Clinical Guideline

Oscar Clinical Guideline: pregabalin immediate-release (PG060, Ver. 6)

pregabalin immediate-release

- Capsules: 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg
- Oral Solution: 20 mg/mL

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Pregabalin (Lyrica) is a medication that is used for several conditions such as neuropathic pain, fibromyalgia, seizures, and anxiety. For neuropathic pain, it works by reducing the calcium currents in the nervous system. Pregabalin is structurally similar to gabapentin (Neurontin) which is also used for similar conditions.

Definitions

"Neuropathic pain" is nerve pain that can result from several conditions affecting the nervous system and can present as burning, tingling, numbness, or itching.

"Fibromyalgia" is a condition presenting as widespread, chronic pain in which other symptoms can include fatigue and sleep issues.

"Pruritus" refers to an uncomfortable, itchy sensation on the skin, which can be associated with various conditions, including chronic kidney disease (uremic pruritus), malignancies, and neuropathies.

"**Refractory chronic cough**" is a persistent, hard-to-treat cough that remains unresponsive to standard treatment and significantly impacts quality of life.

"Vasomotor symptoms" typically refer to symptoms like hot flashes, night sweats, or other physiological responses to changing hormone levels, often seen during menopause.

Medical Necessity Criteria for Authorization

The Plan considers **pregabalin** medically necessary when ALL the following criteria are met for the applicable indication listed below:

For the management of fibromyalgia

1. The member is 18 years of age or older; ***AND***
2. The member has a diagnosis of fibromyalgia; ***AND***
3. The member is unable to use, or has adequately tried and failed **ALL** of the following:
    a. non-pharmacologic therapy (e.g., aerobic or strength exercises, mindfulness); ***and***
    b. gabapentin at the maximum tolerated dose for at least a 30 day duration; ***and***
    c. at least **ONE** of the following (at the maximum tolerated dose after a minimum 30 day trial) :
        i. Serotonin and norepinephrine reuptake inhibitors (e.g., duloxetine); ***or***
        ii. Tricyclic antidepressants (e.g., amitriptyline); ***or***
        iii. cyclobenzaprine.

For the management of neuropathic pain

1. The member is 18 years of age or older; ***AND***
2. The member has **ONE** of the following diagnoses:
    a. postherpetic neuralgia (PHN); ***or***
    b. pain associated with diabetic peripheral neuropathy (DPN); ***or***
    c. pain associated with spinal cord injury; ***or***
    d. other types of neuropathic pain (e.g., central post-stroke pain, HIV-related peripheral neuropathy, cancer-related neuropathy, chronic neuropathic pain); ***AND***
3. The member is unable to use, or has adequately tried and failed gabapentin (at the maximum tolerated dose after a minimum 30 day trial).

For seizure disorders

1. The requested medication is prescribed by, or in consultation with, a neurologist; ***AND***
2. The member has a diagnosis of focal onset (partial-onset) seizures; ***AND***
3. The requested medication will be used as adjunctive therapy (i.e., in combination with other anticonvulsant agents); ***AND***
4. The member is unable to use, or has adequately tried and failed gabapentin (at the maximum tolerated dose after a minimum 30 day trial).

For other off-label uses

1. The member is 18 years of age or older; ***AND***
2. The medication is being requested for treatment of **ONE** of the following:
    a. chronic kidney disease–associated pruritus (including chronic uremic pruritus) **OR** chronic neuropathic or malignancy-related pruritus (including brachioradial pruritus), **AND** the member is unable to use, or has tried and failed gabapentin; ***or***
    b. generalized anxiety disorder, **AND** the member is unable to use, or has tried and failed selective serotonin reuptake inhibitors (SSRIs) (e.g., escitalopram, paroxetine, sertraline) and serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., duloxetine, venlafaxine); ***or***
    c. moderate to severe primary restless legs syndrome (RLS) with predominant evening symptoms, **AND** the member is unable to use, or has tried and failed dopamine agonist (e.g., bromocriptine, pramipexole, or ropinirole); ***or***
    d. refractory chronic cough in combination with speech pathology therapy, **AND** the member is unable to use, or has tried and failed gabapentin***; or***
    e. social anxiety disorder, **AND** the member is unable to use, or has tried and failed selective serotonin reuptake inhibitors (SSRIs) (e.g., escitalopram, paroxetine, sertraline) and serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., duloxetine, venlafaxine); ***or***
    f. vasomotor symptoms (e.g., hot flashes) associated with menopause, **AND** the member is unable to use, or has tried and failed hormonal therapy (e.g., oral estrogen, transdermal estrogen patch).

If the above prior authorization criteria are met for the applicable indication, pregabalin will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Pregabalin immediate-release for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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