Reference number(s)
1780-A

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.

IV. CONTINUATION OF THERAPY

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. Prediction and Prevention of Spontaneous Preterm Birth: ACOG Practice Bulletin, Number. 234. *Obstet Gynecol*. 2021 Aug 1;138(2):e65-e90.