Texas Medicaid/CHIP – Community Health Choice, Cook Children's Health Plans, and Texas Children's Health Plans

Clinical Prior Authorization Form and Policy

MAKENA (hydroxyprogesterone caproate injection)

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:

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

Dosage and frequency:

- 250mg intramuscular or 275mg subcutaneous once weekly

Age:

- Patient is 16 years of age or older

Length of treatment:

- Begin treatment between 16 weeks, 0 days and 26 weeks, 6 days of gestation
- Continue until 36 weeks, 6 days of gestation or delivery, whichever occurs first
- Maximum 21 doses

Preferred Products based on Vendor Drug Program (VDP) Preferred Drug List (STAR/STAR KIDS Only):

- Requests for non-preferred generic hydroxyprogesterone caproate injection must meet at least one (1) of the below:
    - Patient has failed a 10-day treatment trial with at least one (1) preferred agent in the last 180 days
    - Patient has a documented allergy or contraindication to the preferred agent, brand MAKENA
    - The drug is necessary for treatment of stage-4 advanced metastatic cancer and associated conditions

Denial Criteria:

Dosage and frequency:

- Greater than 250mg intramuscular or 275mg subcutaneous once weekly

Age:

- Less than 16 years of age

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, 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 Navitus at 1-855-668-8553.

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Section 1: Patient Information			
First Name:		Last Name:	MI:
DOB:	Medicaid ID:	Address:	

Section 2: Patient Condition
Current singleton pregnancy with past 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/1.1mL auto injector ☐ hydroxyprogesterone caproate 250 mg/mL vial **(Non-Preferred)**	Quantity: Days' Supply:
Medical Rationale for Non-Preferred Product (STAR/STAR KIDS members only):	
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:

Please fax completed form to Navitus at 1-855-668-8553.

If criteria not met, submit chart documentation with form citing complex medical circumstances.