Medical Drug Clinical Criteria

Subject:	Vyalev (foscarbidopa/foslevodopa)		
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Table of Contents

Overview

This document addresses the use of Vyalev (foscarbidopa/foslevodopa) for the treatment of advanced Parkinson's disease. Vyalev (foscarbidopa/foslevodopa) is an injectable drug that may help minimize complications seen with oral dosing (such as the short half-life and inconsistent absorption of oral tablets due to impaired gastric motility). Foscarbidopa/foslevodopa are prodrugs of carbidopa/levodopa, provided in a soluble formulation that is administered over the individual's waking hours or as a 24-hour/day continuous subcutaneous infusion. In a 12-week, phase 3, double-blind, double-dummy study, treatment with foscarbidopa/foslevodopa when compared to oral immediate-release carbidopa/levodopa resulted in greater improvements in motor fluctuations (NCT04380142).

Parkinson's disease (PD) is a progressive neurodegenerative disorder associated with motor complications such as tremor, bradykinesia, and rigidity. The decision to initiate pharmacologic therapy for the management of symptoms associated with PD is determined by the degree to which the individual is functionally impaired and influenced by a variety of individual and medication-related factors. Treatment is individualized and combination therapy is often employed to manage symptoms and reduce "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes).

Levodopa and dopamine agonists are approved as first-line treatment options for early PD. Dopamine agonists, MAO B inhibitors or COMT inhibitors can be used as adjunct therapy to levodopa in individuals who have continued motor symptoms despite optimal levodopa therapy. Rasagiline is also approved as a monotherapy option for those with early PD. At least one agent from each drug class is available as a generic agent.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Vyalev (foscarbidopa and foslevodopa injection)

Initial requests for Vyalev (foscarbidopa and foslevodopa injection) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced Parkinson's disease; **AND**
II. Documentation is provided that individual is considered levodopa-responsive; **AND**
III. Documentation is provided that individual has motor symptoms inadequately controlled by current therapy; **AND**
IV. Individual has an average off time of at least 2.5 hours per day.

Continuation requests for Vyalev (foscarbidopa and foslevodopa injection) may be approved if the following criteria are met:

I. Documentation is provided that there is clinically significant improvement or stabilization in clinical signs and symptoms of disease defined as an increase of on-time with a decrease in the number of off episodes compared to baseline.

Quantity Limits

Vyalev (foscarbidopa and foslevodopa injection) Quantity Limit

Drug	Limit
Vyalev (foscarbidopa and foslevodopa injection) 12 mg-240 mg	42 vials (4200 mL) (6 cartons) per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Vyalev (foscarbidopa and foslevodopa)]
J3490	Unclassified drugs [when specified as Vyalev (foscarbidopa and foslevodopa)]

ICD-10 Diagnosis

	All diagnosis pend

Document History

New: 12/09/2024
Document History:

- 12/09/2024 – Select Review: Add new criteria and quantity limits for Vyalev. Administrative update to add documentation. Coding Reviewed: Added HCPCS NOC C9399, J3490, and all diagnosis pend.

References

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5. Pahwa R, Factor SA, Lyons KE, et al.; Quality Standards Subcommittee of the American Academy of Neurology. Practice Parameter: treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Neurology. 2006; 66(7):983-995.
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