# Texas Medicaid/CHIP – Community First, Dell Children's (Seton), Driscoll Children's, El Paso, FirstCare, Parkland, and Baylor Scott & White 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 24 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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**MAKENA (hydroxyprogesterone caproate injection)**

| **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: | Quantity: |
|---|---|
| ☐ MAKENA 250 mg/mL vial<br>☐ MAKENA 275 mg/1.1mL auto injector<br>☐ hydroxyprogesterone caproate 250 mg/mL vial **(Non-Preferred)** | 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: |
|---|---|

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