Fetal Fibronectin and Salivary Estriol in Preterm Labor

<table>
<thead>
<tr>
<th>Type: Medical Necessity and Investigational / Experimental</th>
<th>Policy Specific Section: Laboratory/Pathology</th>
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<tr>
<td>Original Policy Date: January 7, 2011</td>
<td>Effective Date: January 7, 2011</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Preterm birth is considered a major healthcare problem worldwide. The identification of women at risk for preterm labor has been a research focus for many years, with the hope that early intervention can prevent the progression of preterm labor to preterm birth. Two identification techniques, the measurement of fetal fibronectin (FFN) and the measurement of salivary estriol levels, are addressed here.
The assessment of FFN is proposed for use in the diagnosis and management of preterm labor and the management of women at term being considered for induction. A rapid test is available that can provide results within 20 minutes.

It has been observed that salivary estriol levels surge several weeks before the onset of spontaneous preterm labor. Therefore, measurement of salivary estriol has also been explored as a risk predictor for preterm labor. The SalEst™ system has been used every one to two weeks in women with singleton pregnancies between 22 and 36 weeks of gestation.

**Policy**

Fetal fibronectin assay testing is considered **medically necessary** for use in pregnant women experiencing symptoms suggestive of preterm labor when all the following criteria are met:

- Gestation between 24 and 35 weeks
- Singleton or twin gestations
- Intact amniotic membranes
- Cervical dilation less than 3 centimeters (cm)

Fetal fibronectin assay testing is considered **investigational** for all other indications.

Salivary estriol testing is considered **investigational** for all indications.

**Policy Guideline**

CPT code 82731 (fetal fibronectin, cervicovaginal secretions, semi-quantitative) may be used to describe the fetal fibronectin enzyme-linked immunosorbent assay (ELISA) tests performed exclusively at reference laboratories.

There is no CPT code for the rapid FFN test which produces qualitative results (i.e., positive, negative, or indeterminate).

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<tr>
<th>Documentation Required for Clinical Review</th>
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<tbody>
<tr>
<td>- History and physical</td>
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<td>- Progress notes</td>
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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.