SmartHealth

Ascension

HYDROXYprogesterone caproate

(Makena®) J1726 (10mg)

Covered with prior authorization

Hydroxyprogesterone caproate (Makena®) may be authorized when the following criteria are met:

- Pregnant female 16 years of age or older; **AND**
- Current singleton pregnancy; **AND**
- History of a prior spontaneous preterm (<37 weeks gestation) birth of a singleton pregnancy ; **AND**
- Treatment is
    - initiated between gestation 16 weeks 0 days and 20 weeks 6 days (see Makena Calculators); **AND**
    - Discontinued by gestation week 37 (through 36 weeks, 6 days) or by delivery, whichever occurs first; **AND**
- Dosing is 275 mg once weekly subcutaneously with auto-injector; **OR**
- Dosing is 250 mg once weekly intramuscularly

Exclusion criteria:

Requests may not be approved for the any of the following:

- Non-pregnant females;
- Risk factors for preterm labor in the current pregnancy, including, but not limited to:
    - Current multifetal pregnancy (twins or greater); **OR**
    - Cervical cerclage; **OR**
    - Short cervix with or without cerclage and no prior preterm birth; **OR**
    - A uterine anomaly; **OR**
    - Positive tests for cervicovaginal fetal fibronectin; **OR**
    - Previous medically indicated preterm birth; **OR**
    - Initiation after 20 weeks, 6 days of gestation; **OR**
    - Preterm labor
- Current or history of thrombosis or thromboembolic disorders
- Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions
- Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
- Cholestatic jaundice of pregnancy
- Liver tumors, benign or malignant, or active liver disease
- Uncontrolled hypertension

- History of allergic reactions, including urticaria, pruritus, and angioedema, after receiving any products containing castor oil

Authorization is provided no longer than through gestational week 36 day 6.

Caution:

- HYDROXYprogesterone caproate should not be self-administered;
- HYDROXYprogesterone caproate (Makena®) is indicated ONLY for reduction of preterm birth risk (PA Required);
- HYDROXYprogesterone caproate (J1729) is indicated ONLY for non-pregnancy conditions (No PA Required);

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Makena is a progestin 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.

References:

Hydroxyprogesterone Caproate Injection USP Label. (2015, August). Accessdata.fda.gov. Retrieved June 15, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/200271lbl.pdf
HYDROXYprogesterone Caproate (Lexi-Drugs). (2022, May 17). Lexicomp. Retrieved June 15, 2022, from https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/398?cesid=1jPbgClX008&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dhydroxy%2Bprogesterone%26t%3Dname%26acs%3Dfalse%26acq%3Dhydroxy%2Bprogesterone#
MAKENA® (hydroxyprogesterone caproate injection). (2018, February). Accessdata.fda.gov. Retrieved June 15, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021945s012lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Developed by: Ascension Ambulatory Care Expert Review Panel
January 2022	Approved by: Ascension Ambulatory Care Steering Committee
February 2022	Approved by: Ascension Therapeutic Affinity Group
June 2022	Criteria for use summary revised by Ascension Medical Specialty Prior Authorization Team

July 2022	Revised criteria for use summary approved by Ascension Ambulatory Care Expert Review Panel
July 2022	Revised criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.