| Pharmacy Policy Bulletin: J-0214 Drizalma Sprinkle (duloxetine) – Commercial and Healthcare Reform | |
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| **Number:** J-0214 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.)**<br>1. Other Managed Drugs = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-0214-009 | **Original Date:** 08/07/2019 |
| **Effective Date: 10/08/2025** | **Review Date:** 09/17/2025 |

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| **Drugs Product(s):** | • Drizalma Sprinkle (duloxetine) delayed-release capsules |
| **FDA-Approved Indication(s):** | • Major depressive order (MDD) in adults<br>• Generalized anxiety disorder (GAD) in adults and pediatric patients ages 7 years and older<br>• Diabetic peripheral neuropathic pain (DPNP) in adults<br>• Chronic musculoskeletal pain in adults<br>• Fibromyalgia (FM) in adults |

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| **Background:** | • Drizalma Sprinkle is a selective serotonin and norepinephrine reuptake inhibitor (SNRI). Although the exact mechanisms of the antidepressant, central pain inhibitor, and anxiolytic actions of Drizalma Sprinkle are unknown, these actions are believed to be related to its potentiation of serotonergic and noradrenergic activity in the central nervous system (CNS).<br>• Prior authorization is utilized to ensure appropriate use. Other SNRI extended-release dosage forms are unable to be opened and sprinkled onto food or used via nasogastric tube. Effexor IR (venlafaxine immediate-release), an SNRI, is available in tablets that are able to be crushed, however, administration is two to three times daily.<br>• Prescribing Considerations:<br>  ○ Drizalma has a black box warning for suicidal thoughts and behaviors. There is an increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants.<br>  ○ In the pediatric population, the only FDA approved indication for Drizalma Sprinkle is the treatment of GAD.<br>  ○ Drizalma Sprinkle can be taken with or without food. It can be swallowed whole or should be opened and the pellets sprinkled onto one tablespoonful of applesauce; the mixture should be swallowed right away. Drizalma pellets should not be crushed or chewed. Do not save the applesauce and pellet mixture for later use. |

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| | ○ For use in a nasogastric tube, the Drizalma should be opened and the contents mixed with 50 mL of water in a plastic catheter tip syringe; other liquids should not be used. Gently shake for 10 seconds, then administer the mixture through the nasogastric tube. The mixture should be used promptly. Ensure no pellets are left in the syringe. Rinse with additional water, about 15 mL, if needed. Do not save the mixture for later use. |

## Approval Criteria

**I. Generalized Anxiety Disorder (GAD)**

**A. Initial Authorization**

When a benefit, coverage of Drizalma Sprinkle may be approved when all of the following criteria are met **(1., 2., and 3.):**

**1.** The member is 7 years of age or older
**2.** The member has a diagnosis of GAD **ICD-10: F41.1**
**3.** The member has an inability to swallow capsules/tablets

**B. Reauthorization**

When a benefit, reauthorization of Drizalma Sprinkle may be approved when all of the following criteria are met **(1. and 2.):**

**1.** The prescriber attests that the member has experienced positive clinical response to therapy.
**2.** The prescriber attests that the member continues to have an inability to swallow capsules/tablets.

**II. Major Depressive Disorder (MDD), Diabetic Peripheral Neuropathic Pain (DPNP) or Chronic Musculoskeletal Pain**

**A. Initial Authorization**

When a benefit, coverage of Drizalma Sprinkle may be approved when all of the following criteria are met **(1., 2., and 3.)**:

**1.** The member is 18 years of age or older
**2.** The member has a diagnosis of MDD, DPNP, or chronic musculoskeletal pain **ICD-10: F32-F33, E11.40, M79.1**
**3.** The member has an inability to swallow capsules/tablets

**B. Reauthorization**

When a benefit, reauthorization of Drizalma Sprinkle may be approved when all of the following criteria are met **(1. and 2.):**

**1.** The prescriber attests that the member has experienced positive clinical response to therapy.
**2.** The prescriber attests that the member continues to have an inability to swallow capsules/tablets.

**III. Fibromyalgia**

**A. Initial Authorization**

When a benefit, coverage of Drizalma Sprinkle may be approved when all of the following criteria are met **(1. through 4.)**:

**1.** The member is 18 years of age or older.
**2.** The member has a documented diagnosis of fibromyalgia **(ICD-10: M79.7)**
**3.** There is clinical documentation (i.e., chart notes) of the fibromyalgia diagnosis including all of the following **(a., b., and c.):**
  **a.** Widespread bilateral pain above and below the waist
  **b.** Pain of at least 3 months duration
  **c.** At least one (1) fibromyalgia-related symptoms from the following **(i. through v.):**
    **i.** Cognitive impairment
    **ii.** Fatigue

iii. Sleep disturbance
iv. Neurological symptoms
v. Exercise intolerance

4. The member has an inability to swallow capsules/tablets.

**B. Reauthorization**

When a benefit, reauthorization of Drizalma Sprinkle may be approved when all of the following criteria are met **(1. and 2.):**

1. The prescriber attests that the member has experienced positive clinical response to therapy.
2. The prescriber attests that the member continues to have an inability to swallow capsules/tablets.

**IV.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None.

**References:**


1. Drizalma Sprinkle [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries Inc.; August 2023.
2. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Accessed July 9, 2025.
3. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2025. Accessed July 9, 2025.