

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

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 |

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| 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.