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Last P&T Approval/Version: 07/27/2022  
Next Review Due By: 7/2023  
Policy Number: C10447-A

## Makena (hydroxyprogesterone caproate injection)

### PRODUCTS AFFECTED

Makena (hydroxyprogesterone caproate injection), 17-alpha hydroxyprogesterone caproate [17P], compounded

### COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.*

*This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive*

#### **DIAGNOSIS:**

Current singleton pregnancy with a history of a previous singleton spontaneous preterm birth (defined as delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membrane)

#### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

#### **A. REDUCE THE RISK OF PRETERM BIRTH:**

1. Documentation that member currently has singleton (not twins or other multiple) pregnancy.  
AND
2. Documentation that member has a history of previous singleton spontaneous preterm

## Drug and Biologic Coverage Criteria

[Preterm birth (PTB) refers to a delivery that occurs between 20-37 weeks of gestation birth]

\*\*\*There is no data to support the use in a patient who delivered prior to 20 weeks and the use would be considered “off-label”. \*\*\*

AND

3. Prescriber attestation that Makena will be initiated between 16 weeks, 0 days and 26 6/7 weeks (3,4) of gestation  
AND
4. FOR REQUESTS FOR THE 275 MG PEN: Prescriber submits detailed justification of medical rationale for use of 275 mg pen product (SC) instead of utilizing the generic dosage form (250mg IM)  
AND
5. Prescriber attestation that the member does NOT meet the following indications as it is considered experimental/investigational and of unproven medical efficacy: Short cervix (with or without cerclage) and no prior preterm birth, Current multi-fetal pregnancy (twins or greater), or Previous medically indicated preterm birth.  
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to hydroxyprogesterone caproate include: 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]

### CONTINUATION OF THERAPY:

N/A

### DURATION OF APPROVAL:

21 weeks or time of delivery, whichever occurs first

### PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified obstetrician or a specialist in maternal fetal medicine. Submit consultation notes, if applicable.

### AGE RESTRICTIONS:

16 years old and older

### QUANTITY:

21 doses (16 weeks gestation to 36 weeks gestation) per pregnancy. Intramuscular vials: Single- dose (1mL), preservative free: up to 21 vials, Multi-dose (5mL): up to 5 vials, subcutaneous auto- injector: up to 21 injectors  
J1726– 25 units (250 mg) every 7 days

**Maximum Quantity Limits – 21 doses / injectors per pregnancy**

### PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program

Note: Site of Care Utilization Management Policy applies for Makena (hydroxyprogesterone caproate). For information on site of care, see

[Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://www.molinamarketplace.com)

## DRUG INFORMATION

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## Drug and Biologic Coverage Criteria

### **ROUTE OF ADMINISTRATION:**

Intramuscular (vial) or subcutaneous (auto-injector)

### **DRUG CLASS:**

Progestins

### **FDA-APPROVED USES:**

To reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

\*\*For the treatment of inoperable, recurrent, and metastatic endometrial cancer- See Molina Standard Oncology Criteria C16154-A (J1729)

### **COMPENDIAL APPROVED OFF-LABELED USES:**

None

## APPENDIX

### **APPENDIX:**

None

## BACKGROUND AND OTHER CONSIDERATIONS

### **BACKGROUND:**

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. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

### **CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Makena (brand) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

Allergic reaction to any ingredients in Makena (ingredients: hydroxyprogesterone, castor oil, benzyl benzoate, and benzyl alcohol) or 17-alpha hydroxyprogesterone caproate (17P), Current or history of thrombosis or thromboembolic disorders, Known, suspected or past history of breast cancer or other hormone-sensitive cancers, such as cervical cancer, uterine cancer, or vaginal cancer.

Undiagnosed abnormal vaginal bleeding unrelated to pregnancy, Hepatocellular cancer, benign liver tumors, or active hepatic disease.

### **OTHER SPECIAL CONSIDERATIONS:**

None

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPCS CODE	DESCRIPTION
J1726	Injection, hydroxyprogesterone caproate, (Makena), 10 mg

## Drug and Biologic Coverage Criteria

### AVAILABLE DOSAGE FORMS:

HYDROXYprogesterone Caproate OIL 250MG/ML

Makena OIL 250MG/ML

Makena SOAJ 275MG/1.1ML

17- alpha hydroxyprogesterone caproate [17P], compounded

### REFERENCES

1. Makena [package insert]. Waltham, MA: AMAG Pharmaceuticals Inc.; November 2020
2. American College of Obstetricians and Gynecologists Committee on Practice Bulletins—Obstetrics. ACOG practice bulletin no. 130: prediction and prevention of preterm birth. *Obstet Gynecol.* 2012;120(4):964-973
3. How HY, Barton JR, Istwan NB, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation oftreatment matter? *Am J Obstet Gynecol.* 2007;197(3): 260.e1-4.
4. González-Quintero VH, Istwan NB, Rhea DJ, et al. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. *J Matern FetalNeonatalMed.* 2007;20(3):249-52.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file