Criteria for Nonformulary Use of Pregabalin

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations. A summary of the literature review used to support the criteria for nonformulary use of pregabalin is available at http://www.pbm.va.gov or vaww.pbm.va.gov.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive pregabalin.*

☐ Hypersensitivity to pregabalin or product components.

☐ Use of pregabalin for chronic low back pain, chronic pain due to osteoarthritis of the hip, or panic disorder.

☐ Use of pregabalin in combination with gabapentin.

Inclusion Criteria *The answers to one of the following (A–C) must be fulfilled in order to meet criteria.*

A. Patient has painful diabetic neuropathy AND has well documented insufficient response despite an adequate trial at maximally tolerated doses of gabapentin (up to 3600 mg/d) AND at least one oral agent that is *not classified as a controlled substance*, used alone or in combination, from 1 of the 4 drug classes shown below (**minimum total of 2 oral agents including gabapentin**) OR patient has documented intolerance, hypersensitivity, or contraindication to gabapentin and the following agents and is therefore precluded from undertaking an adequate trial of at least one oral agent from 1 of the 4 drug classes.

Painful Diabetic Neuropathy (treatment duration: 6–12 wk)

Gabapentin (up to 3600 mg/d) AND at least one oral agent from 1 of the 4 drug classes below:

☐ 1) Antidepressants, tricyclic: e.g., amitriptyline (nortriptyline) 25–150 mg/d; desipramine 12.5–200 mg/d; imipramine 25–225 mg/d
Tricyclic antidepressants are reasonable options in patients less than 65 years old.

☐ 2) Antidepressants, SNRI: e.g., venlafaxine 150–225 mg/d; duloxetine 60 mg/d

☐ 3) Antiepileptic drugs (AEDs): e.g., carbamazepine 200–600 mg/d, phenytoin 300 mg/d, valproate 500–1200 mg/d
These AEDs only apply to patients who may already have had trials of these agents. New trials of these agents are not required.

☐ 4) Opioid: e.g., tramadol 50–400 mg/d
The criteria suggest tramadol, a nonscheduled opioid, as a prior treatment alternative to pregabalin. The criteria do not recommend a prior trial of schedule II to IV opioids before considering pregabalin. However, patients already prescribed schedule II to IV opioids may be considered for pregabalin therapy as long as the minimum of 2 prior agents is met.

B. Patient has postherpetic neuralgia, requires systemic therapy, AND has a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite an adequate trial at maximally tolerated doses of **gabapentin**. Patients with localized postherpetic neuralgia should also have had a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite a prior adequate trial of either one of the topical agents indicated below.

Postherpetic Neuralgia, Oral Agents (treatment duration: 6–8 wk)

☐ 1) Antiepileptic drugs: gabapentin 1200–3600 mg/d

Note: Tricyclic antidepressants are reasonable options in patients less than 65 years old: e.g., amitriptyline (nortriptyline) 25-150 mg/d; desipramine 12.5–200 mg/d; imipramine 25–225 mg/d

Localized Postherpetic Neuralgia, Topical Agents

☐ 1) Capsaicin cream 0.075%: apply 3 to 4 times daily for at least 6 wk

☐ 2) Lidocaine patch 5%: apply up to 3 patches, only once for up to 12 h, within a 24-h period.

C. Patient has partial-onset seizure disorder, is concurrently treated with at least one other antiepileptic drug, and has a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite an adequate trial at maximally tolerated doses of at least 2 of the agents listed below.

Partial-onset Seizures, Adjunctive Therapy (treatment duration: 12 wk)

☐ Carbamazepine, gabapentin, lamotrigine, levetiracetam, phenytoin, topiramate, valproate

Discontinuation Criteria

☐ NO benefit after at least 12 wk of treatment with pregabalin at maximally tolerated doses.

Refills

No refills allowed with initial prescription; requests for pregabalin should be re-evaluated after 12 weeks of therapy

Evaluate on a case-by-case basis

Use of pregabalin for conditions other than those covered in the criteria above.

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