Fosdenopterin (Nulibry™)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Infusion Administration HCPCS: J3490 NDC: • 73129-001-01: 9.5 mg as a lyophilized powder or cake in a single-dose vial

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

- Molybdenum cofactor deficiency type A

AHFS therapeutic class: Miscellaneous therapeutic agent

Mechanism of action: Cyclic pyranopterin monophosphate (cPMP) substrate replacement therapy

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for fosdenopterin (Nulibry™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Molybdenum cofactor deficiency type A

1. Prescribed by or in consultation with a pediatric neurologist

Covered Doses
Patients one year of age or older: 0.9 mg/kg 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
Indefinitely

ICD-10:
E61.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for fosdenopterin (Nulibry™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

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

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Nulibry™ (fosdenopterin) [Prescribing information]. Boston, MA: Origin Biosciences, Inc.; 10/2022.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee