MEDICATION AUDIT CRITERIA AND GUIDELINES: SERTRALINE (ZOLOFT®)

**Indications**

- Depressive Disorders
- Obsessive-compulsive Disorder (OCD) adults and children >6
- Post-traumatic stress disorder (PTSD)
- Premenstrual dysphoric disorder (PMDD)
- Anxiety Disorders

**Black Box Warning**

- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Closely monitor for clinical worsening and emergence of suicidal thoughts and behaviors.

**Contraindications**

- Taking, or within 14 days of stopping, MAOIs (including the MAOIs linezolid and intravenous methylene blue) because of an increased risk of serotonin syndrome.
- Taking pimozide
- With known hypersensitivity to sertraline (e.g., anaphylaxis, angioedema)
- In addition to the contraindications listed above, Zoloft oral solution is contraindicated in patients taking disulfiram (Zoloft oral solution contains alcohol).

**Warnings and Precautions**

- Suicidal thoughts and behaviors in pediatric and young adult patients
- Serotonin syndrome
- Increased risk of bleeding
- Activation of mania or hypomania
- Discontinuation syndrome
- Seizures
- Angle-closure glaucoma
- Hyponatremia
- False-positive effects on screening tests for benzodiazepines
- QTc prolongation

**Adverse Reactions**

- (>5% and twice placebo): nausea, diarrhea/loose stool, tremor, dyspepsia, decreased appetite, hyperhidrosis, ejaculation failure, decreased libido
Pregnancy and Breastfeeding

- Pregnancy Category C: See package insert, section 8.1

Drug Interactions of Major Significance

- Monoamine oxidase inhibitors (MAOI), risk of serotonin syndrome. MAOI examples: selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue
- Pimozide. Increased plasma concentrations of pimozide may increase the risk of QTc prolongation and ventricular arrhythmias. Contraindicated.
- Serotonergic drugs (SSRIs, SNRIs, triptans, TCAs, fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, St. John’s wort)
- Drugs that interfere with hemostasis (NSAIDs, aspirin, warfarin, etc.)
- Drugs highly bound to plasma proteins (warfarin)
- Drugs metabolized by CYP2D6.
- Phenytoin. Sertraline may increase phenytoin concentrations.
- Drugs that prolong the QT interval—ziprasidone, iloperidone, chlorpromazine, mesoridazine, droperidol, erythromycin, gatifloxacin, moxafoxacin, sparfloxacin, quinidine, procainamide, amiodarone, sotalol, pentamidine, levomethadyl acetate, methadone, halofantrine, mefloquine, dolasetron mesylate, probucol or tacrolimus

Special Populations

- Pediatric use: safety and effectiveness of sertraline in pediatric patients other than those with OCD have not been established.
- Hepatic impairment: Mild (Child-Pugh score 5 or 6): recommended starting and maximum dosage is half recommended dosage. Moderate (Child Pugh score 7 to 10) or severe (Child Pugh score 10-15): not recommended.
- No dosage adjustment is needed in patients with mild to severe renal impairment.
- Elderly patients may be at greater risk of hyponatremia

Patient Monitoring Parameters

- Pregnancy test—as clinically indicated
- Monitor for emergence of suicidal ideation or behavior
- EKG—as clinically indicated

Dosing

- See Texas Health and Human Services Health and Specialty Care System Drug Formulary for dosage guidelines. Exceptions to maximum dosage must be justified as per medication rule.