UnitedHealthcare Community Plan

July 2019-E

Makena Authorization Request

About

Makena® (hydroxyprogesterone caproate injection) is approved in women to reduce the risk of preterm birth in women with a history of spontaneous singleton preterm birth. Makena is a once a week treatment administered by a health care provider.

Approval Criteria

- Diagnosis of singleton pregnancy in a woman with a history of spontaneous singleton preterm birth
- Dosage of 250 mg intramuscularly or 275 mg subcutaneously once weekly
- Age 16 or older
- Starting treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Continue until 36 weeks, 6 days of gestation or delivery, whichever occurs first.
- Maximum of 21 doses.
- Preferred Products
    - Request for products other than a preferred product may require additional justification. Please refer to the VDP Preferred Drug List at: txvendordrug.com/formulary/prior-authorization/preferred-drugs.

Denial Criteria

- Length of treatment greater than 21 weeks and 0 days
- Contraindications:
    - 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
    - Allergic reaction to any ingredients in Makena
        - Ingredients: hydroxyprogesterone, castor oil, benzyl benzoate and benzyl alcohol
- Unapproved Indications:
    - Amenorrhea
    - Endometrial carcinoma
    - Multifetal gestation
    - Short cervix without history of a preterm birth
    - Testing for endogenous estrogen production

Approval prior to 16 weeks gestation

Makena requests may be submitted for approval just prior to 16 weeks, 0 days gestation to allow time for the prior authorization approval process and shipping from the pharmacy.

Submission

- **By fax:**
    - 866-940-7328
    - Attention: OptumRx Pharmacy Prior Authorization

Questions

Direct questions about this form to the OptumRx Pharmacy Prior Authorization Help Desk at 800-310-6826.

Section 1 – Patient Information

First Name:	Last Name:	MI:
Date of Birth	Medicaid ID:	

Section 2 – Patient Condition

Current singleton pregnancy with a history of singleton spontaneous preterm birth less than 37 weeks of gestation? ◯ Yes ◯ No

Please select applicable ICD-10 Code

◯ O09.212 Supervision of pregnancy with history of preterm labor, second trimester

◯ O09.213 Supervision of pregnancy with history of preterm labor, third trimester

◯ O09.219 Supervision of pregnancy with history of preterm labor, unspecified trimester

Current Gestation: Weeks _____ Days _____ Date Recorded:

Is the patient currently receiving Makena or Hydroxyprogesterone Caproate? ◯ Yes ◯ No Start date:

Section 3 – Prescription Information

Please specify product selection: ◯ Makena 250 MG/ML Vial ◯ Makena 275 MG/1.1 ML Auto Injector ◯ Hydroxyprogesterone Caproate 250 MG/ML Vial	Quantity: Days' Supply:
Directions:	Expected Therapy Durations in Weeks:

Section 4 – Pharmacy Information

Pharmacy Name:	Area Code and Phone No.
Address (Street, City, State and ZIP Code):	

Section 5 – Prescriber Information

Prescriber Name (Last, First):	Prescriber NPI:	Practice Name:	Texas License No.:
Address (Street, City, State and ZIP Code):		Office Area Code and Phone No.:	Office Area Code and Fax No.:

Preparer Name (if other than prescriber):	Agency Name:	Area Code and Phone No.:	Area Code and Fax No.:

Section 6 – Signature

By signing below, I, the prescriber, certify that the information provided above is verifiable and accurate to the best of my knowledge.

_____ _____

Prescriber Signature Date