



Medication Audit Criteria and Guidelines

Clomipramine (Anafranil®)

PEFC Approved: August 2019

Indications

- Autism spectrum disorder
- Depression
- Obsessive – compulsive disorder
- Panic disorder

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

Absolute

- Co-administration with an MAOI, including linezolid or IV methylene blue, or use within 14 days of discontinuing an MAOI
- History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed or to other tricyclic antidepressants
- Recovery phase of myocardial infarction

Relative

- Pheochromocytoma

- Pregnancy/nursing mothers

Precautions

- Alcohol intoxication
- Bipolar disorder in the absence of a mood stabilizer
- Cardiovascular disorders including arrhythmia
- Concomitant use with agents that impair metabolism of serotonin (e.g., MAO inhibitors including phenelzine, tranylcypromine, linezolid, methylene blue)
- Concomitant use with other serotonergic agents (e.g., SSRIs, SNRIs, triptans, TCAs, fentanyl, lithium, tramadol, buspirone, St John's wort, tryptophan)
- Diagnosis of a seizure disorder or history of seizures
- Discontinuation syndrome
- Disease states where increased anticholinergic activity may complicate disease course (narrow-angle glaucoma, benign prostatic hypertrophy, urinary retention)
- Heart block and failure
- Hepatic function impairment
- Hyperthyroidism or hypothyroidism (e.g., patients receiving thyroid supplementation)
- Recent or current blood dyscrasias
- Renal failure
- Suicidal thoughts and behaviors in children, adolescents, and young adults (≤ 24 years)

Adverse Reactions

Side Effects Which Require Medical Attention

- Anticholinergic effects
- Dizziness, lightheadedness or fainting (orthostatic hypotension)
- Jaundice

- QTc>500 msec
- Seizures
- Sexual function impairment
- Tachycardia greater than 100 beats/min

Pregnancy and Breastfeeding

- See relative contraindications
- Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling

Drug Interactions of Major Significance

- Cimetidine
- Concomitant monoamine oxidase inhibitors (furazolidone, procarbazine, selegiline, tranylcypromine, phenelzine, isoniazid)
- Concomitant use of CNS depressants
- Concomitant use of medications with anticholinergic effects
- Linezolid
- Methylene blue
- Noradrenergic anti-hypertensive agents (clonidine, guanabenz, guanethidine)
- SSRI

See table A: Cytochrome P450 Drug Metabolism/Inhibition

Clomipramine:

Substrate of 1A2, 2C19, and 2D6

Inhibitor of 2D6

Special Populations

Age-Specific Considerations

- Not recommended for use in children under age 10, conservative dosing is advised.
- Geriatrics: Start at the lower end of the dosing range; use caution

Patient Monitoring Parameters

- Blood pressure during dosage titration and as clinically indicated
- CBC – baseline and as clinically indicated (children, adolescents)
- EKG – baseline and as clinically indicated
- Height and weight – baseline, monthly and as clinically indicated (children, adolescents)
- Hepatic function – baseline and as clinically indicated
- Monitor for 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, 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.