

## Medical Policy



An Independent Licensee of the  
Blue Cross and Blue Shield Association

### Title: Home Uterine Activity Monitoring

#### Professional

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#### Institutional

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### DESCRIPTION

The home uterine activity monitor (HUAM) is a device intended to provide early detection of preterm labor (PTL) in women at high risk of developing PTL and preterm birth (PTB). A monitoring device worn by the patient collects data on uterine activity. After using the device, the patient transmits data recordings to a provider who assesses risk of PTL onset based on frequency of uterine contractions and responses to interview questions.

The home uterine activity monitoring device consists of a guard-ring tocodynamometer (worn as a belt around the abdomen), a data recorder, and a data transmitter. Usually, the patient is instructed to use the device daily for two 1-hour periods. After monitoring, the patient transmits the recordings by telephone modem link to a remote base station. Base station nurses not only facilitate transmission and analysis of the monitor tracings,

they also maintain daily telephone contact with the patient to assess signs and symptoms and to provide advice and counseling.

Nurses employed in HUAM services look for evidence of the onset of PTL, either on the basis of uterine activity exceeding a threshold level or from the findings of a telephone interview with the patient. Signs and symptoms of PTL include back pain, increased vaginal discharge, menstrual-like cramps, and pelvic pressure or heaviness. The threshold number of uterine contractions signaling the possible onset of PTL is usually 4 to 6 per hour. If signs and symptoms are present or the uterine activity exceeds a certain threshold, patients are instructed to perform the following: empty the bladder, hydrate orally, and assume the left lateral recumbent position. The patient is also instructed to remonitor for 1 additional hour. If uterine activity still exceeds threshold or signs and symptoms persist, the patient is instructed to see her physician immediately for a cervical examination. The cervical examination would then play a pivotal role in diagnosing whether PTL is occurring and whether to initiate tocolytic therapy.

### Regulatory Status

In March 2001, the U.S. Food and Drug Administration (FDA) reclassified HUAMs from class III (Premarket Approval) to class II (Special Controls) devices. The HUAM is a post-amendment device and thus, was automatically reclassified into class III. Devices with 510(k) marketing clearance from the FDA include the Fetal Assist (Huntleigh Diagnostics, Eatontown, NJ) and the Carefone Home Uterine Activity Monitoring System (Carelink Corp, Santa Ana, CA). The HUAM is described as 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 HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. The FDA indicates that the device is intended for use in women at least 24 weeks' gestation with a previous preterm delivery to aid in the detection of preterm labor.

### POLICY

Home uterine activity monitoring through a monitoring device and/or daily nursing contact is considered **not medically necessary**.

### RATIONALE

At the time the 1996 TEC Assessment was published, there had been numerous randomized controlled trials (RCTs) of home uterine activity monitor (HUAM); many of these contained methodological weaknesses. (1) In addition, several meta-analyses had been published. The three meta-analyses that specifically addressed whether HUAM or nursing contact, alone or combined, achieved better health outcomes than standard care found that the data were insufficient to support the clinical use of HUAM. None of the meta-analyses identified significant effects of monitoring on referral to neonatal intensive care units, (NICU) the intermediate outcome most related to neonatal morbidity.

Most recently, in 2012, a Cochrane review was published in HUAM for detecting preterm labor. (2) The review identified 15 RCTs that compared use of HUAM to standard care, or to an alternative type of surveillance, for women at increased risk of preterm labor. Although the literature was searched through November 2011, all of the trials identified were published in 1999 or earlier. The trials included a total of 6008 participants; sample sizes ranged from fewer than 100 participants to over 1000 participants. Only 2 studies (those with a sham-control) were double-blind. Two of the 15 trials did not contribute data to the meta-analysis; one did not report relevant outcomes and the other did not report data in a form that could be included in the analyses. Two trials (total sample size: 2589) reported the perinatal mortality rate as a study outcome. A pooled analysis of data from these studies did not find a statistically significant difference in perinatal mortality in groups that did and did not receive HUAM [risk ratio (RR): 1.22, 95% CI: 0.86 to 1.72]. In addition, in a pooled analysis of data from 8 trials (total sample size: 4834), there was not a significant difference between groups in the rate of preterm birth at less than 37 weeks' gestation (RR: 0.85, 95% CI: 0.72 to 1.01). There was a significantly lower rate of preterm birth before 34 weeks' gestation in women managed with HUAM compared to an alternative intervention (RR: 0.78, 95% CI: 0.62 to 0.99). That analysis included 3 studies with a total sample size of 1596. However, a sensitivity analysis that excluded data from the 2 lower-quality and substantially smaller trials and included one trial with n=1292 found a non-significant difference between groups in the rate of preterm birth before 34 weeks (RR: 0.75, 95% CI: 0.57 to 1.00). Similarly, a pooled analysis of 5 studies (n=2367) found a significantly lower rate of admission to NICUs in the group that used HUAM (RR: 0.77, 95% CI: 0.62 to 0.96). The difference in NICU admission rates was not statistically significant when lower-quality studies were excluded and only the single higher-quality large study (n=1292) remained in the analysis (RR: 0.86, 95% CI: 0.74 to 1.01).

Another systematic review was published in 2009 by the Health Technology Assessment program in the United Kingdom. (3) The investigators conducted a systematic review of literature on various screening techniques for preventing spontaneous preterm birth; one of these techniques was HUAM. The review of HUAM included 3 trials with a total sample size of 618. Only one of the trials was considered to be of good quality; the others were considered to be poor quality. Study findings were not pooled due to clinical heterogeneity. According to the assessment, the trials found no statistically significant difference in the incidence of preterm birth before 34 or 37 weeks' gestation in women who received HUAM compared to controls. Similarly, there were no statistically significant differences in the rate of admission to NICUs.

Two of the studies with larger sample sizes and designed to determine whether adding HUAM to nursing contact would improve clinical outcomes are described briefly below. In 1995, the Collaborative Home Uterine Monitoring Study (CHUMS) Group published a randomized double-blind multicenter trial that randomly assigned 1292 women to active or sham HUAM compared to twice-daily nursing contact. (4) The investigators found similar outcomes in the 2 groups e.g. rates of preterm labor, preterm birth and need for neonatal intensive care. Another large study was published in 1998 by Dyson and colleagues (5) The investigators randomly assigned 2,422 pregnant women at high risk for preterm labor to receive either weekly contact with a nurse, daily contact with a nurse, or daily contact with a nurse plus HUAM. However, there were no significant differences among the groups for the primary endpoint of birth at less than 35 weeks' gestation.

There is less evidence specifically on the use of HUAM for the tertiary prevention of preterm delivery. Most trials on HUAM included only patients who were considered “at risk” for preterm birth, and many specifically excluded those patients who had a history of preterm labor in the current pregnancy. Four trials were identified that evaluated the use of HUAM for tertiary prevention; none of these found that HUAM improved health outcomes. All of these trials are included in the 2012 Cochrane review, described above. The trials are briefly summarized below:

- Iams and colleagues conducted a trial looking at HUAM in 76 women who had been successfully treated for preterm labor. (6) Women were randomly assigned to receive either HUAM or a program of education and uterine self-palpation. Both groups also received nursing contact 5 days per week. Rates of recurrent preterm labor and preterm delivery did not differ between the groups.
- Blondel and colleagues randomly assigned 74 women with successfully treated preterm labor to either undergo HUAM and nursing contact or weekly or biweekly home nursing visits. There was no significant difference in the rate of preterm deliveries between the 2 groups. (7)
- Nagey and colleagues reported on a study that randomly assigned 56 women with a history of successfully treated preterm labor to receive either HUAM or standard treatment. (8) There was no difference in the incidence of preterm birth between the 2 groups.
- Brown and colleagues reported on the results of a trial that randomly assigned 162 women who had experienced an episode of preterm labor in the current pregnancy to undergo HUAM plus standard care or standard care alone. (9) There were no differences in outcomes between the two groups, including percentage of women delivered at less than 35 weeks’ gestation, the term delivery rate, neonatal intensive care admissions, and percentage of women receiving corticosteroid treatment for prevention of neonatal complications.

### **Summary**

There is a substantial evidence base on home uterine activity monitoring for reducing preterm birth in high-risk pregnant women. Numerous RCT’s have been performed prior to the year 2000. The trials that were the largest in size and highest in quality have not reported a benefit for HUAM, and systematic reviews of the available trials have not concluded that health outcomes are improved. The available evidence suggests that HUAM does not improve health outcomes, and HUAM is not recommended by national organizations such as the American College of Obstetricians and Gynecologists (ACOG) and the U.S. Preventive Services Task Force. Thus, home uterine activity monitoring can be considered not medically necessary.

### **Practice Guidelines and Position Statements**

The organizations’ most recent statements are as follows:

The U.S. Preventive Services Task Force current topic page on HUAM states, “Home uterine monitoring is no longer considered a part of standard obstetric care and is not relevant to clinical practice. The USPSTF stated that it would not be updating its 1996 recommendation.” (10)

In 2002, the National Institute of Child Health and Human Development (NICHD) issued a news release declaring that home uterine monitors are not useful for predicting premature birth. The news release describes a study sponsored by the NICHD which found that ambulatory monitoring of uterine contractions did not identify women most likely to have preterm delivery. (11)

In 2003, an ACOG Practice Bulletin included the following statement: "No evidence exists to support the use of tocolytic therapy, HUAM, elective cerclage, or narcotics to prevent preterm delivery in women with contractions but no cervical change. " (12) The position statement was affirmed in 2008. (13)

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.**

### CPT/HCPCS

99500 Home visit for prenatal monitoring and assessment to include fetal heart rate, non-stress test, uterine monitoring and gestational diabetes monitoring

S9001 Home uterine monitor with or without associated nursing services

### DIAGNOSIS

644.00 Early or threatened labor; threatened premature labor, unspecified as to episode of care

644.03 Early or threatened labor; threatened premature labor, antepartum

644.10 Early or threatened labor; other threatened labor, unspecified as to episode of care

644.13 Early or threatened labor; other threatened labor, antepartum

644.20 Early or threatened labor; early onset of delivery, unspecified as to episode of care

644.21 Early or threatened labor; early onset of delivery, with or without mention of antepartum condition

## **REVISIONS**

03-08-2010	Policy added to the bcbsks.com web site.
12-07-2012	Added Medical Policy and Coding Disclaimers
	Rationale section updated.
	Reference section updated.
	In the Coding section: <ul style="list-style-type: none"> <li>▪ Updated coding format</li> </ul>

## **REFERENCES**

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2. Urquhart C, Currell R, Harlow F et al. Home uterine monitoring for detecting preterm labour. *Cochrane Database Syst Rev* 2012; 5:CD006172.
3. Honest H, Forbes CA, Duree KH et al. Screening to prevent spontaneous preterm birth: systematic reviews of accuracy and effectiveness literature with economic modeling. *Health Technol Assess* 2009; 13(43):1-627.
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10. U.S. Preventive Services Task Force. Screening Home Uterine Activity Monitoring. 1996. Available online at: <http://www.uspreventiveservicestaskforce.org/uspstf/uspshuam.htm>. Last accessed October, 2012.
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13. American College of Obstetricians and Gynecologists (ACOG). Management of Preterm Labor. Available online at: <http://www.guideline.gov>. Last accessed October, 2012.

**Other References:**

1. Blue Cross and Blue Shield of Kansas OB/GYN Liaison Committee, July 2008.