Oscar Clinical Guideline: Fetzima (levomilnacipran) (PG063, Ver. 6)

# Fetzima (levomilnacipran)

**Disclaimer**

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

## Summary

Fetzima (levomilnacipran), FDA approved in 2009, is a serotonin and norepinephrine reuptake inhibitor (SNRI) used to treat major depressive disorder. Major depressive disorder is a mental health disorder that causes symptoms of sadness, hopelessness, and loss of interest in things. It can disrupt relationships and everyday activities, such as work, school, and activities that are usually pleasant. There are many medications from several classes that are available to treat major depressive disorder including selective serotonin-reuptake inhibitors (SSRIs), serotonin- and norepinephrine-reuptake inhibitors (SNRIs), tricyclic antidepressants, monoamine oxidase (MAO) inhibitors, and other antidepressants (e.g., bupropion, mirtazapine, trazodone).

NOTE: Fetzima (levomilnacipran) is not approved for the management of fibromyalgia, and the efficacy and safety of the drug for the management of this condition have not been established.

## Definitions

**"Major depressive disorder",** also known as **(MDD),** is a psychiatric condition characterized by persistent low mood, low energy, or loss of interest in enjoyable activities causing substantial impairment in daily life. MDD is thought to be caused by a combination of genetic, environmental and psychological factors. Risk factors include family history, major life changes, certain medications, chronic health problems, and substance use disorders.

**"Selective serotonin reuptake inhibitors (SSRIs)"** are a class of drugs that work by increasing the availability of serotonin to transmit signals between neurons.

**"Serotonin-norepinephrine reuptake inhibitors (SNRIs)"** are a class of drugs that work by increasing the availability of serotonin and norepinephrine to transmit signals between neurons.

**"Tricyclic antidepressants"** are a class of drugs used in depression. The name "tricyclic" is derived from the three rings in their molecular structure.

## Medical Necessity Criteria for Initial Authorization

The Plan considers **Fetzima (levomilnacipran)** medically necessary when **ALL** the following criteria are met:

1. The member is 18 years of age or older; ***AND***
2. The member has a diagnosis of major depressive disorder (MDD); ***AND***
3. The member is unable to use or has adequately tried and failed a minimum **ONE** (1) month trial of at least **THREE** (3) therapies, from at least **THREE** (3) of the following classes:
    a. Noradrenergic and dopaminergic antidepressants (bupropion)***; and/or***
    b. Noradrenergic and specific serotonin antidepressants (e.g., mirtazapine)***; and/or***
    c. Selective serotonin reuptake inhibitors (e.g., citalopram, escitalopram, fluoxetine, paroxetine, sertraline)***; and/or***
    d. Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine IR/ER)***; and/or***
    e. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)***; AND***
4. Clinical chart documentation is provided for review to substantiate the above listed requirements.

**If the above prior authorization criteria are met, Fetzima (levomilnacipran) will be approved for 12 months**

## Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if recent chart documentation (within the last 12 months) shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** (1) of the following:

1. clinical improvement (e.g., reduction in signs and symptoms, including residual symptoms) in symptoms since starting the requested medication; ***OR***
2. stability in condition (e.g., restoration of prior level of psychosocial and occupational function) since starting the requested medication.

## Experimental or Investigational / Not Medically Necessary

Fetzima (levomilnacipran) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Tobacco Use Disorders

## References


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## Clinical Guideline Revision / History Information

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