Commercial/Healthcare Exchange PA Criteria

Effective: November 11, 2020

Prior Authorization: Xywav (calcium, magnesium, potassium, and sodium oxybates)

Products Affected: Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution

Medication Description:

Xywav is a central nervous system depressant containing a mixture of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate (gamma-hydroxybutyrate which is an endogenous compound and metabolite of the neurotransmitter GABA). The exact mechanism of Xywav in the treatment of narcolepsy is unknown. It is hypothesized that the therapeutic effects of Xywav on cataplexy and excessive daytime sleepiness are mediated through $GABA_B$ actions during sleep at noradrenergic and dopaminergic neurons as well as at thalamocortical neurons.

Covered Uses:

A) Treatment of cataplexy in patients with narcolepsy
B) Treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy

Exclusion Criteria:

1. In combination with sedative hypnotics
2. In combination with alcohol
3. In patients with succinic semialdehyde dehydrogenase deficiency

Required Medical Information:

1. Diagnosis

Age Restrictions: 7 years of age and older

Prescriber Restrictions: Prescriber must be a neurologist or sleep specialist certified in the Xywav Risk Evaluation and Mitigation Strategy (REMS) program as required by the FDA

Coverage Duration:

Initial: 2 months
Renewal coverage: Re-evaluated every 3 months

Other Criteria:

Inital

Cataplexy Treatment in Patients with Narcolepsy.

Approve if the patient meets the following criteria (A and B):

A. Diagnosis of narcolepsy with cataplexy has been confirmed by a sleep study; **AND**
B. Patient has tried one of the following treatments: a tricyclic antidepressant (TCA) (e.g. amitriptyline, desipramine, and imipramine), a selective serotonin reuptake inhibitor (SSRI)(e.g. fluoxetine, sertraline, and paroxetine), or venlafaxine.

Excessive Daytime Sleepiness in Patients with Narcolepsy
Approve if the patient meets the following criteria (A and B):

A. Diagnosis of narcolepsy with excessive daytime sleepiness has been confirmed by a sleep study; **AND**
B. Patient has tried one of the following treatments: a central nervous system (CNS) stimulant (e.g. methylphenidate, dexmethylphenidate, and dextroamphetamine), modafinil, or armodafinil.

Continuation
Approve renewal of Xywav if the patient meets the following criteria (A, B, C, and D):

A) The provider confirms the patient reports a decrease in cataplexy attacks OR increased wakefulness test score since initiating Xywav therapy; **AND**
B) The patient has not reported any serious or concerning adverse events while taking Xywav (e.g. respiratory depression, suicidality, etc.); **AND**
C) The provider has confirmed the patient does not misuse or abuse Xywav; **AND**
D) The provider has confirmed the patient continues to abstain from alcohol while on Xywav therapy.

References:

1. Xywav™ oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; July 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/21/20