Medication Audit Criteria and Guidelines

Duloxetine (Cymbalta®)

PEFC Approved: April 2022

Indications

This document lists only FDA-approved indications from the product labeling. The PEFC acknowledges that there are off-label indications for use that have supporting evidence for efficacy. If a medication is prescribed for an off-label indication, documentation in the patient chart is recommended.

- Generalized anxiety disorders (GAD) in adults, children ≥ 7 yo
- Chronic Musculoskeletal Pain
- Major depressive disorder (MDD) in adults
- Diabetic Peripheral Neuropathic Pain (DPNP) in adults
- Fibromyalgia in adults, children ≥ 13 yo

Black Box Warning

Increased risk of suicidal thinking and behavior in children, adolescents, and young adults (≤ 24 years) taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors.

Contraindications

- Monoamine Oxidase Inhibitors (MAOIs)– MAOIs intended to treat psychiatric disorders with duloxetine or within 5 days of stopping treatment with duloxetine (increased risk of serotonin syndrome)
- Duloxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders (increased risk of serotonin syndrome)
- Duloxetine initiation in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue (increased risk of serotonin syndrome)
- History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Warnings and Precautions

- Suicidal thoughts and behaviors in children, adolescents, and young adults (≤ 24 years)

- Hepatotoxicity
  - Discontinue if jaundice or other evidence of clinically significant liver dysfunction develops. Do not resume unless another cause can be established
  - Avoid with substantial alcohol use, evidence of chronic liver disease
- Orthostatic hypotension, falls and syncope
- Serotonin syndrome
- Increased risk of bleeding
- Severe skin reactions
- Discontinuation syndrome
- Activation of Mania or Hypomania
- Angle-closure glaucoma
- Seizures
- Increases in blood pressure
- Hyponatremia
- Glucose control in diabetes
- Inhibitors of CYP1A2 or thioridazine—avoid co-administration with duloxetine
- Severe renal impairment, see Special Populations
- Conditions that slow gastric emptying
- Urinary hesitation and retention
- Sexual dysfunction

Adverse Reactions

Side Effects Which Require Medical Attention

- Elevated liver enzymes
- Hypersensitivity reaction (rash)
- Hypertension or hypotension
- Increased suicidality
- Seizure
- Serotonin syndrome
- Severe GI distress
- Sexual dysfunction
- Tachycardia
- Withdrawal symptoms

Drug Interactions of Major Significance

See: Indiana Univ Drug Interaction Table

See: Lexicomp, Micromedex for more information

Special Populations

- Pediatrics/Adolescents
  - See "Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)" for specific details.
- Geriatric
  - Included in Beers Criteria
- Renal impairment: avoid with GFR < 30 mL/min
- Hepatic impairment: avoid in patients with chronic liver disease or cirrhosis
- Pregnancy and Breastfeeding
  - Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling.

Patient Monitoring Parameters

- Height and weight—baseline, then monthly and as clinically indicated (children, adolescents)
- Hepatic function—baseline and as clinically indicated
- Renal function—baseline and as clinically indicated
- Blood pressure before initiating treatment and regularly throughout treatment
- Emergence of suicidal ideation or behavior
- Pregnancy test—baseline and as clinically indicated
- Sodium level in high-risk patients (e.g., older than 65 years, previous history of antidepressant-induced hyponatremia, low body weight, concomitant use of thiazides or other hyponatremia-inducing agents, experiencing symptoms of hyponatremia), baseline, then at 4 weeks and as clinically indicated

Dosing

- See HHSC Psychiatric Drug Formulary for dosage guidelines.
- Exceptions to maximum dosage must be justified as per medication rule.