Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania & Keystone First	**Submission Date**: 9/1/2024
Policy Number: CCP.1042	**Effective Date:** 8/2015 **Revision Date:** August 1, 2024
Policy Name: Home uterine activity monitoring	

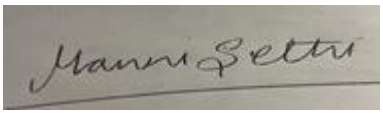
Type of Submission – Check all that apply:

☐**New Policy**
☒ **Revised Policy***
☐ **Annual Review – No Revisions**
☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Home uterine activity monitoring

Clinical Policy ID: CCP.1042

Recent review date: 8/2024

Next review date: 12/2025

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 peer-reviewed 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 by Keystone First, on a case by case basis, 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. Keystone First'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. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First'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, 2015):

- 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 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 (2022), 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. The U.S. Food and Drug Administration (2021) classifies home uterine activity monitoring systems as Class II devices (21CFR884.2730). It is a prescription-use only system that is indicated for use, 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

The U.S. Preventive Services Task Force concluded that home uterine monitoring is no longer part of standard care, and not useful for clinical practice (U.S. Preventive Services Task Force, 1993). In 2002, a (now-archived) National Institute of Child Health and Human Development study, later published in the New England Journal of Medicine, concluded that home uterine monitors were unable to detect patterns of contractions during pregnancy that would predict premature birth (National Institutes of Health, 2002).

Large early studies failed to establish effectiveness of home uterine activity monitoring. In 1995, a multicenter trial (n = 1,292) randomized patients to active/sham home uterine activity monitoring versus twice-daily nursing contact. No differences were found in rates of preterm labor, preterm births, or need for neonatal intensive care (no authors listed, 1995).

A trial (n = 2,422) randomized pregnant woman at high risk for pre-term labor to 1) weekly contact with a nurse; 2) daily contact with a nurse; and 3) daily contact with a nurse, plus home uterine activity monitoring. No differences between groups were found in the percent born before 35 weeks gestation (14%, 13%, and 14%) (Dyson, 1998).

A recent update of a systematic review inclusive of 6,008 pregnant women found home monitoring may result in fewer neonatal intensive care unit admissions but more unscheduled antenatal visits and tocolytic treatment (Urquhart, 2015). The level of evidence is low–to-moderate in this regard.

In 2017, Urquhart et al updated their 2015 Cochrane review of home uterine activity monitoring for detecting preterm labor. They identified no new information since their 2015 publication. 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.

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 currently policy, and no changes are warranted.

In 2019, we added one Cochrane review (Medley, 2018) of interventions during pregnancy to prevent preterm birth that found home uterine monitoring was of unknown benefit or harm. No policy changes are warranted.

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.

References

On July 11, 2024, 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.

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.0000000000001711.

Centers for Disease Control and Prevention. Preterm birth. http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm. Updated November 1, 2022.

Dyson DC, Danbe HK, Bamber JA, et al. Monitoring women at risk for preterm labor. *N Engl J Med*. 1998;338(1):15-19. Doi: 10.1056/NEJM199801013380103.

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.

National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development. Home Uterine Monitors Not Useful for Predicting Premature Birth. https://www.nichd.nih.gov/newsroom/releases/uterine. Published January 23, 2002.

No authors listed. A multicenter randomized controlled trial of home uterine monitoring: Active versus sham device. The Collaborative Home Uterine Monitoring Study (CHUMS) group. *Am J Obstet Gynecol*. 1995;173(4):1120-1127. Doi: 10.1016/0002-9378(95)91337-8.

U.S. Food and Drug Administration. Final guidance for industry and FDA reviewers: Class II special controls guidance for home uterine activity monitors. https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm237292.htm. Updated March 9, 2001.

U.S. Preventive Services Task Force. Home uterine monitoring for preterm labor. *JAMA*. 1993;270(3):371-376. https://pubmed.ncbi.nlm.nih.gov/8315784/.

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.