

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 confirmations of a mutation in the *MOCS1* gene; AND
- Based on current condition, the patient is expected to derive benefit with Nulibry and the disease state is not considered to be too advanced; AND
- 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 Recommendation

Approve up to 0.9 mg/kg given by intravenous infusion once daily.

References

1. Nulibry injection [prescribing information]. Boston, MA: Origin Biosciences; February 2021.
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.