

Clinical Oversight Review Board (CORB) Criteria for Prescribing/
Criteria-Based Consultation (CBC) Criteria for Coverage

Foscarbidopa and foslevodopa (Vyalev)

Notes:

- Quantity Limits: Yes
- ^ A time when a patient's medications are not working well, causing an increase in Parkinson's disease symptoms, such as tremor and difficulty walking.

Non-Formulary **foscarbidopa and foslevodopa (Vyalev)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-Formulary **foscarbidopa and foslevodopa (Vyalev)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by neurologist with expertise in diagnosis and management of Parkinson's disease
- Patient has a diagnosis of Parkinson's disease
- Patient experiences at least 2.5 hours of "OFF" time[^] per day that significantly interferes with functioning, as documented by neurologist
- Patient has tried and failed extra, as needed, oral doses of carbidopa/levodopa for "OFF" episodes[^]
- Patient has failed an adequate trial of, or patient has an allergy or intolerance or contraindication to a dopamine agonist (ropinirole or pramipexole) **AND** entacapone
- Patient is currently taking carbidopa/levodopa immediate release or controlled release 5 or more times per day **OR** is currently taking carbidopa/levodopa extended release (Rytary).

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: foscarbidopa and foslevodopa (Vyalev) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a diagnosis of Parkinson's disease
- Prior to foscarbidopa and foslevodopa (Vyalev) start:
 - Patient was experiencing at least 2.5 hours of "OFF" time[^] per day that significantly interfered with functioning, as documented by neurologist

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- Patient tried and failed extra, as needed, oral doses of carbidopa/levodopa for “OFF” episodes^
- Patient failed an adequate trial of, or has an allergy or intolerance or contraindication to a dopamine agonist (ropinirole or pramipexole) **AND** entacapone
- Patient was taking carbidopa/levodopa immediate release or controlled release 5 or more times per day **OR** is currently taking carbidopa/levodopa extended release (Rytary).

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-Formulary **foscarbidopa and foslevodopa (Vyalev)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist
- Patient has experienced a positive clinical response to treatment, as documented by neurologist