


<b>MEDICAL POLICY STATEMENT</b>		
Effective Date	Next Annual Review Date	Last Review / Revision Date
5/2005	7/2012	7/2011
<b>Author</b>		
James Foster, MD		



CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

## **A. SUBJECT**

Tocolysis Policy

## **B. BACKGROUND**

Tocolysis in the physician directed intervention wherein medications are prescribed for the treatment of pre-term labor (PTL). PTL is a well recognized antepartum complication that may result in the delivery of a pre-term infant and result in significant morbidity and mortality to the infant. Examples are fetal demise, bronchopulmonary dysplasia, retinopathy of prematurity, necrotizing enterocolitis, etc.

There are multiple medications that have been used by the obstetrical community to diminish or eliminate PTL:

1. Prostaglandin Synthetase Inhibitors: Prostaglandins facilitate uterine smooth muscle contraction. Indomethacin (Indocin) inhibits these prostaglandins. These inhibitors have multiple serious side effects to both mother and the neonate.
2. Calcium (CA++) Channel Blockers: These medications also relax uterine smooth muscles. However, multiple cardiac and hypotensive side effects are common. An example is nifedipine (Procardia).
3. Beta (β) adrenergics: β adrenergics decrease the effect of calcium's role in uterine smooth muscle contraction. Ritodrine is the only FDA-approved tocolytic, but is seldom used by OB practitioners because of expense and adverse side effects. The most commonly used β adrenergic is terbutaline.
4. Magnesium Sulfate: MGSO<sub>4</sub> competes with calcium for entry into the calcium channels of the myometrium for contraction.

Of all the above tocolytics, the most commonly used agent is terbutaline. Terbutaline is a β mimetic approved by the FDA for asthma treatment. According to the FDA, the safety and effectiveness of terbutaline as a tocolytic has not been established.

Based upon published literature, the demonstrated value of tocolytic therapy is limited to an initial brief period of treatment, probably no longer than 48 to 72 hours. In addition, the safety of long term subcutaneous terbutaline for tocolysis has not been addressed. The medical literature regarding terbutaline tocolysis is conflicting and still in question. Several studies

advocate terbutaline tocolysis while others do not. A 1998 article in the American Journal of OB-GYN concluded that “Maintenance terbutaline therapy by infusion pump does not prolong gestation in women with PTL.”

Subcutaneous tocolytic therapy can be delivered by a small external infusion pump programmed to deliver terbutaline doses based upon the levels of uterine contractile activity.

## **C. POLICY**

---

**For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).**

There is no evidence that tocolytics reduce the risk of pre-term delivery. In addition, the literature concludes that even though tocolytics may prolong some pregnancies, they have not been shown to improve perinatal or neonatal outcomes. While the literature debates the efficacy of terbutaline tocolysis, CSMG recognizes the broad based and longstanding acceptance of tocolysis modalities (including terbutaline tocolysis) by the organized OB medical community.

As a broad concept, CSMG considers the use of a terbutaline pump for administration of subcutaneous terbutaline to be investigational and not medically necessary in the prevention of premature labor. Exceptions will be considered only in cases that result in repeat hospitalizations and where there are other compelling clinical conditions to warrant a trial of tocolytics.

**If there is no LCD or NCD present reference the CSMG Policy for coverage.**

## **D. REVIEW / REVISION HISTORY**

---

Date Issued: 5/2005  
Date Revised: 7/2007  
Date Reviewed: 7/2009, 7/1/2011

## **E. REFERENCES**

- 
1. American Journal of Obstetrics & Gynecology : 1998; 179:874-8. Guinn et al. Terbutaline pump maintenance therapy for prevention of pre-term delivery; a double-blind trial.
  2. American Journal of Perinatology: 1997; 14:87-91. Wenstrom et al. A placebo controlled randomized trial of the terbutaline pump for prevention of pre-term delivery.
  3. Institute for Clinical Systems Improvement: Technology Assessment Report: Tocolytic Therapy for Preterm Labor. March, 2000
  4. Clinical Perinatology. December, 2003 (4): 841-54
  5. ACOG Practice Bulletin # 43, May 2003

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.