Home Parenteral Tocolytic Therapy

[NOT COVERED FOR ANY LINE OF BUSINESS]

Medical Policy: MP-RX-06-09
Original Effective Date: March 26, 2009
Revised: June 10, 2015
Next Revision: July, 2016

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Tocolytic therapy is the use of pharmacologic agents to inhibit uterine contractions in preterm labor. A few classes of pharmacologic agents have been studied for their potential role in tocolysis. Betamimetic Tocolytic drugs including terbutaline, ritodrine, and others have been widely used as tocolytics for many years. These agents are structurally related to epinephrine and norepinephrine, and act to relax smooth muscle. The most commonly used β-mimetic in the United States is terbutaline (marketed as drug for asthma). Ritodrine was approved by the FDA as a parenteral Tocolytic in 1980, but it did not become widely used because of frequent maternal side effects.

In February 2011, the US Food and Drug Administration (FDA) required the addition of a new Black Box Warning and contraindication to the terbutaline prescribing information to warn about the risk of use for preterm labor. The decision was based on reports of death and serious adverse reactions, including tachycardia, transient hyperglycemia, hypokalemia, arrhythmias, pulmonary edema, and myocardial ischemia following prolonged the administration of oral or injectable terbutaline to pregnant women. The FDA concluded that the risk of serious adverse events outweighs any potential benefit to pregnant women receiving prolonged treatment with terbutaline injection (> 48 - 72 h) or acute or prolonged treatment with oral terbutaline.

The American College of Obstetricians and Gynecologists (ACOG), through a Clinical Management Guideline for Obstetrician-gynecologists on the management of preterm labor (ACOG, 2012) states for tocolytic therapy that:

- The evidence supports the use of first-line tocolytic treatment with beta-adrenergic agonist therapy, calcium channel blockers, or NSAIDs for short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal steroids.

- Maintenance therapy with tocolytics is ineffective for preventing preterm birth and improving neonatal outcomes and is not recommended for this purpose.

While agents other than terbutaline may be considered for tocolytic therapy, this Coverage Position focuses on the use of terbutaline administered subcutaneously, continuously and/or intermittently via an infusion pump.
COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

INDICATIONS

Medical Card System, Inc., (MCS) DOES NOT consider medically necessary the use of Home Parenteral Tocolytic Therapy for the prevention or treatment of preterm labor for the following reasons:

- It is considered investigational and not safe for the prevention or treatment of preterm labor in the home setting.

CONTRAINDICATIONS/LIMITATIONS

1. Injectable terbutaline should not be used in pregnant women for prevention or prolonged treatment (beyond 48 to 72 hours) of preterm labor in either the hospital or outpatient setting because of the potential for serious maternal heart problems and death.

2. Oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has similar safety concerns.

CODING INFORMATION

HCPCS CODES (List may not be all inclusive)

<table>
<thead>
<tr>
<th>HCPCS® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>J3105</td>
<td>Injection, terbutaline sulfate, up to 1 mg</td>
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<tr>
<td>S9349</td>
<td>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</td>
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ICD-9 CM® Diagnosis Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD-9 CM® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>644.03</td>
<td>Threatened premature labor, antepartum condition or complication.</td>
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</table>

ICD-10 Codes (Preview Draft)
In preparation for changes in the coding systems from ICD-9 to ICD-10, this policy includes a sample list of ICD-10 codes for your reference. These codes may become subject to changes or modifications since they will be in effect on October 1, 2015.

<table>
<thead>
<tr>
<th>ICD 10 CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>O60.02</td>
<td>Preterm labor without delivery, second trimester</td>
</tr>
<tr>
<td>O60.03</td>
<td>Preterm labor without delivery, third trimester</td>
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</tbody>
</table>

REFERENCES


POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
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<tr>
<td>March 23, 2009</td>
<td>Origination of Policy</td>
<td>Service remains NON-COVERED FOR ALL LINES OF BUSINESS. FDA published new warning for this medication for indication for the prevention or treatment of preterm labor.</td>
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</tbody>
</table>
| June 01, 2011   | Yearly Review | References updated. Added new references: numbers 3, 4, & 10-15. To the Description Section:  
• Deleted: The American Congress of Obstetricians and Gynecologists (ACOG) through a Clinical Management Guideline for Obstetrician-gynecologists on the management of preterm labor states, originally in 2003 and then reaffirmed in 2011, that: Neither maintenance treatment with tocolytic drugs nor repeated acute tocolysis improve perinatal outcome; neither should be under taken as a general practice. Tocolytic therapy may prolong gestation for 2-7 days, which can provide time for the administration of steroids and maternal transport to a facility with intensive care unit.  
• Added: The American College of Obstetricians and Gynecologists (ACOG), through a Clinical Management Guideline for Obstetrician-gynecologists on the management of preterm labor (ACOG, 2012) states for tocolytic therapy that: The evidence supports the use of first-line tocolytic treatment with beta-adrenergic agonist therapy, calcium channel blockers, or NSAIDs for short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal steroids. Maintenance therapy with tocolytics is ineffective for preventing... |
| July 9, 2012    | Yearly Review | References updated. Added new references: numbers 3, 4, & 10-15. To the Description Section:  
• Deleted: The American Congress of Obstetricians and Gynecologists (ACOG) through a Clinical Management Guideline for Obstetrician-gynecologists on the management of preterm labor states, originally in 2003 and then reaffirmed in 2011, that: Neither maintenance treatment with tocolytic drugs nor repeated acute tocolysis improve perinatal outcome; neither should be under taken as a general practice. Tocolytic therapy may prolong gestation for 2-7 days, which can provide time for the administration of steroids and maternal transport to a facility with intensive care unit.  
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| June 26, 2013   | Revised | References updated. Added new references: numbers 3, 4, & 10-15. To the Description Section:  
• Deleted: The American Congress of Obstetricians and Gynecologists (ACOG) through a Clinical Management Guideline for Obstetrician-gynecologists on the management of preterm labor states, originally in 2003 and then reaffirmed in 2011, that: Neither maintenance treatment with tocolytic drugs nor repeated acute tocolysis improve perinatal outcome; neither should be under taken as a general practice. Tocolytic therapy may prolong gestation for 2-7 days, which can provide time for the administration of steroids and maternal transport to a facility with intensive care unit.  
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Clinical Medical Policy Department
Clinical Affairs Division

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<th>Date</th>
<th>Action</th>
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<td>August 7, 2013</td>
<td>Reviewed</td>
<td>References updated.</td>
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<tr>
<td>February 21, 2014</td>
<td>Revised</td>
<td>To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.</td>
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<td>July 01, 2014</td>
<td>Revised</td>
<td>References Updated: To the References Section: References #14 and 17 were added to the Policy.</td>
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<tr>
<td>June 10, 2015</td>
<td>Revised</td>
<td>References Updated.</td>
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This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Medical Card System, Inc., (MCS) medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Medical Card System, Inc., (MCS) reserves the right to review and update its medical policies at its discretion. Medical Card System, Inc., (MCS) medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.