

SPECIALTY GUIDELINE MANAGEMENT

MAKENA (hydroxyprogesterone caproate) hydroxyprogesterone caproate (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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 effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

- A. Current or history of thrombosis or thromboembolic disorders
- B. Known or suspected breast cancer, other hormone-sensitive cancer, or a history of these conditions
- C. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
- D. Cholestatic jaundice of pregnancy
- E. Liver tumors, benign or malignant, or active liver disease
- F. Uncontrolled hypertension

III. CRITERIA FOR INITIAL APPROVAL

Prevention of preterm birth

Authorization of 21 weeks or through 36 weeks, 6 days of gestational age, whichever is less, may be granted for the prevention of preterm birth when all of the following criteria are met:

- A. The current pregnancy is a singleton pregnancy (i.e., member is currently pregnant with only one baby).
- B. The member has a history of singleton spontaneous preterm birth, defined as delivery at less than 37 weeks gestation following preterm labor, preterm rupture of membranes, and cervical insufficiency.
- C. Makena will be initiated between 16 weeks, 0 days and 24 weeks, 6 days of gestation.³

IV. CONTINUATION OF THERAPY

Reference number(s)
1780-A

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Makena [package insert]. Waltham, MA: AMAG Pharmaceuticals; February 2018.
2. Hydroxyprogesterone caproate [package insert]. Shirley, NY. American Regent, Inc; July 2018.
3. American College of Obstetricians and Gynecologists Committee on Practice Bulletins—Obstetrics. ACOG practice bulletin no. 130: prediction and prevention of preterm birth. *Obstet Gynecol.* 2012;120(4):964-973.