



Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Makena (hydroxyprogesterone caproate injection), is subject to the prior authorization process.

## PROCEDURE

### Initial Authorization Criteria:

*Must meet all of the criteria listed below:*

- Must have a diagnosis of singleton pregnancy
- Must have a history of singleton spontaneous preterm birth (prior to 37 weeks gestation)
- Must not have any of the following contraindications to use
  - Current or history of thrombosis or thromboembolic disorders
  - Known or suspected breast cancer, or other hormone sensitive cancer or history of these disorders
  - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
  - Cholestatic jaundice of pregnancy
  - Liver tumors (benign or malignant), or active liver disease
  - Uncontrolled hypertension
- Must be starting or have started treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.

### Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months (21 doses) or duration remaining until 36 weeks, 6 days gestation
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

## REFERENCES



**Makena (hydroxyprogesterone caproate injection)**

**POLICY NUMBER: RX.PA.160.E**

**REVISION DATE: 12/15**

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1. Makena [package insert]. McPherson, KS: Hospira, Inc; February 2015.
2. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. N Engl J Med. 2003;348(24):2379-85.
3. Northen A, Norman G, Anderson K, et al. Follow-up of children exposed in utero to 17 alpha-hydroxyprogesterone caproate. Obstet & Gynecol. 2007; 110:865-872.
4. Rouse D, Caritis S, Peaceman A, et al. A Trial of 17- Alpha Hydroxyprogesterone Caproate to Prevent Prematurity in Twins. N Engl J Med. 2007;357(5):454-461.
5. Meis PJ. 17 Hydroxyprogesterone for the Prevention of Preterm Delivery. Obstetrics and Gynecology. 2005;105(5):1128-1135.

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

