



TERBUTALINE SUBCUTANEOUS PUMP FOR TREATMENT OF PRETERM LABOR HS-015



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

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WellCare Prescription Insurance, Inc.

Terbutaline Subcutaneous Pump for Treatment of Preterm Labor

Policy Number: HS-015

Original Effective Date: 3/14/2008

**Revised Date(s): 6/25/2009; 6/25/2010;
8/2/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Preterm birth, in which an infant is born before 37 weeks gestation, occurs in approximately 12% of pregnancies in the United States leading to approximately 75% of neonatal deaths and 50% of long-term neurological disorders. Since preterm labor poses such serious risks, many strategies have been developed for its treatment including bed rest, avoidance of intercourse, preventative suturing to hold the uterus closed, treatment of bacterial vaginal infections, and use of various drugs. Treatments for preterm labor can generally be classified as acute therapies, those performed in the hospital in an effort to prevent imminent preterm birth, and long-term or maintenance therapies, which are usually administered on an outpatient or home-care basis to prevent a recurrence of preterm labor.

Although the Food and Drug Administration approved terbutaline for treatment of asthma, not preterm labor, subcutaneous infusion of this drug has been evaluated as a long-term or maintenance therapy for preterm labor. Terbutaline is administered using a pump that supplies a steady, continuous dose and that can also provide bolus infusions if needed in response to an increase in uterine contractions. The more recent studies of subcutaneous terbutaline infusion have involved rather intensive guidance and supervision of home treatment including the following: individualized dosage schedules, home uterine activity monitoring, regular changes in the site of subcutaneous infusion, and daily phone calls from nursing staff. Average duration of infusion ranges from 4 to 7 weeks; however, some patients may require more than 10 weeks of this treatment (Hayes, 2008).

Pump Systems

Terbutaline is sold under the brand names Brethine® (AIPharma Inc.) and Bricanyl® (AstraZeneca Pharmaceutical LP) and as generic terbutaline sulfate (Sicor Pharmaceuticals Inc.; Bedford Laboratories Inc.; and other manufacturers not listed here). The list of pumps suitable for subcutaneous terbutaline infusion is too long for inclusion here; however, the units used in the reviewed studies were MiniMed® pumps (Medtronic MiniMed Inc.) and Disetronic® pumps (Disetronic Medical Systems Inc.).

POSITION STATEMENT

The use of a subcutaneous terbutaline microinfusion pump for the treatment of preterm labor **is considered experimental and investigational and is not considered a covered benefit.**

CODING

Covered CPT® Codes

99601 Home infusion/specialty drug administration, per visit (up to 2 hours)

99602+ each additional hour
+(List separately in addition to code for primary procedure)

ICD-9-CM Procedure Code No applicable code

Covered HCPCS Code

J3105 Injection, terbutaline sulfate, up to 1 mg

E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater

E0780 Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours

- E0781** Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
- 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

Covered ICD-9-CM Description Diagnosis Codes

644.03 Threatened premature labor; Gestational age is between 24 and 34 weeks;

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Ambrose, S., Rhea, D.J., Istwan, N.B., Collins, A., & Stanziano, G. (2004). Clinical and economic outcomes of preterm labor management: inpatient vs. outpatient. *Journal of Perinatology*, 24, 515-519.
2. Hayes Directory. (2008, September 9). Continuous subcutaneous terbutaline infusion for treatment of preterm labor. Retrieved from <http://www.hayesinc.com>

Government Agencies, Professional and Medical Organizations

1. American College of Obstetricians and Gynecologists. (2003). ACOG practice bulletin (no. 43): management of preterm labor. Retrieved from <http://www.nubc.org/public/pubagenda/ACOG%20Mgmt%20of%20PTL%20Bulletin.pdf>
2. Institute for Clinical Systems Improvement. (2007, March). Management of labor.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/2/2011	<ul style="list-style-type: none">• Approved by MPC.