Clinical Policy: Hydroxyprogesterone Caproate (Makena/compound)

Reference Number: PA.CP.PHAR.14
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® medical policy for hydroxyprogesterone caproate intramuscular injection (Makena®/compound).

FDA Approved Indication(s)
Makena is indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

Limitation(s) of use: Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness Corporation® that hydroxyprogesterone caproate is **medically necessary** for members meeting the following criteria:

A. Prevention of Preterm Birth (must meet all)**:**
1. Current singleton pregnancy;
2. History of singleton spontaneous preterm birth (delivery at < 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes);
3. Therapy to begin between 16 weeks, 0 days and 27 weeks, 6 days of gestation;
4. Request is for Makena unless there is a contraindication or documented reason to use an alternative formulation;
5. Dose does not exceed 250 mg (1 ml) IM once weekly.

Approval duration: up to a total of 21 doses to reach week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

B. Other diagnoses/indications
1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed

II. Continued Therapy

A. Prevention of Preterm Birth (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 250 mg (1 ml) IM once weekly.

Approval duration: Up to a total of 21 doses to reach week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

B. Other diagnoses/indications (must meet 1 or 2)**:**

1 Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed
2. For use in women with multiple gestations.

Background

Description/Mechanism of Action:

Hydroxyprogesterone caproate is a synthetic progestin. The mechanism by which hydroxyprogesterone caproate reduces the risk of recurrent preterm birth is not known.

Formulations:

Makena is supplied as

- 1 mL of a sterile solution in a single dose glass vial.
  - Each 1 mL vial contains hydroxyprogesterone caproate USP, 250 mg/mL (25% w/v), in castor oil USP (30.6% v/v) and benzyl benzoate USP (46% v/v).
  - Single unit carton: Contains one 1 mL single dose vial of Makena containing 250 mg of hydroxyprogesterone caproate.
- 5 mL of a sterile solution in a multidose glass vial.
  - Each 5 mL vial contains hydroxyprogesterone caproate USP, 250 mg/mL (25% w/v), in castor oil USP (28.6% v/v) and benzyl benzoate USP (46% v/v).
    - Includes the preservative benzyl alcohol NF (2% v/v).
  - Single unit carton: Contains one 5 mL multidose vial of Makena (250 mg/mL) containing 1250 mg of hydroxyprogesterone caproate.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1725	Injection, hydroxyprogesterone caproate, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and approved	2.18	

References

1. Makena Prescribing Information. Waltham, MA: AMAG Pharmaceuticals, Inc.; August 2017. Available at http://www.makena.com/pdf/makena_pi.pdf. Accessed November 20, 2017.
2. Clinical management guidelines for obstetrician-gynecologists – practice bulletin 130: prediction and prevention of preterm birth. The American College of Obstetricians and Gynecologists. Obstet Gynecol. October 2012; 120(4): 964-973.
3. Mason MV, Poole-Yaeger A, Lucas B, Krueger C, et al. Effects of a pregnancy management program on birth outcomes in managed Medicaid. Manag Care. April 2011; 20(4): 39-46.
4. Mason MV, Poole-Yaeger A, Krueger C, et al. Impact of 17P usage on NICU admissions in a managed Medicaid population – a five-year review. Manag Care. February 2010; 19(2): 46-52.
5. Romero R, Stanczyk FZ. Progesterone is not the same as 17α-hydroxyprogesterone caproate: implications for obstetrical practice. Am J Obstet Gynecol. June 2013; 208(6): 421-426.