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1.0 Description of the Service

Home tocolytic infusion therapy utilizes a low-dose subcutaneous infusion of a tocolytic agent as a means to prevent preterm labor in pregnant women.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 Recipients with Medicaid for Pregnant Women Coverage

Tocolytic infusion therapy is covered for eligible recipients with regular Medicaid or Medicaid for Pregnant Women.

2.3 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396(d)(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service,

product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does NOT eliminate the requirement for prior approval.
- a. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/medbill/caguide.htm>

EPSDT provider page: <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>

3.0 When the Product, Procedure, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.3** of this policy.

3.1 General Criteria

Medicaid covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

3.2.1 Recipient

The recipient must

- a. have direct access in her home to functional telephone service for necessary contact with the provider agency;
- b. have the ability to communicate with a nurse trained in tocolytic infusion therapy or an obstetrician;

- c. be a suitable candidate for self-administration of injectable medication;
- d. be compliant with the treatment regimen in the home; and
- e. have a home environment suitable for the administration of the infusion.

3.2.2 Medical Necessity

Each recipient's condition must be evaluated on an individual basis by the treating physician. All of the indicators listed below and throughout this section must be present for a recipient to qualify for home tocolytic infusion therapy.

- a. The recipient must be between 24 and 34 weeks' gestation.
- b. The recipient must be experiencing preterm labor and all of the following conditions:
 - 1. Contractions occurring at a frequency of four in 20 minutes or eight in 60 minutes plus progressive changes in the cervix
 - 2. Cervical dilation of greater than 1 cm
 - 3. Cervical effacement of 80% or greater
 - 4. Previous unsuccessful trial of oral tocolytic therapy (continued infusion of the drug is required to stop further progression of preterm labor)
- c. The recipient must be able to operate the infusion pump, care for the infusion site, and maintain the infusion therapy after receiving training.
- d. The recipient must be able to communicate by telephone with either a nurse trained in tocolytic infusion therapy management or an obstetrician.

4.0 When the Procedure, Product, or Service Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see Section 2.3 of this policy.

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the criteria specified in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria

N.C. Medicaid does not cover home tocolytic infusion therapy when one or more of the conditions specified below exist. It is important to note that there may be other indications for non-coverage and that this listing is not all inclusive.

- a. Ruptured membranes
- b. Evidence of suspected chorioamnionitis
- c. Indicated delivery
- d. Undiagnosed second- or third-trimester bleeding
- e. Known drug allergy to the tocolytic agent

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

All services must be prior approved by the Division of Medical Assistance (DMA). However, if conditions warrant, the physician may order therapy to begin on an emergency basis. All of the documentation indicated in **Attachment B** must be provided to DMA within three business days to determine coverage of services. Failure to adhere to this protocol may result in an adverse decision.

- a. The provider must submit a request to DMA on a Tocolytic Prior Approval Referral Form, DMA 3600 (**Attachment B**), that includes the following information:
 1. Recipient's name, date of birth, address, telephone number, and Medicaid identification number
 2. Provider's name, address, telephone number, and Medicaid provider number
 3. Hospital name, address, and telephone number and date(s) of admission and discharge, if applicable
 4. Date of last menstrual period (LMP) or estimated date of confinement (EDC) confirmed by ultrasound
 5. Name of oral tocolytic and start and stop dates for failed oral tocolytic therapy
- b. A documented perinatology consult is required when the ordering physician is not a perinatologist. This documentation may be noted by the perinatologist writing an order for the services.
- c. A physician (perinatologist or obstetrician) letter of medical necessity, along with written orders for the service, is required. Submit a plan of care if available. A verbal order documented by the nurse is acceptable to start the service, but the order must be signed by the physician in accordance with home care licensure rules. A copy of the signed order should be submitted to DMA to be kept on file in the recipient's record.
- d. A copy of current uterine monitoring strips showing frequency of contractions must be submitted with the initial request.

- e. A clinical update must be submitted to DMA every 10 business days to obtain continued authorization for the service.

5.2 Service Components

The per diem rate for the service includes all of the following:

- a. Initial registered nurse (RN) assessment of maternal/fetal environmental and psychosocial factors
- b. Assessment of recipient's ability to recognize and detect signs and symptoms of preterm labor, correctly operate monitoring and infusion devices, and comply with self-care protocols/treatment regimen as defined in the plan of care
- c. Assessments conducted by a RN with high-risk obstetrical experience
- d. Additional RN assessments as ordered by the physician
- e. Additional components as ordered by the physician shall include but not be limited to blood pressure and pulse monitoring, assessment, weight analysis, and dietary assessment
- f. Initial nurse education of the recipient regarding preterm labor, pregnancy, care plan objectives, data collection activities and devices, and infusion pumps to be used
- g. Ongoing reinforcement of recipient regarding preterm labor and management with subcutaneous tocolytic therapy
- h. Recipient education materials related to preterm labor, tocolytics, and subcutaneous infusion therapy
- i. Use of infusion pump and uterine monitoring device
- j. Use of contraction monitor
- k. Cost of tocolytic medication, delivery, and related supplies
- l. Telephonic nursing and pharmacy support 24 hours a day, 7 days a week, in accordance with all applicable laws, rules and regulations, agency policy, and the staff qualifications listed in **Section 6.2**
- m. Routine clinical status reporting to the physician
- n. Daily and "as needed" data transmission to the patient service center
- o. Routine and "as needed" contraction and vital sign data collected by the recipient, based upon changes in recipient status, symptom management, and physician's plan of treatment

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

6.1 Eligible Providers

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program are eligible to bill for procedures, products, and services related to this policy when they are within the scope of their practice.

Specifically, home tocolytic infusion services are provided by a home care agency that

- a. is licensed by the Division of Health Service Regulation (DHSR) and approved to provide infusion nursing services pursuant to 10A NCAC 13J, North Carolina Rules Governing Licensure of Home Care Agencies (and adopted by reference);
- b. meets the Medicaid qualifications for participation as a home infusion therapy (HIT) provider; and
- c. is currently enrolled with the N.C. Medicaid program to provide this service.

6.2 Staff Qualifications

The agency staff must be properly trained and capable of providing the needed services. The services requiring licensed personnel must be provided by staff who are currently licensed by the appropriate North Carolina licensure board.

- a. Pharmacy services must be provided by a registered pharmacist.
- b. Infusion nursing services must be provided by an RN who is trained in tocolytic infusion therapy and in assessment of maternal and fetal status and is directly employed and/or contracted by the HIT agency.
- c. The staff member cannot be the recipient's spouse, child, parent, grandparent, grandchild, or sibling, or be a person with an equivalent step- or in-law relationship to the recipient.
- d. The agency must make all services available 24 hours a day, 7 days a week.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including but not limited to the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

7.2 Communication

The agency must provide routine contacts and reports to the referring physician at a frequency adequate for assessment of the recipient's clinical status as the pregnancy progresses and in accordance with agency policy.

8.0 Policy Implementation/Revision Information

Original Effective Date: September 1, 2006

Revision Information:

Date	Section Revised	Change
11/1/06	Sections 2 through 5	A special provision related to EPSDT was added.
12/1/06	Section 2.3	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0, 4.0, and 5.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2.3, 3.0, and 4.0	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.

Date	Section Revised	Change
7/1/07	Attachment B	Updated the Tocolytic Prior Approval Request Form.
8/1/07	Section 6.1	Changed the name of Division of Facility Services (DFS) to Division of Health Service Regulation (DHSR).
1/1/09	Section 5.1, Attachment B	Updated prior approval requirements to show that DMA is the contact and approver, not CCME.
1/1/09	Throughout	Updated standard language.
8/31/11	Throughout	Policy Termination Date

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

Code	Modifier	Description
S9349	UA	Home infusion therapy, tocolytic infusion therapy

D. Modifiers

Providers are required to follow applicable modifier guidelines.

The UA modifier must be appended to the HCPCS code to indicate that all charges are combined.

E. Billing Units

1 unit = 1 day

F. Place of Service

Recipient's home

G. Co-Payments

Not applicable to HIT program

H. Reimbursement

The service is reimbursed as a daily charge at a per diem rate based on the reasonable cost of providing the care. Providers must bill their usual and customary charges.

1. The service requires prior approval (refer to **Section 5.1**).
2. The per diem for home tocolytic infusion therapy includes the initial on-site nursing assessment and additional obstetrical nursing assessments as ordered by the physician. Refer to **Section 5.2** for a list of service components.
3. The modifier UA is appended to the HCPCS code to indicate that all charges are combined.

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Attachment B: North Carolina Department of Health and Human Services—Division of Medical Assistance
TOCOLYTIC PRIOR APPROVAL REQUEST FORM
Fax to Division of Medical Assistance (DMA) at 919-715-9025.

For Prior Approval questions, contact the DMA HIT Program Consultant at 919-855-4380.

Initial Request

Re-authorization Request

Initial Request: Attach **a)** a copy of the perinatologist's order for tocolytic therapy (or perinatology consult if the ordering MD is not a perinatologist); **b)** the MD letter of medical necessity, which includes frequency of contractions, cervical dilatation, and effacement; **c)** plan of care, if available; **d)** copy of current strips; and **e)** documentation of the recipient's home environment adequacy and her ability to self-perform the therapy.

Reauthorization Request: Attach **a)** a clinical update from the MD; **b)** the nurse's notes from the previous approval period; **c)** documentation supporting infusion therapy administration during previous approval period (start/stop dates, dosage, etc.); and **d)** current strips.

Requested Tocolytic Dates of Service _____ Initial Start Date _____ Initial End Date _____
Re-Auth Start Date _____ Re-Auth End Date _____

Recipient Information

Name _____ Date of Birth _____
Address _____ City _____ Zip Code _____
Home Telephone # _____ MID# _____

Caregiver Information

Name _____ Relationship _____
Address _____ Daytime Phone # _____

Physician Information

Name _____ Office Phone # _____
Address _____
Names & Phone Numbers of Other Physicians Ordering Care
Name _____ Office Phone # _____
Name _____ Office Phone # _____

Provider Agency Information

Agency Name _____ Contact Name _____
Address _____ Provider # _____
Phone # _____ Fax # _____

Medical Information

Diagnoses _____
Gestational Age _____ EDC _____ LMP _____
Hospital Admission No Yes Admit Date _____ Discharge Date _____
Name of Hospital for Above Admission _____
Address _____ Phone # _____
Describe treatment and outcome _____
Failed Oral Tocolytic Therapy No Yes Describe treatment, including start and stop dates _____

Referred By (Name) _____ Title _____
Agency _____ Phone # _____