

PHARMACY COVERAGE GUIDELINE

CREXONT® (carbidopa and levodopa) extended-release oral RYTARY™ (carbidopa and levodopa) extended-release oral TASMAR® (tolcapone) oral Tolcapone oral Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for CREXONT (carbidopa and levodopa) and RYTARY (carbidopa and levodopa)

Criteria for Initial Therapy:

Indication

- Parkinson’s disease
- Post encephalitic parkinsonism

PHARMACY COVERAGE GUIDELINE

CREXONT® (carbidopa and levodopa) extended-release oral RYTARY™ (carbidopa and levodopa) extended-release oral TASMAR® (tolcapone) oral Tolcapone oral Generic Equivalent (if available)

- Carbon monoxide or manganese intoxication parkinsonism

Age Requirement

- 18 years or older

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance to:
 - Generic extended release carbidopa and levodopa tablets
 - **For Rytary only:** extended release Crexont (carbidopa and levodopa extended release)

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No FDA label contraindications such as use with or within 14 days of stopping nonselective monoamine oxidase inhibitors (e.g., isocarboxazid, phenelzine, tranylcypromine)
- Requested agent will not be used with other levodopa products
- Crexont and Rytary will not be used concurrently

Documentation Requirements

- A completed request form must be submitted, including:
 - Chart notes
 - Lab results
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration:

- 6 months OR end of plan year
-

Criteria for Continuation of Therapy (renewal therapy)

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Clinical Response

- Positive clinical response defined as **ONE** of the following:
 - Able to perform most activities of daily living
 - Improvement in symptoms of tremor, bradykinesia, rigidity
 - Achieved and maintains reduced “off” time during waking hours

PHARMACY COVERAGE GUIDELINE

CREXONT® (carbidopa and levodopa) extended-release oral **RYTARY™ (carbidopa and levodopa) extended-release oral** **TASMAR® (tolcapone) oral** **Tolcapone oral** **Generic Equivalent (if available)**

- Achieved and maintains increased “on” time without troublesome dyskinesia

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No new contraindications or significant adverse drug effects such as:
 - Use with or within 14 days of stopping nonselective monoamine oxidase inhibitors (e.g., isocarboxazid, phenelzine, tranylcypromine)
 - Hallucinations or psychosis
 - Impulse control issues or compulsive behavior
 - Significant daytime sleepiness or episodes of falling asleep during activities of daily living
- Requested agent will not be used with other levodopa products
- Crexont and Rytary will not be used concurrently

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration:

- 12 months OR end of plan year
-

Medical Necessity Requirements for **TASMAR** (tolcapone) and **Tolcapone** generic

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician specializing in Parkinson’s disease or in consultation with a neurologist

Age Requirement

- 18 years or older

PHARMACY COVERAGE GUIDELINE

CREXONT® (carbidopa and levodopa) extended-release oral RYTARY™ (carbidopa and levodopa) extended-release oral TASMAR® (tolcapone) oral Tolcapone oral Generic Equivalent (if available)

Indication

- Diagnosis of Parkinson's disease with symptom fluctuations

Baseline Clinical Evaluation

- Continued use of carbidopa and levodopa
- Experiencing symptom fluctuations and not responding satisfactorily to or not appropriate candidates for other adjunctive therapies (e.g., pramipexole, ropinirole, selegiline)
- Completed baseline liver function test before initiation of treatment and will have continued monitoring as clinically appropriate

Alternative Therapies

- **For brand TASMAR only:**
 - Failure (trial for at least three months duration), contraindication, intolerance to:
 1. Generic tolcapone
 2. Entacapone (brand or generic)

Safety

- No FDA label contraindications such as:
 - Liver disease
 - Prior withdrawal from TASMAR or tolcapone due to hepatic injury
 - History of non traumatic rhabdomyolysis
 - Hyperpyrexia and confusion related to medication
 - Hypersensitivity to TASMAR or tolcapone or its ingredients
- No severe dyskinesia or dystonia
- No clinical evidence of liver disease or two alanine transaminase (ALT) or aspartate transaminase (AST) values greater than the upper limit of normal or prior hepatocellular injury from TASMAR or tolcapone
- Will not use requested agent with non selective monoamine oxidase inhibitors (e.g., phenelzine, tranylcypromine)

Documentation Requirements

- A completed request form must be submitted, including:
 - Chart notes
 - Lab results
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration:

- 6 months OR end of plan year

PHARMACY COVERAGE GUIDELINE

CREXONT® (carbidopa and levodopa) extended-release oral
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Criteria for Continuation of Therapy (renewal therapy)

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues to be seen by a physician specializing in Parkinson's disease or in consultation with a neurologist

Clinical Response

- Positive clinical response defined as **ONE** of the following:
 - Able to perform most activities of daily living
 - Improvement in symptoms of tremor, bradykinesia, rigidity
 - Achieved and maintains reduced "off" time during waking hours
 - Achieved and maintains increased "on" time without troublesome dyskinesia

Adherence

- Adherence to the prescribed therapy regimen has been documented
- Continued use of carbidopa and levodopa

Alternative Therapies

- **For brand TASMAR only:**
 - Failure (trial for at least three months duration), contraindication, intolerance to generic tolcapone

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No new contraindications or significant adverse drug effects such as:
 - Hepatotoxicity (ALT and AST greater than two times upper limit of normal or clinical symptoms)
 - Significant daytime sleepiness or episodes of falling asleep during activities of daily living
 - Paranoid ideation, delusions, hallucinations, confusion, psychotic like behavior, disorientation, aggressive behavior, agitation, and delirium
 - Frequent dyskinesias
 - Impulse control or compulsive behaviors
- No severe dyskinesia or dystonia
- No clinical evidence of liver disease or two ALT or AST values greater than the upper limit of normal or prior hepatocellular injury from TASMAR or tolcapone
- Will not use requested agent with non selective monoamine oxidase inhibitors

ORIGINAL EFFECTIVE DATE: 09/15/2017 | ARCHIVE DATE: | LAST REVIEW DATE: 08/21/2025 | LAST CRITERIA REVISION DATE: 08/21/2025

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Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration:

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
2. Off-Label Use of Cancer Medications

Description:

Rytary (carbidopa/levodopa) extended-release capsule is indicated for the treatment of Parkinson's disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. Tasmар (tolcapone) tablet is indicated as an adjunct to carbidopa and levodopa for the treatment of signs and symptoms of idiopathic PD in patients who are experiencing symptom fluctuations and are not responding satisfactorily to or are not appropriate candidates for other adjunctive therapies.

Motor symptoms of PD are caused by a progressive degeneration of Dopamine (DA) containing neurons in the brain. Non-motor manifestations such as cognitive and psychiatric symptoms are thought to be due to degeneration of other neurotransmitter systems within the brain. Degeneration of the DA neurons leads to DA deficiency and as a result the development of the classic triad of motor symptoms of resting tremor, muscle rigidity and bradykinesia. With the development of DA deficiency, there is also a relative excess of acetylcholine activity.

Drug therapy is targeted at reducing symptoms by enhancing the effects of DA or inhibiting the effects of acetylcholine. Levodopa has been long recognized in clinical practice guidelines and texts as the standard of care for PD. It is a precursor of DA and is able to cross the blood brain barrier where it is converted to DA. Levodopa is thought to be protective against the dopaminergic neuron damage observed in PD. Levodopa is converted to DA in the periphery before it is able to cross the blood brain barrier resulting in gastrointestinal adverse effects and a lower-than-expected concentration of levodopa within the brain. To avoid this, levodopa is combined with carbidopa resulting in a decrease in the peripheral conversion of levodopa to DA and allowing for more levodopa to reach the brain to then be converted to DA. The combination of carbidopa/levodopa is one of the most effective treatments available for symptomatic relief of PD.

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In the early stages of levodopa therapy, patients experience a smooth and even response. As PD advances, the effect of levodopa wears off approximately 4 hours after each dose. As many as 50% of patients on levodopa for 5 years, will eventually experience motor fluctuations and dyskinesia. Motor fluctuations are shifts between “on” periods where the patient is responding to levodopa therapy and “off” periods, or end-of-dose effect, where the patient experiences PD symptoms. Dyskinesia consists of a wide range of involuntary movements and typically appears during the patient’s “on” period. These symptoms of motor fluctuations and dyskinesia are commonly seen in patients with early onset (< 50 years of age) PD and are unique to levodopa therapy. For treatment of PD with motor fluctuations and dyskinesia, adjunctive therapy is often necessary to address these complications.

Other treatments for PD include DA receptor agonists, catechol-O-methyltransferase (COMT) inhibitors, selective mono-amine oxidase type-B (MAOI-B) inhibitors, amantadine, and selective use of anticholinergic agents. These agents are effective and safe in controlling motor symptoms in patients with advanced PD when used as adjunctive treatment to Levodopa. There is insufficient evidence to conclude that any one of these medications is clinically superior to another and there is insufficient evidence that shows one PD medication as superior to another in terms of improvement in functional outcomes.

Low-cost generic options are available in immediate and extended-release formulations of carbidopa/levodopa as well as for each class of adjunctive therapy and are sufficient to meet the needs of most patients.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Oral Anti-Parkinson’s disease agents	
Carbidopa	Carbidopa generic tabs Lodosyn tabs
Carbidopa+Levodopa	Carbidopa+Levodopa – immediate release generic tabs Carbidopa+Levodopa ER – extended-release generic tabs Carbidopa+Levodopa ODT generic tabs Crexont – extended release caps Rytary – extended-release caps Sinemet – immediate release tabs Sinemet CR – extended-release tabs
Carbidopa+Levodopa+Entacapone	Carbidopa+Levodopa+Entacapone generic tabs Stalevo tabs
COMT inhibitors	Entacapone generic tabs Comtan (entacapone) tabs Ongentys (opicapone) caps Tolcapone generic tabs

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	Tasmar (tolcapone) tabs
DA agonists	Bromocriptine generic tabs Parlodel (bromocriptine) tabs Pramipexole – immediate release generic tabs Pramipexole ER – extended-release generic tabs Mirapex (pramipexole) – immediate release tabs Mirapex ER (pramipexole) – extended-release tabs Ropinirole – immediate release generic tabs Ropinirole ER – extended-release generic tabs Requip (ropinirole) – immediate release tabs Requip XL (ropinirole) – extended-release tabs
MAO-B inhibitors	Rasagiline generic tabs Azilect (rasagiline) tabs Xadago (safinamide) tabs Selegiline generic tabs and caps Eldepryl (selegiline) caps Zelapar (selegiline) – ODT tab
Anticholinergic agents for PD	Benzotropine Diphenhydramine Trihexyphenidyl

The Child-Pugh classification system:

	Score: 1 point	Score: 2 points	Score: 3 points
Serum Albumin (g/dL)	>3.5	3.0 - 3.5	<3.0
Serum Bilirubin (mg/dL)	<2.0	2.0 - 3.0	>3.0
Prothrombin time (seconds)	1 - 4	4 - 6	>6
Ascites	none	moderate	severe
Encephalopathy	none	mild	severe

The three classes and their scores are:

- **Class A** is score 5 – 6: Well compensated
- **Class B** is score 7 – 9: Significant functional compromise
- **Class C** is score >9: Decompensated disease

Activities of daily living (ADL):

Instrumental ADL:

Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

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Self-care ADL:

Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Resources:

Crexont (levodopa and carbidopa) extended release capsule product information, revised by Amneal Pharmaceuticals, LLC. 08-2024. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2025.

Rytary (levodopa and carbidopa) extended release capsule product information, revised by Amneal Pharmaceuticals, LLC. 12-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2025.

Tasmar (tolcapone) product information, revised by Bausch Health US, LLC. 10-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2025.

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