

<b>Subject: 17 Alpha-Hydroxyprogesterone Caproate (17-P)</b>	
<input type="checkbox"/> Original	<b>Original Committee Approval: 12-12-07</b>
<input checked="" type="checkbox"/> Revised	<b>Last Committee Approval: 12-3-08</b>
	<b>Last Review: November 2007</b>

### **Background:**

Preterm delivery, defined as occurring before 37 weeks gestation, is a leading cause of neonatal morbidity and mortality. Estimated incidence of preterm delivery is between 7% and 12%, with approximately 34% of these occurring before 34 weeks. There is growing evidence that the use of weekly intramuscular injections of progesterone (in the form of 17-alpha hydroxyprogesterone caproate, or 17-P), starting in the second trimester of pregnancy in asymptomatic women at high risk of spontaneous preterm delivery, is effective in preventing this. This results in a prolongation of gestation and subsequently decreases the risk of significant neonatal complications. This is especially true for those pregnancies associated with previous preterm deliveries before 34 weeks.

### **Indications/Criteria:**

17-P, as an intramuscular injection of 250 mg given once weekly, is considered medically necessary under the following distinct criteria:

- History of pre-term delivery at or before 35 and 0/7 weeks
- Short cervix (documented at 15 mm or less in length) at or before 24 weeks gestation

17-P is not indicated for prevention of pre-term delivery in:

- Multiple gestation (e.g., twins)
- Uterine anomalies

Therapy needs to be initiated between 16-24 weeks and should end at 36 weeks.

### **Limitations/Exclusions:**

<b>Healthy Options:</b>	None; pre-authorization required.
<b>Basic Health Plan:</b>	None; pre-authorization required.
<b>GAU:</b>	None; pre-authorization required.

### **Required Review and Approvals:**

Requests for this injectable require CHP Case Management referral for authorization of this service.

## **References:**

1. Meis P, et al. Prevention of Recurrent Preterm Delivery by 17-Alpha Hydroxyprogesterone Caproate. *New England Journal of Medicine* 2003; 348:2379-85.
2. Spong C, Meis P, et al. Progesterone for Prevention of Recurrent Preterm Birth: Impact of Gestational Age at Previous Delivery. *American Journal of Obstetrics and Gynecology* 2005;193:1127-31.
3. Rouse D, Caritis S, et al. A Trial of 17-Alpha Hydroxyprogesterone Caproate to Prevent Prematurity in Twins. *New England Journal of Medicine* 2007;357: 454-461.
4. Hayes, Inc. Medical Technology Directory (July 7, 2007)
5. Aetna Clinical Policy Bulletin #0510 (rev. 9/18/07)
6. Premera Blue Cross Corporate Medical Policy CP.MP.AR.4.01.501 (rev. 2/13/07)