

Title: *hydroxyprogesterone (Makena)*

Origination:	Revised:	Annual Review: 12/15/11
---------------------	-----------------	--------------------------------

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Makena (Hydroxyprogesterone caproate), approved in February 2011, is an injectable synthetic progestin indicated to reduce the risk of preterm birth in a Member with a singleton pregnancy who has a history of singleton spontaneous preterm births. Hydroxyprogesterone caproate has been a compounded product for many years.
- The exact mechanism of action for the medication is not well understood. Progesterone is thought to be an important hormone in the maintenance of pregnancy. Progesterone is a smooth muscle relaxant in several organs, including the uterus during pregnancy.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member carrying multiple fetuses.
- Member is less than 16 years of age, as safety and efficacy has not been established in children or adolescents.
- Member diagnosed or suspected to have a hormone-sensitive cancer (breast, cervical, uterine, or vaginal).
- Member diagnosed with hepatocellular cancer, benign liver tumors, active hepatic disease or symptomatic cholestasis related to pregnancy (cholestatic jaundice of pregnancy).
- Member with history of thrombosis or thromboembolic disease.
- Member with undiagnosed abnormal vaginal bleeding unrelated to pregnancy.
- Member with uncontrolled hypertension.

Title: hydroxyprogesterone (Makena)

Procedure:

- 1.0 Request for *initiation* with Makena for **preterm delivery prophylaxis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Provider is medical OB/GYN; **AND**
 - 1.2 Member is between 16 and 50 years old; **AND**
 - 1.3 Member has past history of singleton preterm pregnancy less than 37 weeks; **AND**
 - 1.4 Confirmed pregnancy with a single fetus between 16 weeks, 0 days and 20 weeks, six (6) days of gestation;
 - 1.5 Documentation that Makena is a medical necessity rather than 17- alpha-hydroxyprogesterone that is compounded;
 - 1.6 If the Member meets the above criteria, initiation of therapy may be approved for 250 mg IM once weekly through 36 weeks, six (6) days.

References:

1. Mackenzie R, Walker M, Armson A, et al. Progesterone for the prevention of preterm birth among women at increased risk: a systematic review and meta-analysis of randomized controlled trials. *Am J Obstet Gynecol* 2006;194:1234-42.
2. Makena (hydroxyprogesterone caproate injection) package insert. Bloomington, IN: Baxter Pharmaceutical Solutions LLC; 2011 Feb.
3. Rouse DJ, Caritis SN, Peaceman AM, et al. A trial of 17 alpha-hydroxyprogesterone caproate to prevent prematurity in twins. *N Engl J Med* 2007;357:454-461.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.