

EFFECTIVE DATE: 06|01|2018

POLICY LAST UPDATED: 07|02|2019

OVERVIEW

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. This policy addresses treatment with the use of progesterone (injectable) to prevent preterm birth.

Note: Intravaginal formulations are covered as part of the member's pharmacy benefit.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Makena[®] (hydroxyprogesterone caproate) is medically necessary when all of the following criteria has been met:

Initial and Renewal Evaluation

1. The patient has a current singleton pregnancy **AND**
2. The patient is currently between 16 weeks 0 days and 20 weeks 6 days gestation **AND**
3. The patient has a history of spontaneous singleton preterm birth (defined as a birth occurring between 20 weeks 0 days through 36 weeks 6 days gestation. Birth occurring prior to 20 weeks is considered a miscarriage or spontaneous abortion) **AND**
4. The patient does not have any FDA labeled contraindications to therapy **AND**
5. The dose is 250 mg once weekly.

Length of Approval: up to 6 months or 36 weeks 6 days gestation, whichever occurs first.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare for brand name Makena[®] only.

POLICY STATEMENT

BlueCHiP for Medicare

Compounded 17P and Generic hydroxyprogesterone caproate

Progesterone therapy (Compounded 17P and Generic hydroxyprogesterone caproate) is medically necessary for women with a singleton pregnancy and prior history of spontaneous preterm birth before 37 weeks of gestation or for women with a singleton pregnancy and a short cervix (<20 mm). All other indications are not medically necessary that there is not any peer reviewed scientific evidence to support its efficacy.

Makena[®] - Brand name hydroxyprogesterone caproate

If it is necessary for a patient to take the brand Makena rather than the compounded version 17P, Makena[®] is medically necessary if the medical criteria above is met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug or specialty pharmacy benefits/coverage.

BACKGROUND

Preterm labor is defined as the presence of uterine contractions of sufficient frequency and intensity to effect progressive effacement and dilation of the cervix prior to term gestation (between 20 and 37 week). Preterm labor is the leading cause of neonatal mortality in the United States. Early identification of at-risk gravidas with timely referral for subspecialized obstretrical care may help identify women at risk for preterm labor and delivery and decrease the extreme prematurity rate, thereby reducing the morbidity, and mortality associated with prematurity. The goals of obstetric patient management include early identification of risk factors associated with preterm birth, timely diagnosis of preterm labor, identifying etiology of preterm labor, evaluating fetal well-being, providing prophylactic pharmacologic therapy to prolong gestation and reduce the incidence of respiratory distress syndrome (RDS), initiating tocolytic therapy when indicated, and establishing a plan of maternal and fetal surveillance with patient/provider education to improve neonatal outcome.

In women with single gestation pregnancy and a history of spontaneous preterm delivery, antenatal progesterone therapy is the most effective strategy to decrease the risk of a recurrent preterm delivery. Progesterone supplementation is beneficial in these women starting at 16 to 24 weeks gestation and continuing through 34 weeks gestation. Once preterm labor is confirmed, a single course of corticosteroid is the only intervention for improving neonatal outcomes, and may be considered as early as 23 weeks gestation in women likely to deliver within 7 days regardless of membrane status. Magnesium sulfate, tocolytic agents (nifedipine, indomethacin, terbutaline), and antibiotics are also used in preterm labor.

The reproductive effects of the 17-alpha-hydroxyprogesterone and natural progesterone (vaginal preparation) are not identical and have different biological activities. Guidelines recommends the use of 17-alpha-hydroxyprogesterone once weekly preferably beginning at 16 to 20 weeks up to 36 weeks to prevent preterm delivery in women with a history of a previous spontaneous preterm delivery (between 20 to 36 weeks 6 days). There is no evidence for the use of hydroxyprogesterone caproate in women with multiple gestations, short uterine cervix, or other high risk conditions. Natural progesterone is recommended for women with short cervix (≤ 20 mm) before 24 weeks and no previous preterm birth.

The safety and efficacy of hydroxyprogesterone was evaluated in a multicenter, randomized, double-blind, vehicle controlled trial in 463 (treatment group = 310; vehicle group = 153) patients with a history of singleton spontaneous preterm birth (defined as a birth occurring between 20 weeks 0 days through 36 weeks 6 days gestation. Birth occurring prior to 20 weeks is considered a miscarriage or spontaneous abortion.). Patients received weekly intramuscular injections starting between 16 weeks, 0 days and 20 weeks, 6 days of gestation, continuing until 37 weeks of gestation delivery. The primary endpoint was the proportion of women who delivered at <37 (the primary study endpoint), <35 , and <32 weeks of gestation. Compared to the control group (vehicle only) treatment with hydroxyprogesterone reduced the proportion of women who delivered preterm at <37 weeks. In the control group 54.9% versus 37.1% (-17.8% [CI: -28.0%, -7.45] of treated patients delivered at <37 weeks gestation.

CODING

BlueCHiP for Medicare

Brand Name- Makena[®]

The following HCPCS is medically necessary when criteria has been met

J1726 Injection, hydroxyprogesterone caproate, (makena), 10 mg

Compound Formula

The following codes are covered

J1729 Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, September 2019

Provider Update, June 2018

Provider Update, August 2017

Provider Update, November 2016

Provider Update, September 2015

REFERENCES:

1. Makena prescribing information. Lumara Health Inc. February 2018.
2. Ross, Michael G, MD, MPH, et al. Preterm Labor. Medscape. Available at: <http://emedicine.medscape.com/article/260998-overview#aw2aab6b3>. Accessed 08/07/18.
3. Rundell, Kristen, MD and Panchal, Bethany, MD. Preterm Labor: Prevention and Management. Am Fam Physician. 2017;95(6):366-372.
4. Society for Maternal-Fetal Medicine Clinical Guideline: Progesterone and preterm birth prevention: translating clinical trials into clinical practice. American Journal of Obstetrics & Gynecology May 2012; 6:376-386.
5. Norwitz, Errol R, MD, PhD, MBA, et al. Progesterone Supplementation to Reduce the Risk of Spontaneous Preterm Birth. UpToDate. Last updated July 2018.
6. Di Renzo GC, Roura LC, Facchinetti F et al. Guidelines for the management of spontaneous preterm labor: identification of spontaneous preterm labor, diagnosis of preterm premature rupture of membranes, and preventive tools for preterm birth. The Journal of Maternal-Fetal and Neonatal Medicine, May 2011; 24(5):659-667.

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