



## **TERBUTALINE**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Terbutaline is a beta-adrenergic agonist with preferential effects on the beta-2 receptors resulting in smooth muscle relaxation. It is FDA-approved for the treatment or prophylaxis of bronchospasm associated with asthma, bronchitis, and emphysema in patients 12 years old and older (1).

The American Congress of Obstetricians and Gynecologists (ACOG) makes the following recommendations regarding the use of tocolytics in the management of preterm labor (Level A recommendation): There are no clear “first-line” tocolytic drugs to manage preterm labor. Preterm labor is defined as contractions, prior to 37 weeks gestation, with sufficient intensity and frequency to induce progressive softening, effacement and/or dilatation of the cervix (2-3).

Calcium channel blockers and prostaglandin inhibitors are considered experimental / investigational after 72 hours of therapy for tocolysis as is the use of magnesium sulfate for neuroprotection (2-3).

#### **Regulatory Status**

FDA-approved indications: Terbutaline is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema (1).

Terbutaline has a boxed warning regarding that terbutaline has not been approved for prolonged tocolysis and should not be used. In particular, do not use terbutaline for maintenance tocolysis in the outpatient or home setting. Serious adverse reactions, including death, have been reported after administration of terbutaline to pregnant women. In mothers, these adverse reactions include increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema, and myocardial ischemia. Increased fetal heart rate and neonatal hypoglycemia may occur as a result of maternal administration (1-3).

Most common maternal adverse effects of terbutaline are headache, nausea, tachycardia and palpitations (1). However, more serious maternal adverse effects that can occur include cardiac or cardiopulmonary arrhythmias, pulmonary edema, myocardial ischemia, hypotension and



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tachycardia. Further, serious fetal adverse effects including fetal tachycardia, hyperinsulinemia, hyperglycemia, myocardial and septal hypertrophy, and myocardial ischemia can also occur as result of terbutaline use in a pregnant woman (1-3).

Tocolytic therapy in an outpatient basis is not a covered benefit by the plan.

### **Summary**

Terbutaline is a beta-adrenergic agonist with preferential effects on the beta-2 receptors resulting in smooth muscle relaxation. It is FDA-approved for the treatment or prophylaxis of bronchospasm associated with asthma, bronchitis, and emphysema in patients 12 years old and older (1).

Prior authorization is required for terbutaline to ensure their safe, clinically appropriate, and cost-effective use of while maintaining optimal therapeutic outcomes.

### **References**

1. Terbutaline sulfate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; February 2021.
2. American College of Obstetricians and Gynecologists (ACOG) ACOG Committee Opinion No. 514. Obstet Gynecol. 2011;118(6):1465.
3. American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 43. Management of preterm labor. Obstet Gynecol. 2003;101:1039-1047.