

Corporate Medical Policy

Progesterone Therapy in High Risk Pregnancies

File Name: progesterone_therapy_in_high_risk_pregnancies
Origination: 01/2005
Last CAP Review: 9/2011
Next CAP Review: 9/2012
Last Review: 9/2011

Description of Procedure or Service

Preterm birth is the leading cause of neonatal morbidity and mortality, and effective primary preventive interventions have remained elusive. In recent years, there has been renewed interest in the use of progesterone (injectable and intravaginal formulations) to prevent preterm birth.

In recent years, there has been renewed research interest in intramuscular injection of 17 alpha-hydroxyprogesterone caproate (17P). 17P is a weakly acting, naturally occurring progesterone metabolite, which when coupled with caproate dextran works as a long-acting progestin when administered intramuscularly. 17P has been manufactured locally by compounding pharmacies. After an extended application process, Makena®, another injectable form of 17P was approved by the FDA in February 2011. Intravaginal progesterone gel and suppositories have also been used.

Related Policies:

Home Uterine Activity Monitoring
Acute and Maintenance Tocolysis

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for progesterone therapy to reduce preterm birth in high risk pregnancies when the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Any member who is pregnant is eligible to have access to the Member Health PartnershipsSM – Pregnancy program. This program provides up-to-date information on pregnancy, labor and delivery options and costs, newborn care, and choosing a pediatrician, car seat and day-care with access to one-on-one health coaching from a pregnancy case manager.

When Progesterone Therapy is covered in High Risk Pregnancies

For women with a singleton pregnancy and prior history of spontaneous preterm birth before 37 weeks' gestation, the following may be considered medically necessary:

- Weekly injections of 17 alpha-hydroxyprogesterone caproate, performed in the office setting,

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initiated between 16 and 20 weeks of gestation and continued until 36 weeks 6 days.

- Daily vaginal progesterone between 24 and 34 weeks of gestation.

For women with a singleton pregnancy and a short cervix (less than 20 mm), the following may be considered medically necessary:

- Daily vaginal progesterone initiated between 20 and 23 weeks 6 days of gestation and continue until 36 weeks 6 days.

When Progesterone Therapy is not covered in High Risk Pregnancies

Progesterone therapy as a technique to prevent preterm labor is considered investigational in pregnant women with other risk factors for preterm delivery, including, but not limited to multiple gestations, or positive tests for cervicovaginal fetal fibronectin, cervical cerclage, or a uterine anomaly.

Administration of 17 alpha-hydroxyprogesterone caproate or vaginal suppositories in the home setting by a health professional is considered not medically necessary.

Policy Guidelines

There are no data comparing specialized services for home-based administration of 17P to other approaches such as office-based injections.

In October 2008, the American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion, Use of Progesterone to Reduce Preterm Birth. This document replaces the committee opinion of November 2003. The document states that "...based on current knowledge, it is important to offer progesterone for pregnancy prolongation to only women with a documented history of a previous spontaneous birth at less than 37 weeks of gestation. Progesterone supplementation for the prevention of recurrent preterm birth should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes. Current evidence does not support the routine use of progesterone in women with multiple gestations. Progesterone has not been studied as a supplemental treatment to cervical cerclage for suspected cervical insufficiency, as a preventive agent for asymptomatic women with positive cervico-vaginal fetal fibronectin screen result, as a tocolytic agent, or as a therapeutic agent after tocolysis, and it should not be used at this time for these indications alone."

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J1725, S9208

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

From policy titled: Preventing Premature Labor and Delivery

Meis PJ, Klebanoff M, Thom E et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. N Eng J Med 2003;348(24):2379-85.

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da Fonseca EB, Bittar RE, Carvalho MH et al. Prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk: a randomized placebo- controlled double-blind study. Am J Obstet Gynecol 2003;188(2):419-24.

American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 291. Use of Progesterone to Reduce Preterm Birth. Obstet Gynecol 2003;102:1115-6

Specialty Matched Consultant Advisory Panel - 12/2004.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.03, 12/14/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.11, 3/7/06.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.09, 12/14/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.04.16, 12/14/05.

Specialty Matched Consultant Advisory Panel - 12/13/2006

For policy titled: Progesterone Therapy in High Risk Pregnancies

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.04.16, 12/12/06.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.04.16, 4/9/08.

17-Alpha hydroxyprogesterone caproate for prevention of preterm birth: overview of FDA background document. Rockville, MD: Food and Drug Administration. 2006 Available at: <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4227B1-02-01-FDA-Background.pdf>.

Specialty Matched Consultant Advisory Panel - 12/2008

American College of Obstetricians and Gynecologists' Committee on Obstetric Practice and the Society for Maternal Fetal Medicine. Use of Progesterone to Reduce Preterm Birth. ACOG Committee Opinion Number 419 (replaces No. 291. November 2003). Obstet Gynecol 2008; 112(4):963-5.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.04.16, 10/06/09

Senior Medical Director review 9/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.04.16, 7/14/2011

Policy Implementation/Update Information

From policy titled: Preventing Premature Labor and Delivery

- 1/6/2005 Specialty Matched Consultant Advisory Panel review - 12/9/04. Added Section re: Progesterone Therapy in High Risk Pregnancies. Reference sources added.
- 1/17/07 Specialty Matched Consultant Advisory Panel review - 12/13/06. Under Section II - Progesterone Therapy in High Risk Pregnancies, second paragraph, added "by a health care professional" to the following sentence: " Administration of 17 alpha-hydroxyprogesterone caproate or vaginal suppositories in the home setting *by a health professional* is considered not medically necessary." Reference sources added. Added CPT code 90772 to the "Billing /Coding" section. Deleted CPT code 90782 from "Billing /Coding" section. No other changes. (pmo)

For policy titled: Progesterone Therapy in High Risk Pregnancies

- 1/12/09 Section II: Progesterone Therapy in High Risk Pregnancies removed from policy entitled: "Preventing Premature Labor and Delivery". Separate policy issued entitled "Progesterone Therapy in High Risk Pregnancies". Separate policy has no changes to policy criteria (What is covered and What is not covered), only added policy guidelines and reference sources. (pmo)

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- 6/22/10 Policy Number(s) removed (amw)
- 10/26/10 Description section revised. When Progesterone Therapy is Covered section revised to read: “Weekly injections of 17 alpha-hydroxyprogesterone caproate, performed in the office setting, between 16 and 36 weeks of gestation may be considered **medically necessary** for women with a singleton pregnancy and a prior history of spontaneous preterm birth before 37 weeks’ gestation. Daily vaginal progesterone between 24 and 34 weeks of gestation may be considered **medically necessary** for women with a singleton pregnancy and a prior history of spontaneous preterm birth before 37 weeks’ gestation.” The When Progesterone Therapy is Not Covered section revised to read: “In the absence of a prior history of spontaneous preterm birth, progesterone therapy as a technique to prevent preterm labor is considered **investigational** in pregnant women with other risk factors for preterm delivery, including, but not limited to multiple gestations, short cervical length, or positive tests for cervicovaginal fetal fibronectin, cervical cerclage, or a uterine anomaly.” Policy Guidelines updated. References updated. (adn)
- 1/18/2011 Specialty Matched Consultant Advisory Panel review 12/16/2010. Policy accepted as written. (adn)
- 10/11/11 Description section updated. When Covered section was changed to read: “For women with a singleton pregnancy and prior history of spontaneous preterm birth before 37 weeks’ gestation, the following may be considered medically necessary: Weekly injections of 17 alpha-hydroxyprogesterone caproate, performed in the office setting, initiated between 16 and 20 weeks of gestation and continued until 36 weeks 6 days, Daily vaginal progesterone between 24 and 34 weeks of gestation. For women with a singleton pregnancy and a short cervix (less than 20 mm), the following may be considered medically necessary: Daily vaginal progesterone initiated between 20 and 23 weeks 6 days of gestation and continue until 36 weeks 6 days.” The first statement in the When Not Covered section was revised to read: “Progesterone therapy as a technique to prevent preterm labor is considered investigational in pregnant women with other risk factors for preterm delivery, including, but not limited to multiple gestations, or positive tests for cervicovaginal fetal fibronectin, cervical cerclage, or a uterine anomaly.” Deleted CPT codes 90772 and 99506 from the Billing/Coding section and added code Q2042. Specialty Matched Consultant Advisory Panel review 9/28/11. (adn)
- 1/1/12 Code Q2042 deleted and replaced with code J1725 in Billing/Coding section. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.