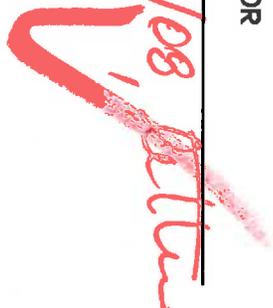


**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR**

**ACTION REFERRAL**

<b>TO</b> <i>Migens</i>	<b>DATE</b> <i>1-8-08</i>
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<b>DIRECTOR'S USE ONLY</b>	<b>ACTION REQUESTED</b>
1. LOG NUMBER  <b>000332</b>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <i>Cleaveland 1/3/08</i> <i>at the Dept</i> 	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>1-18-08</i>  <input type="checkbox"/> FOIA DATE DUE _____  <input type="checkbox"/> Necessary Action

<b>APPROVALS</b> <small>(Only when prepared for director's signature)</small>	<b>APPROVE</b>	<b>* DISAPPROVE</b> <small>(Note reason for disapproval and return to preparer.)</small>	<b>COMMENT</b>
1.			
2.			
3.			
4.			



RECEIVED

January 3, 2008

JAN - 8 2008

MEDICAL SERVICES  
DHHS



JAN 0 8 2008

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Ms. Felicity Myers  
Deputy Director  
Bureau of Health Services  
South Carolina Medicaid  
P.O. Box 8206  
Columbia, SC 29202-8206

Dear Ms. Myers:

Thank you for your letter dated December 20, 2007 concerning coverage of the HUAM Services.

However, we were attempting to address our Terbutaline Pump Home Therapy which includes coverage of the HUAM Equipment (see enclosure). We would like to have some dialogue with you before you make a final decision and publish your changed policy in your Medicaid Bulletin.

I have also included some information for you and your department to review about our Terbutaline Pump Therapy that is currently being reimbursed at an all inclusive rate of \$210 per day. Matria would again reiterate that we are classified as DME in South Carolina and Infusion Therapy in North Carolina. Please consider the difference in billing guidelines under HIPPA and CMS when reviewing this letter.

Matria Healthcare has a long history of saving the State of South Carolina Medicaid dollars and proving great clinical outcomes for pregnant Medicaid beneficiaries. We would like to continue our partnership with the State and help you to address the cost and clinical outcome for high-risk pregnancies.

Sincerely,

Stan Watson  
Vice President of Government Affairs  
Matria Healthcare, Inc.

Enclosures

cc: Honorable Michael I. Fair  
Honorable Harvey S. Peeler  
Honorable Leon Howard  
Honorable Kay Patterson  
O. Marion Burton, MD  
Mr. Jim Assey

log in please

Dr Burton  
draft response  
w/ consult  
w/ B2 + Jim Assey.  
Thx  
Felicity



**Stan Watson**  
Vice President of Government Affairs

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www.matria.com

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(770) 767-7809 (Fax)  
stan\_watson@matria.com

**THE HEALTH ENHANCEMENT COMPANY**

## **Home Infusion Therapy for Preterm Labor**

Treatment would include home infusion therapy, tocolytic infusion therapy, administrative services, pharmacy services, drugs, nursing visits, care coordination, all supplies, equipment and telephonic care coordination.

### **Definition of Preterm Labor**

Preterm labor is defined by regular uterine contractions and cervical changes.

### **Authorized Provider**

Providers that are authorized to perform this treatment shall be restricted to the following:

DME – Durable Medical Equipment Provider

HH – Home Health Provider

HIT – Home Infusion Therapy Provider

These providers would be authorized to bill Medicaid under HCPCS Code S9349 at an all inclusive per-diem rate of (\$230 - \$260 average) daily. Managed Medicaid Plans may provide this therapy on a contractual basis.

### **Department Authorization**

All requests for this service shall be submitted to the South Carolina Department of Medicaid for prior authorization. Request shall include a signed plan of treatment and a statement of medical necessity. For reimbursement providers shall show that the following services were provided:

- Initial assessments by a Registered Nurse (RN) with high-risk obstetrical experience. The initial assessment may be conducted in the hospital or in the patient's home.
- Additional RN assessments as ordered by the patient's physician.
- Additional components as ordered by the physician, including, but not limited to blood pressure and pulse monitoring, assessment, weight analysis, diabetes screening and dietary assessment.
- Initial and ongoing nurse education of the patient regarding pre-term labor, pregnancy, care plan objectives, data collection activities, uterine monitoring devices, infusion pump and supplies to be used.
- Ongoing reinforcement of the patient regarding pre-term labor and management with subcutaneous tocolytic therapy (plan of treatment)
- Patient education materials related to pre-term labor, tocolytics, subcutaneous infusion therapy, use of infusion pump and uterine monitoring device.
- Provision and delivery of tocolytic medication and related supplies and equipment as needed.

- Patient telephonic nursing assessments with nursing and pharmacy support 24 hours a day, seven days a week, in accordance with all applicable state and federal laws, rules and regulations, and agency policy.
- Routine clinical status and update reporting to the physician. Weekly, written updates, and as requested by the patient's physician. Verbal updates per changes in the patient's clinical status.
- Daily and "as needed" data transmission to the patient service center.
- Routine and "as needed" contraction and vital signs data collected by the patient and reported to the physician, based upon changes in the patient's status, symptom management and the physician's plan of treatment.

#### Patient Criteria

Each patient's condition must be individually evaluated by the physician providing treatment. Services may only be initiated for individuals who are currently hospitalized with pre-term labor; this is not preventative treatment.

All of the following indications must be presented to obtain prior authorization for the use of home tocolytic therapy:

- The gestational age is between 24 weeks, 0 days and 35 weeks, 9 days.
- There is a single or multiple fetus pregnancy.
- The patient is currently in the hospital requiring intravenous tocolytic therapy for pre-term labor as defined by regular uterine contractions and cervical change (documented by physical and/or transvaginal ultrasound exam) as:
  - A change in cervical dilation or effacement or cervical length; or
  - Cervical dilation >2 centimeters (cm) and effacement  $\geq$  75 percent; or
  - Cervical length <2.5 cm.
- Failed oral tocolytic therapy was prescribed by the treating physician, as evidence by recurrence of contractions or cervical change (defined above).
- The patient is stable for discharge as judged by the treating physician.
- The patient is a suitable candidate for home care services including the ability to understand operation of the infusion pump and infusion site care, a suitable home environment including telephone and the ability to communicate with the specialized obstetric nurse over the telephone.

### Contraindications / Exclusions

None of the following contraindications may be present to obtain prior authorization for the use of home tocolytic therapy:

- Current maternal or fetal indication for delivery
- Evidence of fetal compromise or placental insufficiency
- Ruptured membranes
- Active vaginal bleeding
- Evidence of suspected chorioamnionitis
- Preeclampsia
- Lethal congenital or chromosomal abnormalities
- Maternal or fetal contraindications to the use of terbutaline
- Known drug allergy to terbutaline

### Fiscal Effect

This therapy will change health outcome associated with preterm labor, infant mortality and morbidity therefore reducing Medicaid expenditures such as costly pregnancy hospitalization and Neonatal Intensive Care Unit (NICU) stays. Some states and health plans utilizing this treatment has reported that there was a savings of \$4.67 in total pregnancy cost. That means that for every dollar spent on this therapy there is a return on investment (ROI).

- Preterm birth is the leading cause of neonatal mortality in the U.S. and preterm labor precedes 40% to 50% of preterm births.
- 48% of all preterm births in the U.S. occur in the Medicaid population.
- Medicaid is the single largest form of health coverage in the U.S.

**Matria's System of Care**  
**Subcutaneous Tocolytic Therapy (PUM 100)**  
**(S-9349)**

*Includes: Administrative, Professional Pharmacy, Care Coordination, Nursing, Equipment, Supplies, and Drug.*

<b>DESCRIPTION OF SERVICE COMPONENT</b>	<b>ITEMS INCLUDED IN THE DAILY PERDIEM: (S230)</b> <i>Patient Medication Usage Dependent on Dosage</i>
<b>1. DRUG: Terbutaline</b>	<b>ITEMS INCLUDED IN THE DAILY PERDIEM:</b> <i>Patient Medication Usage Dependent on Dosage</i> Fees include the medication, syringes and all deliveries of medication to the patient's home.
<b>2. SUPPLIES: Subcutaneous administration supplies.</b>	<u>Supply kit include:</u> <ul style="list-style-type: none"> <li>- Infusion Sets</li> <li>- Pump Batteries</li> <li>- Shower protector for the Pump</li> <li>- Alcohol wipes</li> </ul>
<b>3. EQUIPMENT:</b> <b><i>Ambulatory Micro-Infusion Pump</i></b>  <b><i>Home Uterine Activity Monitor</i></b>	<u>Pump:</u> <ul style="list-style-type: none"> <li>- Daily Pump Rental</li> <li>- Trouble shooting and Maintenance</li> <li>- Replacement Parts, if necessary.</li> </ul> <u>Home Uterine Activity Monitor:</u> <ul style="list-style-type: none"> <li>- Proprietary home uterine activity monitoring device. Disposable belts to secure sensor.</li> <li>- Automated blood pressure cuff for all multiple gestation patients</li> </ul>
<b>4. PATIENT EDUCATION</b>	<u>Education Materials:</u> <ul style="list-style-type: none"> <li>- Proprietary education binder ("Perinatal Expectations") with comprehensive education materials specific to high-risk pregnancy.</li> </ul>

<p><b>5. CARE COORDINATION NURSING:</b> <i>Initial and as needed skilled nursing visit (s)</i></p>	<p><u>Nurse Home Visit:</u></p> <ul style="list-style-type: none"> <li>- Extended nurse visit conducted by high risk obstetrical experienced RN</li> <li>- Education of the patient on signs and symptoms of preterm labor, care plan objectives, data collection activities and monitoring devices to be used.</li> <li>- Compliance assessment including home assessment</li> </ul> <p><u>Routine nurse Assessment /Intervention:</u></p> <ul style="list-style-type: none"> <li>- Assessment signs and symptoms of preterm labor</li> <li>- Education on effects of medication/Assessment of side effects</li> <li>- Daily assessment of pulse values</li> <li>- Evaluate nutritional status</li> <li>- Physical systems assessment</li> <li>- Daily evaluation of uterine activity</li> <li>- Psychosocial assessment</li> <li>- Infusion site assessment</li> <li>- Home visits if necessary for site care</li> <li>- Weekly outcomes collections and reporting</li> </ul>
<p><b>6. CARE COORDINATION NURSING:</b> <i>Daily uterine activity surveillance and coordination of equipment and supplies</i></p>	<ul style="list-style-type: none"> <li>- Terbutaline pump therapy is titrated based on individualized patient response to the medication and identification of side effects associated with the therapy. Highly skilled perinatal clinicians with a minimum of 3 years of high-risk obstetrical experience are available to the patient 24 hours a day, 7 days a week. These nurses collect and analyze this data, collaborate with the clinical pharmacist, dietician, case manager, and physician in order to adjust patient's plan of care.</li> <li>- Prompt identification of symptoms and intervention in order to avoid <b>short-term hospitalizations and preterm delivery.</b></li> <li>- Equipment: Home uterine activity device, automated blood pressure cuff as ordered. Proprietary education binder ("Perinatal Expectations") with comprehensive education materials specific to high-risk pregnancy.</li> <li>- Coordination of all deliveries of equipment and supplies.</li> </ul>
<p><b>7. PROFESSIONAL PHARMACY:</b> <i>Clinical pharmacists</i></p>	<ul style="list-style-type: none"> <li>- Specialized clinical pharmacists available 24 hours a day, 7 days a week</li> <li>- Review of patient's daily status and response to tocolytic therapy.</li> <li>- Initial consultation and ongoing recommendation/modification to dosages based on gestational age, parity, concomitant medication regime, uterine activity, cervical status, drug side effects, etc.</li> </ul>
<p><b>8. ADMINISTRATIVE:</b> <i>Reporting and billing</i></p>	<p>Includes:</p> <ul style="list-style-type: none"> <li>- Prior authorization requirements</li> <li>- Weekly reports to case managers and physicians</li> <li>- Annual outcome report and cost benefits analysis</li> <li>- Claims submissions and collections</li> </ul>

**SERVICES ARE ALL INCLUSIVE**

Log # 332



*State of South Carolina*  
*Department of Health and Human Services*

Mark Sanford  
Governor

Emma Forkner  
Director

January 3, 2008

Mr. Stan Watson  
Vice President of Government Affairs  
Matria Healthcare  
1850 Parkway Place, 6<sup>th</sup> Floor  
Marietta, GA 30067

Dear Mr. Watson:

Thank you for corresponding regarding your company's Terbutaline Pump Service. Our obstetrical colleagues in South Carolina greatly value this service for their high risk pregnancies who meet the criteria for its use. I have long admired the excellent nursing support that accompanies this intervention.

As you indicated, the agency has been reviewing its coverage for this service. In consultation with obstetrical colleagues and Matria professionals, we feel that we have a consensus opinion that the criteria need to be better defined. My staff colleagues at DHHS are relying heavily upon Matria's input for this revision.

Although not involved directly in pricing decisions, I do have some uncertainty about the current level of payment. First, I did not have any information as to how the original value of this service was established in 2001. Further, other pump and/or infusion therapies are priced lower. In addition, our DHHS staff, utilizing data from comparable South Carolina Medicaid beneficiaries who did or did not use the Terbutaline Pump Service, could not validate the clinical and cost benefits outcomes you referenced. Were your outcomes for SC Medicaid beneficiaries compared to data from national comparisons as opposed to control groups of SC Medicaid beneficiaries? Finally, recent national publications indicate that the home uterine monitoring feature of this intervention may not have substantial benefit.

We too would like to continue supporting this very valuable service for our Medicaid beneficiaries and our obstetrical colleagues. We appreciate the support Matria has given us in our further consideration and revision of criteria for its use. If you would like to discuss this further with me please call 803-898-2500 or 803-255-3400.

Sincerely,

A handwritten signature in cursive script, appearing to read "O. Marion Burton".

O. Marion Burton, MD  
Medical Director

OMB/bk