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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

**P&T Date: 02/12/2026**

**Parkinson's Disease Products**  
**Duopa®** (carbidopa/levodopa suspension)  
**Onapgo™** (apomorphine)  
**Vyalev™** (foscarnidopa/foslevodopa)

**HCPCS:** Duopa: J7340; Onapgo: J3490; Vyalev: J7356

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

- A. Coverage of the requested drug is provided when all the following are met:
  - a. FDA approved indications
  - b. FDA approved age
  - c. Drug-specific criteria as listed below:
    - i. Duopa, Onapgo, Vyalev
      - 1. Member must be established on and responsive to a levodopa-containing treatment regimen
      - 2. Current treatment regimen must include at least one of the following in addition to levodopa-based therapy:
        - a) Dopamine agonist
        - b) Catechol-o-methyltransferase (COMT) inhibitor
        - c) Monoaminoxidase-B (MAO-B) inhibitor
        - d) Amantadine
      - 3. Motor fluctuations are inadequately controlled by current treatment regimen, with member experiencing an average of at least 2.5 hours of "off" time per day
  - d. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
  - a. Quantity Limits: Align with FDA recommended dosing
  - b. Authorization Period: One year at a time
  - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit, such as disease stability or improvement.

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\*\*\*Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

## Background Information:

- Parkinson's disease (PD) is progressive neurodegenerative disease affecting over 1 million people in the United States. PD is caused by dopaminergic neurons undergoing high levels of oxidative stress due to dopamine degradation. The hallmark features of PD are tremor, bradykinesia, and rigidity; however, over time we have come to recognize that PD is a more complex condition featuring not only motor symptomology, but also neuropsychiatric and other nonmotor manifestations. The true etiology of PD is unknown.
- The primary classes of drugs used for the treatment of PD are levodopa, dopamine agonists, monoamine oxidase (MAO-B) inhibitors, and amantadine. The International Parkinson and Movement Disorder Society's 2018 updated evidence-based medication recommendations for treating motor symptoms of PD and the American Academy of Neurology's (AAN) Dopaminergic Therapy for Motor Symptoms in Early Parkinson Disease Practice Guideline (2021) do not consider any of the agents superior to another. The choice of therapy must take into account factors and risks individualized to each patient, including the impact of improving motor disability (better with levodopa) compared with lessening motor complications (better with dopamine agonists).
- MAO-B inhibitors and amantadine have modest antiparkinson effects but are well tolerated and convenient.; they are primarily reserved for mild disease with minimal impact of symptoms on daily function and quality of life. When motor symptoms of PD begin to interfere with daily function and quality of life, treatment with levodopa or a dopamine agonist is indicated. The choice of treatment depends on the patient's needs and the advantages and disadvantages of available options.
- Dopamine agonists improve motor symptoms and have a lower risk of motor complications than levodopa, but they carry a high risk of neurological side effects and are often ill-tolerated in older patients.
- Levodopa is most effective for controlling PD motor symptoms and is recommended as the initial preferential dopaminergic therapy in early PD by the AAN when able; however, it may require frequent dosing and has the highest risk of dopaminergic motor complications. If the decision is made to treat with levodopa, it is combined with a peripheral decarboxylase inhibitor (carbidopa in the United States) to block its conversion to dopamine in systemic circulation and liver to prevent nausea, vomiting and orthostatic hypotension.
- Carbidopa/levodopa has been a mainstay of treatment for patients who have PD and is available in a variety of forms (immediate-release, extended-release, orally disintegrating tablets, enteral suspension, subcutaneous infusion).
  - Duopa and Vyalev are the only non-oral formulations of carbidopa/levodopa. They are indicated for the treatment of motor fluctuations in patients with advanced PD.
- Although carbidopa/levodopa is highly effective and the gold standard for treatment of the motor symptoms related to PD, levodopa concentrations may wear off before the next dose causing motor fluctuations that are referred to as "off" episodes. There are several options available for treating "off" episodes in PD, including increasing the levodopa dose, adjusting the timing of levodopa preparations to a shorter time interval, changing to alternative levodopa preparations, and adding adjunctive therapies to carbidopa/levodopa to extend "on" time.
- Options for adjunctive therapy to levodopa/carbidopa include dopamine agonists (e.g. pramipexole (ER/IR), ropinirole (ER/IR)), MAO-B inhibitors (e.g. safinamide, rasagiline), catechol-O-methyltransferase (COMT) inhibitors (e.g.

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entacapone, opicapone), and istradefylline. The International Parkinson and Movement Disorder Society's 2018 updated evidence-based medication recommendations for treating motor symptoms of PD do not consider any of the adjunctive agents superior to another. The recommendation is that the choice of add-on therapy for treating motor fluctuations in PD should be based on patient characteristics, side effect profiles, cost, and availability. Many of these adjunctive therapies are available as cost-effective generics and may provide greater value over branded alternatives.

- Nourianz (istradefylline) and Ongentys (opicapone) are FDA-approved as adjunct therapy for the treatment of “off” episodes in patients with PD being treated with carbidopa/levodopa. These agents are not effective as monotherapy and must be taken in combination with carbidopa/levodopa.
  - Nourianz is the first adenosine A2A receptor antagonist for the treatment of PD; it provides a novel non-dopaminergic treatment option for “off” episodes in PD.
  - Ongentys is the third COMT inhibitor approved in the United States along with Tasmar® (tolcapone) and Comtan® (entacapone). Both Tasmar and Comtan are available in generic form. Tasmar has limited use in the United States due to its boxed warning for potentially fatal, acute fulminant liver failure, and is often reserved for those who have failed or are not candidates for other adjunctive therapies.
- Patients have advanced PD when optimized pharmacologic treatments are ineffective at controlling motor symptoms, to the point where motor complications are persistent and impair a patient's quality of life. It is at this stage that optimizing the dose or frequency of oral PD medications without inducing dyskinesia is difficult to achieve. Continuously infused therapies provide a potential solution to this challenge; these include Duopa, Vyalev, and Onapgo.
  - Duopa is available as a 16-hour enteral suspension designed to be delivered through either a naso-jejunal tube for short-term administration, or through a PEG-J for long-term administration.
    - In a Phase III trial, infusion of Duopa over 16 hours via PEG-J device showed significantly greater decrease in “off” time and increase in “on” time without troublesome dyskinesias at week 12 compared to immediate-release oral carbidopa/levodopa treatment (1.9- and 1.9-hour difference, respectively).
    - Eligible patients were required to have levodopa-responsive advanced PD inadequately controlled on current therapy, including at least 3 hours of average daily “off” time. Most patients were taking at least one concomitant medication for PD in addition to oral carbidopa/levodopa.
  - Vyalev offers an alternative, nonsurgical infusion option of carbidopa/levodopa. It is available as a subcutaneous infusion of prodrugs foscarbidopa and foslevodopa, which are converted in vivo to carbidopa and levodopa to quickly achieve steady blood concentrations of levodopa. Vyalev is administered subcutaneously via the VYAFUSER™ pump and can be dosed over a 24-hour period or over a patient's waking period (i.e., 16 hours).
    - In a Phase III clinical trial, 24-hour continuous subcutaneous infusion of Vyalev showed a significantly greater decrease in “off” time and increase in “on” time without troublesome dyskinesias compared to immediate-release oral carbidopa/levodopa treatment (1.79- and 1.75-hour difference, respectively).
    - Eligible patients were required to have levodopa-responsive advanced PD inadequately controlled on current therapy, including at least 2.5 hours of average daily “off” time.

- Onapgo is a subcutaneous continuous infusion of apomorphine for the treatment of motor fluctuations in adults with advanced PD, the same population as Vyalev and Duopa. Onapgo is not substitutable for apomorphine products intended for intermittent use, and unlike Vyalev and Duopa, Onapgo requires pre-treatment with trimethobenzamide starting three days prior to the first dose of Onapgo and continued for as long as necessary (generally no longer than 2 months) due to the incidence of nausea and vomiting with apomorphine. Additionally, initiation and dose titration of Onapgo should be done under medical supervision.
  - In the Phase III TOLEDO trial, an up to 16-hour continuous subcutaneous infusion of Onapgo showed a significantly greater decrease in “off” time and increase in “on” time without troublesome dyskinesias compared to placebo (1.65 hour and 1.64-hour difference, respectively). Eligible patients were required to experience at least three hours of average daily “off” time while receiving optimized PD treatment. At baseline, all patients were taking at least one concomitant medication to treat PD (e.g., dopamine agonist 87%, COMT-inhibitor 58%, MAO-B inhibitor 40%, amantadine 27%) in addition to oral immediate- or extended-release carbidopa/levodopa.
- Despite using these strategies, patients may still experience sudden, unpredictable “off” episodes in more advanced PD that may require on-demand therapy. Options currently available and FDA approved for on-demand treatment of acute, intermittent “off” episodes in adult patients with advanced PD include Apokyn® (apomorphine subcutaneous injection) and Inbrija® (levodopa inhalation powder). These agents are adjunctive therapies and should only be used as needed when symptoms of an “off period” return in patients who are established on PD treatment. Inbrija is specifically indicated for use in patients being treated with carbidopa/levodopa.
- Dyskinesia is another complication that may manifest in PD and refers to abnormal, involuntary movements caused by a drug. Dyskinesia is caused by overstimulation of dopamine receptors, primarily by the use of levodopa but also by agents that stimulate or enhance the effect of dopamine (e.g. dopamine agonists, MAO-B inhibitors, and COMT inhibitors). It may also, however, occur at low therapeutic levodopa doses depending on the patient’s sensitivity.
- First-line treatment strategies for dyskinesia include lowering the dose of levodopa and/or adjunctive dopaminergic therapies if possible, and the use of medication to help suppress dyskinesia. The International Parkinson and Movement Disorder Society’s updated (2018) evidence-based medication recommendations for treating motor symptoms of PD state that the most effective target for reducing dyskinesia in PD appears to be amantadine.

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| Policy History |                               |                                                                                                                                                                                                                                                                                                                                                         |
|----------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| #              | Date                          | Change Description                                                                                                                                                                                                                                                                                                                                      |
| 2.2            | Effective Date:<br>03/02/2026 | UM medical management system update for BCBS and BCN for Duopa, Onapgo, and Vyalev                                                                                                                                                                                                                                                                      |
| 2.1            | Effective Date:<br>02/12/2026 | Changed Neupro restless legs syndrome criteria to require a trial and failure of two alternatives instead of requiring all three, and added generic Lyrica (pregabalin) as an option<br>Updated supporting information to include the 2025 American Academy of Sleep Medicine guidelines for restless legs syndrome and periodic limb movement disorder |
| 2.0            | Effective Date:<br>06/05/2025 | Added criteria to Nourianz requiring a trial and failure of at least one adjunctive therapy used in combo with levodopa-containing product                                                                                                                                                                                                              |
| 1.9            | Effective Date:<br>04/10/2025 | Added Onapgo and related criteria to the policy<br>Updated Duopa and Vyalev criteria to align with Onapgo<br>Removed Inbrija and Ongentys from the policy; no longer managed with PA                                                                                                                                                                    |
| 1.8            | Effective Date:<br>12/12/2024 | Added Vyalev and related criteria to the policy                                                                                                                                                                                                                                                                                                         |
| 1.7            | Effective Date:<br>10/03/2024 | Removed Apokyn and Osmolex ER from the policy; no longer managed<br>Removed Kynmobi from the policy; product discontinued<br>Added Crexont to the policy                                                                                                                                                                                                |
| 1.6            | Effective Date:<br>02/04/2021 | Addition of Osmolex ER and related criteria back to the document for management under preferred drug list                                                                                                                                                                                                                                               |
| 1.5            | Effective Date:<br>08/13/2020 | Addition of Kynmobi and Apokyn to the document<br>Updated supporting information<br>Updated pricing table<br>Updated pipeline information                                                                                                                                                                                                               |
| 1.4            | Effective Date:<br>06/11/2020 | Policy converted to updated format<br>Addition of Ongentys to policy<br>Removal of drugs not managed with PA/ST from the policy (Mirapex ER, Gocovri, Osmolex ER, and Xadago)<br>Addition of Medicare B language to document<br>Pricing table updated<br>Supporting and safety information updated                                                      |
| 1.3            | Effective Date:<br>11/07/2019 | Addition of Nourianz to document<br>Pricing table updated<br>Updated initial authorization period, renewal authorization period, and renewal authorization criteria                                                                                                                                                                                     |
| 1.2            | Effective Date:<br>02/14/2019 | Addition of Inbrija to document<br>Addition of criteria to require preferred drugs as listed in the BCBSM/BCN's prior authorization and step therapy documents<br>Pricing table updated                                                                                                                                                                 |
| 1.1            | Effective Date:<br>05/03/2018 | Addition of Osmolex ER to document                                                                                                                                                                                                                                                                                                                      |
| 1.0            | Effective Date:<br>06/11/2020 | New criteria document                                                                                                                                                                                                                                                                                                                                   |

\* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

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# Blue Cross Blue Shield/Blue Care Network of Michigan

## Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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| PATIENT INFORMATION                                                  | PHYSICIAN INFORMATION        |
|----------------------------------------------------------------------|------------------------------|
| Name                                                                 | Name                         |
| ID Number                                                            | Specialty                    |
| D.O.B. <input type="checkbox"/> Male <input type="checkbox"/> Female | Address                      |
| Diagnosis                                                            | City /State/Zip              |
| Drug Name                                                            | Phone/Fax: P: ( ) - F: ( ) - |
| Dose and Quantity                                                    | NPI                          |
| Directions                                                           | Contact Person               |
| Date of Service(s)                                                   | Contact Person Phone / Ext.  |

### STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: \_\_\_\_\_
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: \_\_\_\_\_  
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: \_\_\_\_\_  
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: \_\_\_\_\_
- Please specify location of administration if hospital inpatient infusion: \_\_\_\_\_
- Please provide the NPI number for the place of administration: \_\_\_\_\_
- Initiation AND Continuation of therapy:**
  - What is the patient's diagnosis? \_\_\_\_\_
  - What other medication has the patient received for their condition? Please list \_\_\_\_\_  
    - Please describe the response to previous therapies: \_\_\_\_\_
  - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: \_\_\_\_\_
  - Please list any labs values important for diagnosing or monitoring this patient's condition: \_\_\_\_\_
- Continuation of therapy:**
  - Has the patient progressed while on this medication? ☐ yes ☐ no
  - How has the patient's condition changed while on this medication?
 

☐ Improved: Please describe: \_\_\_\_\_
 ☐ Stable: please describe: \_\_\_\_\_
 ☐ Worsened; Please describe: \_\_\_\_\_
 ☐ Other; Please describe: \_\_\_\_\_

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

**Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.**

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

| Physician's Name            | Physician Signature                                                                                 | Date                                                                                               |
|-----------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Step 2:</b><br>Checklist | <input type="checkbox"/> Form Completely Filled Out<br><input type="checkbox"/> Provide chart notes | <input type="checkbox"/> Attach test results                                                       |
| <b>Step 3:</b><br>Submit    | <b>By Fax: BCBSM Specialty Pharmacy Mailbox</b><br><b>1-877-325-5979</b>                            | <b>By Mail: BCBSM Specialty Pharmacy Program</b><br><b>P.O. Box 312320, Detroit, MI 48231-2320</b> |

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021