Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Nulibry® (fosdenopterin)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) - Approved Indications

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Nulibry for Members when the following criteria are met:

Initial Authorization Criteria

1. Documentation of **one (1)** of the following:
    a. Documented diagnosis of molybdenum cofactor deficiency type A confirmed by genetic testing
    b. The Member is a neonate (up to 28 days after birth) and has a presumptive diagnosis of MoCD Type A based on **one (1)** of the following:
        i. Prenatal genetic diagnosis
        ii. Onset of clinical signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., seizures, feeding difficulties, high-pitched cries, exaggerated startle reactions, increased/decreased muscle tone) within the first 28 days after birth
        iii. Onset of laboratory signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., elevated urinary sulfite and/or S-sulfocysteine, elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood) within the first 28 days after birth

Reauthorization Criteria

1. Documented diagnosis of molybdenum cofactor deficiency Type A confirmed by genetic testing

AND

2. Documentation the Member has experienced a therapeutic response as evidenced by **one (1)** of the following:
    a. Improved change in molybdenum cofactor deficiency biomarkers
    b. Improved growth parameters
    c. Improved feeding patterns

Limitations

- Initial approval will be limited to 4 months. Reauthorization for Nulibry will be provided in 12-month intervals.
- Members new to the plan who are stable on Nulibry should be reviewed using Reauthorization Criteria.
- Nulibry will not be authorized for the treatment of MoCD Type B or C.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1809	INJECTION, FOSDENOPTERIN, 0.1 MG

References

1. Atwal PS, Scaglia F. Molybdenum cofactor deficiency. Mol Genet Metab. 2016;117(1):1-4.
2. ClinicalTrials.gov. Safety & efficacy study of ORGN001 (formerly ALXN1101) in pediatric patients with MoCD type A currently treated with rcPMP. Available at: https://clinicaltrials.gov/ct2/show/NCT02047461.
3. Nulibry [package insert]. Boston, MA: Origin Biosciences, Inc.; October 2022.
4. ClinicalTrials.gov. Study of ORGN001 (formerly ALXN1101) in neonates with molybdenum cofactor deficiency (MOCD) type A. Available at: https://clinicaltrials.gov/ct2/show/NCT02629393. Accessed: March 2, 2021.
5. Schwahn BC, Van Spronsen FJ, Belaidi AA, et al. Efficacy and safety of cyclic pyranopterin monophosphate substitution in severe molybdenum cofactor deficiency type A: a prospective cohort study. Lancet. 2015; 386: 1955-1963.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Removed the Limitation Nulibry should be discontinued if MoCD Type A is not confirmed with genetic test results (eff 12/1/2023).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 12, 2024: No changes.
- September 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template. Added HCPCs code (J1809), effective 10/1/25.
- December 2025 E-Vote: no changes (effective 1/1/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management uidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.