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5.30.006

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	January 13, 2012
Subject:	Tocolytics	**Page:**	1 of 4

Last Review Date: December 13, 2024

Tocolytics

Description

Terbutaline

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 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.

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 may be considered **medically necessary** for indications other than preterm labor.

Terbutaline may be considered **investigational** for tocolysis therapy.

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have the following:

1. Diagnosis **other than** preterm labor

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

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 (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.

Policy History

Date	Action

December 2012	Annual editorial review and update.
September 2014	Annual editorial review and update. Addition of FDA boxed warning.
January 2015	Removal of Standard Allowance and the addition of oral terbutaline
March 2015	Annual editorial review and reference update
September 2016	Annual editorial review Addition of the statement of tocolytic therapy in an outpatient basis is not a covered benefit by the plan Policy number changed from 5.07.06 to 5.30.06
January 2017	Removal of Magnesium sulfate from criteria
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
December 2019	Annual review
December 2020	Annual review
December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.30.006
December 2023	Annual review
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.