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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc., take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

In the United States, preterm birth complicates 1 in 8 deliveries. Preterm babies account for over 85 percent of all perinatal morbidity and mortality. Ideally, in a healthy pregnancy, a baby is carried to full term (39-40 weeks gestation) and has plenty of time to grow and develop. Preterm babies are those born before 37 weeks of gestation. Any woman can be at risk for having a preterm delivery, but those who have a preterm delivery in the past are at higher risk for having another preterm baby. Common risk factors for preterm births are multiple gestation pregnancies, problems with the uterus or cervix, short time between pregnancies and certain infections and sexually transmitted diseases. Women of African American heritage, those with high blood pressure or diabetes, those who are overweight and those who drink alcohol, smoke or use illicit drugs are also at higher risk for preterm delivery.

Progesterone has been found to contribute to maintaining pregnancy in several ways. Corpus luteum progesterone production is critical for pregnancy maintenance until the placenta takes over this function at 7 to 9 weeks of gestation. Also progesterone maintains uterine dormancy or inactivity during the latter half of pregnancy. Finally, progesterone prevents apoptosis in fetal membrane explants under both basal and pro-inflammatory conditions and therefore may protect the membranes from preterm prelabor rupture and, in turn, preterm birth.

Progesterone supplementation has been shown to contribute to maintaining pregnancy in several ways. Progesterone production is critical for pregnancy maintenance until the placenta takes over this function at 7 to 9 weeks of gestation. Also progesterone maintains uterine dormancy or inactivity during the latter half of pregnancy. Finally, progesterone prevents apoptosis in fetal membrane explants under both basal and pro-inflammatory conditions and therefore may protect the membranes from preterm prelabor rupture and, in turn, preterm birth.

Progesterone supplementation has been shown to reduce the rate of preterm birth in women with a singleton pregnancy. It has not, however, been found effective in woman with multiple gestations (twins, triplets, etc.).

Makena® (hydroxyprogesterone caproate injection) is a progestin medication indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. It was originally approved for use in the United States in 1956. Makena® is only intended for use in women with singleton pregnancies and is not for use in women with multiple gestations.
Makena® can be administered subcutaneously or intramuscularly. Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation, but may begin as late as 26 weeks, 6 days of gestation. Administration should be continued once weekly until week 37 of gestation or delivery, whichever comes first. Intramuscular administration can be done by a healthcare provider in their office or in the home. The most commonly reported adverse reactions with Makena® were injection site reactions, swelling, pruritus and urticaria.

**POSITION STATEMENT**

**Applicable To:**
- [x] Medicaid – Kentucky

**Exclusions**

Administration of Makena® (17P) in a home health setting by a home health nurse is not considered medically necessary and not a covered benefit when any of the following apply:

1. Member has a history of any of the following contraindications:
   - Thrombosis or thromboembolic disorders; OR
   - Known or suspected breast cancer or history of these conditions; OR
   - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; OR
   - Cholestatic jaundice of pregnancy; OR
   - Liver tumors (benign or malignant) or active liver disease; OR
   - Uncontrolled hypertension

2. Makena® (17P) is not intended for use in women with multiple gestations.

**Coverage**

Administration of Makena® (17P) in a home health setting by a home health nurse is considered medically necessary and a covered benefit when any of the following apply:

1. Prescriber is: the Member’s obstetrician; AND,
2. Member is between 16 and 50 years of age; AND,
3. Medication must be initiated between week 16, 0 days and 26 weeks, 6 days of gestation with the coverage duration being up to 21 weeks; AND,
4. Maximum dose is 250 mg weekly; AND,
5. Member must have a statement of need (medical necessity) for preterm delivery prophylaxis in females with a singleton pregnancy who have a history of singleton spontaneous preterm birth; AND,
6. Medication must be continued weekly until week 37 of gestation or delivery, whichever comes first

**CODING**

**Covered CPT Codes** – None.

**Covered HCPCS Codes**
- J1726 Injection, hydroxyprogesterone caproate (Makena), 10 mg
- J1729 Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg

**Covered ICD-10 Codes**
- O09.211 Supervision of pregnancy with history of pre-term labor, first trimester
- O09.212 Supervision of pregnancy with history of pre-term labor, second trimester
- O09.213 Supervision of pregnancy with history of pre-term labor, third trimester
- O09.219 Supervision of pregnancy with history of pre-term labor, unspecified trimester
- O20.0 Threatened abortion
- O20.8 Other hemorrhage in early pregnancy
Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/state laws.
REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
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<td>11/7/2019</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>11/1/2018</td>
<td>Approved by MPC. Added NE specific criteria for prescribing provider.</td>
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<tr>
<td>8/24/2018</td>
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