MP 1.01.06
Home Cardiorespiratory Monitoring

BCBSA Ref. Policy: 1.01.06
Last Review: 06/20/2019
Effective Date: 06/20/2019
Section: Durable Medical Equipment

DISCLAIMER/INSTRUCTIONS FOR USE
Medical Policy provides general guidance for applying Blue Cross of Idaho benefit plans (for purposes of Medical Policy, the terms “benefit plan” and “member contract” are used interchangeably). Coverage decisions must reference the member specific benefit plan document. The terms of the member specific benefit plan document may be different than the standard benefit plan upon which this Medical Policy is based. If there is a conflict between a member specific benefit plan and the Blue Cross of Idaho’s standard benefit plan, the member specific benefit plan supersedes this Medical Policy. Any person applying this Medical Policy must identify member eligibility, the member specific benefit plan, and any related policies or guidelines prior to applying this Medical Policy. Blue Cross of Idaho Medical Policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member specific benefit plan coverage. Blue Cross of Idaho reserves the sole discretionary right to modify all its Policies and Guidelines at any time. This Medical Policy does not constitute medical advice.

POLICY
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 one 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. Various commercially available infant 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.

The 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) depends 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 & Bancalari, 2001).

**Table PG1. Diagnosis of BPD**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Gestational Age</th>
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</thead>
<tbody>
<tr>
<td>Time point of assessment</td>
<td>36 wk PMA or discharge to home, whichever comes first</td>
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<tr>
<td>Treatment With Oxygen &gt;21% for at Least 28 Days Plus</td>
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</tr>
<tr>
<td>Mild BPD</td>
<td>Breathing room air at 36 wk PMA or discharge, whichever comes first</td>
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<td>Moderate BPD</td>
<td>Need for &lt;30% oxygen at 36 wk PMA or discharge, whichever comes first</td>
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<tr>
<td>Severe BPD</td>
<td>Need for ≥30% oxygen and/or positive pressure at 36 wk postnatal age or discharge, whichever comes first</td>
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</tbody>
</table>

Adapted from Jobe & Bancalari (2001).

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 infants 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.

**BENEFIT APPLICATION**

**BLUECARD/NATIONAL ACCOUNT ISSUES**

Coverage for services such as physician visits and diagnostic testing in conjunction with sudden infant death syndrome monitoring should be provided in accordance with individual contracts. Coverage is usually not provided for:
• a backup electrical system;
• parental training sessions, including cardiopulmonary resuscitation or instructions in the use of the monitor when identified as a separate charge. These charges are usually included in the rental or purchase fee.

BACKGROUND

Home Monitoring

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 sounds 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.

Sudden Infant Death Syndrome

SIDS refers to the sudden death of an infant younger than one year of age whereby 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. The American Academy of Pediatrics (AAP; 2011) 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 U. S. decreased dramatically between 1992 and 2001, especially in the years after the first supine sleep position recommendations were issued.

Other 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 devices 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. Apparent life-threatening events 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 limpniness), choking, or gagging. In some cases, the observer fears that the infant has died." The AAP (2016) updated a clinical practice guideline that proposed replacing the term apparent life-threatening events with the term brief resolved unexplained event, 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 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. Food and Drug Administration product code: NPF and DQA.

RATIONALE

This evidence review was created in March 1996 and archived from 2003 until 2010 when it returned to active status. It has since been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through April 3, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

RESPIRATORY FAILURE in Infants

Clinical Context and Therapy Purpose

The purpose of home cardiorespiratory monitoring is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard care without monitoring, in patients with risk of respiratory failure in infancy.
The question addressed in this evidence review is: is home cardiorespiratory monitoring for infants at risk of respiratory failure medically reasonable?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals with risk of respiratory failure in infancy.

**Interventions**
The therapy being considered is home cardiorespiratory monitoring.

Patients with risk of respiratory failure in infancy are actively managed by cardiologists, critical care doctors, and primary care providers in an inpatient clinical setting.

**Comparators**
Comparators of interest include standard care without monitoring. Treatment includes blood pressure support, involuntary nervous system blockers, and antiarrhythmics.

**Outcomes**
The general outcomes of interest are overall survival and morbid events.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

**Sudden Infant Death Syndrome**
During the 1970s and 1980s, it was hypothesized that in the susceptible infant, prolonged periods of apnea and bradycardia were markers for SIDS risk and preceded the ultimate SIDS event. If this was the case, home apnea monitors could alert caregivers to the presence of an impending event. However, a technical report from the American Academy of Pediatrics (AAP; 2011) did not recommend home apnea monitoring to prevent SIDS, citing a lack of evidence that home monitors are effective for this purpose.1

The Collaborative Home Infant Monitoring Evaluation (CHIME) study, a longitudinal cohort study conducted from 1994 to 1998, was designed to address whether severe episodes of apnea and bradycardia occur more commonly in infants considered at higher risk for SIDS.2 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. Monitor alarms were set off 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. In a subsequent multivariate logistic regression analysis of the CHIME study
data, Hoppenbrouwers et al (2008) found that extreme events were not significantly associated with any known SIDS risk factors.\(^5\)

Strehle et al (2012) published a systematic review of the literature on the impact of home monitoring (apnea monitoring, respiratory monitoring, or cardiorespiratory monitoring) on mortality in infants at increased risk of SIDS.\(^5\) The literature search, conducted through June 2010, identified 11 studies for inclusion- a pilot study that assessed the feasibility of an RCT to evaluate home monitoring (level I evidence) and 10 unique case series (level III evidence). Reviewers concluded that there was a lack of high-level evidence that home monitoring would be beneficial in preventing SIDS.

**Other Respiratory Conditions**

There is a lack of evidence on the use of home cardiorespiratory monitors in other conditions. For many 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 by AAP (2003) addressed the use of home apnea monitors for other respiratory conditions.\(^7\) 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 AAP (2003) consensus statement was retired in 2012.\(^8\) 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 regarding the event severity and underlying pathology. Systematic reviews have found wide variation in the eventual diagnosis given after an ALTE.\(^5\) In a systematic review of 37 studies of ALTE, Tieder et al (2013) suggested that rates of recurrent events were higher in patients with a history of recurrent ALTE, prematurity, or suspected child maltreatment.\(^10\) An observational cohort study by Mittal et al (2013) reported on 4-week follow-up outcomes for 300 infants seen in an emergency department with a diagnosis of ALTE.\(^11\) 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 four weeks after hospitalization. Study limitations included nonstandardized evaluation of patients with ALTE and whether results of an in-hospital pneumography study translate to the home setting.

The AAP (2016) published a consensus statement on the evaluation of low-risk infants based on an update of the 2013 systematic review on ALTEs.\(^4\) Eighteen additional studies were identified in the updated systematic review. The updated guidelines defined patients at lower risk of recurrent events after a brief resolved unexplained event, and recommended against the initiation of home cardiorespiratory monitoring in this group (evidence quality: B; strength of recommendation: moderate). This recommendation was 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 without an event occurs, but some infants are discharged to home with a home monitor. For example, in a 3-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, Veit et al (2016) reported that 4.5% of infants were discharged to home with a monitor.12

Summary of Evidence

For individuals who have a risk of respiratory failure in infancy who receive home cardiorespiratory monitoring, the evidence includes primarily observational studies. The relevant outcomes are overall survival and morbid events. For prevention of SIDS, the available published literature is primarily from a longitudinal cohort study, the CHIME study. Results from CHIME do not support the use of monitoring. For other respiratory conditions, there is a lack of published evidence due to small numbers of patients and the difficulty of enrolling infants with respiratory conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty societies and 2 academic medical centers while this policy was under review in 2017. There was general agreement with the existing medically necessary statements and consensus that the use of monitoring for infants with prematurity after discharge may be considered medically necessary.

Practice Guidelines and Position Statements

American Academy of Pediatrics

The AAP (2016) issued clinical practice guidelines on brief resolved unexplained events, which addressed the use of home apnea monitoring for low-risk infants.4

These guidelines outlined criteria for risk stratification for recurrent events. Low-risk patients were 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."
- "Event lasted <1 minute."
- "First event."

For low-risk patients, the guidelines stated that management should not include initiation of home cardiorespiratory monitoring.
The AAP (2016) published a clinical report on apnea of prematurity.\textsuperscript{13} This report made 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."

The AAP (2003) also published a policy on home apnea monitoring, reaffirmed in 2007.\textsuperscript{7} In 2012 the policy was retired.\textsuperscript{8} The document noted that infants who may benefit from home monitoring include those who have experienced an apparent life-threatening event 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 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."

The AAP (2008) also published policy on the hospital discharge of high-risk neonates that addressed the role of home apnea monitors for preterm and otherwise high-risk infants.\textsuperscript{14} The guidelines stated:

"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.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in April 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

**ESSENTIAL HEALTH BENEFITS**

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits ("EHBs"), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or
contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


CODES

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<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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ICD-10-PCS is for use only on inpatient services. Policy is only for outpatient services.

Place of Service: Home

Type of Service: Medicine/DME
### POLICY HISTORY

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<td>Replace policy</td>
<td>Policy updated with literature review through January 28, 2014. References 4, 5, and 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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<td>08/10/16</td>
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<td>Blue Cross of Idaho annual review; no change to policy.</td>
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<td>01/27/17</td>
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<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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<td>Blue Cross of Idaho adopted changes as noted. Policy updated with literature review through April 9, 2018. No references added. Policy statements unchanged.</td>
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