VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Ongentys Prior Authorization Policy
- Ongentys® (opicapone capsules – Neurocrine Biosciences)

REVIEW DATE: 07/15/2020; selected revision 08/19/2020

OVERVIEW
Ongentys, a peripheral, selective and reversible catechol-o-methyltransferase inhibitor, is indicated for adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.[1]

Guidelines
The American Academy of Neurology published guidelines in 2006 on the treatment of Parkinson's disease with motor fluctuations and dyskinesia.[2] The guidelines are dated and do not include more recently approved medications, including Ongentys. It is recommended to offer entacapone and rasagiline to reduce "off" time (Level A). Pergolide (withdrawn from the market in 2007 due to risk of valvular fibrosis), pramipexole, ropinirole, and tolcapone (used with caution; requires monitoring for hepatotoxicity) should be considered to reduce "off" time (Level B). Apokyn® (apomorphine hydrochloride injection), cabergoline, and selegiline may be used to reduce "off" time (Level C). According to the guidelines, the available evidence does not establish superiority of one medication over another in reducing "off" time (Level B). Sustained-release levodopa/carbidopa and bromocriptine should not be considered to reduce "off" time (Level C). Amantadine may be used to reduce dyskinesia (Level C).

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Ongentys. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ongentys as well as the monitoring required for adverse events and long-term efficacy, approval requires Ongentys to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Ongentys is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Parkinson's Disease.** Approve for 1 year if the patient meets all of the following criteria (A, B, and C):
   - **A)** Patient is currently receiving carbidopa/levodopa therapy; AND
   - **B)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient has tried an entacapone product and meets ONE of the following criteria (a or b):
       - **a)** Patient had significant intolerance, according to the prescriber; OR
       - **b)** Patient had inadequate efficacy, according to the prescriber; OR
     - **ii.** Patient is currently receiving Ongentys; AND
   - **C)** Ongentys is prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ongentys is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ongentys® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; May 2020.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice parameter: treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the quality standards subcommittee of the American Academy of Neurology. *Neurology*. 2006;66:983-995.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/15/2020
Selected Revision	**Parkinson's Disease.** For patients currently receiving Ongentys therapy, criteria was added to allow for continuation without trial of entacapone. For patients with a trial of entacapone, wording of "unacceptable tolerability" was changed to "significant intolerance" and "could not achieve adequate benefit" was changed to "had inadequate efficacy".	08/19/2020