CareSource

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Makena (hydroxyprogesterone caproate)
BILLING CODE	J1726
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
STATUS	Prior Authorization Required

Makena is a progestin originally approved by the FDA in 1956. It 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. 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.

Reduction of Risk of Preterm Birth

For **initial** authorization:

1. Member is 16 years of age or older; AND
2. Medication is prescribed by an obstetrician or maternal-fetal medicine specialist; AND
3. Member has current singleton pregnancy; AND
4. Member has a documented history of spontaneous singleton preterm birth that occurred between 16 and 36 weeks 6 days gestation; AND
5. Prescriber attests Makena will be initiated during the period of 16-20 weeks 6 days gestation; AND
6. Member does not have any of the following:
   a) Current multiple gestations;
   b) Current or history of thrombosis or thromboembolic disorders;
   c) Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions;
   d) Undiagnosed abnormal vaginal bleeding unrelated to pregnancy;
   e) Cholestatic jaundice of pregnancy;
   f) Liver tumors, benign or malignant, or active liver disease;
   g) Uncontrolled hypertension; AND
7. **Dosage allowed:** Initiate treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first. Quantity Limit: 21 doses
   Makena 275 mg/mL auto-injector 1.1 mL pre-filled syringe: Administer 275mg (one 1.1 mL syringe) weekly subcutaneously
   Makena 250 mg/mL single-dose 1 mL vial: Administer 250mg (one 1 mL vial) weekly intramuscularly
   Makena 250 mg/mL multi-dose 5 mL vial: Administer 250mg (1 mL) weekly intramuscularly

If all the above requirements are met, the medication will be approved for the period of the pregnancy up to 36 weeks and 6 days gestation.

For **reauthorization**:

1. Makena will not be reauthorized.

CareSource considers Makena (hydroxyprogesterone caproate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2022	New policy for Makena created.

References:

1. Makena [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc: Lumara Health, February 2018.
2. How, MD, H. Y., Batron, MD, J.R., Istwan, RN, N. B. , Rhea, MPH, D. J., & Stanziano, MD, G.J. (2007). Prophylaxis with 17-alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? American Journal of Obstetrics & Gynecology. 2007.07.013, 260.e1-260.e3.
3. Tita ATN, Rouse DJ. Progesterone for preterm birth prevention: an evolving intervention. American Journal of Obstetrics & Gynecology 2009; March, pp 219-224.
4. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice American Journal of Obstetrics & Gynecology, 2012, Volume 206, Issue 5, 376 - 386.
5. 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.

Effective date: 10/01/2022
Revised date: 05/09/2022