Home Cardiorespiratory Monitoring

Description

Home cardiorespiratory monitors track respiratory effort and heart rate to detect episodes of apnea. They have been used for a variety of indications that may be associated with increased risk of respiratory compromise.

Background

Home Cardiorespiratory Monitoring for Apnea Monitoring

Home cardiorespiratory monitors track respiratory effort and heart rate, and have been used 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 of postconceptual age) and in other infants at risk of apnea. 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 for 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.

Home Monitoring for Sudden Infant Death Syndrome Prevention

Sudden infant death syndrome (SIDS) refers to the sudden death of an infant younger than 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, clinical studies have failed to establish that the use of home monitoring reduces the incidence of SIDS. In 2011, the American Academy of Pediatrics (AAP) reiterated its recommendations that home monitoring should not be used as a strategy to prevent SIDS. Instead, AAP recommended 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 AAP, as well as by the
National Institute of Child Health and Development and the Maternal Child Health Bureau of Human Resources and Services Administration. The campaign is a national effort to educate health care professionals, parents, and caregivers about the significance of placing infants in the supine sleeping position to reduce SIDS. The incidence of SIDS in the United States decreased dramatically between 1992 and 2001, especially in the years after the first supine sleep position recommendations were issued.

OTHER HOME MONITORING INDICATIONS

Home cardiorespiratory monitors are used for reasons other than preventing SIDS. They include monitoring infants at high risk of respiratory compromise due to chronic ventilator or oxygen requirements, tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise, and central apnea, including apnea, bradycardia, and oxygen desaturations associated with prematurity. Former premature infants with bronchopulmonary dysplasia (ie, neonatal chronic lung disease), which may lead to chronic oxygen requirement, may have indications for home cardiorespiratory monitoring.

An additional potential use of home cardiorespiratory monitors is monitoring infants who have had acute events associated with apnea, color change, or loss of tone. Originally, these events were referred to as apparent life-threatening events (ALTEs). ALTE was defined by a 1986 National Institutes of Health Conference as “an episode that is frightening to the observer and that is characterized by some combination of apnea (central or occasionally obstructive), color change (usually cyanotic or pallid but occasionally erythematous or plethoric), marked change in muscle tone (usually marked limpness), choking, or gagging. In some cases, the observer fears that the infant has died.” In 2016, AAP issued updated clinical practice guideline, which proposed a replacement of the term ALTE with the term brief resolved unexplained event (BRUE), which is defined as follows:

“An event occurring in an infant younger than 1 year when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following: (1) cyanosis or pallor; (2) absent, decreased, or irregular breathing; (3) marked change in tone (hyper- or hypotonia); and (4) altered level of responsiveness. A BRUE is diagnosed only when there is no explanation for a qualifying event after conducting an appropriate history and physical examination.”

Regulatory Status

A number of infant apnea/cardiorespiratory monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. This includes the SmartMonitor 2 Apnea Monitor (Philip Children’s Medical Ventures, Respironics), which is intended for continuous monitoring of respiration, heart rate, and 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
Home cardiorespiratory monitoring may be considered medically necessary when initiated in infants younger than 12 months of age (see Policy Guidelines for further discussion of age limits) in the following situations:

- Those who have experienced a brief resolved unexplained event (previously known as apparent life-threatening event) and are not considered lower risk following clinical evaluation; 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; see Policy Guidelines).

Home cardiorespiratory monitoring is considered not medically necessary in infants with any siblings with a history of sudden infant death syndrome, but without at least 1 of the indications cited.

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

Policy Guidelines

This policy does not address the use of an unattended (unsupervised) home sleep study for the diagnosis and management of obstructive sleep apnea. If obstructive sleep apnea is a consideration, refer to evidence review 2.01.18.

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, they are not sold as medical devices and are therefore not cleared for marketing by FDA.

2016 Clinical Practice Guidelines from the American Academy of Pediatrics (Tieder et al, 2016) defined brief resolved unexplained event (BRUE; formerly apparent life threatening event [ALTE]) as: “An event occurring in an infant younger than 1 year when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following:

(1) cyanosis or pallor;
(2) absent, decreased, or irregular breathing;
(3) marked change in tone (hyper- or hypotonia); and
(4) altered level of responsiveness.”
The diagnosis of bronchopulmonary dysplasia (BPD) is dependent on gestational age, and is outlined in Table PG1 based on the 2001 consensus definition from the U.S. National Institute of Child Health and Human Development (Jobe et al, 2001).

**Table PG1: Diagnosis of Bronchopulmonary Dysplasia**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Gestational Age</th>
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<tbody>
<tr>
<td></td>
<td>&lt;32 wk</td>
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<tr>
<td>Time point of assessment</td>
<td>36 wk PMA or discharge to home, whichever comes first</td>
</tr>
<tr>
<td>Mild BPD</td>
<td>Breathing room air at 36 wk PMA or discharge, whichever comes first</td>
</tr>
<tr>
<td>Moderate BPD</td>
<td>Need for &lt;30% oxygen at 36 wk PMA or discharge, whichever comes first</td>
</tr>
<tr>
<td>Severe BPD</td>
<td>Need for ≥30% oxygen and/or positive pressure at 36 wk PMA or discharge, whichever comes first</td>
</tr>
</tbody>
</table>

BPD: bronchopulmonary dysplasia; PMA: postmenstrual age.

As suggested by a policy statement from the American Academy of Pediatrics (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 of postmenstrual age be recommended. Home cardiorespiratory monitoring for apnea 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.

**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. 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. 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.

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. 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 on use of home cardiorespiratory 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 would make trial enrollment difficult. As a result, the best available recommendations for treatment currently rely on expert consensus.

A consensus document published in 2003 by AAP addressed the use of home apnea monitors for other respiratory conditions. 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. A review of the literature since 2012 did not identify major studies addressing outcomes with 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 underlying pathology. Systematic reviews have found wide variation in resource utilization for evaluating patients after an ALTE and in the eventual diagnosis given after an ALTE. 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. One 2013 observational cohort study reported 4-week follow-up outcomes for 300 infants seen in an emergency
department with a diagnosis of ALTE. Of the 228 patients admitted, 110 (48.2%) had in-hospital pneumography (101 with esophageal pH monitoring, 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 between positive findings on pneumography and recurrent ALTE in the 4 weeks after hospitalization. Limitations of this study include nonstandardized evaluation of patients with ALTE and whether results of an in-hospital pneumography study translate to the home setting.

In 2016, AAP published a consensus statement on the evaluation of low-risk infants with ALTEs, which the consensus statement authors proposed renaming “brief resolved unexplained events” (BRUE). This consensus statement was based on an update of the 2013 systematic review on ALTEs. Eighteen additional studies were identified in the updated systematic review. The updated guidelines defined patients at lower risk of recurrent events after a BRUE, and recommended against the initiation of home cardiorespiratory monitoring in this group (evidence quality: B; strength of recommendation: moderate). This recommendation is based on studies reporting on the occurrence of respiratory pauses and bradycardia in normal infants, studies showing no improvements in outcomes or SIDS prevention with home apnea monitors, and lack of correlation between ALTEs and SIDS. The guidelines and updated systematic review did not address the use of home monitoring in high-risk infants with unexplained events.

Home apnea monitors are sometimes used in neonates with apnea, bradycardia, and oxygen desaturation events. Apnea of prematurity is extremely common in preterm infants, but may also occur in late preterm infants. In many cases, infants with these events are observed in the hospital until a “safe” period of time without an event occurs, but some infants are discharged to home with a home monitor. For example, a 2016 three-center, 5-year case series reporting on the evaluation and management of apnea, bradycardia, and oxygen desaturation events in infants born at 34 or more weeks of gestational age reported that 4.5% of infants were discharged to home with a monitor.

### PRACTICE GUIDELINES AND POSITION STATEMENTS

#### AMERICAN ACADEMY OF PEDIATRICS

In 2016, the American Academy of Pediatrics (AAP) issued clinical practice guidelines on brief resolved unexplained events (BRUE), formerly *apparent life-threatening events* (ALTEs), which addressed the use of home apnea monitoring for low-risk infants. BRUE is defined as follows:

> “An event occurring in an infant younger than 1 year when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following: (1) cyanosis or pallor; (2) absent, decreased, or irregular breathing; (3) marked change in tone (hyper- or hypotonia); and (4) altered level of responsiveness. A BRUE is diagnosed only when there is no explanation for a qualifying event after conducting an appropriate history and physical examination.”

These guidelines outline criteria for risk stratification for recurrent events. Low-risk patients are defined as follows, along with having no concerns identified on history or physical exam:

- “Age >60 days.”
- “Born ≥32 weeks gestation and corrected gestational age ≥45 weeks.”
- “No CPR [cardiopulmonary resuscitation] by trained medical provider.”

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<table>
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<th>Section:</th>
<th>Durable Medical Equipment</th>
<th>Effective Date:</th>
<th>April 15, 2017</th>
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<tbody>
<tr>
<td>Subsection:</td>
<td>Medical Equipment</td>
<td>Original Policy Date:</td>
<td>December 7, 2011</td>
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<tr>
<td>Subject:</td>
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</table>
• “Event lasted <1 minute.”
• “First event.”

For low-risk patients, the guidelines state that management should not include initiation of home cardiorespiratory monitoring.

In 2016, AAP published a clinical report on apnea of prematurity. This report makes the following statement about home monitoring for infants with apnea of prematurity:

“Routine home monitoring for preterm infants with resolved apnea of prematurity is not recommended. Cardiorespiratory monitoring after hospital discharge may be prescribed for some preterm infants with an unusually prolonged course of recurrent, extreme apnea. Current evidence suggests that if such monitoring is elected, it can be discontinued in most infants after 43 weeks' PMA [postmenstrual age] unless indicated by other significant medical conditions.”

AAP published a policy on home apnea monitoring in 2003 reaffirmed in 2007. In 2012, the policy was retired. 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, AAP recommended 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 also published a policy on the hospital discharge of high-risk neonates in 2008 that addressed the role of home apnea monitors for preterm and otherwise high-risk infants. 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 OF EVIDENCE

For individuals who have risk of respiratory failure in infancy who receive home cardiorespiratory monitoring, the evidence includes primarily observational studies. Relevant outcomes are overall survival and morbid events. For prevention of sudden infant death syndrome, the available published literature, primarily from the CHIME study, does not support the use of monitoring. 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 AAP as benefiting from home cardiorespiratory monitoring may therefore be considered medically necessary.

**Medicare National Coverage**

There is no national coverage determination.

**References**

**Section:** Durable Medical Equipment  
**Effective Date:** April 15, 2017  
**Subsection:** Medical Equipment  
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### Policy History

<table>
<thead>
<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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<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through May 2, 2016 and clinical input; references 3 and 13-14 added. Title changed to “Home Cardiorespiratory Monitoring.” Policy statements clarified to add that monitoring should be initiated in infants under 12 months; term “apparent life threatening event” replaced with “brief resolved unexplained event”.</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

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 17, 2017 and is effective April 15, 2017.

**Signature on File**

Deborah M. Smith, MD, MPH