# Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

## Gabapentin ER (Gralise)

#### Notes:

- QL: Yes
- Wear-off of effect occurring after adjusting dose, frequency and/or timing.
- <sup>2</sup> Adequate trial is defined as 2 months treatment duration
- <sup>3</sup> Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- <sup>4</sup> Formulary tricyclic antidepressants: nortriptyline, desipramine, amitriptyline
- <sup>5</sup> Formulary serotonin-norepinephrine reuptake inhibitors: duloxetine, venlafaxine, desvenlafaxine succinate
- <sup>6</sup> Formulary anti-epileptic: carbamazepine, oxcarbazepine

<u>Initiation (new start) criteria</u>: Non-formulary **gabapentin ER (Gralise)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Diagnosis of Postherpetic Neuralgia (PHN)
- Trial of immediate-release gabapentin with at least partial response but effect wears off<sup>1</sup> and unable to take another dose
- Trial of immediate-release pregabalin
- Trial of extended-release pregabalin, if at least partial response to immediaterelease but effect wears off <sup>1</sup> and unable to take another dose
- Adequate trial<sup>2</sup> of or contraindication, allergy or intolerance<sup>3</sup> to 2 medications from any of the following drug classes:
  - o a formulary tricyclic antidepressant<sup>4</sup>
  - o a formulary serotonin-norepinephrine reuptake inhibitor<sup>5</sup>
  - o a formulary anti-epileptic<sup>6</sup>

### -OR-

- Diagnosis of Restless Leg Syndrome (RLS)
- Serum ferritin is greater than 100 ng/mL and %sat is greater than 45% within the past 3 months
- Trial of immediate-release gabapentin with at least partial response but effect wears off<sup>1</sup> during sleep
- Trial of immediate-release pregabalin
- Trial of extended-release pregabalin, if at least partial response to immediaterelease but effect wears off<sup>1</sup> during sleep

kp.org



# Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

# Gabapentin ER (Gralise)

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously and 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)**

- Trial of immediate-release gabapentin with at least partial response but effect wears off<sup>1</sup> and unable to take another dose
- Trial of immediate-release pregabalin
- Trial of extended-release pregabalin, if at least partial response to immediaterelease but effect wears off <sup>1</sup> and unable to take another dose

#### -OR-

### Diagnosis of Restless Legs Syndrome (RLS) on Problem List

- Trial of immediate-release gabapentin with at least partial response but effect wears off<sup>1</sup> during sleep
- Trial of immediate-release pregabalin
- Trial of extended-release pregabalin, if at least partial response but effect wears off<sup>1</sup> during sleep

<u>Continued use criteria for patients stable on the medication</u>: Non-formulary gabapentin ER (Gralise) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

 Patient continues to report sustained improvement in postherpetic neuralgia or restless leg symptoms, as documented by prescriber

