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Clinical Coverage Guideline



Home Health Nursing for the Administration of Progesterone for the Prevention of Preterm Birth in High- Risk Women

Guideline Number: HS_014

Original Effective Date: 3/14/2008

Revision Date: 5/15/2009; 7/21/2011; **RETIRED
1/5/2012**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline HS-014

Obstetric Home Health for the administration of Progesterone for the Prevention of Preterm Birth in High-Risk Women

Original Effective Date: 3/14/2008

Revised Date(s): 5/15/2009, 5/28/2010, 07/21/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Weekly injections of 17 alpha-hydroxyprogesterone caproate is considered medically necessary for the prevention of preterm birth if ALL of the following criteria are met:

- Member is between 16 and 36 weeks gestation; **AND**,
- Member has a prior history of preterm delivery before 37 weeks gestation
- Travel to a physician's office weekly is not feasible because of bed rest order or undue burden on the member

Progesterone therapy to prevent preterm birth is considered NOT medically necessary in the following circumstances:

- Member does not meet the above criteria;

BACKGROUND

Preterm birth is defined as the birth of an infant at < 37 completed weeks of gestation, or at least 3 weeks before the due date at 40 weeks. Of more than 4 million births in the United States during 2004, 12.5% were preterm, a 30% increase in the rate of preterm births in 1981. Preterm births in the United States are most common in African American women (17.8% of births). A 2006 CDC study found that preterm birth was the leading cause of all infant deaths in 2002. While treatment improvements for preterm infants have greatly improved survival rates, these babies are susceptible to many medical complications, and, in the long term, these children, and especially those born at < 32 weeks of gestation, are at higher risk for health and development problems such as cerebral palsy, mental retardation, visual and hearing impairments, behavior and social-emotional problems, learning difficulties, and poor growth and general health. In the U.S., the cost to society that is associated with preterm birth has been estimated at \$51,600 per preterm infant, or a total of \$26.2 billion, in 2005, nearly two thirds for medical care, of which 85% was for care delivered in early infancy.

The causes, predictors, and pathological processes of spontaneous preterm birth (SPTB) are not well understood, and accurately predicting a preterm birth remains impossible. In the majority of cases, SPTB is related to infection. Risk factors associated with SPTB include a history of preterm birth or a second trimester miscarriage in a previous pregnancy, a family history of preterm birth, or having been born preterm herself; age, anxiety/ depression, smoking, socioeconomic factors, and biological and environmental factors are also risk factors. Other medical conditions such as chronic hypertension and diabetes are also associated with preterm birth. Predictors such as fetal fibronectin (FFN), cervical length, and other biochemical markers have been found useful in many patients, but additional large studies are needed to test the predictive value of these tests, as well as screening tools combining these tests and other risk factors. Furthermore, investigations to further scientific understanding of the mechanism of processes underlying SPTB are needed.

For pregnant women considered to be at high risk of SPTB, preventive efforts have included education and increased frequency of prenatal care visits, cervical cerclage (suture), treatment of infections, and progesterone. Treatment for imminent preterm labor has focused on slowing contractions using acute and/or maintenance tocolysis. Studies using treatment with antibiotics in preterm labor have been unsuccessful. Of these interventions, studies have shown that the use of progesterone has the most promise.

Progesterone is a progestational steroid hormone produced by the corpus luteum, placenta, and adrenal cortex. In early pregnancy, progesterone is critical in maintaining pregnancy before the placenta assumes this function at week 7 to 9. The role of progesterone in later pregnancy is not clear. Several studies over the last half-century have investigated the use of progesterone during pregnancy to prevent SPTB in women at increased risk. For this purpose, progesterone has been used in the form of weekly injections of 17 alpha-hydroxyprogesterone caproate (17 α -HPC, also referred to as 17P) or daily vaginal suppositories in asymptomatic women, or regular doses of progesterone by oral capsules in symptomatic women. Study results through the 1980s were conflicting and inconclusive. But recent interest in and prescribing of the drugs has increased in the maternal-fetal medicine community since 2003 when two studies were published indicating significant success in reducing the likelihood of preterm birth in asymptomatic women at high risk, one using injections of 17 α -HPC and one using vaginal suppositories. This technology assessment will review these and other studies, focusing on the questions of the efficacy and safety of progesterone use during pregnancy for the prevention of SPTB in asymptomatic women at high risk and, to a lesser extent, in symptomatic women.

The use of progesterone during pregnancy for prevention of preterm birth in high-risk women is currently under intense investigation, due to the promising results shown by two studies published in 2003, and the significance of the problem of preterm birth for public health in the United States and internationally. Based on the reviewed evidence, a 250-mg weekly intramuscular dose of 17 α -HPC given beginning in the second trimester of pregnancy appears to be effective in preventing preterm and very preterm birth in a significant proportion of cases, and a daily dose of progesterone in a vaginal suppository form shows promise of being effective, pending results from additional studies. The results of the studies assessing the effectiveness of progesterone in preventing preterm birth in women with imminent preterm labor are also inconclusive. Use of progesterone for prevention of preterm birth is not yet standard practice, and, as of this writing, no form or regimen of progesterone treatment has FDA approval for this indication. Many questions remain regarding a number of issues, including long-term safety, optimal treatment protocols, and appropriate patient selection criteria, as well as the mechanism of action of the treatment (Hayes, 2007).

Preterm Risk Factors

Preterm labor risk factors include, but are not limited to:

1. Previous premature birth
2. Current multiple gestation
3. Previous preterm labor during current pregnancy
4. Shortened cervix (15 mm or less)
5. Uterine bleeding in the current pregnancy after 14 weeks

Signs and symptoms suggestive of immediate risk for preterm delivery in women >20 weeks and <37 weeks gestation include:

1. Complaints of abdominal pain, pelvic pressure, abdominal cramps or low, dull backache.
2. Increased vaginal discharge and/or spotting.
3. Change in type (watery, mucus or bloody) of vaginal discharge.
4. Ruptured membranes.
5. Cervical dilation and/or effacement.
6. Persistent or frequent contractions or uterine tightening, often painless.

CODING

Covered CPT® Codes

96372 Therapeutic, prophylactic or diagnostic injection; (specify substance or drug); Subcutaneous or intramuscular; Physician or physician supervised

Covered ICD-9-CM Procedure Codes

99.24 Injection of Hormone

Covered HCPCS Code

J2675 Injection, progesterone, per 50 mg

S9560 Home injectable therapy; hormonal therapy;
i.e. Progesterone for the prevention of preterm birth in High-Risk Women

Covered ICD-9-CM Diagnosis Code when the above criteria have been met.

V13.21 Personal History of Pre-term Labor (excludes that occurring in current pregnancy)

***Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©**

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