Medical Policy
Fetal Fibronectin Enzyme Immunoassay

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Policy Number: 298
BCBSA Reference Number: 2.04.03A

Related Policies
- Progesterone Therapy as a Technique to Reduce Preterm Birth in High-Risk Pregnancies, #552

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

The use of fetal fibronectin (FFN) assays may be MEDICALLY NECESSARY for use in women with singleton or twin gestations, with intact membranes, cervical dilation less than 3 cm, and who are experiencing symptoms suggestive of preterm labor between 24 and less than 35 weeks’ gestation. This population represents women who are most likely to be hospitalized and treated in an attempt to prevent preterm birth.

All other applications of the FFN assay, including but not limited to the following, are INVESTIGATIONAL:
- As part of routine pregnancy monitoring in asymptomatic women with singleton gestation and no risk factors for preterm birth
- As part of clinical monitoring of asymptomatic women at high risk for preterm birth, including but not limited to, those with multiple gestations, history of preterm birth, uterine malformation, cervical incompetence, or history of 2 or more spontaneous second trimester abortions
- As part of clinical monitoring in women with triplet or higher-order gestations, intact membranes, cervical dilation less than 3 cm, and who are experiencing symptoms suggestive of preterm labor, or
- As a test to identify women at term being considered for induction who are likely to deliver within 24–48 hours and therefore, do not require induction.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
Prior authorization is NOT required.

Commercial Members: PPO, and Indemnity
Prior authorization is NOT required.
Medicare Members: HMO Blue<sup>SM</sup>
Prior authorization is NOT required.

Medicare Members: PPO Blue<sup>SM</sup>
Prior authorization is NOT required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>82731</td>
<td>Fetal fibronectin, cervicovaginal secretions, semi-quantitative</td>
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### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>644.00</td>
<td>Threatened premature labor, unspecified as to episode of care or not applicable</td>
</tr>
<tr>
<td>644.03</td>
<td>Threatened premature labor, antepartum condition or complication</td>
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### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>O60.00</td>
<td>Preterm labor without delivery, unspecified trimester</td>
</tr>
<tr>
<td>O60.02</td>
<td>Preterm labor without delivery, second trimester</td>
</tr>
<tr>
<td>O60.03</td>
<td>Preterm labor without delivery, third trimester</td>
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### Description

Assessment of fetal fibronectin (FFN) is proposed for use in the diagnosis and management of preterm labor (PTL) and in the management of women at term being considered for induction. A rapid test is available that can provide results within 20 minutes.

FFN is a high-molecular-weight glycoprotein that can be isolated from fetal connective tissue, placenta, and amniotic fluid. It has been hypothesized that elevated FFN signals the separation of the placental uterine junction, and thus FFN may be a useful marker in predicting which women will experience spontaneous labor within a short period of time. Generally, a FFN level of 50 ng/mL or higher is considered a positive test.

The clinical importance of FFN measurement relates to the diagnosis and management of PTL. Clinical symptoms of PTL are nonspecific and if the signs and symptoms of PTL are sufficiently advanced or suspicious, delivery within 7 days may be highly probable. In these cases, particularly if gestation is 34 weeks or less, corticosteroid treatment for the induction of fetal lung maturity is indicated.

However, accurate diagnosis of PTL is extremely difficult; current methods of assessing risk result in overdiagnosis of PTL. FFN has been investigated as a method to more accurately diagnose PTL and thus
eliminate unnecessary hospitalizations, tocolytic therapy, and corticosteroid treatment in women who do not truly have PTL. The use of FFN has been studied in several different categories of patients:

- Women of average risk who are experiencing symptoms suggestive of preterm labor
- Women with multiple gestations or other high-risk factors for preterm birth who are experiencing symptoms of preterm labor
- Asymptomatic women with no risk factors for preterm birth; FFN is used in these patients as a screening test at certain intervals during pregnancy
- Asymptomatic women with multiple gestations or other high-risk characteristics of preterm birth; FFN is used in these patients as a screening test at certain intervals during pregnancy, and
- Women at term being considered for induction who are likely to deliver within 24–48 hours and therefore do not require induction.

An example of a rapid qualitative FFN test for the assessment of the risk of preterm delivery is the Fetal Fibronectin Enzyme Immunoassay from Adeza Biomedical. All rapid qualitative FFN testing for the assessment of the risk of preterm delivery are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except as noted in the policy statement.

**Summary**

Systematic reviews have found a significant impact of FFN testing in women with singleton pregnancies and symptoms of preterm labor on reduced rates of preterm birth before 37 weeks’ gestation and on hospitalization rates. There is insufficient evidence that FFN testing improves the net health outcome for asymptomatic women at average risk or at increased risk of preterm labor. No published evidence was identified on FFN assessment in women with triple or higher-order gestations or in women being considered for induction.

Thus, FFN assessment may be considered medically necessary in women with singleton or twin gestations who have signs or symptoms of preterm labor, since the original premise has not been disproven. However, use of FFN assessment is considered investigational for all other applications.

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>11/2013</td>
<td>Removed ICD.9 diagnosis codes: 640.00-640.03; 644.10, 644.13, 644.20, 644.21 as they do not meet the intent of the policy.</td>
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### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

### References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Fetal fibronectin enzyme immunoassay. TEC Assessments 1997; Volume 12, Tab 16.