envolve Pharmacy Solutions

Clinical Policy: Hydroxyprogesterone Caproate (Makena)

Reference Number: ERX.SPA.198
Effective Date: 01.11.17
Last Review Date: 11.17 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Hydroxyprogesterone caproate (Makena®) is a progestin.

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
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Makena is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prevention of Preterm Birth (must meet all)**:**

1. Current singleton pregnancy;
2. Age ≥ 16 years;
3. History of singleton spontaneous preterm birth (delivery at < 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes);
4. Therapy to begin between 16 weeks, 0 days and 27 weeks, 6 days of gestation;
5. Request is for Makena unless there is a contraindication or documented reason to use an alternative formulation;
6. Dose does not exceed 250 mg (1 mL) once weekly (every 7 days) by intramuscular injection.

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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Preterm birth	250 mg IM once weekly	250 mg IM once weekly

VI. Product Availability

- Single dose vial: 250 mg/1mL
- Multi-dose vial: 1250 mg/5mL

VII. References

1. Makena Prescribing Information. Waltham, MA: AMAG Pharmaceuticals, Inc.; August 2017. Available at http://www.makena.com/. Accessed October 1, 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, Ahmed T, Duncan I. Effects of a pregnancy management program on birth outcomes in managed Medicaid. Managed Care April 2011.
4. Mason MV, Poole-Yaeger A, Krueger C, House K, Lucas B. Impact of 17P usage on NICU admissions in a managed Medicaid population – a five-year review. Managed Care February 2010.
5. Romero R and 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.01.16	01.17
4Q17 Annual Review No significant changes. References reviewed and updated. Added age per PI.	10.01.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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