Home Apnea Monitoring in Children

Description

Home apnea monitors track respiratory effort and heart rate in order to detect episodes of apnea. They have been proposed for a variety of indications including but not limited to children at increased risk of sudden infant death syndrome (SIDS) and children who have experienced a life-threatening event.

Background

Home apnea monitors track respiratory effort and heart rate and have been utilized to monitor central apnea of prematurity in newly discharged at-risk or high-risk premature infants (infants are at increased risk of cardiorespiratory events until 43 weeks’ post-conceptual age). An alarm will sound if there is respiratory cessation (central apnea) beyond a predetermined time limit (eg, 20 seconds) or if the heart rate falls below a preset rate (bradycardia) to notify the parent that intervention (stimulation, mouth-to-mouth resuscitation, cardiac compressions) is required. Unless an oximeter is added to the 2-channel devices, home apnea monitors are not effective at detecting obstructive sleep apneas. False alarms due to movement artifact are common with pulse oximeters, and these devices are not intended for the diagnosis of sleep-disordered breathing in a child.

SIDS is the sudden death of an infant under 1 year of age; the circumstances are unexplained after a thorough investigation that includes autopsy, examination of the death scene, and review of the family history. As a means to decrease the incidence of SIDS, in the 1970s, cardiorespiratory monitoring was suggested. However over time, scientific medical studies have failed to establish that the use of home monitoring reduces the incidence of SIDS. In 2011, the American Academy of Pediatrics (AAP) Task Force on Sudden Infant Death Syndrome reiterated the recommendations of previous policy statements that home monitoring should not be used as a strategy to prevent SIDS. (1) Instead, AAP recommends that proven practices should be promoted to reduce the incidence of SIDS, which include supine sleeping, use of a firm bed surface, routine immunizations, breast-feeding and avoidance of exposure to tobacco smoke, alcohol and illegal drugs. One of these proven practices, supine sleeping, has been promoted in the “Safe to Sleep” campaign (formerly called the “Back to Sleep” campaign) initiated in 1994 by the National Institute of Child Health and Development, and the Maternal Child Health Bureau of Human Resources and Services Administration, American Academy of Pediatrics (AAP). The campaign is a national process to educate healthcare professionals, parents, and caregivers about the significance of placing infants in the supine sleeping position to reduce SIDS. (2) The incidence of SIDS in the U.S. decreased dramatically between 1992 and 2001; especially in the years after the first
supine sleep position recommendations were issued. The incidence of SIDS has remained relatively constant since 2001, and SIDS remains a major cause of infant mortality in the United States.

**Regulatory Status**

A number of infant apnea monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA). One device is the SmartMonitor 2 Apnea Monitor (Philip Children’s Medical Ventures, Respironics), which was cleared for marketing through the 510(k) process in October 2003. The intended use is for continuous monitoring of respiration, heart rate, and SpO₂ (pulse oximetry of infant patients) in a hospital or home environment.

FDA product code: NPF and DQA

**Related Policies**

2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Home cardiorespiratory monitoring may be considered **medically necessary** in infants younger than 12 months of age (see Policy Guidelines for further discussion of age) in the following situations:

- Those who have experienced an apparent life-threatening event; OR
- Those with tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise; OR
- Those with neurologic or metabolic disorders affecting respiratory control, including central apnea and apnea of prematurity; OR
- Those with chronic lung disease (ie, bronchopulmonary dysplasia), particularly those requiring supplemental oxygen; continuous positive airway pressure; or mechanical ventilation.

Home cardiorespiratory monitoring is considered **not medically necessary** in infants with any siblings with a history of sudden infant death syndrome (SIDS), but without at least one of the indications cited above.

Home cardiorespiratory monitoring in all other conditions, including but not limited to the diagnosis of obstructive sleep apnea, is considered **not medically necessary**.

**Policy Guidelines**

This policy does not address the use of home monitoring for the diagnosis and management of obstructive sleep apnea. If obstructive sleep apnea is a consideration, refer to policy 2.01.18.
An apparent life-altering event (ALTE) is defined as an episode that is characterized by some combination of apnea, color change, marked change in muscle tone, choking, or gagging and is frightening for the parent or caretaker to observe.

This policy applies only to the use of U.S. Food and Drug Administration (FDA)-approved home monitoring systems. A variety of commercially available baby monitoring devices are marketed to parents for monitoring infants’ sleep, breathing, and behavior. Although some of the devices include pulse oximetry, these devices are not sold as medical devices and are therefore not cleared for marketing by FDA.

As suggested by a Policy Statement from the American Academy of Pediatrics (AAP) (see Rationale section) the physician should establish a review of the problem, a plan of care, and a specific plan for periodic review and termination. Clear documentation of the reasons for continuing monitoring is necessary should monitoring beyond 43 weeks' postconceptual age be recommended. Home cardiorespiratory monitoring is generally not considered appropriate for pediatric patients older than 1 year of age. There may be a subset of young children who require cardiorespiratory monitoring beyond 1 year of age, such as certain patients with home noninvasive or invasive ventilator use or chronic lung disease.

Home monitors should be equipped with an event recorder.

Note: Home cardiorespiratory monitoring is intended, in part, to alert caregivers of the need for intervention at the time of an event in patients with apnea, and is not appropriate for diagnosis of sleep-disordered breathing (central or obstructive).

Rationale

This policy includes the policy statement by the American Academy of Pediatrics (AAP) regarding home cardiorespiratory monitoring (ie, apnea monitoring).

Sudden Infant Death Syndrome (SIDS)

During the 1970s and 1980s, it was hypothesized that prolonged periods of apnea and bradycardia were markers for sudden infant death syndrome (SIDS) risk in the susceptible infant and preceded the ultimate SIDS event; if this was the case, home apnea monitors could alert caregivers to the presence of an impending event. A 2011 technical report from AAP’s Task Force on Sudden Infant Death Syndrome does not recommend home apnea monitoring to prevent SIDS. (1) The AAP report cited a lack of evidence that home monitors are effective for this purpose.

The Collaborative Home Infant Monitoring Evaluation (CHIME) study, a longitudinal cohort study conducted from 1994 to 1998, was designed to address the question of whether severe episodes of apnea and bradycardia occur more commonly in infants considered at higher risk for SIDS. (4) The study included 1079 infants, both healthy and considered at high risk for SIDS based on a history of an apparent life-threatening event (ALTE), siblings with SIDS, and preterm gestation, who were observed with home cardiorespiratory monitoring for the first 6 months after birth. Alarming of the
monitors occurred frequently across all risk groups, occurring in 41% of all subjects. So-called "extreme" events occurred in all groups, but preterm infants were at higher risk until 43 weeks postconceptual age. The authors concluded that episodes of prolonged apnea or bradycardia primarily occurred before the developmental age when most SIDS deaths occurred. Follow-up analyses to the CHIME study found that extreme events were not significantly associated with any known SIDS risk factors. (5)

In 2012, Strehle et al published a systematic review of literature on the impact of home monitoring (apnea monitoring, respiratory monitoring or cardiorespiratory monitoring) on mortality in infants at increased risk of SIDS. (6) The review identified 1 pilot study to assess the feasibility of a randomized controlled trial (RCT) evaluating home monitoring and 10 unique case series. The authors concluded that there is a lack of high-level evidence that home monitoring is beneficial in preventing SIDS.

Other Respiratory Conditions

There is a lack of evidence for use of home apnea monitors in other conditions. For many of these conditions, trials would be difficult to perform due to small numbers of patients and logistic difficulties for these conditions that make enrollment in trials difficult. As a result, the best available recommendations for treatment currently rely on expert consensus.

A consensus document published in 2003 by the AAP Committee on Fetus and Newborn addressed the use of home apnea monitors for other respiratory conditions. (3) The AAP policy statement identified infants who could benefit from home monitoring, not because of an increased risk of SIDS but because of other factors that increase the risk of sudden death. These infants include those who have:

- experienced an ALTE
- tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise
- neurologic or metabolic disorders affecting respiratory control
- chronic lung disease (ie, bronchopulmonary dysplasia), particularly those requiring supplemental oxygen; continuous positive airway pressure; or mechanical ventilation.

The 2003 AAP consensus statement was retired in 2012. (7) Although the consensus guidelines have been retired, a review of the literature since that time did not identify major studies that address outcomes from home apnea monitoring that would significantly call into question the 2003 policy statement's criteria for home cardiorespiratory monitoring.

Children who present with ALTEs represent a heterogeneous group in terms of the event severity and the underlying pathology. Systematic reviews have found wide variation in resource utilization for evaluating patients after an ALTE (8) and in the eventual diagnosis given after an ALTE. (9) A 2013 systematic review of 37 studies of ALTE suggested that rates of recurrent events were higher in patients with a history of recurrent ALTE, prematurity, or suspected child maltreatment. (10) One observational cohort study reported 4-week follow-up outcomes for 300 infants who were seen in an emergency department with a diagnosis of ALTE. (11) Of the 228 patients who were admitted, 110 (48.2%) had in-hospital pneumography (101 with esophageal pH monitoring, and 9 without
esophageal pH monitoring). Of those with pneumography, 33 patients had apnea, with or without evidence of gastroesophageal reflux. There was no significant association with positive findings on pneumography with recurrent ALTE in the 4 weeks following hospitalization. Limitations of this study include the fact that evaluation of patients with ALTE was nonstandardized; in addition, it is not clear that results of an in-hospital pneumography study are translatable to the home setting. Further studies regarding the role of home apnea monitors following an ALTE would be useful. The use of home apnea monitors after an ALTE should be individualized to the specific case.

Ongoing and Unpublished Clinical Trials
A recent search of ClinicalTrials.gov with “apnea of prematurity”, “apnea monitor,” “sudden infant death syndrome,” and “apparent life threatening event” identified no relevant studies of apnea monitors.

Practice Guidelines and Position Statements
AAP’s Committee on Fetus and Newborn published a policy on home apnea monitoring in 2003 reaffirmed in 2007. (3) In 2012, the policy was retired. (7) The document noted that infants who may benefit from home monitoring include those who have experienced an ALTE, have tracheostomies, have anatomic abnormalities that make them vulnerable to airway compromise, or have neurologic or metabolic disorders affecting respiratory control, including central sleep apnea, chronic lung disease including bronchopulmonary dysplasia and especially those individuals requiring supplemental oxygen, continuous positive airway pressure or mechanical ventilation. Furthermore, the AAP recommends that “if monitoring is to be used at home, parents and other caregivers must be trained in observation techniques, operation of the monitor, and infant cardiopulmonary resuscitation. Medical and technical support staff should always be available for direct or telephone consultation.”

AAP’s Committee on Fetus and Newborn published a policy on the hospital discharge of the high-risk neonate in 2008 that addresses the role of home apnea monitors for preterm and otherwise high-risk infants. (12) The guideline states: “Home monitors are rarely indicated for detection of apnea solely because of immature respiratory control, in part because infants with immature respiratory control, in general, are still hospitalized until they are no longer at risk of apnea of prematurity. Use of a home monitor does not preclude the need for demonstrated maturity of respiratory control before discharge and should not be used to justify discharge of infants who are still at risk of apnea. Home monitors are not indicated for prevention of sudden infant death syndrome (SIDS) in preterm infants, although preterm infants are at increased risk of SIDS.”

U.S. Preventive Services Task Force Recommendations
Not applicable

Summary
There is insufficient evidence from published studies and a lack of support from national guidelines for home apnea monitoring to prevent sudden infant death syndrome. For other respiratory conditions, there is also a lack of published evidence; however national guidelines published by the American Academy of Pediatrics (AAP) have identified specific groups of infants who might benefit from home monitoring because of other factors that increase the risk of sudden death (eg, tracheostomies,
chronic lung disease). These conditions identified by the AAP as benefiting from home apnea monitoring may therefore be considered medically necessary.

Reliable evidence shows home cardiorespiratory monitoring is not considered effective and therefore, not medically necessary in infants with any siblings with a history of sudden infant death syndrome (SIDS), without at least one of the following indications: those who experienced an apparent life-threatening event, or have with tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise, or with neurologic or metabolic disorders affecting respiratory control, including central sleep apnea, or those with chronic lung disease.

Since standard home cardiorespiratory monitors do not detect obstructive apnea (indicated by ongoing struggling or labored breathing that is sensed as ongoing respiratory activity), nor detect hypoxemia, their use in all other conditions, including but not limited to the diagnosis of obstructive sleep apnea, is considered not medically necessary.

Medicare National Coverage
There is no national coverage determination.

References


### Policy History

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<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review through January 2012. Reference number 8 added. Policy statement changed to not medically necessary for all other conditions, including but not limited to the diagnosis of obstructive sleep apnea.</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 4, 5, 7-11 added. Policy statements changed as follows: the phrase “and apnea of prematurity” was added to the indication “those with neurologic or metabolic disorders affecting respiratory control, including central apnea”. The word “sleep” was removed from “central sleep apnea”. A statement that certain children may require monitoring beyond one year added to the policy guidelines. A statement was added to the policy guidelines that this policy does not address the diagnosis or management of obstructive sleep apnea.</td>
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### Keywords

Apnea, Infant, Home Monitoring
Monitoring, Apnea, Infant
Siblings of SIDS Victims, Home Monitoring
Sudden Infant Death Syndrome (SIDS), Home Monitoring
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

Signature on File

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