



Easy Choice Health Plan

Missouri Care

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

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Terbutaline Subcutaneous Pump for Treatment of Preterm Labor (E/I)

Policy Number: HS-015

Original Effective Date: 3/14/2008

Revised Date(s): 6/25/2009; 6/25/2010;
8/2/2011; 4/5/2012; 2/7/2013; 2/6/2014;
2/5/2015; 2/4/2016; 2/2/2017; 1/4/2018;
1/10/2019

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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Preterm birth (an infant 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.¹

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.¹

Pump Systems

Terbutaline is sold under the brand names Brethine® (AAlPharma 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.).

Professional Organizations¹

An American College of Obstetrics and Gynecology (ACOG) evidence-based Practice Bulletin states that tocolytic drugs do not seem to prolong pregnancy more than 2 to 7 days, and the only clear benefits of this treatment are to provide time for administration of steroids and transport to a facility with a neonatal intensive care unit. Further, long-term or maintenance tocolytic therapy was not effective.²

The Institute for Clinical Systems Improvement (ICSI) published guidelines for the management of preterm labor, stating that several well-designed studies have concluded that terbutaline administered by infusion pump may be a safe and effective treatment option for the prolongation of pregnancy. In addition, due in part to the poor quality of existing research, there continues to be debate in the medical literature concerning safety and efficacy.³

The Institute of Medicine of the National Board on Health Sciences Policy (IOM) publication *Preterm Birth: Causes, Consequences, and Prevention* states that chronic tocolytic administration has not been useful for long-term maintenance of contraction inhibition, and in most studies has not improved perinatal outcomes, although its use does allow time for the administration of corticosteroids and maternal transfer to an appropriate hospital.⁴

POSITION STATEMENT

Applicable To:

- Medicaid

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

Non-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)

Non-Covered HCPCS Codes

- 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
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

Non-Covered ICD-10-CM Diagnosis Codes

- O60.10X0 - O60.10X9** Preterm labor with preterm delivery, unspecified trimester
O60.12X0 - O60.12X9 Preterm labor second trimester with preterm delivery second trimester
O60.13X0 - O60.13X9 Preterm labor second trimester with preterm delivery third trimester
O60.14X0 - O60.14X9 Preterm labor third trimester with preterm delivery third trimester

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Continuous subcutaneous terbutaline infusion for treatment of preterm labor. Hayes Directory Web site. <http://www.hayesinc.com>. Published May 17, 2011 (archived on June 17, 2016). Accessed December 30, 2018.
2. ACOG practice bulletin (no. 159): management of preterm labor. American College of Obstetricians and Gynecologists Web site. Published January 2016. Accessed January 29, 2016. *Obstet Gynecol* 2016;127:e29–38 (Interim Update) .
3. Management of labor. Institute for Clinical Systems Improvement (ICSI) Web site. https://www.icsi.org/guidelines_more/catalog_guidelines_and_more/catalog_guidelines/catalog_womens_health_guidelines/labor_mgmt/. Published March 2013. (Retired May 2018) Accessed December 30, 2018.
4. Behrman RE, Butler AS, eds; Institute of Medicine of the National Academies (IOM) Committee on Understanding Premature Birth and Assuring Healthy Outcomes. *Preterm Birth: Causes, Consequences, and Prevention*. 2007. National Academies Press [website]. Available at: http://books.nap.edu/catalog.php?record_id=11622. Accessed December 30, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
1/10/2019, 1/4/2018, 2/2/2017, 2/5/2015, 2/6/2014, 2/7/2013	<ul style="list-style-type: none"> • Approved by MPC. No changes.
4/5/2012	<ul style="list-style-type: none"> • Approved by MPC. Added Hayes (2011) reference providing statements from ACOG, ICSI, IOM citing lack of research proving safety and efficacy.
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.