Medication Audit Criteria and Guidelines

Amoxapine (Asendin®)

PEFC Approved: August 2019

Indications

- Depression with psychotic features

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

- History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
- Recovery phase of myocardial infarction
- Use of Monoamine oxidase inhibitor within 14 days

Relative

- History of neuroleptic malignant syndrome
- Pregnancy/nursing mothers

Precautions

- Alcohol intoxication
- Angle-closure glaucoma

- Bipolar disorder in the absence of a mood stabilizer
- Cardiovascular disorders including cardiac conduction defects, arrhythmia, tachycardia and heart failure
- Diagnosis of a seizure disorder or history of seizures
- Discontinuation syndrome
- Hepatic function impairment
- History of EPS
- Hyperthyroidism
- Parkinson's disease
- Patients at risk for paralytic ileus
- Prostatic hypertrophy
- Recent or current blood dyscrasias
- Renal failure
- Suicidal thoughts and behaviors in children, adolescents, and young adults (≤ 24 years)
- Tardive dyskinesia
- Urinary retention

Adverse Reactions

Side Effects Which Require Medical Attention

- Akathisia
- Anticholinergic effects
- Cardiovascular – heart block, myocardial infarction, prolonged QT interval
- Dizziness, lightheadedness or fainting
- EPS
- Seizures

- Sexual function impairment
- Signs and symptoms of neuroleptic malignant syndrome
- Symptoms of prolactin elevation (galactorrhea, amenorrhea, gynecomastia)
- Tardive dyskinesia

Pregnancy and Breastfeeding

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

Drug Interactions of Major Significance

- Concurrent administration of MAO inhibitors, or within 14 days of an MAO inhibitor

Special Populations

Age-Specific Considerations

- Safety and efficacy have not been established in children younger than 18 years
- Geriatrics: Initial, 25 mg orally 2 to 3 times daily; may increase dosage as needed to 50 mg orally 2 to 3 times daily by the end of the first week; 100 to 150 mg daily may be adequate for many but careful increases up to 300 mg daily may be indicated in some patients

Patient Monitoring Parameters

- EKG – baseline and as clinically indicated
- EPS evaluation baseline then weekly for the first 2 weeks after initiation, and then weekly for 2 weeks after a dose increase. At every visit for outpatients
- Monitor for emergence of suicidal ideation or behavior
- Pregnancy test—baseline and as clinically indicated
- Prolactin level – if evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance, or erectile/ejaculatory disturbances in males

- 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
- Tardive dyskinesia evaluation - every three months and as clinically indicated.

Dosing

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