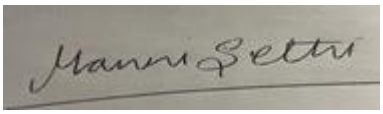
Prior Authorization Review Panel
MCO Policy Submission

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: Keystone First	**Submission Date**: 5/1/2024
Policy Number: ccp.1095	**Effective Date:** 10/2014 **Revision Date:** April 1, 2024
Policy Name: Apnea monitors for infants - in home use	
Type of Submission – Check all that apply: **New Policy** **x 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:** 

Apnea monitors for infants - in home use

Clinical Policy ID: CCP.1095

Recent review date: 4/2024

Next review date: 8/2025

Policy contains: Apnea monitors, cardiorespiratory monitors, sudden infant death syndrome.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP'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- CHIP, 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- CHIP'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- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Apnea monitors (cardiorespiratory monitoring) for members younger than 12 months are clinically proven and, therefore, may be medically necessary durable medical equipment when all of the following criteria are met (Moon, 2022)

- Premature infants who are at high risk of recurrent episodes of apnea, bradycardia, and hypoxemia after hospital discharge, and not beyond the age of 43 weeks' post-conception or after the cessation of extreme episodes (e.g., continued alarms, documented apnea, bradycardia, or hemoglobin desaturation), whichever comes last.
- Infants who are technology dependent (e.g., tracheostomy, continuous positive airway pressure) or have unstable airways, rare medical conditions affecting regulation of breathing, intrauterine drug exposure, or symptomatic chronic lung disease.
- Home cardiorespiratory monitors are equipped with an event recorder.
- Proven practices that decrease the risk of sudden infant death syndrome — such as supine sleep position, safe sleeping environments, and elimination of prenatal and postnatal exposure to tobacco smoke — accompany apnea monitoring.

Limitations

All other uses for apnea monitoring for infants are investigational/not clinically proven, and therefore, not medically necessary, including the prevention of sudden infant death syndrome (Moon, 2022).

Apnea monitors that employ contactless remote infrared sensors are investigational/not clinically proven and, therefore, not medically necessary.

Alternative covered services

Increased network physician office visits and evaluation.

Background

Apnea is a serious sleep-related disorder in which breathing is disrupted during sleep. The central respiratory centers are relatively immature in infants, particularly in preterm infants, which make them vulnerable to apneic episodes.

Two definitions describe apnea in infants. Apnea of prematurity is the sudden cessation of breathing that lasts for at least 20 seconds or is accompanied by bradycardia or oxygen desaturation (cyanosis) in an infant younger than 37 weeks' gestational age. Apnea of infancy is an unexplained episode of cessation of breathing for 20 seconds or longer, or a shorter respiratory pause associated with bradycardia, cyanosis, pallor, and/or marked hypotonia. Left untreated, apnea can result in failure to thrive, loss of intellect, cor pulmonale, and death (Kondamudi, 2023).

Even among premature infants, apnea and bradycardia are not especially common. One study of 1,403 infants born earlier than 34 weeks gestation found that only 15.8% and 21.5% had apnea and bradycardia events after they were otherwise ready for discharge (Lorch, 2011).

The etiology of apnea in infants is broad and varies according to the infant's age and the underlying pathophysiological mechanism. Apnea may present intermittently and have undesirable consequences if left untreated. There are three types of infant apnea (Kondamudi, 2023):

- **Central apnea** — Both the inspiratory effort and airflow cease simultaneously (absence of chest wall movement and airflow) caused by central respiratory center depression.
- **Obstructive apnea** — Airflow is absent or inadequate in the presence of inspiratory efforts to maintain ventilation.
- **Mixed apnea** — Central apnea is preceded or followed by airway obstruction. This is the most frequent type of apnea in preterm infants.

Care management consists of determining the underlying etiology and instituting therapy targeted to the identified cause. Polysomnography is considered the standard diagnostic tool for detecting sleep related breathing disorders, but home sleep testing may be an option (Espinosa, 2023).

Many premature newborns are successfully treated for sleep apnea while in the hospital; caffeine citrate is an effective means of treatment, achieving results superior to those from methylxanthamine therapy (Schmidt, 2014). Infants with apnea of prematurity may benefit from nasal continuous positive airway pressure if apneic spells are frequent, prolonged, need frequent stimulation, or are associated with bradycardia and hypoxia (Kondamudi, 2023).

The decision of whether or not to discharge an infant after a life-threatening event such as apnea or brachycardia/tachycardia is a difficult one, with limited ability to predict future risk of such an event, according to a systematic review of 37 studies (Tieder, 2013). However, if an infant with apnea is otherwise cleared for discharge, the physician may recommend an apnea monitor for home use.

A home apnea monitor typically uses a belt-like device or electrodes to detect chest movement and physiologic parameters such as heart rate and blood oxygen saturation linked to the presence or absence of adequate respiration (Code of Federal Regulations, 2002). The U.S. Food and Drug Administration (2024) has approved one device for home use: The SmartMonitor® 2 Professional Series Infant Apnea Monitor (Respironics, Inc., Murrysville, Pennsylvania).

Most monitors are programmed to alarm after cessation of breathing for 20 seconds or if the heart rate slows to less than 80 beats per minute. Bani Amer (2010) described the development of noncontact infant apnea detection using a remote infrared sensor, but is not marketed as of this writing.

Findings

Use of a home sleep apnea monitor is not recommended for the diagnosis of sleep apnea, according to the American Academy of Sleep Medicine (Kirk, 2017).

The American Academy of Pediatrics recommended prescribing apnea monitors for use at home to detect apnea or bradycardia and, when pulse oximetry is used, decreases in oxyhemoglobin saturation for infants at risk of these conditions. The Academy did not recommend routinely prescribing home cardiorespiratory monitors as a strategy to reduce the risk of sudden infant death syndrome, as the evidence did not support that the use of such devices reduced the incidence of sudden infant death syndrome (Moon, 2022).

A systematic review of 11 studies (n = 2,210) assessed the ability of home monitoring to reduce sudden infant death syndrome, but only one study compared results to a control group; the others were cohort studies considered to be level III evidence. The one randomized controlled trial in the review calculated the sudden infant death syndrome mortality rate for babies with home monitors to be 5.0 deaths per 1,000 patients, compared to a rate for non-monitored infants ranging from 1.2 to 5.6 deaths per 1,000 patients (Strehle, 2012). Moreover, in-hospital cardiorespiratory monitoring was not predictive of sudden death, as most apnea cases resolve prior to the usual age of sudden infant death syndrome (45.8 weeks and 52.3 weeks postmenstrual for infants born 24 – 28 weeks and all infants, respectively) (Freed, 2017).

Evidence-based practices known to reduce sudden infant death syndrome include supine sleep position, firm sleeping surfaces, breastfeeding, room sharing without bed-sharing, routine immunizations, avoidance of soft bedding and overheating, and elimination of prenatal/postnatal exposure to tobacco smoke. In addition, risk of sudden infant death syndrome in later siblings is extremely low (Eichenwald, 2016; Moon, 2022).

Individual studies and systematic reviews describe the characteristics of infants most likely to benefit from home apnea monitoring. A study of 741 infants born with a gestational age older than 34 weeks at two Boston neonatal intensive care units from 2009 to 2013 documented the likelihood of home monitor use was greater in infants with either a prolonged inpatient stay or greater gestational age at birth who had discharge-delaying apnea, bradycardia, or oxygen desaturation events (Veit, 2016).

A 2014 review of 272 discharged infants with complex chronic conditions, such as those with underlying chronic respiratory illness, tracheostomy, ventilator dependence, or need for multiple medications, found that home apnea or pulse oximetry use was linked to a greater chance ($P = .02$) of a readmission within 30 days of discharge on univariate analysis, but not on multivariable analysis (Jurgens, 2014).

Compliance with home sleep apnea monitors has been a concern for practitioners. One review of 175 families who used 12,862 days of home monitoring documented that families who used telemedicine to report results had a higher compliance rate (70%) than those using the conventional system (50%) (Piumelli, 2012).

In 2022, we updated the references and found no new relevant literature to add to the policy. We added a statement to the limitations stating that apnea monitors that employ contactless remote infrared sensors are not clinically proven.

In 2023, we added an updated guideline from the American Academy of Pediatrics (Moon, 2022) on reducing the risk of sleep-related infant deaths. The recommendations for cardiorespiratory monitoring are unchanged. No policy changes are warranted.

In 2024, we updated the references and identified no newly published relevant literature to add to the policy. No policy changes are warranted.

References

On January 22, 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 “sleep apnea syndrome (MeSH),” “home apnea monitor,” and “apnea of prematurity.” 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.

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Policy updates

3/2014: initial review date and clinical policy effective date: 10/2014

3/2015: Policy references updated.

3/2016: Policy references updated.

3/2017: Policy references updated.

3/2018: Policy references updated.

3/2019: Policy references updated. Policy number changed to CCP.1095.

4/2020: Policy references updated.

4/2021: Policy references updated.

4/2022: Policy references updated. Coverage limitations modified.

4/2023: Policy references updated. Coverage limitations modified.

4/2024: Policy references updated.