Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Gabapentin ER (Gralise)

Notes:
& Intolerance occurring after adjusting dose and interval AND intolerance expected to improve with ER formulation.
^ Adequate trial is defined as 2 months treatment duration
* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary gabapentin ER (Gralise) will be covered on the prescription drug benefit for 4 months when the following criteria are met:

Diagnosis of Postherpetic Neuralgia (PHN) on Problem List
- Documented clinically significant intolerance to immediate-release gabapentin and pregabalin & AND
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to a formulary tricyclic antidepressant, and an alternative anti-epileptic, and a serotonin-norepinephrine reuptake inhibitor ( duloxetine or venlafaxine) AND
- Patient has not had a gastric-reduction procedure

-OR-

Diagnosis of Restless Legs Syndrome (RLS) on Problem List
- Prescribed by Sleep Specialist AND
- Patient has failed an adequate trial^ of or patient has an allergy or intolerance* to ropinirole, and pramipexole AND
- Documented clinically significant intolerance to immediate-release gabapentin and pregabalin & AND
- Patient has not had a gastric-reduction procedure

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary gabapentin ER (Gralise) will be covered on the prescription drug benefit when the following criteria are met:

- Not applicable
Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary gabapentin ER (Gralise) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

**Diagnosis of Postherpetic Neuralgia (PHN) on Problem List**
- Intolerance to immediate-release gabapentin and pregabalin AND
- Patient has failed an adequate trial of or patient has an allergy or intolerance* to a formulary tricyclic antidepressant, and an alternative anti-epileptic, and a serotonin-norepinephrine reuptake inhibitor ( duloxetine or venlafaxine) AND
- Patient has not had a gastric-reduction procedure

-OR-

**Diagnosis of Restless Legs Syndrome (RLS) on Problem List**
- Patient has failed an adequate trial of or patient has an allergy or intolerance* to ropinirole, and pramipexole AND
- Intolerance to immediate-release gabapentin and pregabalin AND
- Patient has not had a gastric-reduction procedure

**Continued use criteria (3 months after initiation):** Non-formulary gabapentin ER (Gralise) will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:
- Patient has experienced improvement in postherpetic neuralgia symptoms or restless leg symptoms, as documented by prescriber

**Continued use criteria for patients stable on the medication:** Non-formulary gabapentin ER (Gralise) will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:
- Office or telephone visit with prescriber in the past 12 months
- Patient continues to report sustained improvement in postherpetic neuralgia symptoms or restless leg symptoms, as documented by prescriber