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PHARMACY POLICY – 5.01.521

Pharmacologic Treatment of Neuropathy, Fibromyalgia, and Seizure Disorders

		RELATED POLICIES / GUIDELINES:	
Effective Date:	April 1, 2024*	5.01.520	Antidepressants: Pharmacy Medical Necessity Criteria for Brands
Last Revised:	Mar. 12, 2024	5.01.529	Management of Opioid Therapy
Replaces:	N/A	5.01.550	Pharmacotherapy of Arthropathies
		5.01.605	Medical Necessity Criteria for Pharmacy Edits
*This policy has been updated. View upcoming changes here.			

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Neuropathy is a term that refers to problems with one or more nerves. Neuropathy doesn't always cause symptoms, but usually it does. Depending on the location of the nerve and the type of damage, symptoms can include loss of feeling, numbness, tingling, or pain. Neuropathic nerve pain has been described as feeling like an electric shock, burning, or knifing. Extreme sensitivity to touch may be another symptom. Fibromyalgia is a long-term medical condition that often causes pain in muscles and bones, areas that are tender to the touch, and fatigue. It's believed that fibromyalgia is the result of changes in how the brain and spinal cord process pain signals from the nerves. Seizure disorders are the result of unusual electrical activity in the brain. Uncontrolled electrical signals in the brain produce several symptoms, including seizures. This policy describes specific medications that may be approved for neuropathy, fibromyalgia, and seizure disorders.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Documentation in the form of chart notes/medical records must be provided with prior authorization review for the agents described below.

Drug	Medical Necessity

Savella (milnacipran)	**Savella (milnacipran) may be considered medically necessary for the treatment of fibromyalgia when all the following are met:**
	• The individual is 18 years of age or older
	• The individual has tried and had an inadequate response or intolerance to gabapentin
	• The individual has tried and had an inadequate response or intolerance to TWO of the following:
	  ○ A tricyclic antidepressant (e.g., amitriptyline)
	  ○ A generic SNRI (e.g., duloxetine, venlafaxine)
	  ○ Cyclobenzaprine
	  ○ Tramadol

Lyrica (pregabalin)	**Lyrica (pregabalin) may be considered medically necessary for the treatment of neuropathic pain when all the following are met:**
	• The individual is 18 years of age or older
	• The individual has tried and had an inadequate response or intolerance to gabapentin
	• The individual has tried and had an inadequate response or intolerance to ONE of the following:
	  ○ A tricyclic antidepressant (e.g., amitriptyline)
	  ○ A generic SNRI (e.g., duloxetine, venlafaxine)
	• The individual has tried and had an inadequate response or intolerance to generic pregabalin or generic pregabalin extended-release
	
	Lyrica (pregabalin) may be considered medically necessary for the treatment of a seizure disorder when all the following are met:

Drug	Medical Necessity

	• The individual is 1 month of age or older
	• The individual has tried and had an inadequate response or intolerance to generic pregabalin or generic pregabalin extended-release
	
	Lyrica (pregabalin) may be considered medically necessary for the treatment of fibromyalgia when all the following are met:
	• The individual is 18 years of age or older
	• The individual has tried and had an inadequate response or intolerance to gabapentin
	• The individual has tried and had an inadequate response or intolerance to TWO of the following:
	  ○ A tricyclic antidepressant (e.g., amitriptyline)
	  ○ A generic SNRI (e.g., duloxetine, venlafaxine)
	  ○ Cyclobenzaprine
	  ○ Tramadol
	• The individual has tried and had an inadequate response or intolerance to generic pregabalin or generic pregabalin extended-release
	
	Lyrica (pregabalin) may be considered medically necessary for the treatment of generalized anxiety disorder when all the following are met:
	• The individual is 18 years of age or older
	• The individual has tried and had an inadequate response or intolerance to an SSRI (e.g., citalopram, fluoxetine)
	• The individual has tried and had an inadequate response or intolerance to ONE of the following:
	  ○ Benzodiazepines (e.g., alprazolam, clonazepam)
	  ○ Buspirone
	  ○ Venlafaxine
	  ○ Hydroxyzine
	  ○ Duloxetine
	• The individual has tried and had an inadequate response or intolerance to generic pregabalin or generic pregabalin extended-release

Drug	Medical Necessity

Lyrica CR (pregabalin extended-release)	**Lyrica CR (pregabalin extended-release) may be considered medically necessary for the treatment of diabetic peripheral neuropathy or postherpetic neuralgia when all the following are met:**
	• The individual is 18 years of age or older
	• The individual has tried and had an inadequate response or intolerance to gabapentin
	• The individual has tried and had an inadequate response or intolerance to ONE of the following:
	  ○ A tricyclic antidepressant (e.g., amitriptyline)
	  ○ A generic SNRI (e.g., duloxetine, venlafaxine, desvenlafaxine)
	• The individual has tried and had an inadequate response or intolerance to generic pregabalin or generic pregabalin extended-release

Drug	Not Medically Necessary
Lyrica (pregabalin), Lyrica CR (pregabalin extended-release), and Savella (milnacipran)	**All other uses of Lyrica (pregabalin), Lyrica CR (pregabalin extended-release), and Savella (milnacipran) for conditions not outlined in this policy are considered not medically necessary.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**All drugs listed in policy may be approved up to 12 months.**
Re-authorization criteria	**Future re-authorization of all drugs listed in policy may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

N/A

Related Information

Benefit Application

All drugs in this policy are managed through the pharmacy benefit.

Consideration of Age

The ages stated in this policy for which Lyrica (pregabalin), Lyrica CR (pregabalin extended-release), and Savella (milnacipran) are considered medically necessary are based on the ages approved in the FDA prescribing information.

Evidence Review

Description

Pathophysiology and Disease Burden of Neuropathy

Neuropathy is a general term for pain or other sensory disturbance resulting from a lesion or dysfunction in the nervous system. Neuropathic pain may be associated with abnormal

sensations (dysesthesia) which occur without external stimuli and allodynia, abnormal sensations occurring in response to stimuli. Neuropathic pain may be continuous or episodic. Individuals often describe neuropathic pain in terms of familiar sensations such as electric shock, burning or knifing pain. Sensations of coldness, "pins and needles", numbness and itching may also be present, and allodynia may result from normal stimuli, such as bedclothes touching or rubbing the individual's skin.

A general population-based survey in the U.K. published in 2006 estimated neuropathic pain prevalence to be 8%. Neuropathic pain may result from disorders of the peripheral nervous system or the central nervous system and is common in such conditions as stroke, spinal cord injury, multiple sclerosis, diabetes, HIV and cancer, where it may be cause by the tumor compressing nerves, by pathologic fractures in individuals with bone metastases or by many of the cytotoxic chemotherapeutic agents employed in cancer treatment. Neuropathic pain may be peripheral or central in origin, and it may be nociceptive (direct result of physical trauma) or nonnociceptive. Diabetic and post-herpetic neuropathy were covered in previous reviews.

Pharmacology of Duloxetine

Duloxetine is a potent inhibitor of neuronal serotonin and norepinephrine reuptake and a less potent inhibitor of dopamine reuptake. Duloxetine has no significant affinity for dopaminergic, adrenergic, cholinergic, histaminergic, opioid, glutamate, and GABA receptors in vitro. Although the exact mechanisms of the antidepressant and central pain inhibitor action of duloxetine are unknown, they are believed to be related to the drug's potentiation of serotonergic and noradrenergic activity in the CNS.

Evidence suggests that pain reduction in response to duloxetine is independent of its antidepressant effect and can be demonstrated even in non-depressed individuals. Analysis suggests that 50-90% of the observed effect is independent of antidepressant activity.

Rationale

Therapeutic Alternatives

Prior to the approval of duloxetine and pregabalin, individuals with neuropathies were treated with a number of unapproved different medications. While some other agents have shown efficacy in controlled clinical trials the treatment of this condition has frequently been seen as unsatisfactory. One guideline exists for the treatment of neuropathic pain, but it was created

prior to the introduction of duloxetine and pregabalin. The neuropathic pain guideline was drafted by members of the faculty of the Fourth International Conference on the Mechanisms and Treatment of Neuropathic Pain. Five first-line medications (gabapentin, the 5% lidocaine patch opioid analgesics, tramadol hydrochloride, and TCAs) are recommended on the basis that their efficacy have been consistently demonstrated in randomized controlled trials.

Tricyclic Antidepressants

These drugs, most specifically amitriptyline and imipramine, are serotonin and norepinephrine reuptake inhibitors (SNRI). They were the first class of drugs proven to be effective in neuropathic pain. The doses used in neuropathic pain are lower than those used for depression. They are usually initiated at 10 to 25 mg at night then titrated up every 3 to 7 days as tolerated. This class of drugs significant adverse effects has limited their usefulness in many individuals. Amitriptyline is the most studied agent in this class, but efficacy seems to correlate with the SNRI profile, found mostly in the tertiary amine compounds.

Gabapentin

Gabapentin, an amino acid structurally related to GABA, has been shown in clinical trials to significantly reduce neuropathic pain compared to placebo. Doses up to 3600mg/day were used with long titration phases of up to 3-8 weeks. Some of the studies also demonstrated improvements in sleep, mood, and quality of life scores. The mechanism of gabapentin in analgesia is not fully understood.

5% Lidocaine Patch

Lidocaine patch is a topical anesthetic that works by preventing the generation and conduction of nerve impulses. It is FDA approved for the treatment of post herpetic neuralgia and efficacy for this indication was demonstrated in two published placebo-controlled trials. Individuals in these studies obtained significantly greater pain relief from the lidocaine patch compared to a vehicle only placebo patch. The patches are dosed as no more than three patches on at a time for no more than 12 hours out of the day. The patch is also limited to individuals whose lesions can be covered by three patches.

Opioid Analgesics

Long-acting oxycodone, an opioid agonist, has been studied in both PHN and DPN. In PHN, individuals on oxycodone CR up to 60mg/day had a significant reduction in pain, disability, and allodynia compared to individuals in the placebo group. DPN individuals on oxycodone CR up to 120mg/day obtained significantly reduced pain, improvement of daily activities and sleep. However, the value of this class of drugs in neuropathic pain individuals is limited by the risk of opioid dependence.

Tramadol

Tramadol, a serotonin and norepinephrine reuptake inhibitor with a μ opioid agonist metabolite, has been shown in two trials to be effective in the treatment of DPN. In these two trials, doses up to a maximum of 400mg/day significantly reduced pain compared to placebo.

Combination therapy is generally more effective than a single agent. Anecdotally, combining an NSAID, an opioid and a pain blocking agent (antidepressant, AED, lidocaine, etc.) seems to be the most effective strategy. When patients do not have a satisfactory response to treatment with the five first-line medications alone or in combination, several medications may be considered for second-line use. Recommendations for second-line medications are based on positive results from a single randomized controlled trial or inconsistent results from multiple randomized controlled trials. Other medications sometimes used for the treatment of neuropathic pain patients include capsaicin, clonidine, dextromethorphan, and mexiletine. Non-drug therapies (i.e., massage, physical therapy, acupuncture, etc.) are also frequently employed for neuropathic pain, as well as several other alternative medicine approaches.

The extent to which non-allopathic treatments for neuropathy are resorted is indicative of the failure of allopathic approaches to adequately manage this all-too-common problem. Neuropathy patients are often frustrating and can easily become dependent on opioid medications. A combination of two or three drugs is often the best pharmacologic way to manage these patients. Unfortunately, the appropriate combination must be empirically determined, often after repeated trial of alternatives. Referral of these patients to a multidisciplinary pain clinic may be necessary.

Cymbalta (duloxetine)

Two short-term (12 week) Phase III, pivotal, placebo-controlled trials, and one 52-week, open-label, parallel group extension safety study provided the evidence for FDA approval for diabetic

peripheral neuropathy. These unpublished studies consistently indicate that short-term, acute use of duloxetine, at doses of 60-120 mg QD, significantly decreases 24-hour average pain score, and increases the proportion of "responders" (defined as a ≥30% reduction in baseline pain severity) compared with placebo. While a dose of 120 mg/day was shown to be safe and effective, there is no evidence that doses >60 mg/day confer additional significant benefit, and the higher dose is less well tolerated.

For fibromyalgia, there are currently no head-to-head trials being conducted to compare duloxetine against any of the other agents recommended for treatment of FM. The three published trials comparing duloxetine versus placebo in treating FM resulted in conclusive evidence of duloxetine's efficacy in treating FM, albeit the treatment phase for all three trials were relatively short (12 weeks, 12 weeks, and 6 months). Duloxetine, dosed at 60mg to 120mg/d, was shown to be efficacious at significantly reducing painful symptoms of FM, as well as the amount of tender points and interference with various aspects of daily life. Data from two of the 3 trials suggested better efficacy and improved outcomes are seen in women versus men.

Savella (milnacipran)

Milnacipran is an SNRI approved for fibromyalgia. Efficacy studies show milnacipran is more effective than placebo at 3 months for fibromyalgia; however, data at 6 months appears less consistent. No comparative trials with other agents for fibromyalgia are available. Elevated blood pressure, heart rate and LFTs appear to be of concern with milnacipran and use of this agent is not recommended in patients with liver dysfunction, substantial alcohol use, or uncontrolled blood pressure or heart rate.

Lyrica (pregabalin)

Pregabalin has demonstrated modest efficacy in placebo-controlled trials in neuropathic pain individuals. No head-to-head comparison studies with other drugs have been reported. The level of evidence of effectiveness in treating neuropathic pain is greatest for tricyclic antidepressants with mixed serotonin and norepinephrine reuptake inhibition (SNRIs) such as amitriptyline. Pregabalin may be of benefit to a subset of complex partial seizure individuals who are refractory to standard first line therapies and is approved to treat fibromyalgia.

Pregabalin is more effective than placebo for symptomatic relief of associated pain and management of symptoms associated with fibromyalgia. Individuals were considered responders if they had at least a 30% decrease in pain on the Pain Visual Analog Scale (VAS).

The greatest relief of pain and symptoms was seen at a dose of 450mg/day. There was no evidence of greater effect of pain scores for the 600mg daily dose than the 450mg daily dose.

Three studies examining the efficacy have been conducted. Subjects taking pregabalin had a higher percentage of people with a 30% reduction in pain and had overall improvement of symptoms compared to placebo. These results aren't all that clinically relevant. At best, the proportion of subjects experiencing at least a 30% reduction in pain score was 50% for pregabalin vs. 30% for placebo. The data show that pregabalin is statistically better than placebo, but not much better. In many cases, relevant data have been omitted, e.g., baseline mean values of the endpoints that would indicate the magnitude of actual improvement with pregabalin.

A 2016 randomized, double-blind, placebo-controlled study evaluated 107 adolescents (12 – 17 years) with fibromyalgia who received pregabalin or placebo. Improvement in the primary endpoint, change from baseline in mean pain score at 15 weeks, was not statistically significant between pregabalin and placebo, with a treatment difference -0.66 (95% CI -1.51 – 0.18; P=0.121). Of all individuals with adverse events (AEs) there were 70.4% in the pregabalin arm and 64.% in the placebo arm. The study noted a post hoc analysis demonstrated there were significant differences in response between subjects from the US and those from other countries, but no explanation was provided. The most common adverse events with pregabalin were dizziness (29.6%) and nausea (22.2%), with 13.2% and 9.4% in the placebo arm. A 6-month open-label extension study with a total of 63 subjects were evaluated from the original study for additional safety information. There were 71.4% of individuals who experienced one or more adverse events. The most commonly reported adverse events were dizziness (22.2%), fatigue (12.7%), headache (9.5%), and nausea/abdominal pain/upper abdominal pain (7.9%).

2010 Update

A recent update of the NICE guidelines for drug treatment of neuropathic pain as well as a review newly published in the U.S. (Dworkin, et al.) recommend amitriptyline and gabapentin as first line agents. The importance of evaluating psychosocial factors and use of cognitive behavioral therapy in management was discussed in a recent review by Turk, et al. These and other systematic reviews and expert recommendations continue to support this policy.

2011 Update

Policy updated to incorporate newly FDA-approved indication for Cymbalta in chronic musculoskeletal pain. No other significant updates to the literature were found.

2012 Update

No information was revealed that would prompt a change in policy.

2014 Update

Policy updated to include generic SNRI trial as a qualifier for coverage.

2015 Update

Policy updated with the addition of duloxetine as a qualifier for Generalized Anxiety Disorder.

2016 Update

A literature search was conducted between June 1, 2015, and December 6, 2016. No new information was found that would prompt a change to the existing policy criteria.

2017 Update

A literature search was conducted between July 1, 2016, and November 2, 2017. No new information was found that would prompt a change to the existing policy criteria.

2018 Update

A literature search was conducted between November 1, 2017, and October 2, 2018. An updated Cochrane meta-analysis of SNRI use in fibromyalgia reported that evidence quality for this therapy continues to be “low to very low”. Another Cochrane review found little evidence for

combination therapy involving drugs from several classes. Evidence also does not support the use of cannabidiol. No new information was found that would indicate need for a change to the existing policy criteria.

2019 Update

Reviewed Lyrica (pregabalin), Lyrica CR (pregabalin extended-release) and Savella (milnacipran) prescribing information and conducted a literature search from August 1, 2018, through August 20, 2019. Updated coverage criteria based on the ages approved in the FDA labeling. Added buspirone as a qualifying medication for the treatment of generalized anxiety disorder for Lyrica (pregabalin).

2020 Update

Reviewed Lyrica (pregabalin), Lyrica CR (pregabalin extended-release) and Savella (milnacipran) prescribing information. No new information was identified that would result in a change to the policy coverage criteria.

2021 Update

Reviewed Lyrica (pregabalin), Lyrica CR (pregabalin extended-release) and Savella (milnacipran) prescribing information. No new information was identified in prescribing information that would result in a change to the policy coverage criteria. Added generic pregabalin extended-release to policy and updated coverage criteria for Lyrica and Lyrica CR to require use of generic pregabalin or generic pregabalin extended-release first.

2022 Update

Reviewed Lyrica (pregabalin), Lyrica CR (pregabalin extended-release) and Savella (milnacipran) prescribing information and conducted a literature search on the management of fibromyalgia. No new information was identified that would result in a change to the policy coverage criteria. Removed generic pregabalin and generic pregabalin extended-release from policy as prior authorization was removed for these two generic drugs.

2023 Update

Reviewed prescribing information of all the drugs in this policy. No new information was identified that would result in a change to the policy coverage criteria. Changed "patient" to "individual" for the process of standardization.

2024 Update

Reviewed prescribing information of all the drugs in this policy. No new information was identified that would result in a change to the policy coverage criteria.

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History

Date	Comments
12/13/05	Add to Prescription Drug Section - New Policy—effective January 1, 2006.

Date	Comments
08/08/06	Replace Policy - Policy reviewed with literature search by Pharmacy and Therapeutic Committee on July 25, 2006. Policy statement updated with exenatide and thiazolidinediones added as medically necessary; Policy Guidelines and Rationale sections updated; references added.
05/08/07	Replace Policy - Policy statement for exenatide updated with additional criteria; Policy Guidelines updated to reflect addition to policy statement. Reviewed by P&T on March 27, 2007.
06/12/07	Replace Policy - Policy statement on coverage criteria for exenatide (Byetta), sitagliptin and esomeprazole (Nexium) expanded; medically necessary indications for 5HT3 antagonists, Actiq and Fentora added to policy statement. Policy Guidelines updated and Rationale updated; references added
12/11/07	Replace Policy - Policy reviewed with literature search by Pharmacy and Therapeutic Committee on May 15, 2007.Policy statement updated to include Pregabalin as either medically necessary or investigational under the criteria. Acyclovir, famciclovir and valacyclovir as medically necessary under criteria. References added.
04/08/08	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement was updated to include fibromyalgia as a medically necessary indication under Pregabalin. References added.
12/16/08	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement updated to include the use of leukotriene modifiers for the treatment of allergic rhinitis refractory to nasal corticosteroids under the medically necessary indication.
02/10/09	NEW PR Policy PR.5.01.521 - Policy updated with literature search by Pharmacy. New PR policy. Medically Necessary and Investigational statements added. Policy split from PR.5.01.605
07/14/09	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement updated to include milnacipran (Savella) for the treatment of fibromyalgia under the medically necessary indication. References added.
08/11/09	Minor update to Policy Guidelines section - Added “agents” after pharmacologic for all 3 drugs in the policy guidelines section.
09/15/09	Minor updates - Corrected spelling errors, no other changes.
06/08/10	Minor update to Policy guidelines section - Policy updated with literature search. Removed “: may be approved after a three month trial” from the policy guidelines for each drug. Added references.
05/10/11	Replace Policy - Policy updated with literature review; newly FDA-approved indication for Cymbalta in chronic musculoskeletal pain added to policy statements. No other changes.
06/26/12	Replace policy. Policy updated with literature review; no change in policy statements.

Date	Comments
11/13/12	Replace policy. Policy Guidelines section updated with updated to the labeling on Lyrica, which now includes patients with post-herpetic neuropathy or neuropathic pain resulting from spinal cord injury.
11/26/12	Update Related Policies. Add 5.01.529.
02/11/13	Replace policy. Minor update to policy statement for duloxetine; clarification added to the medically necessary labeled indication for chronic musculoskeletal pain due to chronic osteoarthritis pain and chronic low back pain (previously this stated "including" versus "due to"). The Policy Guidelines were updated to align with this change.
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
12/06/13	Update Related Policies. Change title for 5.01.520.
03/17/14	Replace policy. Policy updated to include generic SNRI trial as a qualifier for coverage.
04/14/14	Interim update. Policy updated with the addition of pregabalin (Lyrica) as medically necessary for the treatment of Generalized Anxiety Disorder when there have been trials and failure of at least two standard anxiolytic medications. Related policy 5.01.601 replaced with 5.01.550.
09/08/14	Interim update. Policy updated within the Policy Guidelines section only: indication for Pregabalin (Lyrica) changed to patients with neuropathic pain, with reference of root cause of the neuropathy or neuropathic pain removed, when criteria are met.
03/20/15	Update Related Policies. Change title to 5.01.550.
07/14/15	Annual Review. Added duloxetine as a qualifier for Generalized Anxiety Disorder.
01/01/17	Annual Review, approved December 13, 2016. No new information was found that would prompt a change to the existing policy criteria. Minor grammatical corrections were made to the reference section.
12/01/17	Annual Review, approved November 21, 2017. Clarified criteria for Lyrica. Added a reference.
03/01/18	Interim Review, approved February 27, 2018. Added criteria for Lyrica CR and revised duplicative content in Savella and Lyrica criteria sections. Dosage guide for Lyrica was removed.
07/01/18	Interim Review, approved June 5, 2018. Added requirement of documentation in the form of chart notes/medical records for medical necessity review of medications within this policy.
11/01/18	Annual Review, approved October 26, 2018. Annual review completed. No changes to policy criteria.
10/01/19	Annual Review, approved September 5, 2019. Updated coverage criteria for Lyrica and Savella. Added generic pregabalin to policy.

Date	Comments
02/01/20	Interim Review, approved January 9, 2020. Updated coverage criteria for Lyrica and Lyrica CR to require use of generic pregabalin first.
10/01/20	Annual Review, approved September 1, 2020. No changes to policy statements.
07/01/21	Annual Review, approved June 22, 2021. Updated coverage criteria for Lyrica and Lyrica CR to require use of generic pregabalin or generic pregabalin extended-release first. Added generic pregabalin extended-release to policy.
07/01/22	Annual Review, approved June 27, 2022. Removed generic pregabalin and generic pregabalin extended-release from policy as prior authorization was removed for these two generic drugs.
06/01/23	Annual Review, approved May 22, 2023. Reviewed prescribing information of all the drugs in this policy. No new information was identified that would result in a change to the policy coverage criteria. Changed "patient" to "individual" for the process of standardization.
04/01/24	Annual Review, approved March 12, 2024. Reviewed prescribing information of all the drugs in this policy. No new information was identified that would result in a change to the policy coverage criteria.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.

Premera Blue Cross is an independent licensee of the Blue Cross Blue Shield Association serving businesses and residents of Alaska and Washington State, excluding Clark County.
052493 (07-01-2021)