Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

duloxetine

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

Medications	Quantity Limit
Cymbalta (duloxetine) Drizalma Sprinkles (duloxetine)	May be subject to quantity limit or Dose Optimization

APPROVAL CRITERIA

Requests for duloxetine (Cymbalta, Drizalma Sprinkles generic 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 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

III. Individual has a diagnosis of Generalized Anxiety Disorder; **AND**
IV. 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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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

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. Tricyclic antidepressants (AACE 2015, AAFP 2010, ADA 2017, NICE 2013); **OR**
   B. Gabapentin (AACE 2015, ADA 2017, NICE 2013, AHFS, DRUGDex B, IIa); **OR**
   C. Venlafaxine (immediate or extended-release products) (AACE 2015, ADA 2019); **OR**
   D. Lyrica (Label)

OR

VII. 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**

VIII. Individual meets ALL of the following criteria:
   A. Symptoms have been present at a similar level for at least 3 months; **AND**
   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) (CFCG 2012; **OR**
      5. Savella (Label)*; **OR**
      6. Lyrica (Label);

OR

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

X. 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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

OR
Requests for Drizalma Sprinkle (duloxetine delayed-releases capsules) may be approved based on the following criteria:

I. Individual is unable to swallow the oral dose from due to a clinical condition such as but not limited to the following:
   A. Dysphagia; **OR**
   B. Individual's age.

Note:
SNRI antidepressants have a black box warning for suicidal thoughts and behaviors. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. Use is not approved in the pediatric population. Individuals, who are started on antidepressant therapy, should be monitored closely for worsening, and emergence of suicidal thoughts and behaviors. Monitoring should especially occur during the initial few months of a course of therapy, or at times of dose changes, either increases or decreases.

*Prior authorization may be required

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Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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.