APPENDIX to Tocolysis with Intravenous or Subcutaneous Terbutaline Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Despite the numerous management methods proposed, according to the American College of Obstetricians and Gynecologists (ACOG, 2008), the incidence of preterm birth has changed little over the past 40 years. Tocolytic drugs may only prolong gestation for two to seven days. However, delay of preterm delivery does allow further fetal development and may preclude the complications of preterm delivery, especially neonatal respiratory distress syndrome. Even a short-term delay of delivery is thought to be beneficial in that it allows treatment of the mother with corticosteroids, which has proven beneficial in ameliorating the effects of neonatal respiratory distress syndrome. In some cases, a short delay in delivery may also allow transport of the mother to a medical center better equipped to handle premature delivery and provide neonatal intensive care. Tocolytic agents include beta mimetics, magnesium sulfate, ethanol, indomethacin, calcium channel blockers, and various combinations of these drugs. Terbutaline, a beta mimetic, which can be administrated orally, subcutaneously, or intravenously, has been investigated as a first-line tocolytic agent and in maintenance therapy for preterm labor.

Randomized clinical trials (RCTs) have shown that terbutaline is more effective than placebo in inducing tocolysis (Parilla et al., 1995; How et al., 1995; Lewis et al., 1996). However, controlled clinical trials have not focused on the use of intravenous or subcutaneous terbutaline for maintenance tocolysis.

Sanchez-Ramos and colleagues (1999) published a meta-analysis of the efficacy of maintenance therapy after acute tocolysis. Twelve RCTs of tocolytic maintenance therapy were evaluated; three of these trials used subcutaneous tocolytic therapy, the rest used oral therapy. No overall benefit of maintenance tocolysis was seen for the following outcomes: decreased risk of recurrent preterm labor, increased mean gestational age at delivery, or improved birth weight. The meta-analysis did show a prolongation of the mean number of days gained in patients receiving maintenance tocolysis. However, this prolongation did not result in improved perinatal outcomes. The authors concluded that the meta-analysis did not support routine administration of maintenance tocolytic treatment after acute treatment halted preterm labor.

Berkman and colleagues (2003) published a review on the role of tocolytics in the management of preterm labor and also found no improvements in birth or infant outcomes with maintenance tocolytics when compared to placebo. For first-line tocolysis, the review concluded there were small improvements in prolonging pregnancy and in term births. However, the data did not show any direct beneficial effects on neonatal morbidity and mortality. In addition, a 2005 meta-analysis by Thornton also concluded the evidence was insufficient to support the use of maintenance tocolysis in preterm labor.

In 2008, ACOG reaffirmed their Clinical Management Guidelines for Obstetricians and Gynecologists: Management of Preterm Labor with the following recommendations:

- There are no clear “first-line” tocolytic drugs to manage preterm labor. Clinical circumstances and physician preferences should dictate treatment.
- Neither maintenance treatment with tocolytic drugs nor repeated acute tocolysis improve perinatal out-come; neither should be undertaken as a general practice.

In summary, intravenous or subcutaneous terbutaline offers some improvement in prolonging pregnancy in the in-patient setting. However, maintenance therapy with intravenous or subcutaneous terbutaline has provided no additional clinical benefit.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
	96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
	96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
	99601	Home infusion/specialty drug administration, per visit (up to 2 hours);
	99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)
HCPC	J3105	Injection, terbutaline sulfate, up to 1 mg
	S9208	Home management of preterm labor, including administrative services, professional pharmacy services, care coordination, and all necessary supplies or equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusion per diem code)
	S9349	Home infusion therapy, tocolytic infusion therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
ICD9 Procedure	None	
ICD9 Diagnosis	640.0	Threatened abortion
	644	Early or threatened labor
	644.03	Threatened premature labor, antepartum
	644.1	Other threatened labor

Type	Number	Description
	644.10	Other threatened labor, unspecified as to episode of care
	644.13	Other threatened labor, antepartum
	644.2	Early onset of delivery
	644.20	Early onset of delivery, unspecified as to episode of care
	644.21	Early onset of delivery, delivered, with or without mention of antepartum condition
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

References

- Berkman ND, Thorp JM Jr, Lohr KN, Carey TS, Hartmann KE, Gavin NI, et al. Tocolytic treatment for the management of preterm labor: a review of the evidence. Am J Obstet Gynecol 2003; 188(6):1648-59.
- How HY, Hughes SA, Vogel RL, Gall SA, Spinnato JA. Oral terbutaline in the outpatient management of preterm labor. Am J Obstet Gynecol 1995; 173(5):1518–22.
- Jones JS, Morrison J, Istwan N, Rhea D, Collins A, Stanziano G. The interval to spontaneous delivery following discontinuation of maintenance tocolysis. J Matern Fetal Neonatal Med 2006; 19(6):331-5.

- Lewis R, Mercer BM, Salama M, Walsh MA, Sibai BM. Oral terbutaline after parenteral tocolysis: a randomized, double-blind placebo-controlled trial. Am J Obstet Gynecol 1996; 175(4 pt 1):834–7.
- Parill BV, Dooley SL, Minogue JP, Socol ML. The efficacy of oral terbutaline after intravenous tocolysis. Am J Obstet Gynecol 1995; 169(4):965–9.
- Sanchez-Ramos L, Kaunitz AM, Gaudier FL, Delke I. Efficacy of maintenance therapy after acute tocolysis: a meta-analysis. Am J Obstet Gynecol 1999; 181(2):484-90.
- Thornton JG. Maintenance tocolysis. BJOG 2005; 112(suppl 1):118-21.

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
9/13/1989	BCBSA Medical Policy adoption	Medical Policy Committee
10/7/1992	Administrative Review	Medical Policy Committee
1/12/2002	Administrative Review	Medical Policy Committee
7/12/2002	Administrative Review	Medical Policy Committee
9/25/2009	Policy Title Revision, criteria revised	Medical Policy Committee
10/1/2010	Criteria Revised	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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