New Hampshire Medicaid Fee-for-Service Program

Duloxetine Criteria

Approval Date: July 12, 2022

Medications

Brand Name	Generic Name	Dosage Strengths	Indication
Cymbalta®	duloxetine delayed release	20 mg, 30 mg, 60 mg	• Diabetic peripheral neuropathic pain (DPNP) in adults • Fibromyalgia in patients ≥ 13 years old • Generalized anxiety disorder (GAD) in adults and pediatric patients ≥ 7 years old • Major depressive disorder (MDD) in adults • Musculoskeletal pain, chronic in adults
Drizalma® Sprinkle	duloxetine delayed release	20 mg, 30 mg, 40 mg, 60 mg	• Major depressive disorder in adults • GAD in adults and pediatric patients ages 7–17 years old • DPNP in adults • Chronic musculoskeletal pain in adults • Fibromyalgia in adults
Irenka® (brand no longer available)	duloxetine delayed release	40 mg	• DPNP in adults • Major depressive disorder in adults • GAD in adults and pediatric patients ≥ 7 years old • Chronic musculoskeletal pain in adults

Criteria for Approval

1. Diagnosis of a depressive disorder;
    a. For diagnosis of a depressive disorder, brands Cymbalta®, and Drizalma® Sprinkle require additional preferred drug list prior approval (PA); **OR**
2. Diagnosis of GAD
    a. Brand name Cymbalta®and Drizalma® Sprinkle require trial and failure with, or not being a candidate for, generic duloxetine; **OR**

3. Diagnosis of diabetic peripheral neuropathy (DPN)
    a. Brand name Cymbalta® and Drizalma® Sprinkle require trial and failure with, or not being a candidate for, generic duloxetine; **AND**
    b. Trial and failure of, or contraindication to, any tricyclic antidepressants or gabapentin treatment; **OR**
4. Diagnosis of fibromyalgia (brand and generic Cymbalta® and Drizalma® Sprinkle); **AND**
    a. Patient is ≥ 13 years old (brand and generic Cymbalta®) or patient is ≥ 18 years old (Drizalma® Sprinkle); **AND**
    b. Physical Fitness Intervention (e.g., physical therapy, exercise); **AND**
    c. Failure of, or not being a candidate for, treatment with one of the following two for age ≥ 18 years (for patients ≥ 13 and < 18 years, no trial and failure is required):
        i. Amitriptyline 50 mg daily; **OR**
        ii. Cyclobenzaprine 30 mg daily; **OR**
5. Diagnosis of chronic musculoskeletal pain, which includes chronic lower back pain or chronic pain due to osteoarthritis; **AND**
    a. Brand name Cymbalta® and Drizalma® Sprinkle require trial and failure with, or not being a candidate for, generic duloxetine; **AND**
    b. Trial and failure of, or contraindication to, treatment with:
        i. Acetaminophen (not to exceed 4 g/day); **AND**
        ii. At least one non-steroidal anti-inflammatory drug (NSAIDs); **AND**
        iii. Cyclooxygenase – 2 inhibitors. **AND**
6. No concurrent therapy of these medications (i.e., duloxetine, pregabalin, milnacipran) beyond 30 days

Criteria for Denial

1. Criteria for approval not met.
2. For diagnosis of DPN, no medications for diabetes in the member's claim history.
3. Concurrent therapy of pregabalin or milnacipran beyond 30 days.

Length of Authorization: 1 year

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date
Pharmacy and Therapeutic Committee	Update	09/05/2006
Commissioner	Approval	09/29/2006
Pharmacy and Therapeutic Committee	Update	11/06/2008
Commissioner	Approval	12/01/2008
DUR Board	Revision	03/22/2010
Commissioner	Revision	04/30/2010
DUR Board	Revisions to separate fibromyalgia criteria	06/22/2010
Commissioner	Revisions to separate fibromyalgia criteria	08/03/2010
DUR Board	Revision	03/23/2011
Commissioner	Revision	06/07/2011
DUR Board	Revisions to separate fibromyalgia criteria	10/19/2011
Commissioner	Revisions to separate fibromyalgia criteria	04/12/2012
DUR Board	Revision	10/11/2016
Commissioner	Approval	11/22/2016
DUR Board	Update	09/27/2018
Commissioner Designee	Approval	11/27/2018
DUR Board	Update	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022