Effective Date: 7/28/2021
Last P&T Approval/Version: 07/28/2021
Next Review Due By: 04/2022
Policy Number: C21117-A

MAKENA (hydroxyprogesterone caproate injection) Illinois Medicaid Only

PRODUCTS AFFECTED

Makena OIL 250MG/ML Vial, Hydroxyprogesterone Caproate OIL 250MG/ML Vial, Makena 275MG/1.1ML Pen

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:
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:
A. REDUCE THE RISK OF PRETERM BIRTH:

1. Documentation that member currently has a singleton (not twins or other multiple) pregnancy.
   AND
2. Documentation that member has a history of previous singleton spontaneous preterm birth
   NOTE: Spontaneous pre-term birth is defined as delivery at less than 37 weeks gestation following spontaneous preterm labor or premature rupture of membranes.
   AND
3. FOR A PHARMACY BENEFIT REQUEST FOR A NON-PREFERRED PRODUCT: Documentation of contraindication or trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis.
   AND
4. FOR A MEDICAL BENEFIT REQUEST FOR MAKENA 275 MG PEN: Prescriber submission of a detailed justification of medical rationale for use of the 275 mg pen product instead of utilizing the generic dosage form.

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
21 weeks or time of delivery, whichever occurs first

PRESCRIBER REQUIREMENTS:
N/A

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 or subcutaneous injectable products 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)

DRUG INFORMATION

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 , J1729 Injection, hydroxyprogesterone caproate (antineoplastic agents and adjunctive therapy)- See Molina Standard Oncology Criteria C16154-A

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; Liver tumors, benign or malignant, or active liver disease; Uncontrolled hypertension

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

AVAILABLE DOSAGE FORMS:

Hydroxyprogesterone Caproate OIL 250MG/ML
Makena OIL 250MG/ML
Makena SOAJ 275MG/1.1ML

REFERENCES

1. Makena [package insert]. Waltham, MA: AMAG Pharmaceuticals Inc.; February 2018. 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

2. 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 of treatment matter? Am J Obstet Gynecol. 2007;197(3): 260.e1-4.
3. González-Quintero VH, Istwan NB, Rhea DJ, et al. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. J Matern Fetal Neonatal Med. 2007;20(3):249-52.
4. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 1.22.20, revised