

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 a 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: 1-844-474-3341

Questions

Direct questions about this form to the Pharmacy Department at 1-800-454-3730.

Section 1 – Patient Information

First Name:	Last Name:	MI:	Date of Birth	Medicaid ID:
Please indicate if patient is enrolled in: Fee-for-Service Managed Care				

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 the applicable ICD-10 Code

- O09.212 Supervision of pregnancy with a history of preterm labor, second trimester
- O09.213 Supervision of pregnancy with a 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 275 MG/1.1 ML Auto Injector Hydroxyprogesterone Caproate 250 MG/ML Vial

Quantity:	Days' Supply:
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Directions:

Expected Therapy Durations in Weeks:

Section 4 – Pharmacy Information

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

Section 5 – Prescriber Information

Prescriber Name (<i>Last, First</i>):	Prescriber NPI:
Practice Name:	Texas License No.:
Address (<i>Street, City, State and ZIP Code</i>):	
Office Area Code and Phone No.:	Office Area Code and Fax No.:
Preparer Name (<i>if other than prescriber</i>):	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