Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 238.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Nulibry (fosdenopterin)

I. Policy:
Nulibry (fosdenopterin)

II. Purpose/Objective:
To provide a policy of coverage regarding Nulibry (fosdenopterin).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Nulibry is a cyclic pyranopterin monophosphate that undergoes conversion to molybdopterin, which is further converted to molybdenum cofactor. Molybdenum cofactor is required for molybdenum-dependent enzyme activation, including sulfite oxidase, which reduces levels of neurotoxic sulfites (eg, S-sulfocysteine).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Nulibry (fosdenopterin) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Nulibry is prescribed by a neonatologist, geneticist, or pediatric neurologist **AND**
- Medical record documentation of a diagnosis of molybdenum cofactor deficiency (MoCD) Type A as confirmed by genetic testing indicating a mutation in the molybdenum cofactor synthesis gene 1 (MOCS1) gene **OR**
- Medical record documentation of both of the following:
    - Documentation of biochemical and clinical features consistent with a diagnosis of molybdenum cofactor deficiency (MoCD) Type A, including but not limited to encephalopathy, intractable seizures, elevated urinary S-sulfocysteine levels, and decreased uric acid levels **AND**
    - Documentation that the member will be treated presumptively while awaiting genetic confirmation

AUTHORIZATION DURATION:
For patients with a presumptive diagnosis of molybdenum cofactor deficiency (MoCD) Type A awaiting genetic confirmation:
Approval will be given for an **initial duration of one (1) month** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of genetic testing confirming a diagnosis of molybdenum cofactor deficiency (MoCD) Type A.

For patients with genetically confirmed MoCD Type A diagnosis:
Approval will be given for an **initial duration of twelve (12) months**. Subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of a clinically significant positive response or lack of disease progression with Nulibry treatment.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Nulibry [prescribing information]. Charleston, SC: Alcami Carolinas Corporation; October 2022.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/20/21

Revised: 6/27/22 (Medicaid PARP statement), 6/6/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/29/24

MA UM Committee approval: 12/31/23