

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

*FHK- Florida Healthy Kids

Cymbalta (duloxetine)

Override(s)	Approval Duration
Prior Authorization	1 Year

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

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

Medications	Quantity Limit
Cymbalta (duloxetine HCl)	May be subject to Quantity Limits or Dose Optimization

APPROVAL CRITERIA

- I. Individual has a diagnosis of Major Depressive Disorder (MDD), Depressive disorder or Dysthymia; **AND**
- II. Individual has been on Cymbalta (duloxetine) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);
OR
- III. Individual had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **two** preferred antidepressants

Preferred agents: amitriptyline HCl, amoxapine, bupropion HCl, citalopram hydrobromide, clomipramine HCl, desipramine HCl, doxepin HCl, escitalopram oxalate, fluoxetine HCl except 60mg tablets, fluvoxamine maleate tablets, imipramine HCl, imipramine pamoate, maprotiline HCl, mirtazapine, nefazadone HCL, nortriptyline HCl, paroxetine HCl, paroxetine ER, paroxetine CR, phenelzine sulfate, protriptyline HCl, sertraline HCl, tranylcypromine sulfate, trazodone HCl, trimipramine maleate, venlafaxine HCl, venlafaxine ER

OR

- IV. Individual has a diagnosis of Generalized Anxiety Disorder; **AND**
- V. Individual has been on Cymbalta (duloxetine) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);
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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VI. 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. Venlafaxine (immediate or extended release products); **OR**
- B. Buspirone; **OR**
- C. Escitalopram; **OR**
- D. Paroxetine; **OR**
- E. Individual is 7 -18 years of age;

OR

VII. Individual has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy; **AND**

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

OR

IX. 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. Tricyclic antidepressants (AACE 2015, AAFP 2010, ADA 2017, NICE 2013); **OR**
- B. Gabapentin (AACE 2015, ADA 2017, NICE 2013); **OR**
- C. Venlafaxine (immediate or extended-release products) (AACE 2015, ADA 2017);
- OR**
- D. Lyrica*

OR

X. 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**

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

OR

XII. Individual meets ALL of the following criteria:

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

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B. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **two** of the following medications that are FDA approved or medically accepted for the treatment of fibromyalgia:

1. Tricyclic antidepressants (CFCG 2012, EULAR 2016); **OR**
2. Gabapentin (CFCG 2012); **OR**
3. Cyclobenzaprine(CFCG 2012, EULAR 2016); **OR**
4. Fluoxetine (CFCG 2012) or alternative selective serotonin reuptake inhibitor (SSRI); **OR**
5. Savella*; **OR**
6. Lyrica*

OR

XIII. Individual has a diagnosis of chronic musculoskeletal pain (such as, chronic low back pain [CLBP] or chronic pain from osteoarthritis); **AND**

XIV. Individual had a previously approved clinical prior authorization through Anthem for Cymbalta (duloxetine) in the past year that has recently expired

OR

XV. Individual has 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. Non-steroidal anti-inflammatory drug (NSAID) (individually or as part of a combination product); **OR**
- B. Acetaminophen (individually or as part of a combination product); **OR**
- C. Tramadol

Note: Cymbalta (duloxetine) has a black box warning for suicidal thoughts and behaviors. In short-term studies, antidepressants increased the risk for suicidal thoughts and behavior in individuals younger than 24 years of age. Cymbalta is not approved for use in pediatric population. Individuals of all ages, who are started on antidepressant therapy, should be monitored closely for worsening or emergence of suicidal thoughts and behaviors.

*Prior authorization may be required

State Specific Mandates	
Maryland Medicaid	Maryland behavioral health is state carve out.

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Virginia Medicaid	12/01/16	<p>PHASE I – Provider Education & Measures to Prevent Fatal Overdoses from Opioid Misuse Effective 12/1/16</p> <p>1) Expand formularies to include the following drugs without PA for ALL Patients:</p> <ul style="list-style-type: none"> • SNRIs including duloxetine
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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 30, 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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