

Nulibry® (fosdenopterin)

When requesting Nulibry® (fosdenopterin intravenous infusion), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved Indication

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

Coverage Guidelines

Molybdenum Cofactor Deficiency (MoCD) Type A

The individual must meet **all** of the following criteria for initial authorization:

- Patient has genetic testing confirmation of a mutation in the *MOCS1* gene;
- Based on current condition, the patient is expected to derive benefit with Nulibry and the disease state is not considered to be too advanced;
- The drug is being prescribed by or in consultation with a pediatrician, geneticist, or a physician who specializes in MoCD Type A.

Approval duration (initial and renewal): 12 months

Dosing Recommendations

The recommended dosage is given by intravenous infusion as follows:

Recommended Initial Dosage and Titration Schedule of Nulibry for Patients Less Than One Year of Age by Gestational Age

Titration Schedule	Preterm Neonates (gestational age less than 37 weeks)	Term Neonates (gestational age 37 weeks and above)
Initial dosage	0.4 mg/kg once daily	0.55 mg/kg once daily
Dosage at month 1	0.7 mg/kg once daily	0.75 mg/kg once daily
Dosage at month 3	0.9 mg/kg once daily	0.9 mg/kg once daily

For patients one year of age or older, the recommended dosage of NULIBRY is 0.9 mg/kg (based on actual body weight) administered as an intravenous infusion once daily.

References

1. Nulibry injection [prescribing information]. Boston, MA: Origin Biosciences; October 2022.
2. Mechler K, Mountford WK, Hoffmann GF, et al. Ultra-orphan diseases: a quantitative analysis of the natural history of molybdenum cofactor deficiency. *Genet Med*. 2015 Dec;17(12):965-70.