Medical Policy:
MAKENA® (hydroxyprogesterone caproate) for the Prevention of Preterm Labor

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.357	June 26, 2023	

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. Makena is also available as a subcutaneous auto-injectable, administered in the back of either upper arm by a healthcare provider.

Length of Authorization

Coverage will be provided for 6 months and may NOT be renewed.

Dosing Limits [Medical Benefit]

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. Continue administration once weekly until week 37, (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

Makena auto injector: Administer subcutaneously using auto-injector at a dose 275mg (1.1 mL) once weekly (every 7 days) in the back of either upper arm by a healthcare provider.

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

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:

1. History of spontaneous preterm birth of a singleton pregnancy (< 37 weeks gestation; defined by either spontaneous labor or premature rupture of membrane)
2. 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.

Limitations/Exclusions

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

1. Member must be 16 years of age or older
2. Current or history of thrombosis or thromboembolic disorders
3. Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions
4. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
5. Cholestatic jaundice of pregnancy
6. Liver tumors, benign or malignant, or active liver disease
7. Uncontrolled hypertension

Applicable Procedure Codes

Code	Description
J1726	Injection, hydroxyprogesterone caproate, (Makena), 10 mg

Applicable NDCs

Code	Description
71225-0104-01	Hydroxyprogesterone Caproate 250mg/mL Solution
71225-0105-01	Hydroxyprogesterone Caproate 250mg/mL Solution
67457-0967-01	Hydroxyprogesterone Caproate 250mg/mL Solution
00517-1791-01	Hydroxyprogesterone Caproate 250mg/mL Solution

55150-0310-01	Hydroxyprogesterone Caproate 250mg/mL Oil
69238-1797-01	Hydroxyprogesterone Caproate 250mg/mL Solution
66993-0038-83	Hydroxyprogesterone Caproate 250mg/mL Solution
55150-0309-01	Hydroxyprogesterone Caproate 250mg/mL Oil
66993-0039-01	Hydroxyprogesterone Caproate 250mg/mL Solution
00517-1767-01	Hydroxyprogesterone Caproate 250mg/mL Solution
64011-0301-03	Makena 275MG/1.5mL Solution Auto-Injector
64011-0243-01	Makena 250mg/mL Solution
64011-0247-02	Makena 250 mg/mL Solution
67457-0886-05	Hydroxyprogesterone Caproate 250mg/mL Solution

ICD-10 Diagnoses

Code	Description
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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	6/26/2023	Annual Review: Removed code: J1729, Removed ICD-10 Codes: O60.00, O60.02, O60.03, O09.211 and Z87.51 Modified length of authorization: from "Coverage will be provided for 6 months and may be renewed." To "Coverage will be provided for 6 months and may NOT be renewed."
EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	04/8/2020	Updated age restriction per FDA Label
EmblemHealth & ConnectiCare	12/18/2019	Annual Review Added criteria: requiring previous preterm birth to have been with a singleton pregnancy Added under definitions: Makena is also available as a subcutaneous auto-injectable, administered in the back of either upper arm by a healthcare provider. Added under Dosage and Administration: per FDA label
EmblemHealth & ConnectiCare	05/01/2019	Added: Length of Authorization section
EmblemHealth & ConnectiCare	01/12/2018	Added note: for case-by-case consideration modified to remove language pertaining to the member being confined to the home or prescribed bed rest.

References

1. Ther-Rx Corporation. Makena™ Package Insert. February 2018. http://www.makena.com/pdf/makena_pi.pdf. Accessed December 2019.

2. Product Information: Hydroxyprogesterone Caproate intramuscular injection, hydroxyprogesterone caproate intramuscular injection. ANI Pharmaceuticals Inc (per manufacturer), Baudette, MN, 2016.