, achievement of developmental milestones
- ❑ Member's current weight must be noted: _____ **(submit current chart notes documenting weight)**

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- ❑ Member does not have a Modified Glasgow Coma Scale (mGCS) for infants and children score of less than 7 for more than 24 hours **(must submit mGCS scale with results)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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:** 5/20/2021
REVISED/UPDATED: ~~9/14/2021;~~ **10/8/2021**