Prior Authorization Criteria for Use of Makena
(17 alpha-hydroxyprogesterone caproate injection)

17P alpha-hydroxyprogesterone is a weakly acting, naturally occurring progesterone metabolite, which when coupled with caproate dextran works as a long-acting progestin when administered intramuscularly. Makena is indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

The following criteria must be met for approval of Makena:

- Singleton pregnancy
- Treatment must begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation
- History of singleton spontaneous preterm birth (before 37 weeks of gestation)

Criteria must be documented with medical records submitted with prior authorization request.

Dosing of Makena is as follows:

- 250 mg (1 ml) intramuscularly once weekly (every 7 days) by a health care provider.
- Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
- Administration should continue once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

Makena is considered experimental and investigational for all other indications including multiple gestation, cervical insufficiency/incompetent cervix, women with a cerclage in place, as a tocolytic agent for women with contractions, or other risk factors for preterm birth.

Makena is available as a 5 ml vial, 250 mg/ml. If approved, it must be obtained through our specialty pharmacy.