

**EFFECTIVE DATE:** 10|01|2015

**POLICY LAST UPDATED:** 04|20|2022

## OVERVIEW

The home uterine activity monitor (HUAM) is a device intended to provide early detection of preterm labor in women at high risk of preterm labor and preterm birth. 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 preterm labor-onset, based on frequency of uterine contractions and responses to interview questions.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### Medicare Advantage Plans

Home uterine activity monitoring, with or without nursing contact, is not covered, including use with tocolytic therapy (medications used to slow contractions). Despite numerous scientific studies, there is insufficient evidence to determine the effects of the technology on health outcomes.

### Commercial Products

Home uterine activity monitoring, with or without nursing contact, is considered not medically necessary, including use with tocolytic therapy (medications used to slow contractions). Despite numerous scientific studies, there is insufficient evidence to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

The home uterine activity monitor (HUAM) is a monitoring device that consists of a guard-ring tocodynamometer (worn as a belt around the abdomen), a data recorder, and a data transmitter. Typically, 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 preterm labor, 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 preterm labor 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 preterm labor 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 re-monitor 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 preterm labor 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 postamendment 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 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.

There is a substantial evidence base on home uterine activity monitoring for reducing preterm birth in high-risk pregnant women. Numerous RCTs 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. Thus, home uterine activity monitoring can be considered not medically necessary.

#### **CODING**

The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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

#### **RELATED POLICIES**

Not applicable

#### **PUBLISHED**

- Provider Update, June 2022
- Provider Update, August 2021
- Provider Update, May 2020
- Provider Update, September 2019
- Provider Update, November/December 2018

#### **REFERENCES**

1. Urquhart C, Currell R, Harlow F, Callow L. Home uterine monitoring for detecting preterm labour. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD006172.
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.
4. A multicenter randomized controlled trial of home uterine monitoring: active versus sham device. The Collaborative Home Uterine Monitoring Study (CHUMS) Group. Am J Obstet Gynecol 1995; 173(4):1120-7.
5. Dyson DC, Danbe KH, Bamber JA et al. Monitoring women at risk for preterm labor. N Engl J Med 1998; 338(1):15-9.
6. Iams JD, Johnson FF, O'Shaughnessy RW. Ambulatory uterine activity monitoring in the post-hospital care of patients with preterm labor. Am J Perinatol 1990; 7(2):170-3.

7. Blondel B, Breart G, Berthoux Y et al. Home uterine activity monitoring in France: a randomized, controlled trial. *Am J Obstet Gynecol* 1992; 167(2):424-9.
8. Nagey DA, Bailey-Jones C, Herman AA. Randomized comparison of home uterine activity monitoring and routine care in patients discharged after treatment for preterm labor. *Obstet Gynecol* 1993; 82(3):319-23.
9. Brown HL, Britton KA, Brizendine EJ et al. A randomized comparison of home uterine activity monitoring in the outpatient management of women treated for preterm labor. *Am J Obstet Gynecol* 1999; 180(4):798-805.
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, 2013.
11. National Institute of Child Health and Human Development. Home uterine monitors not useful for predicting premature birth. Available online at: <http://www.nih.gov/news/pr/jan2002/nichda23.htm>. Last accessed October, 2013.

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