Hydroxyprogesterone Caproate (Makena®) for the Prevention of Preterm Labor

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Definitions

Preterm Birth — a live birth completed in < 37 weeks gestation. Further definition includes the following:

- Late preterm: 34-36 weeks.
- Moderately preterm: 32-36 weeks.
- Very preterm: < 32 weeks.

Hydroxyprogesterone caproate — a progestogen structurally related to progesterone that is intramuscularly injected into the gluteus muscle (may also be given in the anterior thigh) that is used as preventive treatment for reducing the risk of recurrent preterm birth.

Guideline

Women between 16 and 36 weeks, 6 days of gestation (see Dosing and Administration below) are eligible for coverage of hydroxyprogesterone caproate when both of the following criteria are met

- History of spontaneous preterm birth (< 37 weeks gestation; defined by either spontaneous labor or premature rupture of membrane)
- Singleton pregnancy

Note: Consideration of hydroxyprogesterone caproate administration in the home-setting by either a home health agency or prenatal services vendor will be given to women who are confined to the home on prescribed bed rest or on a case by case basis.

Dosing and Administration

The weekly dosage of hydroxyprogesterone caproate is a 250mg (1 ml) intramuscular injection (ideally given at the same time each week on alternating sides with the suggested time-range between injections at 5 to 9 days).

Treatment should be initiated between 16 weeks, 0 days and 20 weeks, 6 days gestation and may continue until 36 weeks, 6 days or until the woman gives birth, whichever comes first.

Note: If an eligible woman presents to prenatal care late, hydroxyprogesterone caproate may be initiated as late as 26 weeks, 6 days.

Limitations/Exclusions

Hydroxyprogesterone caproate is not considered a medically appropriate intervention when any of the following are applicable:

- 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

Applicable Procedure Codes

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
99506	Home visit for intramuscular injections
J1725	Injection, hydroxyprogesterone caproate, 1 mg
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg (Eff. 07/01/2017)
S9208	Home management of preterm labor, including administrative services, professional pharmacy services, care coordination, and all necessary supplies or equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusions)

Applicable ICD-10 Diagnosis Codes

O60.00	Preterm labor without delivery, unspecified trimester
O60.02	Preterm labor without delivery, second trimester
O60.03	Preterm labor without delivery, third trimester
O09.211	Supervision of pregnancy with history of pre-term labor, first trimester
O09.212	Supervision of pregnancy with history of pre-term labor, second trimester
O09.213	Supervision of pregnancy with history of pre-term labor, third trimester
O09.219	Supervision of pregnancy with history of pre-term labor, unspecified trimester
Z87.51	Personal history of pre-term labor

References

Specialty-matched clinical peer review.

Ther-Rx Corporation. Makena™ Package Insert. August 2013; revised February 2015; revised April 2016. http://www.makena.com/pdf/makena_pi.pdf. Accessed May 15, 2015.