

SummaCare
Progesterone Therapy for Prevention of Preterm Delivery Clinical Practice Guideline

Reviewed and approved 8/1/2019

Risk Intervention	Recommendations
Background	Preterm birth is defined as a birth delivered at less than 37 completed weeks of gestation. This is a concern because babies who are born too early may not be fully developed. As a result, a host of serious health issues stemming from breathing problems, heart complications, temperature control problems, brain development issues, underdeveloped immune system, psychological issues, etc. can affect the baby's development both in early stages of development on into adulthood. In 2016, according to the CDC, preterm births affected about 1 out of every 10 infants born in the United States. The March of Dimes reported the U.S. preterm birth rate in -2017 to be 9.8%, giving it a 'C' rating. Preterm birth rates in the U.S. are highest among women < -18 years of age and > 35 years of age. Among racial ethnicity it is highest among non-Hispanic black mothers, followed by American Indians or Alaskan Natives, Hispanics, non-Hispanic whites, and Asian or Pacific Islanders. Factors influencing these rates may be associated with biological or genetic differences and reflections in socioeconomic, lifestyle, and cultural factors, access to medical care, along with environmental and occupational exposure. In 2016, the news agency Reuters reported that almost 16,000 babies born prematurely, has been linked to air pollution, according to researchers who analyzed air quality data and birth records. They noted that: "U.S. premature births linked to air pollution cost more than \$4 billion a year in medical care and lost economic opportunity, a new analysis estimates."
Treatment Recommendations For Progesterone Therapy	<u>Prevention Progesterone</u> <u>Clinical Considerations</u> • Cervical length-cervical shortening is a known risk factor for preterm birth in both low and high-risk populations. • Prior spontaneous preterm birth • Singleton vs multiple gestation Recommendations per ACOG (Bulletin #130) Oct 2012.Reaffirmed 2016: • Vaginal progesterone can reduce the risk of preterm birth in asymptomatic women with a singleton without prior Preterm Birth (PTB) and short cervix $\leq$ to 20 mm before or at 24 weeks. <u>*Algorithm for use of Progestogens in Prevention of PTB in Clinical Care</u> <pre> graph TD A[Singletons] --> B[History of Spontaneous PTB
(20 0/7- 36 6/7 weeks)] A --> C[No Prior Spontaneous PTB
Spontaneous PTB] B --> D["17-Hydroxyprogesterone
250 mg IM weekly
(Starting at 16-24 weeks per ACOG)"] C --> E[Short cervix ≤ 20 mm
at ≤ 24 weeks] E --> F["Vaginal Progesterone
90 mg gel or 200 mg suppository PV daily"] </pre> * Source: The American College of Obstetricians and Gynecologists. Practice Bulletin 130. Oct 2012. Reaffirmed 2016. In October 2012, the American College of Obstetricians and Gynecologists issued an updated practice bulletin No. 130- Prediction and Prevention of Preterm Birth. Reaffirmed 2016. The following recommendations regarding Progesterone therapy were made:

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	Recommendations based on good and consistent scientific evidence (Level A): • A woman with a singleton gestation and a prior spontaneous preterm singleton birth should be offered progesterone supplementation starting at 16-24 weeks of gestation, regardless of transvaginal ultrasound cervical length, to reduce the risk of recurrent spontaneous preterm birth. • Vaginal progesterone is recommended as a management option to reduce the risk of preterm birth in asymptomatic women with a singleton gestation without a prior preterm birth with an incidentally identified very short cervical length less than or equal to 20 mm before or at 24 weeks of gestation. • Progesterone treatment does not reduce the incidence of preterm birth in women with twin or triplet gestations and, therefore, is not recommended as an intervention to prevent preterm birth in women with multiple gestations. Recommendations based on limited or inconsistent scientific evidence (Level B): • Although this document does not mandate universal cervical length screening in women without a prior preterm birth, this screening strategy may be considered. • Insufficient evidence exists to assess if progesterone and cerclage together have an additive effect in reducing the risk of preterm birth in women at high risk for preterm birth.
Medical Indications for Authorizations	Medically Necessary: Weekly injections of 17 alpha-hydroxyprogesterone caproate between 16 and 36 weeks of gestation are considered <u>medically necessary</u> in pregnant women with: 1. Singleton pregnancy, and 2. Prior history of preterm singleton delivery before 37 weeks, and 3. Absence of preterm labor in current pregnancy Daily vaginal progesterone suppositories between 24 and 34 weeks are considered medically necessary in women who meet the above criteria Medical director review may be necessary in patients who are discovered to have a shortened cervix on transvaginal ultrasound who do not meet the above criteria <u>Not medically necessary</u> Patients who do not meet the above criteria, or those with other risk factors including, but not limited to: Multiple gestation Uterine anomalies Positive cervicovaginal fetal fibronectin testing
References	CDC/National Center for Health Statistics. Last review: June 13, 2018 CDC. Preterm Birth. Last Review: April 24, 2018 Iams, JD. Prevention of Preterm Parturition. The New England Journal of Medicine. 2014; 370: 25-261. March of Dimes Foundation 2017. March of Dimes.org/reportcard The American College of Obstetrics and Gynecologists (ACOG) Committee Practice Bulletin No. 169. Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancies. Oct 2016. The American College of Obstetricians and Gynecologists (ACOG) Committee Practice Bulletin No. 130. Prediction and prevention of preterm birth. Oct 2012, reaffirmed 2018. UpToDate 2017. Diagnosis of preterm labor and overview of preterm birth. This topic last updated: Dec 02, 2016. US Department of Health and Human Services. National Institutes of Health. Preterm labor and birth. Last Reviewed: Date 1/31/2017
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