Tocolytics

Description

Tocolytics (terbutaline, magnesium sulfate injection)

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).

Magnesium sulfate plays an important role in neurochemical transmission and muscular excitability. Magnesium sulfate remains the drug of choice for seizure prophylaxis in severe preeclampsia and for control of seizures in eclampsia (2).

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 (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 (4).
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 (5).

FDA approved indications: Magnesium sulfate is indicated for: (6)

- **Convulsions** (treatment) - Intravenous Magnesium Sulfate is indicated for immediate control of life-threatening convulsions in the treatment of severe toxemias (pre-eclampsia and eclampsia) of pregnancy and in the treatment of acute nephritis in children.

- **Hypomagnesemia** (prophylaxis and treatment) - Magnesium Sulfate is indicated for replacement therapy in magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those of hypocalcemia.

- **Prevent or treat magnesium deficiency** in patients receiving total parenteral nutrition.

- **Tetany, uterine** (treatment) - Magnesium Sulfate is indicated in uterine tetany as a myometrial relaxant.

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 (5).

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 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 (3).

Most common adverse effects of magnesium sulfate include flushing, lethargy, hypotension and muscle weakness. More serious maternal effects include pulmonary edema and cardiac arrest.
The fetal adverse effects are similar to the maternal effects, which includes respiratory depression and demineralization with prolonged use (3).

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

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Terbutaline and magnesium sulfate may be considered medically necessary for indications other than preterm labor.

Terbutaline and magnesium sulfate may be considered investigational for tocolysis therapy.

Prior-Approval Requirements

Age
Terbutaline: 12 years of age or older
Magnesium Sulfate: All ages

Diagnoses
Patient must have the following:
Diagnosis other than preterm labor

Prior – Approval Renewal Requirements

Diagnoses
Patient must have the following:
Diagnosis other than preterm labor

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity
Unlimited
Duration 12 months

Prior – Approval Renewal Limits

**Quantity** Unlimited  
**Duration** 12 months

Rationale

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. Magnesium sulfate plays an important role in neurochemical transmission and muscular excitability (1).

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

References


Policy History

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<td>December 2012</td>
<td>Annual editorial review and update.</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2016 and is effective on October 1, 2016.

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