

Pharmacy Policy

Antidepressants

Policy Number: 9.502

Version Number: R2

Version Effective Date: 9/1/2021

Product Applicability All Plan⁺ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Duloxetine 40 mg capsule (branded generic for Irenka[®])
- Fluoxetine tablet

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	<p>duloxetine 40 mg capsule (branded generic for Irenka[®])</p> <ol style="list-style-type: none"> Documentation of one of the following: <ol style="list-style-type: none"> An appropriate behavioral health diagnosis and an inadequate response to a trial of, a decline in clinical status with a trial of, an intolerance to, or a contraindication to any two covered antidepressants; OR

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	<p>b. A diagnosis of diabetic neuropathy or fibromyalgia and an inadequate response to a trial of, a decline in clinical status with a trial of, an intolerance to, or contraindication to at least one formulary alternative clinically appropriate for the condition being treated and <u>one</u> of the following:</p> <ul style="list-style-type: none"> i. Prescriber must attest that the diagnosis of fibromyalgia has been confirmed by a rheumatologist, physiatrist, pain management specialist or neurologist; OR ii. Prescriber has conducted an evaluation confirming <u>all</u> of the following: <ul style="list-style-type: none"> 1. Physical exam indicating presence of 11 of 18 tender points OR Widespread Pain Index (WPI) is 7 or greater and Symptom Severity (SS) scale score is 5 and greater OR WPI is between 3 and 6 and SS scale score is 9 or greater; AND 2. Symptoms have been present for at least 3 months; AND 3. Attestation that other conditions mistaken for fibromyalgia have been ruled out (e.g. rheumatoid arthritis, peripheral neuropathies, infection); OR <p>c. A diagnosis of chronic musculoskeletal pain (related to low back pain or osteoarthritis of the knee) and an inadequate response to a trial of, a decline in clinical status with a trial of, an intolerance to, or a contraindication to <u>all</u> of the following:</p> <ul style="list-style-type: none"> i. Non-pharmacologic therapy (such as physical therapy, exercise, weight loss, etc) ii. Three prescription strength analgesics iii. One tricyclic antidepressant (if treating chronic low back musculoskeletal pain) <p>fluoxetine tablet</p> <ul style="list-style-type: none"> 1. An allergy to an inactive ingredient in fluoxetine capsules and fluoxetine oral solution that is not found in fluoxetine tablets; OR 2. Clinical rationale why the fluoxetine tablet is medically necessary over the fluoxetine capsules and fluoxetine oral solution <p>Please note: Fluoxetine 10mg tablet is covered for members < 18 years of age</p>
Coverage Duration	1 year
Quantity Limit	Duloxetine: 3 capsules per day

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Clinical Background Information and References

1. Wells BG, Dipro JT, Schwinghammer TL, Hamilton CW, editors. Pharmacotherapy Handbook, 6th ed. Depressive disorders. New York: McGraw-Hill; 2006. p. 706-724.
2. American Psychiatric Association. Highlights of changes from DSM-IV-TR to DSM-5. Accessed August 2014, available at <http://www.dsm5.org>.
3. Karasu TB, Gelenberg A, Merriam A, Wang P. Practice guideline for the treatment of patients with major depressive disorder, second edition. American Psychiatric Association. Apr 2000;1-78. Available from: <http://www.psych.org/>.
4. Wolfe F, Clauw DJ, Fitzcharles M, et al. The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. Arthritis Care Res. 2010 May;62(5):600-610.
5. Schnitzwer TJ. Update on guidelines for the treatment of chronic musculoskeletal pain Clin Rheumatol (2006) 25 (Suppl 1): S22-S29
6. Goldenberg DL. Pharmacological treatment of fibromyalgia and chronic musculoskeletal pain. Best Practice & Research Clinical Rheumatology 2007; 21: 499-511.
7. Katon W, Ciechanowski P. Initial treatment of depression in adults. UptoDate[®]. Accessed August 2013, available at <http://www.uptodate.com>
8. Prescribing Information. Irenka, duloxetine hydrochloride. Lupin Pharma. Baltimore, MD. May 2015.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	Policy updated to reflect NH PDL	1/1/2021	P&T Committee, NH DHHS
2/11/2021	Annual policy review, updated coverage duration from 2 years to 1 year	6/1/2021	P&T Committee, NH DHHS
5/13/2021	P&T review: Added fluoxetine tablets to PA	9/1/2021	P&T Committee, NH DHHS

Next Review Date

5/2022

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Other Applicable Policies

9.058 Pediatric Behavioral Health Medication Initiative

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

^{*} *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.