

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	X

\*FHK- Florida Healthy Kids

## Irenka (duloxetine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

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

Medications	Quantity Limit
Irenka (duloxetine)	May be subject to quantity limit

### APPROVAL CRITERIA

Request for Irenka (duloxetine) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Major Depressive Disorder (MDD), Depressive disorder or Dysthymia; **AND**
- II. 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** 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, nefazodone 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**

- III. Individual has a diagnosis of Generalized Anxiety Disorder; **AND**
- IV. 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. Venlafaxine (immediate or extended-release products); **OR**
  - B. Buspirone; **OR**
  - C. Escitalopram; **OR**
  - D. Paroxetine; **OR**
  - E. Individual is 7 – 18 years of age;

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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**OR**

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

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

\*Prior authorization may be required

**Note:** Irenka (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 the 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Maryland Medicaid		Maryland behavioral health is state carve out.

**Key References:**

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<b>Applicable</b>	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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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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