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.

On April 6, 2023, the U.S. Food and Drug Administration (FDA) announced the final decision to withdraw approval of Makena (hydroxyprogesterone caproate) and its generics. Approvals of these drugs have been withdrawn because the drugs are no longer shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, and the benefits do not outweigh the risks for the indication for which they were approved. Consequently, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce. The FDA recognizes that a limited supply of these drugs has already been distributed and acknowledges that some health care providers might continue to prescribe or administer that limited remaining supply to their patients. However, we recommend health care practitioners consider FDA's conclusion that these drug products are not shown to be effective and do not have benefits that outweigh their risks to patients.

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.
4. U.S. Food and Drug Administration. (2023, April 6). *FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena* [Press release]. https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena