Parkinson’s Agents (Requip XL™ and Mirapex ER®)

**BENEFIT APPLICATION**

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

**DESCRIPTION**

The intent of the Parkinson’s agents drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies, and direct use to more a cost-effective generic immediate release agent first.

Requip XL™ (extended-release ropinirole) and Mirapex ER® (extended-release pramipexole) are approved by the Food and Drug Administration (FDA) for the treatment of signs and symptoms of idiopathic Parkinson’s disease.

**POLICY**

**CRITERIA FOR INITIAL APPROVAL**

I. Extended-release ropinirole and extended-release pramipexole may be considered **medically necessary** for the management of Parkinson’s disease in patients 18 years of age or older who have tried and failed immediate-release formulations of ropinirole and pramipexole.

Note: Patient must try and fail immediate release product of extended-release product requested.

Approval will be granted for **lifetime**.

II. Extended-release ropinirole and extended-release pramipexole are considered **not medically necessary** for patients who do not meet the criteria set forth above.

**CLINICAL RATIONALE**

Parkinson’s disease (PD) is a neurodegenerative disorder characterized by resting tremor, rigidity, bradykinesia, akinesia, and postural instability. Non-motor symptoms also can manifest and include psychiatric and sensory symptoms as well as sleep disorders. PD primarily targets neurons in the substantia nigra, some of which produce dopamine which is responsible for the control of movement. As PD progresses, the amount of dopamine produced in the brain decreases, resulting in the inability of a person to effectively control his or her movement.
Ropinirole and pramipexole are dopamine agonists that increase the brain’s dopamine levels through direct stimulation of dopamine receptors. Both agents are generically available in immediate-release preparations that are dosed up to three times a day. However, some patients experience a “wearing-off” phenomenon with the immediate-release formulations, which leads to fluctuations in symptom response. More frequent dosing of immediate-releasing formulation as well as long-acting formulations of both ropinirole and pramipexole are options to help prevent this “wearing-off” phenomenon.

Studies that have compared the extended-release formulations against immediate-release formulations have found them to be non-inferior, with similar safety and efficacy for both early and advanced Parkinson’s Disease. Based upon these outcomes, it is recommended that patients try and fail the less expensive immediate-release formulations before use of the longer-acting agents.

The immediate- and extended-release preparations of ropinirole and pramipexole have been shown to be effective in both early and advanced stages of PD. The immediate-release preparations are also indicated in the treatment of restless leg syndrome (RLS). Treatment of RLS with dopaminergic agents is sometimes characterized by augmentation, in which there is an increase in the severity of RLS symptoms. The extended-release preparations are not FDA approved for restless leg syndrome (RLS) and have not been well studied. Current recommendations for treatment when augmentation occurs include lowering the dose of the dopamine agonist and dosing twice daily rather than daily or switching to a non-dopaminergic agent.

**PROCEDURES AND BILLING CODES**

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- No applicable codes.

**REFERENCES**

POLICY HISTORY

Policy #: 05.01.47
Original Effective Date: August 2008
Reviewed: July 2018
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