

Progesterones – hydroxyprogesterone caproate

Medical policy no. 26.00.00-1

Effective Date: July 1, 2018

Background:

Preterm birth defined as less than 37 weeks gestation and very preterm birth defined as less than 34 weeks gestation. Infant mortality increases with decreasing gestational age. Women with a previous preterm delivery have an increased risk for preterm delivery with subsequent pregnancies. Progesterone is a hormone that inhibits the uterus from contracting and is involved in maintaining pregnancy. Hydroxyprogesterone caproate is a metabolite of progesterone.

Medical necessity

Drug	Medical Necessity
hydroxyprogesterone caproate injection (MAKENA®)	Makena® may be considered medically necessary when: Used to prevent pre-term labor of singleton pregnancies in women with a history of spontaneous singleton preterm birth, premature labor, or premature rupture of membranes

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
hydroxyprogesterone caproate injection (MAKENA®)	Makena® may be covered when ALL of the following are met: <ol style="list-style-type: none"> 1. Diagnosis of singleton pregnancy 2. Prior history of singleton preterm delivery before 37 weeks of gestation due to either of the following: <ol style="list-style-type: none"> a. Spontaneous preterm labor b. Premature rupture of membranes 3. To be initiated on or after 16 weeks 0 days and continued until 36 weeks 6 days of gestation or delivery, whichever comes first 4. Maximum dose: <ol style="list-style-type: none"> a. Vial; 250mg IM once weekly b. Auto-injector; 275mg SQ once weekly 5. Not to exceed 21 weeks of therapy 6. Greater than or equal to (\geq) 16 years of age <p>Approve up to 21 weeks</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
hydroxyprogesterone caproate injection (MAKENA® vial)	250mg (1mL) once weekly; #4 (1mL preservative-free (PF) vial) per 28-days

	#1 (5mL vial) per 35-days
hydroxyprogesterone caproate injection (MAKENA® auto-injector)	275mg (1.1mL) once weekly; #4 auto-injectors per 28-days

Coding:

HCPCS Code	Description
J1726	Injection, hydroxyprogesterone caproate, 10 mg [Makena]
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg

Definitions

Term	Description
Preterm birth	Less than (<) 37 weeks gestation
Very preterm birth	Less than (<) 34 weeks gestation

References

1. ACOG Committee Opinion number 419 October 2008 (replaces no. 291, November 2003). Use of progesterone to reduce preterm birth. United States, 2008. p. 963-5.
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3. Meis, PJ, Klebanoff, M, Thom, E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. United States, 2003. p. 2379-85.
4. Nelson, DB, McIntire, DD, McDonald, J, Gard, J, Turrichi, P, Leveno, KJ. 17 alpha-hydroxyprogesterone caproate did not reduce the rate of recurrent preterm birth in a prospective cohort study. United States, 2017. p. 1.e-e8.
5. Rouse, DJ, Caritis, SN, Peaceman, AM, et al. A trial of 17 alpha-hydroxyprogesterone caproate to prevent prematurity in twins. United States, 2007. p. 454-61.
6. Gonzalez-Quintero, VH, Istwan, NB, Rhea, DJ, Smarkusky, L, Hoffman, MC, Stanziano, GJ. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. United States, 2007. p. 249-52.
7. How, HY, Barton, JR, Istwan, NB, Rhea, DJ, Stanziano, GJ. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? United States, 2007. p. 260 e1-4.
8. Mason, MV, Poole-Yaeger, A, Krueger, CR, House, KM, Lucas, B. Impact of 17P usage on NICU admissions in a managed medicaid population--a five-year review. *Manag Care*. 2010 Feb;19(2):46-52. PMID: 20550052
9. Product Information: MAKENA® intramuscular injection, hydroxyprogesterone caproate intramuscular injection. AMAG Pharmaceuticals, Inc. (per FDA), Waltham, MA, 2017
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11. Northen, AT, Norman, GS, Anderson, K, et al. Follow-up of children exposed in utero to 17 alpha-hydroxyprogesterone caproate compared with placebo. United States, 2007. p. 865-72.