STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Makena™ (Hydroxyprogesterone caproate injection)

Effective 11/16/2016

Prior Authorization Request Form

INDICATIONS AND USAGE

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.
Limitation of use: Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

DOSAGE AND ADMINISTRATION

- Administer intramuscularly at a dose of 250 mg (1 mL) once weekly
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

CRITERIA ALGORITHM

Questions:

1. Is the patient currently pregnant?
    a. Yes – Go to next question
    b. No – Deny – Denial Reason: Only FDA indicated for use in mothers who are pregnant and have had a previous premature delivery.

2. Is this current pregnancy a multiple fetus pregnancy?
    a. Yes – Deny – Denial Reason: No FDA approved for multiple fetal pregnancies
    b. No – Go to next question

3. Does the mother have a history of single fetus preterm births?
    a. Yes – Go to next question
    b. No – Deny – Denial Reason: Only FDA indicated for use in mothers that have already had a preterm delivery.

4. Is this pregnancy between weeks 16 and 21?
    a. Yes – Approve until 37 week of gestation
    b. No – Deny – Denial Reason: FDA approved use states that the pregnancy must be after start of week 16 and before the start of week 21)

LIMITATIONS OF COVERAGE:

1. Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Treatment must end before week 37 (through 36 weeks, 6 days).

2. Coverage is limited to a maximum total of 20 doses (16 weeks gestation to 36 weeks gestation).

3. Hydroxyprogesterone caproate will not be approved for the prevention of spontaneous preterm birth in women with:
    - Short cervix (with or without cerclage) and no prior history of preterm birth
    - Current multi-fetal pregnancy (twins or greater)
    - Previous medically-indicated (versus spontaneous) preterm birth
    - Initiation of therapy beginning after 20 weeks,6 days of gestation

References

1.) Lexi-Comp drug monograph for (Reviewed 11/10/2016)
2.) Makena package insert (04/2016)