fosdenopterin (Nulibry)

Commercial Medical Benefit Drug Policy

Place of Service
Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Cyclic pyranopterin monophosphate (cPMP) substrate replacement therapy
HCPCS:
J1809:Injection, fosdenopterin, 0.1 mg
How Supplied:
9.5 mg as a lyophilized powder or cake in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Molybdenum Cofactor Deficiency Type A

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Molybdenum Cofactor Deficiency Type A
Meets medical necessity if all the following are met:
1. Prescribed by or in consultation with a pediatric neurologist

Covered Doses:
Patients one year of age or older: 0.9 mg/kg given intravenously (IV) once daily
Patients less than one year of age: see titration table

Titration schedule	Preterm Neonates (gestational age < 37 weeks)	Term Neonates (gestational age ≥ 37 weeks)
Initial dosage	0.4 mg/kg IV once daily	0.55 mg/kg IV once daily
Month 1	0.7 mg/kg IV once daily	0.75 mg/kg IV once daily
Month 3	0.9 mg/kg IV once daily	0.9 mg/kg IV once daily

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
E61.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Nulibry (fosdenopterin) Prescribing Information. Origin Biosciences, Inc., Boston, MA: 10/2022.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- Added HCPCS J1809, effective 10/1/2025

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee