Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Advanced Parkinson's Disease Medications

Effective: September 1, 2025

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 - Approved Indications

- Onapgo (apomorphine hydrochloride) is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease.
- Vyalev (foscarbidopa/foslevodopa) is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease.

Clinical Guideline Coverage Criteria

Onapgo (apomorphine hydrochloride)

Initial Coverage Criteria:

The Plan may cover Onapgo when **ALL** the following clinical criteria is met:

1. The patient has a diagnosis of advanced Parkinson's Disease

AND

2. The member experiences at least 2.5 hours of "off" time per day

AND

3. The medication is prescribed by, or in consultation with, a neurologist

AND

4. There is physician attestation or documentation that the patient is experiencing persistent motor fluctuations despite optimized carbidopa/levodopa therapy

AND

5. The patient has had trial and failure, inadequate response, intolerance, or contraindication to TWO of the following (must be from two different classes:
   a. Dopamine agonist (e.g., pramipexole, ropinirole)
   b. Catechol-o-methyl transferase (COMT) inhibitor (e.g., entacapone)
   c. Monoamine oxidase (MAO) B inhibitor (e.g., rasagiline, selegiline)

Reauthorization Criteria:
Reauthorization may be granted when **ALL** of the following clinical criteria are met:

1. The patient continues to exhibit disease stability

Vyalev (foscarbidopa/foslevodopa)

Initial Coverage Criteria:
The Plan may cover Vyalev when **ALL** the following clinical criteria is met:

1. The patient has a diagnosis of advanced Parkinson's Disease

AND

2. The member experiences at least 2.5 hours of "off" time per day

AND

3. The medication is prescribed by, or in consultation with, a neurologist

AND

4. There is physician attestation or documentation that the patient is experiencing persistent motor fluctuations despite optimized carbidopa/levodopa therapy

AND

5. The patient has had trial and failure, inadequate response, intolerance, or contraindication to TWO of the following (must be from two different classes:
    a. Dopamine agonist (e.g., pramipexole, ropinirole)
    b. Catechol-o-methyl transferase (COMT) inhibitor (e.g., entacapone)
    c. Monoamine oxidase (MAO) B inhibitor (e.g., rasagiline, selegiline)

Reauthorization Criteria:
Reauthorization may be granted when **ALL** of the following clinical criteria are met:

1. The patient continues to exhibit disease stability

Limitations

- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
- Initial approval duration will be for a period of 12 months. Reauthorizations will be for a duration of an additional 12 months.

Codes

The following HCPCS/CPT code(s) are:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7356	INJECTION, FOSCARBIDOPA 0.25 MG/FOSLEVODOPA 5 MG

References

1. Vyalev [package insert]. North Chicago, IL: AbbVie Inc.; 2024
2. Parkinson's disease in adults: diagnosis and management. NICE guideline [NG71]. 2017.
3. Pringsheim, T., Day, G. S., Smith, D. B., et al. (2021). Dopaminergic therapy for motor symptoms in early Parkinson disease practice guideline summary: a report of the AAN Guideline Subcommittee. Neurology, 97(20), 942-957.

Approval And Revision History

June 10, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- August 12, 2025: Effective September 1, 2025: Updated name of existing MNG from Vyalev (foscarbidopa/ foslevodopa) to Advanced Parkinson's Disease Medications. Added coverage criteria for Onapgo (apomorphine).

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 guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.