



Home Uterine Activity Monitoring

Policy # 00068

Original Effective Date: 05/1993

Current Effective Date: 03/11/2024

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of home uterine activity monitor (HUAM) through a monitoring device and/or daily nursing contact to be **investigational**.*

Background/Overview

The 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 HUAM 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 four to six per hour. If signs and symptoms are present or the

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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 one 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In March 2001, the 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. Cleared devices 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 receives processes and displays 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.

Centers for Medicare and Medicaid Services (CMS)

Not applicable.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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At the time the 1996 TEC Assessment was published, there had been numerous randomized controlled trials (RCTs) of HUAM; many of these contained methodologic weaknesses. 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. 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 6,008 participants; sample sizes ranged from fewer than 100 participants to more than 1,000 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: 2,589) 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% confidence interval [CI]: 0.86 to 1.72). In addition, in a pooled analysis of data from 8 trials (total sample size: 4,834), 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 1,596. However, a sensitivity analysis that excluded data from the 2 lower-quality and substantially smaller trials and included one trial with n=1,292 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=2,367) 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=1,292) remained in the analysis (RR: 0.86, 95% CI: 0.74 to 1.01).

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Another systematic review was published in 2009 by the Health Technology Assessment program in the United Kingdom. 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 1,292 women to active or sham HUAM compared to twice-daily nursing contact. 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. 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. 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.

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- 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.
- 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. 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. 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 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 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.

American College of Obstetricians and Gynecologists and other expert organizations recommend not using home uterine activity monitors to monitor women at increased risk for preterm labor (PTL) or recurrent PTL. In a 2017 systematic review and meta-analysis of trials of standard care with versus without home uterine activity monitoring, the intervention had no impact on maternal and perinatal outcomes such as perinatal mortality or preterm birth.

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Policy History

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|------------|---|
| 08/16/2001 | Medical Policy Committee review |
| 09/17/2001 | Managed Care Advisory Council approval |
| 06/24/2002 | Format revision. No substance change to policy. |
| 08/25/2003 | Medical Policy Committee review |
| 05/02/2007 | Medical Director review |
| 05/18/2007 | Medical Policy Committee approval. |
| 06/13/2007 | Medical Director review |
| 06/20/2007 | Medical Policy Committee approval. Coverage eligibility changed to investigational. |
| 07/10/2007 | Medical Director review |
| 11/12/2009 | Medical Policy Committee approval |
| 11/18/2009 | Medical Policy Implementation Committee approval. Coverage statement changed to "Based on review of available data, the Company considers the use of home uterine activity monitor (HUAM) through a monitoring device and/or daily nursing contact to be investigational." Rationale updated. |
| 11/04/2010 | Medical Policy Committee approval |
| 11/16/2010 | Medical Policy Implementation Committee approval. No change to coverage. |
| 11/03/2011 | Medical Policy Committee approval |
| 11/16/2011 | Medical Policy Implementation Committee approval. No change to coverage. |
| 11/01/2012 | Medical Policy Committee approval |
| 11/28/2012 | Medical Policy Implementation Committee approval. No change to coverage. |

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11/07/2013	Medical Policy Committee approval
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee approval
11/21/2014	Medical Policy Implementation Committee approval. No change to coverage.
10/29/2015	Medical Policy Committee review. Recommend archiving policy.
11/16/2015	Medical Policy Implementation Committee approval. Archived.
02/07/2019	Medical Policy Committee approval
02/20/2019	Medical Policy Implementation Committee approval. Brought back to active status.
02/06/2020	Medical Policy Committee approval
02/12/2020	Medical Policy Implementation Committee approval. No change to coverage.
02/04/2021	Medical Policy Committee approval
02/10/2021	Medical Policy Implementation Committee approval. No change to coverage.
02/03/2022	Medical Policy Committee approval
02/09/2022	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2023	Medical Policy Committee approval
02/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2024	Medical Policy Committee approval
02/14/2024	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 02/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	99500
HCPCS	S9001
ICD-10 Diagnosis	O47.00-O47.9, O60.00-O60.03

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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Returned to Active Status: 02/20/2019

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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