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: Nulibry™ (fosdenopterin) **IV (Pharmacy)**

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 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
- ❑ 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)**

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- ❑ 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 Health **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

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- ❑ Member's current weight must be noted: _____ **(submit current chart notes documenting weight)**
- ❑ 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: Specialty Pharmacy – PropriumRx

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.****