Gocovri (amantadine extended release)

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Gocovri (amantadine extended release) when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered
Gocovri is considered medically necessary when the following criteria are met:

Dyskinesia in Patients with Parkinson’s Disease (PD). Approve for the duration noted below if patient meets ONE of the following (A or B):

A) Initial Therapy. Approve Gocovri for 3 months if the patient meets the following criteria (i, ii, and iii):
   i. Gocovri is prescribed by or in consultation with a neurologist; AND
   ii. Patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa); AND
   iii. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following criteria (a or b):
      a) Patient derived benefit from IR amantadine but had intolerable adverse events, as determined by the prescriber; OR
      b) Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber.

B) Patients Currently Receiving Gocovri. Approve Gocovri for 1 year if the patient meets the following criteria (i, ii, and iii):
   i. Gocovri is prescribed by or in consultation with a neurologist; AND
   ii. Patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa); AND
   iii. Patient has had a response to therapy (e.g., decrease in dyskinesia), as determined by the prescriber.

Gocovri is indicated for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

When Policy Topic is not covered
Coverage of Gocovri is not recommended for circumstances not listed in the recommended authorization criteria.
Considerations

Gocovri requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Overview

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson’s disease (PD) receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The initial daily dosage of Gocovri is 137 mg once daily (QD) at bedtime. After one week, increase to the recommended dosage of 274 mg (equivalent to 340 mg amantadine hydrochloride) QD at bedtime.

Amantadine hydrochloride is available as an immediate-release (IR) 100 mg capsule, 100 mg tablet, and 50 mg/5 mL oral solution. The amantadine IR products are indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus; idiopathic PD [Paralysis Agitans], postencephalitic parkinsonism, symptomatic parkinsonism which may follow injury to the nervous system by carbon monoxide intoxication, and in those elderly patients believed to develop parkinsonism in association with cerebral arteriosclerosis; and drug-induced extrapyramidal reactions. For the treatment of PD, the usual dose of amantadine IR is 100 mg twice daily (BID) when used alone. An initial dose of amantadine IR is 100 mg daily for patients with serious associated medical illnesses or who are receiving high doses of other antiparkinson drugs; the dose may be increased to 100 mg BID, if necessary. Patients initially deriving benefit from amantadine may experience a fall-off of effectiveness after a few months; benefit may be regained by increasing the dose to 300 mg/day in divided doses. Occasionally, patients whose responses are not optimal with amantadine IR 200 mg daily may benefit from an increase up to 400 mg/day in divided doses. For the treatment of drug-induced extrapyramidal reactions, the usual dose of amantadine IR is 100 mg BID. Occasionally, patients whose responses are not optimal with amantadine IR 200 mg/day may benefit from an increase up to 300 mg/day in divided doses.

Disease Overview

PD is a common neurodegenerative disease and is a chronic, progressive disorder of the extrapyramidal nervous system affecting the mobility and control of the skeletal muscular system. An estimated 50,000 Americans are diagnosed each year with PD and it is estimated that 1 million people in the US have the condition. PD typically affects patients who are greater than 60 years of age. Its characteristic features include resting tremor, rigidity, bradykinetic movements, and postural instability. As these symptoms become more pronounced, patients with PD may have difficulty walking, talking, or completing other simple tasks. Early symptoms of PD are subtle and occur gradually. The disease course varies considerably as well as the intensity of symptoms. While some patients become severely disabled, others experience only minor motor disruptions. Resting tremor is the major symptom for some individuals, while for others tremor is only a minor complaint and other manifestations may be more troublesome. It is not possible to predict which symptoms will affect an individual. PD symptoms are thought to be related to depletion of dopamine in the corpus striatum. Use of dopamine is ineffective in the treatment of PD because it does not penetrate the blood-brain barrier. However, levodopa, the metabolic precursor of dopamine, does cross the blood-brain barrier and is believed to be converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves PD symptoms. Other medications are also utilized to improve mobility.

Although initially effective, dopaminergic therapies are eventually complicated by motor fluctuations, including “off” time (periods during which PD symptoms return when the medication effect wears off) and dyskinesia (drug-induced involuntary movements, e.g., chorea and dystonia) in most patients. These motor complications can impair patient quality of life and cause substantial disability. Risk factors for motor complications include younger age at the onset of PD, increased disease severity,
higher levodopa dosage, and longer disease duration. These problems are often addressed with levodopa adjustments and the addition of adjunctive medications.

Clinical Efficacy
Gocovri was assessed in two randomized, double-blind, placebo-controlled efficacy trials, EASE LID (n = 121) and EASE LID 3 (n = 75), in patients with PD and dyskinesia. In both studies, the primary efficacy endpoint was the change in total score of the Unified Dyskinesia Rating Scale (UDysRS) between baseline and Week 12. Patients in EASE LID and EASE LID 3 were treated with a stable dose of levodopa, with 32% of patients on levodopa monotherapy; 54% of patients and 44% of patients were treated with concomitant dopamine agonists and/or MAO-B inhibitors, respectively. In EASE LID and EASE LID 3, a significant decrease in mean UDysRS total score (reduction in dyskinesia) was observed at Week 12 in patients treated with Gocovri compared with placebo (EASE LID treatment difference: -7.9; P = 0.0009 and EASE LID 3 treatment difference: -14.4; P < 0.0001). Gocovri has not been compared with amantadine IR or other active treatments in clinical trials.

Rationale

Guidelines
The 2006 American Academy of Neurology (AAN) guideline on the treatment of PD with motor fluctuations and dyskinesia recommends considering the use of amantadine in patients with PD and motor fluctuations to reduce dyskinesia (Level C). The authors concluded that amantadine IR (given as 100 mg BID) is possibly effective in reducing dyskinesia based on one Class II study. The guidelines have not been updated to include Gocovri.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Gocovri. Because of the specialized skills required for evaluation and diagnosis of patients treated with Gocovri as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Gocovri to be prescribed by or in consultation with a physician who specializes in patients with PD. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

References
Other References Utilized


**Billing Coding/Physician Documentation Information**

| NA   | Gocovri is a pharmacy benefit |

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

| 01/2018 | New policy titled Gocovri (amantadine extended release) |

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