AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Antiparkinson Agents

Drug Requested: (Select applicable drug below)

❑ **Crexont®** (carbidopa-levodopa ER capsules)	❑ **Ongentys®** (opicapone capsules)
❑ **Inbrija™** (levodopa inhalation powder)	❑ **tolcapone** (Tasmar) **tablets**
❑ **Lodosyn®** (carbidopa tablets)	❑ **Rytary®**(carbidopa-levodopa ER capsules)
❑ **Neupro®** (rotigotine transdermal system)	❑ **Xadago™** (safinamide tablets)
❑ **Nourianz™** (istradefylline tablets)	

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosage:

- **Crexont®:** Oral: Initial: Carbidopa 35 mg/levodopa 140 mg twice daily for 3 days; may increase dose gradually up to a maximum of carbidopa 525 mg/levodopa 2.1 g per day, in up to 4 divided doses, Maximum quantity limit: 6 capsules per day (all strengths).

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- **Inbrija™:** Oral inhalation: 84 mg up to 5 times daily as needed when symptoms of an OFF period return up to a maximum of 84 mg/dose and 420 mg/day. Maximum quantity limit: 10 capsules per day.
- **Lodosyn® :** Oral: Initial: 25 mg daily with first daily dose of carbidopa/levodopa; if necessary, 12.5 to 25 mg may be given with each subsequent dose of carbidopa/levodopa. Maximum quantity limit: 8 tablets per day.
- **Neupro®:** *Early-stage Parkinson Disease:* Transdermal: Initial: Apply 2 mg/24 hours patch once daily; may increase daily dose by 2 mg/24 hours weekly based on clinical response and tolerability. Maximum: 6 mg/24 hours.

  Advanced-stage Parkinson Disease: Transdermal: Initial: Apply 4 mg/24 hours patch once daily; may increase daily dose by 2 mg/24 hours weekly based on clinical response and tolerability. Maximum: 8 mg/24 hours. Maximum quantity limit: 30 patches/30 days (all strengths).

  Restless legs syndrome : Initial: Transdermal: Apply 1 mg/24 hours patch once daily; may increase daily dose by 1 mg/24 hours weekly, based on clinical response and tolerability to a maximum of 3 mg/24 hours. Maximum quantity limit: 30 patches/30 days (all strengths).
- **Nourianz™:** Oral: 20 mg once daily; may further increase dose based on response and tolerability to a maximum dose of 40 mg once daily. Maximum quantity limit: 1 tablet per day (both strengths).
- **Ongentys®:** Oral: 50 mg once daily at bedtime. Maximum quantity limit: 1 capsule per day (both strengths).
- **tolcapone (Tasmar):** Oral: Initial: 100 mg 3 times daily always as an adjunct to levodopa/carbidopa; may increase as tolerated to 200 mg 3 times daily. Maximum quantity limit: 6 tablets per day.
- **Rytary®:** Oral: Initial: Carbidopa 23.75 mg/levodopa 95 mg 3 times daily for 3 days; on day 4, may increase to carbidopa 36.25 mg/levodopa 145 mg 3 times daily. Maximum quantity limit: 10 capsules per day (all strengths).
- **Xadago™:** Oral: 50 mg once daily (in combination with carbidopa/levodopa); after 2 weeks may increase to 100 mg once daily (in combination with carbidopa/levodopa) based on response and tolerability. Maximum quantity limit: 1 tablet per day (both strengths).

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member must be 18 years of age or older
- ❑ Medication must be prescribed by, or in consultation with a neurologist
- ❑ Member must have a confirmed diagnosis of Parkinson's disease in an individual who is having intermittent OFF episodes while on continuous carbidopa/levodopa therapy and **ALL** the following criteria has been met **(must submit chart notes)**:
  - ❑ Provider has made adjustments to member's carbidopa/levodopa's dose in order to manage symptoms without success
  - ❑ Member is receiving concurrent therapy with carbidopa/levodopa **within the past 30 days** **AND** the requested medication will be used in combination with continuous carbidopa/levodopa treatment

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- ❑ Member is currently not taking or has not recently (within 2 weeks) taken a nonselective MAO inhibitor such as Nardil® (phenelzine), Parnate® (tranylcypromine), or Marplan® (isocarboxazid)

❑ Member must meet **ALL** criteria for requested drug below if prescribed for treatment of Parkinson's disease

❑ **For Crexont & Rytary®,** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of trial and failure of **BOTH** of the following:
  - ❑ Combination therapy of carbidopa/levodopa IR with carbidopa/levodopa extended-release
  - ❑ Member must have documentation of trial and failure of **ONE** of the following:
    - ❑ Dopamine agonist: ropinirole/ropinirole ER, pramipexole/pramipexole ER
    - ❑ Monoamine oxidase type B inhibitors: rasagiline
    - ❑ COMT inhibitor: generic entacapone

❑ **For Inbrija® or Nourianz®,** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of trial and failure of **TWO (2)** of the following:
  - ❑ Monoamine oxidase type B inhibitors: rasagiline
  - ❑ Dopamine agonist: ropinirole/ropinirole ER, pramipexole/pramipexole ER
  - ❑ COMT inhibitor: generic entacapone, Ongentys® (*requires prior authorization), tolcapone (*requires prior authorization)
- ❑ **For Inbrija requests**: Member does **NOT** have a history of asthma, COPD, or other chronic underlying lung disease

❑ **For Lodosyn®,** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is currently receiving carbidopa/levodopa therapy and Lodosyn (carbidopa) is being used in combination to levodopa therapy to reduce the side effects (i.e., nausea) associated and to enhance the effectiveness of levodopa therapy.

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❑ **For Neupro®,** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of **ONE** of the following diagnoses:
  - ❑ Parkinsons Disease
  - ❑ Moderate to severe restless leg syndrome
- ❑ **For Parkinsons Disease:**
  - ❑ Member must meet **ONE** of the following:
    - ❑ Member must meet all initial criteria listed above and have documentation of trial and failure or intolerance to **BOTH** of the following oral dopamine agonists:
      - ❑ pramipexole immediate release tablets
      - ❑ ropinirole extended-release release tablets
    - ❑ Prescriber indicates the patient is unable to swallow or take medications orally
- ❑ **For Restless Legs Syndrome:**
  - ❑ Member must meet **ONE** of the following:
    - ❑ Member must have documentation of trial and failure or intolerance to **TWO** of the following oral dopamine therapies:
      - ❑ pramipexole immediate release tablets
      - ❑ ropinirole extended-release release tablets
    - ❑ Member must have documentation of gabapentin or pregabalin for those with an intolerance to dopamine agonists
    - ❑ Prescriber indicates the member is unable to swallow or take medications orally

❑ **For Ongentys®.** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of trial and failure of a COMT inhibitor: generic entacapone
- ❑ Member does **NOT** have a history of pheochromocytoma, paraganglioma, or other catecholamine-secreting neoplasms

❑ **For tolcapone (Tasmar)**. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of trial and failure of **ALL** the following:
  - ❑ COMT inhibitors: generic entacapone and Ongentys® (opicapone) (*requires prior authorization)
  - ❑ Dopamine agonist: ropinirole/ropinirole ER, pramipexole/pramipexole ER
  - ❑ Monoamine oxidase type B inhibitors: rasagiline

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- ❑ Provider attests to monitoring of liver failure/hepatic dysfunction and should discontinue tolcapone if ALT/AST levels exceed 2 times the upper limit of normal

❑ **For Xadago®,** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have documentation of trial and failure or intolerance to **BOTH** of the following monoamine oxidase inhibitors:
  - ❑ selegiline
  - ❑ rasagiline
- ❑ Member does **NOT** have severe hepatic impairment (Chld-Pugh C)

❑ **Reauthorization: 12 months.** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must continue to meet all applicable initial authorization criteria
- ❑ Member has a documented positive clinical response to treatment (defined as: improvement and stabilization of "off episodes" associated with Parkinson's disease)
- ❑ Requested medication is used in combination with carbidopa/levodopa **(verified by pharmacy paid claims)**
- ❑ Member must be absent of unacceptable toxicity from therapy

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~9/20/2019; 2/20/2020;~~ **1/23/2025**
REVISED/UPDATED/REFORMATTED: ~~10/8/2019; 6/11/2020; 4/1/2021; 6/14/2021;~~ **2/18/2025**