BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/19/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Ongentys (opicapone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in patient's diagnosis or is in consultation with a Neurologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of Parkinson's disease (PD) in an individual experiencing "off" episodes
  4. Use is as adjunctive treatment to levodopa/carbidopa
  5. Individual has failure, contraindication or intolerance to ALL the following preferred step therapy agents:
     a. **One trial** of dopamine agonist: pramipexole, **or** ropinirole
     b. **One trial** of monoamine oxidase inhibitor (MAO) B inhibitor: selegiline (capsule or tablet) **or** rasagiline mesylate tablet
     c. **One trial** of catechol O-methylase inhibitor (COMT): entacapone **or** tolcapone
  6. Will not be used in patients with end-stage renal disease (CrCl < 15 mL/min)
  7. Will not be used in severe hepatic impairment (Child-Pugh Class C)
  8. There are **NO** contraindications. Contraindications include:
     a. Concomitant use of non-selective monoamine oxidase (MAO) inhibitors
     b. History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Ongentys (opicapone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in patient's diagnosis or is in consultation with a Neurologist
  2. Individual's condition responded while on therapy
     a. Response is defined as **THREE** of the following:
        i. No evidence of disease progression
        ii. Functionality retained most activities of daily living
        iii. Achieved and maintains a reduction in off time
        iv. Achieved and maintains an increase in on time of at least 1 hour
  3. Individual has been adherent with the medication

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4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    a. Contraindications or adverse effect.
        i. Emergent or worsening dyskinesia
        ii. Emergent or worsening hallucinations or psychotic behaviors
        iii. Impulse control or compulsive behaviors

5. There are no significant interacting drugs

Renewal duration: 12 months

- Ongentys (opicapone) for all other indications not previously listed is considered ***experimental or investigational*** and will not be covered when any one or more of the following criteria are met:
    1. Lack of final approval from the Food and Drug Administration;
    2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
    3. Insufficient evidence to support improvement of the net health outcome;
    4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
    5. Insufficient evidence to support improvement outside the investigational setting.

    These indications include, but are not limited to:
    - Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

Description:

Ongentys (opicapone) is a peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to
levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

Patients with Parkinson disease (PD) who take levodopa chronically are increasingly likely to develop motor fluctuations and dyskinesia as the disease progresses and nigrostriatal dopaminergic neurons continue to degenerate and lose presynaptic dopamine storage capacity.

Dyskinesia consists of several types of abnormal involuntary movements, most often choreiform, brought on by levodopa or other dopaminergic agents. Dyskinesia is caused by overstimulation of dopamine receptors by the use of levodopa, but also by agents that either stimulate or enhance the effect of dopamine at the receptor (e.g., dopamine agonists, monoamine oxidase type B [MAO B] inhibitors, and catechol-O-methyl transferase [COMT] inhibitors).

Motor fluctuations are alterations between periods of a positive response to medication (commonly referred to as "on" periods), and periods of reemergence of parkinsonian symptoms (commonly referred to as "off" periods). The transition from on to off can be sudden and unpredictable. Unpredictable off periods can also occur that have no relationship to timing of levodopa and the wearing off phenomena. Use of home diaries and direct observation

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can help determine any relationship of levodopa dosing to the off period. Many unpredictable off moments turn out to be end of levodopa dosing wearing off.

“Wearing off" is characterized by the recurrence of parkinsonian symptoms as the effect of levodopa diminishes near the end of the dose interval, usually three to four hours after a dose. Wearing off is often the first and most commonly encountered fluctuation. A majority of patients experience wearing off after five years of levodopa treatment; however, in a minority this phenomenon may occur earlier. Other motor fluctuations include freezing of gait that can lead to falls and ultimately loss of independence, acute akinesia, and failed or lack of an on response to levodopa.

Wearing off may be managed initially by increasing the dose of levodopa and/or interval adjustments and use of longer acting levodopa preparations. If levodopa adjustments for wearing off are not adequate or tolerated, the addition of an adjunctive therapy (e.g., dopamine agonist (pramipexole or ropinirole), COMT inhibitor, MAO B inhibitor, or istradefylline) to the levodopa regimen can help to reduce "off" time.

Resources:

Ongentys (opicapone) product information, revised by manufacturer Neurocrine Biosciences, Inc. 04-2020, at DailyMed http://dailymed.nlm.nih.gov. Accessed October 20, 2020.

Liang TW, Tarsy D. Medical management of motor fluctuations and dyskinesia in Parkinson disease. In: UpToDate, Hurtig HI, Eichler AF (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on October 1, 2020.