Medicaid Managed Care Prior Authorization Criteria and Policy

Makena ® (hydroxyprogesterone caproate injection)

Makena® is approved in women to reduce the risk of preterm birth with singleton pregnancy and a history of spontaneous singleton preterm birth. Makena is a once weekly treatment administered by a healthcare provider.

Approval Criteria:

Diagnosis

- Singleton pregnancy in a woman with a history of spontaneous singleton preterm birth

Dosage and frequency

- 250 mg intramuscularly once weekly

Length of treatment

- Begin 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 21 doses

Denial Criteria:

Age:

- Less than 16 years of age

Dosage and frequency:

- Greater than 250 mg intramuscularly once weekly

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, estrogen measurement, endogenous; diagnosis**,** or any diagnosis other than singleton pregnancy in a woman with a history of spontaneous singleton preterm birth

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.

Please fax completed form to Cigna-HealthSpring STAR+PLUS Pharmacy Services at 1-888-766-6341.

Section 1 - Patient Information

First Name:	Last Name:	MI:
DOB:	Medicaid ID:	Please indicate if patient is enrolled in (choose one): ☐ Fee-for-Service ☐ Managed Care Plan

Section 2 - Patient Condition

Current singleton pregnancy with past history of singleton spontaneous preterm birth less than 37 weeks of gestation? ☐ Yes ☐ No	ICD-10 CM:	
Current gestation: _____ Weeks _____ Days Date Recorded: _____		
Is the patient currently receiving Makena or compounded HPC ("17p")? ☐ Yes ☐ No Start Date: _____		

Section 3 - Prescription Information

Drug Name: Makena®	Strength: 250 mg/ml	Quantity:	Days' Supply:
Directions:		Expected Therapy Duration in Weeks:	

Section 4 - Pharmacy Information

Pharmacy Name:		Phone Number:	
Address:	City:	State:	Zip Code:

Section 5 - Prescriber Information

Prescriber Name (Last, First):		Prescriber NPI:	
Practice Name:		Texas License Number:	
Address:	City:	State:	Zip Code:
Office Phone Number:	Office Fax Number:		

Preparer Name (if other than prescriber):	Phone number:
Agency Name:	Fax Number:

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:

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