

Home uterine activity monitoring

Clinical Policy ID: CCP.1042

Recent review date: 8/2025

Next review date: 12/2026

Policy contains: Home uterine activity monitoring; premature labor; uterine contraction.

Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peerreviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina's clinical policies are not guarantees of payment.

Coverage policy

Home uterine activity monitoring is clinically proven and, therefore, may be medically necessary in either of the following circumstances on an individual case exception basis (American College of Obstetricians and Gynecologists, 2016; Urquhart, 2017):

- For pregnant women with gestational age greater than 18 weeks who cannot feel their contractions and have certain complications.
- For women with physiologic or anatomic factors (e.g., paralysis or neuromuscular disorders such as muscular dystrophy) that limit their ability to self-detect contractions.

Limitations

All other uses of home uterine activity monitoring are investigational/not clinically proven and, therefore, not medically necessary.

Alternative covered services

- Office visits or home health visits by an appropriately trained health professional.
- Measurement of cervical-vaginal fetal fibronectin.
- Ultrasound determination of cervical length.

Background

According to the Centers for Disease Control and Prevention (2024), one in every 10 infants born in the United States is born prematurely. Premature is defined as a birth prior to 37 weeks gestation. Prematurity is associated with significant acute and chronic morbidity in a child, especially those with neurologic and respiratory conditions.

A number of strategies have been developed to reduce the rate of premature labor and delivery. They involve tocolytic therapy, enhanced hospital or home surveillance, and educational programs to help women identify the signs of early labor.

Home uterine activity monitoring is an electronic system for at-home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and receipt and display of the uterine contraction data at the clinic. Home uterine activity monitoring systems are classified as Class II devices (21CFR884.2730). It is a prescription-use only system that is indicated, in conjunction with standard high-risk care, for the daily at-home measurement of uterine activity in pregnancies of at least 24 weeks gestation for women with a history of previous preterm birth.

Findings

Guidelines

The American College of Obstetricians and Gynecologists (2016) updated its guideline on managing preterm labor. Their position, which does not support the use of home uterine activity monitoring to prevent preterm delivery in women with contractions but no cervical change, remains unchanged.

Evidence review

The best available evidence is derived from two Cochrane reviews examining large trials of low-to-moderate quality studies. A systematic review analyzed the results of 6,008 pregnant women and found home monitoring may result in fewer neonatal intensive care unit admissions but more unscheduled antenatal visits and tocolytic treatment; when analyzing a subset of trials rated at low risk of bias, the authors did not observe important group differences in the rate of neonatal intensive care unit admission based on home uterine activity monitoring use (Urquhart, 2017). Another Cochrane review of interventions during pregnancy to prevent preterm birth that found home uterine monitoring was of unknown benefit or harm (Medley, 2018).

The results suggest home uterine activity monitoring is safe but does not appreciably improve perinatal outcomes. Frequent contact, either face-to-face or by telephone, with an experienced provider appears to be as effective as home uterine activity monitoring or continued pharmacological therapy. However, there may be instances in which, despite educational efforts, some women (e.g., paraplegia) may not recognize contractions in time for treatment and are at risk of giving birth early. In such instances, home uterine activity monitoring may be indicated. The new information is consistent with the current policy, and no changes are warranted.

In 2017, we updated the references which warranted no policy changes.

In 2019, we updated the references which warranted no policy changes.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we identified no newly published, relevant literature to add to the policy.

In 2022, we identified no newly published, relevant literature to add to the policy.

In 2023, we identified no newly published, relevant literature to add to the policy.

In 2024, we identified no newly published, relevant literature to add to the policy.

CCP.1042 2 of 3

In 2025, we updated the references and identified no newly published, relevant literature to add to the policy.

References

On June 4, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "uterine monitoring" (MeSH), "home uterine monitoring," and "preterm labor prevention" (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

21CFR884.2730. Home uterine activity monitor.

American College of Obstetricians and Gynecologists. Practice Bulletin No. 171: Management of preterm labor. *Obstet Gynecol.* 2016;128(4):e155-164. Doi: 10.1097/aog.00000000001711.

Centers for Disease Control and Prevention. Preterm birth. https://www.cdc.gov/maternal-infant-health/preterm-

<u>birth/?CDC_AAref_Val=https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm.</u> Updated November 8, 2024.

Medley N, Vogel JP, Care A, Alfirevic Z. Interventions during pregnancy to prevent preterm birth: An overview of Cochrane systematic reviews. *Cochrane Database Syst Rev.* 2018;11:Cd012505. Doi: 10.1002/14651858.CD012505.pub2.

Urquhart C, Currell R, Harlow F, Callow L. Home uterine monitoring for detecting preterm labour. *Cochrane Database Syst Rev.* 2017;2:Cd006172. Doi: 10.1002/14651858.CD006172.pub4.

Policy updates

7/2013: initial review date and clinical policy effective date: 8/2015

8/2016: Policy references updated.

8/2017: Policy references updated.

8/2018: Policy references updated. Policy ID changed.

8/2019: Policy references updated.

8/2020: Policy references updated.

8/2021: Policy references updated.

8/2022: Policy references updated.

8/2023: Policy references updated.

8/2024: Policy references updated.

8/2025: Policy references updated.

CCP.1042 3 of 3