RX.PA.041.MPC *Nulibry® (fosdenopterin)*

PURPOSE

Nulibry® is a cyclic pyranopterin monophosphate (cPMP) indication to reduce the risk of mortality in patients with molybdenum cofactor deficiency (McCD) Type A. Maryland Physicians Care requires Prior Authorization for its use.

Molybdenum Cofactor Deficiency Type A - Approve Nulibry if the member meets **ALL** of the following conditions

A. Initial Therapy:
- a. Must be prescribed by, or in consultation with, a neonatologist, a pediatric neurologist or specialist with expertise in the treatment of inherited metabolic disorders
  AND
- b. Clinical documentation for the diagnosis of molybdenum cofactor deficiency type A:
  - i. Genetic testing confirmation of a mutation in the MOCS1 gene

  AND
- c. Documentation of clinical and/or biochemical features associated with MoCD Type A
  - i. Seizures
  - ii. Limb/axial hypertonia
  - iii. Low serum uric acid
  - iv. Elevated urinary xanthine and hypoxanthine
  - v. Elevated sulfites in urine
- d. Dose does not exceed 0.9mg/kg once daily

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Nulibry will be considered investigational or experimental for any other use and will not be covered.

D. Continuation of therapy:
- a. Member has documented benefit from therapy
  AND
- b. Prescribed by, or in consultation with, a neonatologist, a pediatric neurologist or specialist with expertise in the treatment of inherited metabolic disorders

Approval Duration:

A. Initial Therapy: Approve for 6 months
B. Continuation of Therapy: Approve for 1 year

CPT Code	Description
J3490	Unclassifed drugs Single-dose vial of 9.5mg

References:

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

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*