Clinical Policy Title: Home uterine activity monitoring

Clinical Policy Number: 12.01.01

Effective Date: August 19, 2015
Initial Review Date: July 17, 2013
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Policy contains:
- Home uterine activity monitoring.
- Uterine contraction.
- Premature labor.

Related policies:

CP# 18.01.02 Telehealth
CP# 12.01.02 Prenatal obstetrical ultrasound

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of home uterine activity monitoring to be clinically proven, and therefore, medically necessary in either of the following circumstances on an individual case exception basis:

- For pregnant women with gestational age greater than 18 weeks who cannot feel their contractions and have certain complications.
- For women with physiologic or anatomic factors (e.g., paralysis or neuromuscular disorders such as muscular dystrophy) that limit their ability to self-detect contractions.

Limitations:

All other uses of home uterine activity monitoring are not medically necessary.

Alternative covered services:
• Office visits or home health visits by an appropriately trained health professional.
• Measurement of cervical-vaginal fetal fibronectin.
• Ultrasound determination of cervical length.

**Background**

According to recent Centers for Disease Control and Prevention (2018) information, one in every 10 infants born in the United States is born prematurely. Premature is defined as a birth prior to 37 weeks gestation. Prematurity is associated with significant acute and chronic morbidity in a child, especially those with neurologic and respiratory conditions.

A number of strategies have been developed to reduce the rate of premature labor and delivery. They involve tocolytic therapy, enhanced hospital or home surveillance, educational programs to help women identify the signs of early labor, and electronic home uterine activity monitoring devices.

Home uterine activity monitoring is an electronic system for at-home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The U.S. Food and Drug Administration (2018) classifies home uterine activity monitoring systems as Class II devices (21CFR884.2730). It is a prescription-use only system that is indicated for use, in conjunction with standard high-risk care, for the daily at-home measurement of uterine activity in pregnancies of at least 24 weeks gestation for women with a history of previous preterm birth.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on May 10, 2018. Search terms were: “uterine monitoring” (MeSH), “home uterine monitoring,” and “preterm labor prevention” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Home uterine monitoring may result in fewer admissions to a neonatal intensive care unit, but more unscheduled antenatal visits and tocolytic treatment. There is no impact on maternal and perinatal outcomes, such as perinatal mortality or incidence of preterm birth.

**Policy updates:**

A recent update of a systematic review inclusive of 6,008 pregnant women found home monitoring may result in fewer neonatal intensive care unit admissions but more unscheduled antenatal visits and tocolytic treatment (Urquhart, 2015). The level of evidence is low–to-moderate in this regard.

In 2017, Urquhart et al updated their 2015 Cochrane review of home uterine activity monitoring for detecting preterm labor. They identified no new information since their 2015 publication. The American College of Obstetricians and Gynecologists (2016) updated their guideline on managing preterm labor. Their position, which does not support the use of home uterine activity monitoring to prevent preterm delivery in women with contractions but no cervical change, remains unchanged.

The results suggest home uterine activity monitoring is safe but does not appreciably improve perinatal outcomes. Frequent contact, either face-to-face or by telephone, with an experienced provider appears to be as effective as home uterine activity monitoring or continued pharmacological therapy. However, there may be instances in which, despite educational efforts, some women (e.g., paraplegia) may not recognize contractions in time for treatment and are at risk of giving birth early. In such instances, home uterine activity monitoring may be indicated. The new information is consistent with the currently policy, and no changes are warranted.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urquhart (2017)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Cochrane review</td>
<td>• Systematic review of 15 randomized controlled trials (6,008 total women).</td>
</tr>
<tr>
<td>Home uterine monitoring for detecting preterm labor</td>
<td>• Overall quality: low-to-moderate with moderate-to-high risk of bias.</td>
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<tr>
<td></td>
<td>• Women using home uterine monitoring were less likely to experience preterm birth, but made more unscheduled antenatal visits and had more tocolytic therapy.</td>
</tr>
<tr>
<td></td>
<td>• There was no significant difference in the rate of perinatal mortality or incidence of preterm birth.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</tbody>
</table>
| ACOG (2016) Guideline: Management of preterm labor | - Home uterine monitoring may result in fewer admissions to a neonatal intensive care unit.  
- No data found on maternal anxiety or acceptability.  
- Important group differences were not evident when sensitivity analysis was used for only trials at low risk of bias. |
| Newman (2006) Uterine contraction frequency in twins | **Key points:**  
- Prospective masked observational study with 59 twin pregnancies and 306 singletons enrolled.  
- Mean uterine contraction frequency was significantly higher for twin gestations than singletons.  
- In twin pregnancies, maximum a.m. and p.m. contraction frequency did not predict spontaneous preterm birth in less than 35 weeks gestation. |
| Iams (2002) Frequency of uterine contractions and the risk of spontaneous preterm delivery | **Key points:**  
- Study of 34,908 hours of uterine activity monitoring in 306 pregnant women.  
- More contractions in women who delivered prior to 35 weeks gestation, than those delivering later.  
- No threshold frequency that could effectively identify women who delivered preterm infants.  
- Conclusion: Although the likelihood of preterm delivery increases with an increased frequency of uterine contractions, measurement of this frequency is not clinically useful for predicting preterm delivery. |
| Brooten (2001) Randomized trial of nurse specialist home care for women with high-risk pregnancies | **Key points:**  
- RCT of 173 women with high-risk pregnancies, randomized to usual care or to home nurse visits, with education and support.  
- Intervention group had lower fetal/infant mortality versus the control group (2 versus 9), 11 fewer preterm infants, more twin pregnancies carried to term (77.7% versus 33.3%), fewer prenatal hospitalizations (41 versus 49), fewer infant hospitalizations (18 versus 24), and a savings of more than 750 total hospital days.  
- Conclusion: Home nurses provided better outcomes in high-risk pregnancies than usual care. |

**References**

**Professional society guidelines/other:**

Peer-reviewed references:

21CFR884.2730.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**
No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>82731</td>
<td>Fetal fibronectin, cervicovaginal secretions, semi-quantitative</td>
<td></td>
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<tr>
<td>99500</td>
<td>Home visit for prenatal monitoring and assessment to include fetal heart rate, non-stress test, uterine monitoring, and gestational diabetes monitoring</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>O60.00</td>
<td>Preterm labor without delivery, unspecified trimester</td>
<td></td>
</tr>
<tr>
<td>O60.02</td>
<td>Preterm labor without delivery, second trimester</td>
<td></td>
</tr>
<tr>
<td>O60.03</td>
<td>Preterm labor without delivery, third trimester</td>
<td></td>
</tr>
<tr>
<td>O47.00</td>
<td>False labor before 37 completed weeks of gestation, unspecified trimester</td>
<td></td>
</tr>
<tr>
<td>O47.9</td>
<td>False labor before 37 completed weeks of gestation, second trimester</td>
<td></td>
</tr>
<tr>
<td>O47.00</td>
<td>False labor unspecified</td>
<td></td>
</tr>
<tr>
<td>O47.02</td>
<td>False labor before 37 completed weeks of gestation, second trimester</td>
<td></td>
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<tr>
<td>O47.03</td>
<td>False labor before 37 completed weeks of gestation, third trimester</td>
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<tr>
<td>O47.1</td>
<td>False labor at or after 37 completed weeks of gestation</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>S9001</td>
<td>Home uterine monitor with or without associated nursing services</td>
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<tr>
<td>S9208 - S9214</td>
<td>Home management of preterm labor, preterm rupture of membranes (PROM), gestational hypertension, postpartum hypertension, preeclampsia, or gestational diabetes, including administrative services, professional pharmacy services, care coordination, and all necessary supplies or equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusion per diem code)</td>
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