

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	X

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Lyrica (pregabalin)

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	1 year

***Indiana Medicaid – see State Specific Mandates below**

***Maryland Medicaid – see State Specific Mandates below**

Medications	Quantity Limit
Lyrica (pregabalin) capsule Lyrica (pregabalin) solution	May be subject to quantity limit

APPROVAL CRITERIA

- I. Individual has a diagnosis of partial-onset seizures; **AND**
 - II. Individual has been on Lyrica (pregabalin) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial); **OR**
 - III. Individual is using as adjunctive therapy;
AND
 - IV. Individual is 4 years of age and older;
- OR**
- V. Individual has diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN); **AND**
 - VI. Individual had a previously approved clinical prior authorization review through Anthem for Lyrica (pregabalin) in the past year that has recently expired;
OR
 - VII. Individual had a trial (medication samples/ coupons/ discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **one** of the following medications:
 - A. Serotonin-norepinephrine reuptake inhibitor antidepressant (SNRI) [such as, duloxetine HCl (label)* or venlafaxine (immediate- or extended-release agents)] (AACE 2015, ADA 2017); **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- B. Tricyclic antidepressants (such as, amitriptyline, clomipramine, desipramine, nortriptyline) (AACE 2015, AAFP 2010, 2016 2017, NICE 2013); **OR**
- C. Gabapentin (AACE 2015, ADA 2016 2017, NICE 2013);

OR

- VIII. Individual has a diagnosis of post herpetic neuralgia (PHN); **AND**
- IX. Individual had a previously approved clinical prior authorization review through Anthem for Lyrica (pregabalin) in the past year that has recently expired;
OR
- X. Individual had a trial (medication samples/ coupons/ discount cards are excluded from consideration as a trial) and inadequate response or intolerance to **one** of the following medications:
 - A. Gabapentin; **OR**
 - B. Lidocaine patch (Lidoderm)*; **OR**
 - C. Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline) (IASP 2015, EFNS 2010);

OR

- XI. Individual has a diagnosis of neuropathic pain due to spinal cord injury; **AND**
- XII. Individual had a previously approved clinical prior authorization review through Anthem for Lyrica (pregabalin) in the past year that has recently expired;
OR
- XIII. Individual meets the following for central neuropathic pain:
 - A. Central neuropathic pain^{1,2} caused by a primary lesion or dysfunction of the central nervous system (spinal cord or brain) ; **AND**
 - B. Individual had a trial (medication samples/ coupons/ discount cards are excluded from consideration as a trial) and inadequate response or intolerance to **one** of the following medications:
 1. Gabapentin (IASP 2015); **OR**
 2. Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline) (IASP 2015, EFNS 2010);

OR

- XIV. Individual has a clinical diagnosis of Fibromyalgia (for example, based upon symptoms of widespread pain, typically reported in the muscles and joints, findings of “multiple tender points” in characteristic soft tissue locations, and any disorder that would otherwise explain the pain have been excluded); **AND**

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XV. Individual had a previously approved clinical prior authorization review through Anthem for Lyrica (pregabalin) in the past year that has recently expired;

OR

XVI. Individual meets **ALL** of the following criteria:

A. Symptoms have been present at a similar level for at least 3 months; **AND**

B. Trial of and insufficient response or intolerance to **two** of the following medications that are FDA-approved or medically accepted for the treatment of fibromyalgia:

1. Gabapentin (CFCG 2012); **OR**

2. Tricyclic antidepressants (CFCG 2012, EULAR 2016); **OR**

3. Cyclobenzaprine (CFCG 2012, EULAR 2016); **OR**

4. Fluoxetine (CFCG 2012) or alternative selective serotonin reuptake inhibitor; **OR**

5. Cymbalta (duloxetine HCl)*; **OR**

6. Savella (milnacipran HCl)*

*Prior authorization may be required

Note:

1. Central neuropathic pain conditions may result from a primary lesion or dysfunction to the central nervous system (spinal cord, brain) caused by, but not limited to, the following: Trauma, disease known to result in neuropathic pain (such as Multiple Sclerosis or Parkinson's Disease), vascular lesion (such as infarction, hemorrhage, arteriovenous malformation), infection (such as spinal tuberculosis, HIV, syphilitic myelitis, epidural abscesses with spinal cord compression, tuberculomas, cerebral abscesses), tumors, syringomyelia.
2. The following are not approvable as they are not classified as central neuropathic pain:
 - A. Musculoskeletal and visceral nociceptive pains in individuals with CNS diseases caused by conditions such as spasticity or bladder dysfunction; **OR**
 - B. Acute headaches caused by a stroke or head trauma (classified as secondary headaches).

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Indiana Medicaid		Indiana Medicaid allows for diagnosis of anxiety in addition to diagnoses listed in the above criteria.
Maryland Medicaid		Maryland Medicaid behavioral health is state carve out.

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 6, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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