

	<p>Progesterone Therapy Guidelines</p>	
<p>Guideline # 6198</p>	<p>Categories Clinical → Care Management CM, TCHP Guidelines, Utilization Management UM</p>	<p>This Guideline Applies To: Texas Children's Health Plan</p> <hr/> <p>Document Owner Bhavana Babber</p>

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) requires prior authorization of all 17 alpha-hydroxyprogesterone caproate Progesterone therapy intended to prevent preterm delivery in order to ensure medically appropriate utilization of the medication.

DEFINITIONS:

PRIOR AUTHORIZATION GUIDELINES

1. All requests for prior authorization for 17 alpha-hydroxyprogesterone caproate therapy to prevent preterm delivery are received via online submission fax, phone or mail by the Utilization Management Department and processed during normal business hours.
2. The Utilization Management professional receiving the request evaluates the submitted information to determine if the documentation supports the 17 alpha-hydroxyprogesterone caproate therapy request as an eligible service.
3. To request prior authorization for 17 alpha-hydroxyprogesterone caproate therapy, the following documentation must be provided:
 - 3.1. Patient identifying information
 - 3.2. Documentation of medical necessity
 - 3.3. Prescription information including drug, strength, quantity, directions, and expected therapy duration
 - 3.4. Prescriber information and signature
4. Weekly injections of 17 alpha-hydroxyprogesterone caproate beginning between 16 weeks, 0 days and 26 weeks, 6 days and continuing until 36 weeks and 6 weeks of gestation – for a maximum of 21 doses are considered medically necessary in pregnant women who meet the following criteria:
 - 4.1. Age 16 years and greater; **AND**

- 4.2. A singleton pregnancy; **AND**
- 4.3. A history of a prior spontaneous singleton preterm delivery before 37 weeks gestation due to either of the following:
 - 4.3.1. Spontaneous preterm labor; **Or**
 - 4.3.2. Premature rupture of membranes; **AND**
- 4.4. Treatment is initiated between 16 weeks, 0 days and 26 weeks, 6 days gestation.
- 4.5. Recommended dose is 250mg intramuscular or 275mg subcutaneously once weekly.
5. The following reasons could result in a Denial for medical necessity:
 - 5.1. Age less than 16 years 0 days
 - 5.2. Length of treatment exceeding 21 weeks, 0 days
 - 5.3. Dose greater than 250mg intramuscular or 275mg subcutaneous once weekly
 - 5.4. Medical contraindications including:
 - 5.4.1. Current or history of thrombosis or thromboembolic disorders
 - 5.4.2. Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions
 - 5.4.3. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
 - 5.4.4. Cholestatic jaundice of pregnancy
 - 5.4.5. Liver tumors, benign or malignant, or active liver disease
 - 5.4.6. Uncontrolled hypertension
 - 5.4.7. Allergic reaction to any ingredients in MAKENA - Ingredients: hydroxyprogesterone, castor oil, benzyl benzoate, and benzyl alcohol
 - 5.5. Use for an unapproved indication such as: Amenorrhea, endometrial carcinoma, multifetal gestation, short cervix without history of a preterm birth, testing for endogenous estrogen production, or any diagnosis other than singleton pregnancy in a woman with a history of spontaneous singleton preterm birth.
6. Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.
7. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:

Peer Reviewed Publications:

- How HY, Barton JR, Istwan NB, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? Am J Obstet Gynecol 2007;197:260.e1-260.e4.

Government Agency and Medical Society Publications:

- American College of Obstetricians and Gynecologists (ACOG) Committee Practice Bulletin No. 130. Prediction and prevention of preterm birth. Obstet Gynecol. 2012; 120(4): 964-973.
- Texas Medicaid Provider Procedures Manual Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook May 2021
http://www.tmhp.com/Manuals_HTML1/TMPPM/Current/index.html#t=TMPPM%2F2_Gyne_and_Repro_Health_Srvs%2F2_Gyne_and_Repro_Health_Srvs.htm&rhsearch=hydroxyprogesterone&rhsyns=%20&rhlterm=hydroxyprogesterone

Status	Date	Action
Approved	7/15/2021	Clinical & Administrative Advisory Committee Reviewed and Approved for Implementation

Original Document Creation Date: 10/21/2016	This Version Creation Date: 07/16/2021	Effective/Publication Date: 07/19/2021
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