Clinical Policy Title:	fosdenopterin
Policy Number:	RxA.684
Drug(s) Applied:	Nulibry™
Original Policy Date:	04/27/2021
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

<table>
<tr><th>Drug Name</th><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>fosdenopterin (Nulibry™)</td><td>Reduction in mortality in patient with MoCD Type A</td><td>

Recommended dosage in patient less than one year of age

<table>
<tr><th>Titration schedule</th><th>Preterm Neonates (Gestational Age Less than 37 Weeks)</th><th>Term Neonates (Gestational Age 37 weeks and Above)</th></tr>
<tr><td>Initial Dosage</td><td>0.4 mg/kg once daily</td><td>0.55 mg/kg once daily</td></tr>
<tr><td>Month 1</td><td>0.7 mg/kg once daily</td><td>0.75 mg/kg once daily</td></tr>
<tr><td>Month 3</td><td>0.9 mg/kg once daily</td><td>0.9 mg/kg once daily</td></tr>
</table>

Recommended Dosage in Patients One Year of Age or Older: 0.9 mg/kg given as an intravenous infusion once daily

</td><td>0.9 mg/kg/dose IV once daily</td></tr>
</table>

Dosage Forms

- For injection: 9.5 mg of fosdenopterin as a lyophilized powder or cake in a single-dose vial for reconstitution.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Molybdenum cofactor deficiency type A (must meet all)**:**

1. Diagnosis or presumptive diagnosis of MoCD Type A confirmed by genetic testing;
2. Prescribed by a clinical geneticists or a specialist in inborn errors of metabolism;
3. Dose does not exceed 0.9 mg/kg/dose IV once daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Molybdenum cofactor deficiency type A (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by improvement in neurological function, gross motor function, developmental milestones and patient tolerating therapy;
3. Dose does not exceed 0.9 mg/kg/dose IV once daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MoCD: Molybdenum cofactor deficiency

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information

- Nulibry™ should be discontinued if MoCD Type A is not confirmed by genetic testing.

References

1. Nulibry Prescribing Information. Boston, MA, Origin Biosciences, Inc.; February, 2021. Available at https://www.nulibry.com/pdfs/nulibry-prescribing-information-v2.pdf. Accessed April 27, 2021.
2. IPD Analytics. [Internet database]. Updated periodically. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Nulibry . Accessed April 27, 2021

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/27/2021	06/10/2021