Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Vyalev™ (foscarbidopa/foslevodopa)

Effective: July 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

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

Vyalev is a first-in-class, 24-hour, continuous subcutaneous infusion of levodopa based therapy. Vyalev will replace levodopa-containing oral medications and catechol-O-methyltransferase inhibitors. Vyalev is delivered via AbbVie's nonsurgical Vyafuser Pump, which can be worn under or over clothing throughout the day and night.

An estimated 1 million people in the United States are diagnosed with Parkinson's Disease (PD). There are currently no treatments for PD that prevent or delay disease progression. Symptomatic treatment is the mainstay of PD management. In most patients with early PD seeking control of motor symptoms, levodopa based therapy is recommended as initial therapy.

The approval of Vyalev was based on data from MI5-736 (NCT04380142), a Phase 3, 12-week study that compared Vyalev with oral, immediate-release (IR) carbidopa/LD (CD/LD) in patients with advanced PD, along with data from a 52-week, open-label study (NCT03781167) that evaluated the long-term efficacy and safety of Vyalev. Results from both trials showed improvement in motor fluctuations, with Vyalev providing approximately 3 hours of additional "on" time (the period of time when patients experience optimal symptom control) without troublesome dyskinesia. Vyalev also decreased "off" time (the time when symptoms return) compared with IR CD/LD.

Food and Drug Administration (FDA) Approved Indications:

For the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD)

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Vyalev for Members when all of the following criteria are met:

Initial authorization:

1) The member 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) Physician attestation or documentation that the member is experiencing persistent motor fluctuations despite optimized carbidopa/levodopa therapy
   AND
4) Prescribed by, or in consultation with, a neurologist

Reauthorization:

Physician attestation of continued disease stability

Limitations

- Initial authorization of Vyalev is limited to a total of 12 months if initial authorization criteria are met
- Reauthorization for Vyalev may be granted for a period of up to 12 months when reauthorization criteria are met

Codes

The following code(s) require prior authorization:

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 2025: Joint Medical Policy and Health Care Services UM Committee review

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.