# CIGNA MEDICAL COVERAGE POLICY

*The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.*

**Subject** **Home Uterine Activity Monitoring (HUAM)**

**Effective Date ..... 6/15/2011**
**Next Review Date ..... 5/15/2012**
**Coverage Policy Number ..... 0162**

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***INSTRUCTIONS FOR USE***

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*


## Coverage Policy

**CIGNA does not cover home uterine activity monitoring (HUAM) for any indication because it is considered not medically necessary.**

## General Background

Preterm labor is defined by the American Congress of Obstetricians and Gynecologists (ACOG) (2003) as regular contractions that occur before 37 weeks of gestation and are associated with changes in the cervix. Preterm birth is the leading cause of neonatal mortality in the United States, and preterm labor precedes 40–50% of preterm births. Preterm birth may also be preceded by rupture of membranes or other medical problems. Approximately 467,000 of U.S. births occur before term (11.5% of all live births) and are responsible for 75% of neonatal mortality and 50% of long-term neurologic impairments in children. Although numerous management methods have been proposed, the incidence of preterm birth has not significantly changed over the past 40 years (ACOG Practice Bulletin, 2003, reaffirmed 2008).

Home uterine activity monitoring (HUAM) has been suggested as a screening tool to identify those with increased risk of preterm delivery, and as a diagnostic tool to detect preterm labor in its earliest stages. When contractions result in a thinning and opening of the cervix, the potential for birth is high, and in a preterm pregnancy, interventions to prevent birth are indicated. Oral or parenteral tocolytic drugs may be administered to inhibit contractions and may prolong pregnancy for two to seven days, Short term tocolytic therapy may be provided to temporarily halt contractions and prolong pregnancy for at least 48 hours, allowing the

administration of steroids to improve fetal lung maturity and the consideration of maternal transport to a tertiary care facility. According to ACOG, administration of corticosteroids is the most beneficial intervention for patients in true preterm labor. There is substantial evidence that antenatal corticosteroids reduce the incidence and severity of neonatal complications, including respiratory distress syndrome (ACOG Practice Bulletin 31, 2001; reaffirmed 2010; ACOG Practice Bulletin 43, 2003, reaffirmed 2008; Iams, 2002)

HUAM consists of a portable patient unit and a practitioner unit. The patient unit collects data on uterine activities and transmits the data to the practitioner unit. A healthcare professional analyzes the data for evidence of the onset of preterm labor. HUAM has been used as an adjunct to obstetrical care in patients at high risk for preterm labor and delivery. The goals of HUAM have been to detect early-stage uterine contraction suggestive of preterm labor and to assess the need for intervention in preventing preterm delivery. The goal of therapeutic interventions considered in the setting of preterm labor is to inhibit or reduce the strength and frequency of contractions, thus delaying the time to delivery and optimizing fetal status before preterm delivery.

**U.S. Food and Drug Administration (FDA)**
HUAM devices were reclassified from Class III (PMA) to 510(k) Class II special control devices on March 9, 2001. According to FDA guidance regarding the reclassification of HUAM, the following statements should immediately follow the indications for use statement, boxed with prominent placement:

- The HUAM only monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention. This HUAM does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.
- Clinical studies have shown that when a patient at risk for preterm labor is already enrolled in a daily nursing contact program, the HUAM does not provide any added effectiveness, i.e., a higher rate of detection of preterm labor over and above the detection rate associated with the daily nursing contact.
- No widely-accepted controlled studies have been conducted that show that this device is effective at the early detection of preterm labor other than in patients with a previous preterm delivery.

FDA-approved devices include the following (this list may not be all inclusive):

- Careforn ™ Home Uterine Activity Monitor (Matria Healthcare, Inc., New York, NY)
- Fetal Assist (Huntleigh Healthcare LTD, Eatontown, NJ)
- Genesis® Home Uterine Activity Monitoring System (Matria Healthcare, Inc., New York, NY)
- System 37 Home Uterine Activity Monitoring System (Matria Healthcare, Inc., New York, NY)

**Literature Review**
Reichmann conducted a systematic review to examine the published, peer-reviewed evidence on the use of HUAM for multiple gestations. The review included nine articles, including three randomized controlled trials, one matching cohort trial, and five case series. In the 14 years following the commercial introduction of HUAM, three observational studies and two small randomized controlled trials showed promising results for use in multiple gestations. However, a sufficiently powered, randomized controlled trial (Dyson et al., discussed below), demonstrated no difference in outcomes for patients with HUAM vs. patients receiving weekly calls from a nurse. The author concluded that contractions in multiple gestations are not predictive of preterm birth, and recommended that further use of HUAM should be limited to a randomized, controlled trial designed to demonstrate a clinically significant improvement in neonatal outcomes.

Newman et al. (2006) conducted a prospective observational study to compare uterine contraction frequency in twins compared to singletons, and to determine if contraction frequency can be an efficient predictor of preterm birth in twin gestations. A total of 49 twin and 306 singleton gestations between 22 and 24 weeks were enrolled. Contraction frequency was monitored with HUAM two or more times daily on two or more days per week until delivery or 36-6/7 weeks. There were 34,908 hours of HUAM data recorded by women with singleton gestations and 5,427 hours of data by the women with twins. Mean uterine contraction frequency was significantly higher for twin gestations compared to singletons, throughout the latter half of pregnancy, and between 4:00 p.m. and 3:59 a.m., but was not higher among twins who delivered at less than 35 weeks gestation. The authors stated that neither maximum a.m. nor p.m. contraction frequency predicted spontaneous preterm birth less than 35 weeks gestation in twin pregnancies.

Iams et al. (2002) assessed the frequency of uterine contractions as a predictor of the risk of spontaneous preterm delivery before 35 weeks gestation. Women with singleton pregnancies between 22 and 24 weeks'

gestation were enrolled. Each woman used a HUAM to record contraction frequency twice daily on two or more days per week from enrollment to either delivery or 37 weeks gestation. The authors obtained 34,908 hours of successful HUAM recordings from 306 women. More contractions were recorded from the women who delivered before 35 weeks than from women who delivered at 35 weeks or later, but no threshold frequency that effectively identified women who delivered preterm infants could be determined. The authors report the sensitivity and positive predictive value of a maximal hourly frequency of four or more contractions between 4:00 p.m. and 3:59 a.m. were 9% and 25%, respectively. The authors stated that the measurement of the frequency of uterine contractions is not clinically useful for predicting preterm delivery. While the frequency of uterine contractions is significantly related to preterm delivery, this measure has low sensitivity and low positive predictive values as a screening test for impending preterm delivery in asymptomatic women.

Brown et al. (1998) evaluated HUAM as an intervention to reducing the rate of preterm birth among women treated for preterm labor. A total of 186 women were treated with magnesium sulfate for preterm labor and were prospectively, randomly assigned to the HUAM group (n=82) or the unmonitored control group (n=80). All women received identical prenatal follow-up, including daily perinatal telephone contact and oral Terbutaline therapy. There was no significant difference in the overall rate of preterm delivery at < 35 weeks' gestation between the HUAM group and the control group (10.9% and 15.0%, respectively). The overall rates of delivery at < 37 weeks were high in both the HUAM group (48.8%) and the control group (60%), and the difference between the groups was not significant. The authors concluded that a reduction in the likelihood of preterm delivery at < 35 weeks' gestation was not further enhanced by the addition of HUAM to the outpatient management regimens of women treated for preterm labor.

Dyson et al. (1998) conducted a prospective randomized trial to determine whether the rate of preterm birth can be reduced by frequent contact between nurses and pregnant women or home monitoring of uterine activity. Pregnant women with known risk factors for preterm labor (n=2422) were randomly assigned to weekly telephone contact with a nurse (n=798); daily telephone contact with a nurse (n=796); or twice-daily HUAM in addition to daily telephone contact with a nurse (n=828). All women received education about the symptoms and signs of preterm labor, such as changes in vaginal discharge, cramping, and backache, and about the importance of early diagnosis and treatment. All women were instructed in how to palpate for uterine contractions. There were no significant differences between the three groups in the incidence of preterm birth at < 37 weeks, < 35 weeks, or < 32 weeks gestation. There were no differences between the groups in mean birth weight or any surrogate markers for neonatal morbidity (e.g., percentage admitted to neonatal intensive care units, number of days of oxygen or ventilator therapy, length of time in the hospital). The incidence of neonatal mortality was also similar between the groups: 5.6% in the weekly-contact group, 3.7% in the daily-contact group, and 5.4% in the HUAM group. Daily contact with a nurse, however, increased the mean number of unscheduled visits to obstetricians and in the proportion of women who received prophylactic tocolytic drugs. The authors concluded that women who have daily contact with a nurse, with or without home monitoring of uterine activity, have no better pregnancy outcomes than women who have weekly contact with a nurse

The Collaborative Home Uterine Monitoring Study (CHUMS) conducted a randomized, controlled, double-blinded trial to determine the efficacy of a HUAM system for early detection of preterm labor and reduction of preterm birth. The study group consisted of pregnant women between 24 and 36 weeks' gestation at high risk for preterm labor or birth. Patients were randomly assigned to the active group (n=637) or sham group (n=655). The HUAM device transmitted uterine activity data that was revealed to base station nurses for patients in the active group. The HUAM device transmitted uterine activity data that was concealed from base station nurses for patients in the sham group. Patients in each group received identical education on the use of the device and transmission protocol, signs and symptoms of preterm labor, and self-palpation for uterine contractions. Self palpation was required during all monitoring sessions. Patients received similar daily phone contact with the nurses that included a list of signs and symptoms of preterm labor. A total of 842 patients (72.3%) completed the study. Study end points included mean cervical dilatation and its mean change from a previous visit at preterm labor diagnosis, preterm birth rate, and infant outcomes. Results were similar in the active and sham groups. There were no significant differences in mean gestational age at delivery, birth weight, incidence of low birth weight, deliveries before 37, 36 or 34 weeks' gestation, neonatal intensive care admissions, or major neonatal complications. The authors concluded that uterine activity data obtained from HUAM when added to daily nursing contact were not linked to earlier diagnosis of preterm labor or lower rates of preterm birth or neonatal morbidity in pregnancies at high risk for preterm labor and birth (CHUMS Group, 1995).

**U.S. Preventive Services Task Force (USPSTF):** The USPSTF reports that there is insufficient evidence to recommend for or against HUAM in high-risk pregnancies as a screening test for preterm labor, but recommendations against its use may be made on other grounds. HUAM is not recommended in normal-risk pregnancies. A 1999 USPSTF release states that HUAM is no longer considered a part of standard care and is not relevant to clinical practice. The USPSTF will not update its 1996 recommendation (AHRQ website).

**Professional Societies/Organizations**
**American College of Obstetricians and Gynecologists (ACOG):** Practice Bulletin Number 31, "Assessment of Risk Factors for Preterm Birth", includes the following recommendation based on good and consistent scientific evidence: There are no current data to support the use of salivary estriol, HUAM, or bacterial vaginosis screening as strategies to identify or prevent preterm labor (ACOG, 2001, reaffirmed 2010).

Practice Bulletin Number 43, "Management of Preterm Labor", includes 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 (ACOG, 2003, reaffirmed 2008).

Practice Bulletin Number 56, "Multiple Gestation: Complicated Twin, Triplet, and High-Order Multifetal Pregnancy", includes the following statement: Cerclage, hospitalization, bed rest, or home uterine activity monitoring have not been studied in high-order multiple gestations, and, therefore, should not be ordered prophylactically. There currently is no evidence that their prophylactic use improves outcome in these pregnancies (ACOG, 2004, reaffirmed 2009).

**Summary**
Home uterine activity monitoring (HUAM) was introduced as a screening tool to identify those with increased risk of preterm delivery, and as a diagnostic tool for the early detection of preterm labor. No association between the use of HUAM and a decrease in the incidence of preterm birth and its consequent neonatal complications has been established, however. Several large, randomized clinical trials that assessed the use of HUAM in pregnant women at high risk for preterm labor failed to demonstrate that HUAM reduces the rate of preterm delivery compared to instruction on the signs and symptoms of preterm labor combined with frequent contact with a nurse. In addition, the use of HUAM is not supported in policy statements by the American Congress of Obstetricians and Gynecologists (ACOG).

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Not Medically Necessary/Not Covered:**

| **CPT®* Codes** | **Description** |
|---|---|
| 99500† | Home visit for prenatal monitoring and assessment to include fetal heart rate, non-stress test, uterine monitoring, and gestational diabetes monitoring |

† **Note: Not medically necessary/not covered when used to report home uterine activity monitoring.**

| **HCPCS Codes** | **Description** |
|---|---|
| S9001 | Home uterine monitor with or without associated nursing services |

| **ICD-9-CM Diagnosis Codes** | **Description** |
|---|---|
| 644.00 | Threatened premature labor; unspecified as to episode of care or not applicable |
| 644.03 | Threatened premature labor; antepartum condition or complication |
| | All other codes |

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## Policy History

| Pre-Merger Organizations | Last Review Date | Policy Number | Title |
|---|---|---|---|
| CIGNA HealthCare | 09/15/2008 | 0162 | Home Uterine Activity Monitoring (HUAM) |
| Great-West Healthcare | 07/19/2007 | 02.207.04 | Home Uterine Activity Monitoring (HUAM) |