Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Home Uterine Activity Monitoring

Description/Background

The home uterine activity monitor (HUAM) is a device intended to provide early detection of preterm labor in individuals at high risk of developing preterm labor and preterm birth. The HUAM is a monitoring device that consists of a guard-ring tocodynamometer (worn as a belt around the abdomen), and a device for recording, storing and transmitting data from the sensor. Typically, the patient is instructed to use the device daily for two 1-hour periods. After monitoring, the patient transmits the recordings by either telephone modem link or by electronically uploading information to a clinic or monitoring center. Nurses at the clinic or monitoring center facilitate transmission and analysis of the data, and also maintain telephone contact with the patient to assess signs and symptoms and to provide advice and counseling.[1] Symptoms of preterm labor include back pain, increased vaginal discharge, menstrual-like cramps, and pelvic pressure or heaviness. If symptoms are present or if the uterine activity exceeds a certain threshold, patients are given instructions that may include home interventions, continued monitoring or to contact the physician.

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[2].

The HUAM 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 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 individuals at least 24 weeks' gestation with a previous preterm delivery, to aid in the detection of preterm labor.[2]

Medical Policy Statement

Home uterine activity monitoring has not been established as an effective service for predicting and/or improving the outcome in the management of premature labor and delivery.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

S9001

Rationale

There is a substantial evidence base on home uterine activity monitoring for reducing preterm birth in high-risk pregnant individuals. Numerous randomized controlled trials have been performed; however, 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.

Urquhart et al (2017) updated their 2015 Cochrane Review of home uterine monitoring.[3] The authors re-stated their conclusion that there is no impact on maternal and perinatal outcomes such as perinatal mortality of incidence of preterm birth.

Another large study was published in 1998 by Dyson et al.[4] The investigators randomly assigned 2422 pregnant individuals 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 HAUM. However, there were no signification differences among the groups for the primary end point of birth at less than 35 weeks gestation.

Supplemental Information

Practice Guidelines and Position Statements

National Institute of Child Health and Human Development
In 2002, the National Institute of Child Health and Human Development (NICHD) issued a news release stating[5]: "Portable monitors that detect contractions of the uterus do not appear to be useful for identifying women likely to have a preterm delivery…" The news release describes a study sponsored by the NICHD which found that ambulatory monitoring of uterine contractions did not identify most likely to have preterm delivery.

American College of Obstetricians and Gynecologists

The ACOG published practice bulletin number 169 (2016)D[6], Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancy. This bulletin was updated in June 2021 as number 231. The bulletin states: " No evidence exists to support the use of prophylactic tocolytic therapy, home uterine activity monitoring, cerclage, or narcotics to prevent preterm delivery in women with contractions but no cervical change".

ACOG 171 practice bulletin number 171 October (2016) (reaffirmed 2020) states "No evidence exists to support the use of prophylactic tocolytic therapy, home uterine activity monitoring, cerclage, or narcotics to prevent preterm delivery in women with contractions but no cervical change"[7].

ACOG practice bulletin number 234 titled Prediction and Prevention of Spontaneous Preterm Birth from August 2021 states " Home monitoring of uterine activity previously has been studied, and it has not been shown to reduce the risk of preterm birth"[8]

U.S. Preventive Services Task Force
The U.S. Preventive Services Task Force issued a statement on HUAM in 1996[9].

> "There is insufficient evidence to recommend for or against home uterine activity monitoring (HUAM) in high-risk pregnancies as a screening test for preterm labor, but recommendations against its use may be made on other grounds."

Government Regulations National/Local:

There is no national or local coverage determination on HUAM.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Blue Cross Blue Shield Association. Home Uterine Activity Monitoring. Policy archived November 2013.
2. U.S. Food and Drug Administration. Home Uterine Activity Monitors – Final Class II Special Controls Guidance for Industry and FDA Reviewers. March 9, 2001.
3. Urquhart C, Currell R, Harlow F et al. Home uterine monitoring for detecting preterm labour. Cochrane Database Syst Rev. February 15, 2017, 2:CD006172.
4. Dyson DC , Danbe KH , Bamber JA , Crites YM , Field DR , Maier JA , et al . Monitoring at risk for preterm labor . N Engl J Med 1998 ; 338 : 15 – 9 .
5. National Institute of Child Health and Human Development. Home uterine monitors not useful for predicting premature birth. January 23, 2002.
6. American College of Obstetricians and Gynecologists. Practice Bulletin Number 231. Interim Update. Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancies, June 2021. Multifetal Gestations Twin Triplet and Higher-Order Multifetal Pregnancies | ACOG Accessed 4/18/24
7. American College of Obstetricians and Gynecologists. Practice Bulletin 171, October 2016 (reaffirmed 2020) Management of Preterm Labor
8. American College of Obstetricians and Gynecologists. Practice Bulletin 234 Prediction and Prevention of Spontaneous Preterm Birth. August 2021. Prediction and Prevention of Spontaneous Preterm Birth | ACOG Accessed 4/18/24
9. U.S. Preventive Services Task Force. Home uterine activity monitoring. In: Guide to Clinical Preventive Services. 2nd ed. Philadelphia, PA: Williams & Wilkins; 1996:443-447. U.S. Preventive Services Task Force Recommendations (lsu.edu) Accessed 4/18/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/13/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/10/04	3/10/04	3/12/04	Joint policy established
8/16/05	8/16/05	6/14/05	Routine maintenance
1/1/07	10/31/06	10/19/06	Routine maintenance
1/1/09	10/13/08	12/30/08	Routine maintenance
3/1/10	12/8/09	12/8/09	Routine maintenance
5/1/12	2/21/12	2/21/12	Routine maintenance
3/1/14	12/10/13	1/6/14	Routine maintenance
11/1/15	8/24/15	9/14/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	Routine maintenance Rationale, references and MDHHS information updated.
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance Ref 7 added
9/1/23	6/13/23		Routine maintenance (jf) Vendor managed: NA Added Ref 5 Removed the names of the FDA devices since they are not found as being sold on the market.
9/1/24	6/11/24		Routine maintenance (jf) Vendor managed: NA Added ref: 7 Women replaced with individuals

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: HOME UTERINE ACTIVITY MONITORING (HUAM)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.