What is it?:

17 Alpha-hydroxyprogesterone Caproate (17P) is not commercially available but can be manufactured by compounding pharmacies. 17P is a weakly acting naturally occurring progesterone metabolite, which when coupled with caproate dextran works as a long acting progestin when administered intramuscularly. Orphan Drug Progesterone Injection Gestiva received orphan drug status on January 31, 2007. A request for the drug’s priority review is currently under consideration by the FDA with review extended until early 2009. The drug is not expected to be marketed until the second half of fiscal 2009.

Recently there has been research in intramuscular injection of 17P for women who have had a spontaneous preterm delivery (V23.41). After a preterm delivery there is an increased risk for preterm delivery in subsequent pregnancies. However, to date no treatments have made a significant impact on the incidence of preterm delivery. Scientific evidence does not demonstrate that safety and efficacy on fetal outcomes and long-term follow up of the surviving children have been proven.

Criteria:

- 17 Alpha-Hydroxyprogesterone caproate (17p) use as a technique to prevent preterm labor is considered experimental and investigational. This includes the use of compounded 17P or orphan drug progesterone injections (Gestiva).

Note: According to recent studies - the use of progestational agents to prevent preterm birth among high risk women is promising but trials have gaps in the current knowledge of the biologic contribution of various risk factors to preterm birth. Unanswered questions regarding the possible mechanisms of action of the various progestins in preventing preterm birth have led to uncertainty with respect to choice of agent, route of administration, dose regimen and clinical indication. Further research on progestational agents is needed. In the meantime, the remaining uncertainties about both efficacy and fetal safety mean that even women at high risk for preterm delivery should join one of the ongoing randomized trials rather than take a treatment for which the efficacy and safety have not been proven.