Nulibry® (fosdenopterin)
Effective 11/01/2021

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<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
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<tr>
<td>☐ MassHealth</td>
<td>☑ Prior Authorization</td>
<td>☐ Pharmacy Benefit</td>
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<tr>
<td>☒ Commercial/Exchange</td>
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<td>☒ Medical Benefit (NLX)</td>
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Specialty Limitations: N/A

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<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
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<tr>
<td></td>
<td>All Plans</td>
<td>MassHealth</td>
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<td></td>
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<td>Phone: 866-814-5506</td>
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<td></td>
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<td>Fax: 866-249-6155</td>
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<td>Phone: 800-294-5979</td>
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<td>Fax: 888-836-0730</td>
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<td>Medical Specialty Medications (NLX)</td>
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<td>All Plans</td>
<td>Phone: 844-345-2803</td>
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<td>Fax: 844-851-0882</td>
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Exceptions: N/A

Overview
Nulibry is cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

Coverage Guidelines
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with Nulibry excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:
1. Documented diagnosis of molybdenum cofactor deficiency type A
2. Documentation of ONE of the following:
   a. Diagnosis of molybdenum cofactor deficiency type A confirmed by genetic testing
   b. In neonates (up to 28 days after birth), diagnosis based on ONE of the following:
      i. Prenatal genetic diagnosis
      ii. Onset of clinical signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., seizures, feeding difficulties, high-pitched cries, exaggerated startle reactions, increased/decreased muscle tone) within the first 28 days after birth
      iii. Onset of laboratory signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., elevated urinary sulfite and/or S-sulphocysteine, elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood) within the first 28 days after birth
Continuation of Therapy
Reauthorization will be granted if member meets all of the following criteria:
1. Diagnosis of molybdenum cofactor deficiency Type A confirmed by genetic testing
2. Documented therapeutic response as evidenced by ONE of the following:
   a. Improved change in molybdenum cofactor deficiency biomarkers
   b. Improved growth parameters

Limitations
1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for 12 months

References
5. ClinicalTrials.gov. Safety & efficacy study of ORGN001 (formerly ALXN1101) in pediatric patients with MoCD type A currently treated with rcPMP. Available at: https://clinicaltrials.gov/ct2/show/NCT02047461.

Review History
09/22/2021 – Reviewed and Created for Sept P&T. Effective 11/01/2021

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.