The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

**Description**

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.

**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 one-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 four to six 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 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 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 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 (Formerly Corporate Medical Guideline)**

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

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

