

Prior Authorization criteria: Parkinson's Disease

Approved by P&T committee: May 2018

## Catachol-O-methyl transferase (COMT) Inhibitors and combination therapy

Formulary Medications	Dosage form	FDA approved dosing
Entacapone (Comtan)	200mg tablets	200mg with each dose of carbidopa/levodopa, up to a max of 8 times daily (1600mg per day)
Carbidopa-levodopa-entacapone	12.5-50-200mg tablet	Maximum daily dose of 8 tablets
Carbidopa-levodopa-entacapone	18.75-75-200mg tablet	Maximum daily dose of 8 tablets
Carbidopa-levodopa-entacapone	25-100-200mg tablet	Maximum daily dose of 8 tablets
Carbidopa-levodopa-entacapone	31.25-125-200mg tablet	Maximum daily dose of 8 tablets
Carbidopa-levodopa-entacapone	37.5-150-200mg tablet	Maximum daily dose of 8 tablets
Carbidopa-levodopa-entacapone	50-200-200mg tablet	Maximum daily dose of 8 tablets

\*Request for non-formulary agents must meet all coverage criteria requirements and include documentation demonstrating inability to use formulary therapies for the treatment of Parkinson's disease

### New Start Criteria

1. Is member being treated for an OHP funded condition? *Review for a relevant comorbid condition. Treatment of Restless Legs Syndrome is not an OHP funded condition.*
  - a. Yes; move to question 2
  - b. No; Deny category 1: Not a covered benefit
2. Is the medication being used for the treatment of Parkinson's disease?
  - a. Yes; move to question 3
  - b. No; Deny category 3: Not a covered benefit
3. Has the member developed dyskinesia or motor fluctuations despite optimal levodopa therapy (with 80% or greater adherence)?
  - a. Yes; move to question 4
  - b. No; Deny category 5: Not medically appropriate
4. Is the requested medication a combination product containing carbidopa-levodopa-entacapone?
  - a. Yes; move to question 7.
  - b. No; move to question 5.
5. Is the requested medication entacapone and will the medication be used in combination with carbidopa-levodopa therapy?
  - a. Yes; move to question 6
  - b. No; Deny category 3: Not a covered benefit.
6. Is the member unable to use the combination carbidopa-levodopa-entacapone tablets, and is requested therapy within FDA dosing limits?
  - a. Yes: approve for 12 months
  - b. No: Deny category 5: Not medically appropriate. *Preferred formulary option carbidopa-levodopa-entacapone.* Category 3 denial if not dosed within FDA limits.
7. Is requested medication prescribed within FDA approved dosing limits? *Pharmacist to confirm dose optimization.*

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- a. Yes; approve for 12 months
- b. No: Deny category 3: Not a covered benefit

## Dopamine Agonists

Formulary Medication	Dosage form	Formulary restriction	FDA approved dosing
Pramipexole	0.125mg, 0.25mg, 0.5mg, 0.75mg, 1mg, 1.5mg tablet	No restriction	0.5-1.5mg three times daily
Ropinirole	0.25mg, 0.5mg, 1mg, 2mg tablets	QL 60 tablets per 30 days	Three times daily dosing: up to 24mg daily
Ropinirole	3mg, 4mg 5mg tablet	PA required	Three times daily dosing: up to 24mg daily
Ropinirole	2mg, 4mg, 6mg, 8mg 12mg ER tablets	PA required	Once daily dosing: up to 24mg daily

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1. Is member being treated for an OHP funded condition? *Review for a relevant comorbid condition. Treatment of Restless Legs Syndrome is not an OHP funded condition.*
  - a. Yes; move to question 2
  - b. No; Deny category 1: Not a covered benefit
2. Is the medication being used for the treatment of Parkinson's disease?
  - a. Yes; move to question 3
  - b. No; Deny category 3: Not a covered benefit
3. Does the member have one of the following:
  - Diagnosis of early stage Parkinson's disease with motor symptoms that do not impact quality of life
  - Dyskinesia or motor fluctuations development despite optimal carbidopa-levodopa therapy (with 80% or greater adherence)?
    - a. Yes; move to question 4
    - b. No; deny category 5: Not medically appropriate
4. Is the request for the immediate release formulation?
  - a. Yes; move to question 6
  - b. No; move to question 5
5. Is the request for extended release ropinirole\* and is the member unable to use pramipexole or ropinirole immediate release formulations?
  - a. Yes; move to question 6
  - b. No; Deny category 5: Not medically appropriate
6. Is the requested medication dosed within FDA approved dosing limits? *Pharmacist to confirm appropriate dose optimization.*
  - a. Yes; Approve for 12 months
  - b. No; Deny category 3: Not a covered benefit

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## Monoamine Oxidase (MAO) Inhibitor

Formulary Medications	Dosage forms	FDA approved dosing
Selegiline	5mg capsule	5mg twice daily. Max 10mg daily
Selegiline	5mg tablet	5mg twice daily. Max 10mg daily

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### New Start Criteria

1. Is member being treated for an OHP funded condition? *Review for a relevant comorbid condition. Treatment of Restless Legs Syndrome is not an OHP funded condition.*
  - a. Yes; move to question 2
  - b. No; Deny category 1: Not a covered benefit
2. Is the medication being used for the treatment of Parkinson's disease?
  - a. Yes; move to question 3
  - b. No; Deny category 3: Not a covered benefit
3. Does the member have one of the following:
  - Diagnosis of early stage Parkinson's disease with motor symptoms that do not impact quality of life
  - Dyskinesia or motor fluctuations development despite optimal carbidopa-levodopa therapy (with 80% or greater adherence)?
  - a. Yes; move to question 4
  - b. No; deny category 5: Not medically appropriate
4. Is the requested medication dosed within FDA approved limits?
  - a. Yes; approve for 12 months
  - b. No; Deny category 3: Not medically appropriate

### Continuation of therapy Criteria (COMT inhibitors, dopamine agonists, MAO-B inhibitors)

1. Has the member experienced any of the following symptom improvements since initiation of therapy:
  - Improvement or stability in motor symptoms
  - Improvement or stability in activities in daily living
  - Reduction in "off" time compared to carbidopa-levodopa therapy
  - a. Yes; move to question 2
  - b. No; Deny category 5: Not medically appropriate
2. Has the member been adherent to prescribed regimen (including carbidopa-levodopa therapy if applicable)
  - a. Yes; approve for 12 months
  - b. No; deny category 5: Not medically appropriate