

# SENTARA HEALTH PLANS

## 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 1-800-750-9692.** 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.**

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

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

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ 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/Quantity: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code: \_\_\_\_\_

**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**)
- Member has confirmation of all of the following (**must submit lab test results**):

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- 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 Optima 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  $\leq 11$   $\mu\text{mol}/\text{mmol}$
  - 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**)
- 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**)

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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.\****