

Policies Repository



Policy Title Duloxetine (Cymbalta®)

Policy Number FS.CLIN.39

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Duloxetine (Cymbalta®)** is indicated for the treatment of major depressive disorder (MDD), diabetic peripheral neuropathy (DPN), generalized anxiety disorder (GAD) and fibromyalgia.

The use of duloxetine (Cymbalta®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Duloxetine (Cymbalta®)** is a Serotonin/Norepinephrine Reuptake Inhibitor. Serotonin (5HT) and norepinephrine (NE) play roles in both the cause and maintenance of depression, anxiety, and pain. 5HT is believed to primarily mediate certain depressive symptoms, including appetite, whereas NE is thought to mediate other symptoms, including concentration, attention, and/or motivation. Still other symptoms, such as anxiety and sadness, are mediated by both 5HT and NE. These two neurochemicals also influence the perception of pain by playing a role in the descending pain pathways that inhibit the afferent pain fibers that ascend through the spinal cord. Inhibition of 5HT and NE reuptake leads to greater levels of these neurochemicals remaining within the synapses of the nerves. This is thought to alleviate depression, anxiety, and pain symptoms.

Policy Guideline Inclusion **Duloxetine (Cymbalta®)** is approved when **one** of the following inclusion criteria is met:

- Documentation of neuropathic pain associated with Diabetic Peripheral Neuropathy (DPN) secondary to diabetes with documented use of any diabetic medications
- Documentation of diagnosis of fibromyalgia
- Documentation of a diagnosis of Major Depressive Disorder (MDD) and **one** of the following:
 - Documentation of a trial and failure or intolerance to two of the following agents:
 - A bupropion-containing product
 - Citalopram
 - Escitalopram (Lexapro®)
 - Fluoxetine

- Fluvoxamine
 - A paroxetine-containing product
 - Sertraline
 - A venlafaxine-containing product
 - Documentation of stabilization from an institutional setting with Duloxetine (Cymbalta®)
 - Documentation of current stabilization with Duloxetine (Cymbalta®) for over four weeks with corresponding dates
- Documentation of a diagnosis of Generalized Anxiety Disorder (GAD) and **one** of the following:
 - Documentation of a trial and failure or intolerance to two of the following agents:
 - A bupropion-containing product
 - Citalopram
 - Escitalopram (Lexapro®)
 - Fluoxetine
 - Fluvoxamine
 - A paroxetine-containing product
 - Sertraline
 - A venlafaxine-containing product
 - Documentation of stabilization from an institutional setting with Duloxetine (Cymbalta®)
 - Documentation of current stabilization with Duloxetine (Cymbalta®) for over four weeks with corresponding dates

Policy Guideline Exclusion

Duloxetine (Cymbalta®) is denied when **all** of the following exclusion criteria are met:

- No documentation of neuropathic pain associated with Diabetic Peripheral Neuropathy (DPN) secondary to diabetes with documented use of any diabetic medications
- No documentation of diagnosis of fibromyalgia
- No documentation of a diagnosis of Major Depressive Disorder (MDD) and **one** of the following:
 - Documentation of a trial and failure or intolerance to two of the following agents:
 - A bupropion-containing product
 - Citalopram
 - Escitalopram (Lexapro®)
 - Fluoxetine
 - Fluvoxamine
 - A paroxetine-containing product
 - Sertraline
 - A venlafaxine-containing product
 - Documentation of stabilization from an institutional setting with Duloxetine (Cymbalta®)
 - Documentation of current stabilization with Duloxetine (Cymbalta®) for over four weeks with corresponding dates
- No documentation of a diagnosis of Generalized Anxiety Disorder (GAD) and **one** of the following:
 - Documentation of a trial and failure or intolerance to two of the following agents:
 - A bupropion-containing product
 - Citalopram
 - Escitalopram (Lexapro®)
 - Fluoxetine
 - Fluvoxamine
 - A paroxetine-containing product
 - Sertraline

- A venlafaxine-containing product
 - Documentation of stabilization from an institutional setting with Duloxetine (Cymbalta®)
 - Documentation of current stabilization with Duloxetine (Cymbalta®) for over four weeks with corresponding dates

Policy List of Applicable Drugs

Brand Name	Generic Name
Cymbalta	duloxetine

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

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