

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

Last Review Date: May 1, 2019

Number: MG.MM.ME.33Cd

Medical Guideline Disclaimer

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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 progestin 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

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 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

Revision History

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| 5/1/2019 | Added Length of Authorization section |
| 1/12/2018 | Added note for case-by-case consideration modified to remove language pertaining to the member being confined to the home or prescribed bed rest. |

Applicable Procedure Codes

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|-------|-------------------------------------------------------------------------------------------|
| J1725 | Injection, hydroxyprogesterone caproate, 1 mg (Deleted. 01/01/2018) |
| J1726 | Injection, hydroxyprogesterone caproate, (makena), 10 mg (Eff. 01/01/2018) |
| J1729 | Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg (Eff. 01/01/2018) |
| Q9986 | Injection, hydroxyprogesterone caproate (Makena), 10 mg (Deleted 01/01/2018) |

Applicable ICD-10 Diagnosis Codes

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|---------|--------------------------------------------------------------------------------|
| 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 |

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References

1. Ther-Rx Corporation. Makena™ Package Insert. August 2013; revised February 2015; revised April 2016; revised August 2017. http://www.makena.com/pdf/makena_pi.pdf. Accessed January 16, 2018.
2. Product Information: Hydroxyprogesterone Caproate intramuscular injection, hydroxyprogesterone caproate intramuscular injection. ANI Pharmaceuticals Inc (per manufacturer), Baudette, MN, 2016.