

<b>1.01.06</b>	<b>Home Cardiorespiratory Monitoring</b>		
<b>Original Policy Date:</b>	October 15, 2007	<b>Effective Date:</b>	August 1, 2023
<b>Section:</b>	1.0 Durable Medical Equipment	<b>Page:</b>	Page 1 of 13

## Policy Statement

- I. Home cardiorespiratory monitoring may be considered **medically necessary** when initiated in infants younger than 12 months of age in **any** of the following situations (see Policy Guidelines):
  - A. Those with tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise
  - B. Those with neurologic or metabolic disorders affecting respiratory control, including central apnea and apnea of prematurity
  - C. Those with chronic lung disease (i.e., bronchopulmonary dysplasia; see Policy Guidelines)
- II. Home cardiorespiratory monitoring is considered **investigational** when used as a strategy to reduce the risk of Sudden Infant Death Syndrome (SIDS).
- III. Home cardiorespiratory monitoring is considered **investigational** when used for cardiopulmonary evaluation in lower-risk infants following a brief resolved unexplained event (BRUE), which was previously known as an apparent life threatening event (ALTE) (see Policy Guidelines for further discussion of BRUE risk).
- IV. Home cardiorespiratory monitoring in all other conditions, including but not limited to, the diagnosis of obstructive sleep apnea, is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## 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 Blue Shield of California Medical Policy: Diagnosis of Obstructive Sleep Apnea Syndrome.

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 the FDA. Home monitors should be equipped with an event recorder.

### Age Limits

Upon initiation of home cardiorespiratory monitoring in infants, 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 individuals with home noninvasive or invasive ventilator use or chronic lung disease.

### Bronchopulmonary Dysplasia

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 Bronchopulmonary Dysplasia**

Diagnosis	Gestational Age	
	<32 Weeks	≥32 Weeks
<b>Time point of assessment</b>	36 weeks PMA or discharge to home, whichever comes first	>28 days but <56 days postnatal age or discharge to home, whichever comes first
	Treatment with oxygen >21% for at least 28 days plus	
<b>Mild BPD</b>	Breathing room air at 36 weeks PMA or discharge, whichever comes first	Breathing room air by 56 days postnatal age or discharge, whichever comes first
<b>Moderate BPD</b>	Need for <30% oxygen at 36 weeks PMA or discharge, whichever comes first	Need for <30% oxygen at 56 days postnatal age or discharge, whichever comes first
<b>Severe BPD</b>	Need for ≥30% oxygen and/or positive pressure at 36 weeks postnatal age or discharge, whichever comes first	Need for ≥30% oxygen and/or positive pressure at 56 days postnatal age or discharge, whichever comes first

Adapted from Jobe & Bancalari (2001).

BPD: bronchopulmonary dysplasia; PMA: postmenstrual age.

### Brief Resolved Unexplained Event Risk Assessment: Lower-versus-Higher-Risk of a Repeat Event or a Serious Underlying Disorder

The 2016 clinical practice guideline from the American Academy of Pediatrics reported by Tieder et al (2016) on BRUE and evaluation of lower-risk infants identified the following patient factors as determining a lower risk:

- Age >60 days
- Prematurity: gestational age ≥32 weeks and postconceptional age ≥45 weeks
- First BRUE: no previous BRUE ever and not occurring in clusters
- Duration of event <1 minute
- No cardiopulmonary resuscitation (CPR) required by trained medical provider
- No concerning historical features as detailed in Table 2 of the 2016 AAP guideline (e.g., considerations for possible child abuse, history of the event, recent history, past medical history, family history, environmental history, social history)
- No concerning physical examination findings as detailed in Table 3 of the 2016 AAP guideline (e.g., general appearance, growth variables, vital signs, skin, head, eyes, ears, nose and mouth, neck, chest, heart, abdomen, genitalia, extremities, neurologic)

### Higher Risk

The guidelines committee was not able to establish a definition of higher risk BRUE. "Outcomes data from ALTE studies in the heterogenous high risk population are unclear and preclude the derivation of evidence based recommendations regarding management", which would require further research. However no such trials are listed in clinicaltrials.gov.

### 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.

### Related Policies

- Diagnosis of Obstructive Sleep Apnea Syndrome

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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. A search of the U.S. FDA 510(k) website in April 2023 did not identify any new safety information that would likely influence this policy.

## Rationale

### Background

#### Home Cardiorespiratory 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 (e.g., 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

The American Academy of Pediatrics (AAP) defines Sudden Unexpected Infant Death (SUID), also known as Sudden Unexpected Death In Infancy (SUDI) as "any sudden and unexpected death, whether explained or unexplained" that occurs during infancy. Sudden Infant Death Syndrome (SIDS) is a subcategory of SUID/SUDI, which is defined as the sudden death of an infant younger than 1 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) recommends that home monitoring should not be used as a strategy to prevent SIDS.<sup>1</sup> 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.<sup>2</sup> 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.

### **Brief Resolved Unexplained Event**

The 2016 AAP clinical practice guideline published by Tieder et al<sup>3</sup> 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  $\geq 1$  of the following:

- cyanosis or pallor;
- absent, decreased, or irregular breathing;
- marked change in tone (hyper- or hypotonia); and altered level of responsiveness."

### **Infants With Special Health Care Needs or Dependence on Home Technological Support**

According to AAP's 2008 Policy Statement on Hospital Discharge of the High-Risk Neonate reported by Stark et al (Reaffirmed in 2018),<sup>4</sup> there has been recent increases in discharge of infants dependent on some form of supportive technology due to special health care needs or unresolved medical problems. Conditions that may necessitate use of technological support include apnea of prematurity and bronchopulmonary dysplasia for preterm infants, and upper airway anomalies, central nervous system disorders, and neuromuscular disorders for term infants.<sup>5</sup> For example, home ventilation can be required for infants with tracheostomy for upper airway abnormalities or who cannot be weaned from assisted ventilation prior to discharge. Additionally, to avoid the potential risks of growth failure and cor pulmonale resulting from marginal oxygenation, discharge with home oxygen therapy has been used for infants with bronchopulmonary dysplasia. In both of these cases, home cardiorespiratory monitoring is recommended to accompany the supportive technology for use in detecting airway obstructions or dislodging of the oxygen.

### **Literature Review**

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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## Home Cardiorespiratory Monitoring for Prevention of Sudden Infant Death Syndrome 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 following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with risk of respiratory failure in infancy.

### *Interventions*

The therapy being considered is home cardiorespiratory monitoring for sudden infant death syndrome (SIDS) prevention.

### *Comparators*

Comparators of interest include standard care without monitoring. Standard care 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:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Systematic Reviews

In a 2022 literature review that supported the American Academy of Pediatrics' (AAP) 2022 Policy Statement on SIDS, Moon et al (2022) identified 4 large epidemiological studies conducted between 1986 and 2001 which found that the use of home cardiorespiratory monitors did not decrease the incidence of SIDS.<sup>6</sup> Among those 4 studies is the Collaborative Home Infant Monitoring Evaluation (CHIME) study, a longitudinal cohort study conducted from 1994 to 1998, which was designed to address whether severe episodes of apnea and bradycardia occur more commonly in infants considered at higher risk for SIDS.<sup>7</sup> The study included 1079 infants, both healthy and 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.<sup>7</sup>

Findings from a prior systematic review of the literature on the impact of home monitoring (apnea monitoring, respiratory monitoring, or cardiorespiratory monitoring) published by Strehle et al (2012)<sup>8</sup> are consistent with the 2022 AAP literature review.<sup>6</sup> The systematic review by Strehle et al

(2012) searched the literature through June 2010 and included 1 pilot study that assessed the feasibility of an RCT to evaluate home monitoring (level I evidence) and 10 unique case series (level III evidence). The body of case series evidence included the CHIME study. Reviewers concluded that there was a lack of high-level evidence that home monitoring would be beneficial in preventing SIDS.

### **Section Summary: Home Cardiorespiratory Monitoring for Prevention of Sudden Infant Death Syndrome (SIDS)**

Evidence for the use of home cardiorespiratory monitoring for prevention of SIDS consists of a systematic review and large epidemiological studies, including the CHIME study. These studies consistently found that the use of home cardiorespiratory monitors did not decrease the incidence of SIDS.

### **Home Cardiorespiratory Monitoring for Other Respiratory Conditions**

#### **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 following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of interest is individuals with various respiratory conditions and who are at risk of respiratory failure in infancy.

#### ***Interventions***

The therapy being considered is home cardiorespiratory monitoring for other respiratory conditions.

#### ***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:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Brief Resolved Unexplained Event**

#### **Systematic Reviews**

In a 2016 systematic review that supported the AAP's 2016 Clinical Practice Guideline on BRUE, Tieder et al (2016) assessed studies relevant to use of home cardiorespiratory monitoring in infants presenting with a lower-risk BRUE.<sup>3</sup> Based on searches of numerous bibliographic databases through December 31, 2014, this systematic review identified several studies published between 1986 and 2008 demonstrating that the frequency of respiratory pauses and bradycardia identified by home cardiorespiratory monitors is similar in infants with and without respiratory abnormalities. In

addition, the review noted that other studies have shown no improvements in outcomes or SIDS prevention with home apnea monitors, and “a lack of correlation between ALTEs [now referred to as BRUE] and SIDS.”

### **Observational Studies**

In addition to the studies summarized in the 2016 AAP systematic review, an observational cohort study by Mittal et al (2013)<sup>9</sup> reported on 4-week follow-up outcomes for 300 infants seen in an emergency department with a diagnosis of apparent life threatening event (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. Study limitations included nonstandardized evaluation of patients with ALTE and whether results of an in-hospital pneumography study translate to the home setting.

### **Infants With Special Health Care Needs or Dependence on Home Technological Support Case Series**

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.<sup>10</sup> However, there is a lack of evidence on the effectiveness of home cardiorespiratory monitors in these 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.

### **Section Summary: Use of Home Cardiorespiratory Monitors in Other Respiratory Conditions**

Evidence for the use of home cardiorespiratory monitoring for lower-risk BRUE consists of a systematic review and several observational cohort studies. These studies found no significant differences between infants with and without respiratory abnormalities in the frequency of respiratory pauses and bradycardia identified by home cardiorespiratory monitors. There is a lack of published evidence for other respiratory conditions, which is likely due to small numbers of patients and the difficulty of enrolling infants with respiratory conditions.

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **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, including those that addressed use for tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise; those with neurologic or metabolic disorders affecting respiratory control, including central apnea and apnea of prematurity; or those with chronic lung disease (i.e., bronchopulmonary dysplasia).

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Academy of Pediatrics

#### Sudden Infant Death Syndrome

In 2016, the American Academy of Pediatrics (AAP) (reported by Moon et al) issued a policy statement on sudden infant death syndrome (SIDS) and other sleep-related infant deaths,<sup>11</sup> which addressed the use of home cardiorespiratory monitors. Based on a literature review that identified evidence from 4 large epidemiological studies conducted between 1986-2001, this Policy Statement issued an A-level recommendation against the use of home cardiorespiratory monitoring as a SIDS-prevention strategy. The recommendation stated "Do not use home cardiorespiratory monitors as a strategy to reduce the risk of SIDS." The A-level recommendation indicates that "there is good-quality, patient-oriented evidence" based on the strength-of-recommendation taxonomy. Conflict of interest management was described as including authors filing conflict of interest statements with the AAP and resolution of any conflicts through a process approved by the Board of Directors. A 2022 update to the AAP policy statement included no additional evidence regarding cardiorespiratory monitoring and maintained an A-level recommendation against the use of home cardiorespiratory monitoring as a SIDS-prevention strategy.<sup>1</sup>

#### Brief Resolved Unexplained Events

In 2016, the AAP issued clinical practice guidelines on brief resolved unexplained events (BRUE), which addressed the use of home cardiorespiratory monitoring for low-risk infants.<sup>3,12</sup> This clinical practice guideline was based on a systematic review with searches through December 31, 2014 and the evidence and strength of the recommendations were formally rated using a well-described approach. As with the AAP SIDS Policy Statement described above, conflict of interest management was described as including authors filing conflict of interest statements with the AAP and resolution of any conflicts through a process approved by the Board of Directors. The recommendation stated "Clinicians should not initiate home cardiorespiratory monitoring for cardiopulmonary evaluation." The evidence quality was rated as B, which indicates it was based on "Trials or diagnostic studies with minor limitations; consistent findings from multiple observational studies." The strength of the recommendation was moderate, indicating that "A particular action is favored because anticipated benefits clearly exceed harms (or vice versa) and the quality of evidence is good but not excellent (or is unobtainable). Clinicians would be prudent to follow a moderate recommendation but should remain alert to new information and sensitive to patient preferences."

#### Infants with Special Health Care Needs or Dependence on Home Technological Support

The AAP (2008, reaffirmed in 2018) also published a Policy Statement by Stark et al on the hospital discharge of high-risk neonates that addressed the role of home apnea monitors for preterm and otherwise high-risk infants.<sup>4</sup> This Policy Statement was not clearly based on a systematic review, strength of the policy statements was not formally rated, and clear documentation of conflict of interest management is lacking. Relevant statements include:

- **Hospitalized infants still at risk of apnea:** "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."



- **Bronchopulmonary dysplasia:** “Home oxygen therapy for infants with bronchopulmonary dysplasia has been used as a means of achieving earlier hospital discharge while avoiding the risks of growth failure and cor pulmonale resulting from marginal oxygenation.” “Infants who are discharged on supplemental oxygen are often also discharged on a cardio-respiratory monitor or pulse oximeter in case the oxygen should become dislodged or the supply depleted.”
- **Tracheostomy:** “Tracheostomy is sometimes required for neonates with upper airway abnormalities or occasionally for infants who cannot be weaned from assisted ventilation. Good parental teaching and coordinated multidisciplinary follow-up care are essential for these infants. Infants who require home ventilation should also be on a cardiorespiratory monitor in case the airway should become obstructed, but the home ventilator should also have a disconnect alarm to alert caregivers to ventilator disconnection. Home ventilation requires qualified personnel to provide bedside care; in most cases, home-nursing support will be needed for at least part of the day.”

### 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](https://clinicaltrials.gov) in May 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

## References

1. Moon RY, Carlin RF, Hand I. Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment. *Pediatrics*. Jul 01 2022; 150(1). PMID 35726558
2. National Institute of Child Health and Human Development (NICHD). Safe to Sleep. n.d.; <https://www1.nichd.nih.gov/sts/Pages/default.aspx>. Accessed April 17, 2023.
3. Tieder JS, Bonkowsky JL, Etzel RA, et al. Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants. *Pediatrics*. May 2016; 137(5). PMID 27244835
4. Stark AR, Adamkin DH, Batton DG, et al. Hospital discharge of the high-risk neonate. *Pediatrics*. Nov 2008; 122(5): 1119-26. PMID 18977994
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6. Moon RY, Carlin RF, Hand I. Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping Environment to Reduce the Risk of Sleep-Related Infant Deaths. *Pediatrics*. Jul 01 2022; 150(1). PMID 35921639
7. Hoppenbrouwers T, Hodgman JE, Ramanathan A, et al. Extreme and conventional cardiorespiratory events and epidemiologic risk factors for SIDS. *J Pediatr*. May 2008; 152(5): 636-41. PMID 18410765
8. Strehle EM, Gray WK, Gopiseti S, et al. Can home monitoring reduce mortality in infants at increased risk of sudden infant death syndrome? A systematic review. *Acta Paediatr*. Jan 2012; 101(1): 8-13. PMID 21910748
9. Mittal MK, Donda K, Baren JM. Role of pneumography and esophageal pH monitoring in the evaluation of infants with apparent life-threatening event: a prospective observational study. *Clin Pediatr (Phila)*. Apr 2013; 52(4): 338-43. PMID 23393308

10. Veit L, Amberson M, Freiberger C, et al. Diagnostic Evaluation and Home Monitor Use in Late Preterm to Term Infants With Apnea, Bradycardia, and Desaturations. *Clin Pediatr (Phila)*. Nov 2016; 55(13): 1210-1218. PMID 26957524
11. Moon RY, Darnall RA, Feldman-Winter L, et al. SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*. Nov 2016; 138(5). PMID 27940805
12. AAP Publications Reaffirmed and Retired. *Pediatrics*. August 1 2012;130(2):e467-e468.

## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Discharge summary or progress notes including a plan of care, and specific plan for periodic review and termination of the apnea monitor
- Prescription for home apnea monitor

### Post Service (in addition to the above, please include the following):

- Results/reports of tests performed

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	94772	Circadian respiratory pattern recording (pediatric pneumogram), 12-24 hour continuous recording, infant
	94774	Pediatric home apnea monitoring event recording including respiratory rate, pattern and heart rate per 30-day period of time; includes monitor attachment, download of data, review, interpretation, and preparation of a report by a physician or other qualified health care professional
	94775	Pediatric home apnea monitoring event recording including respiratory rate, pattern and heart rate per 30-day period of time; monitor attachment only (includes hook-up, initiation of recording and disconnection)
	94776	Pediatric home apnea monitoring event recording including respiratory rate, pattern and heart rate per 30-day period of time; monitoring, download of information, receipt of transmission(s) and analyses by computer only
	94777	Pediatric home apnea monitoring event recording including respiratory rate, pattern and heart rate per 30-day period of time; review, interpretation and preparation of report only by a physician or other qualified health care professional
HCPCS	A4556	Electrodes (e.g., apnea monitor), per pair
	A4557	Lead wires (e.g., apnea monitor), per pair

Type	Code	Description
	E0618	Apnea monitor, without recording feature
	E0619	Apnea monitor, with recording feature

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
10/15/2007	BCBSA Medical Policy adoption
02/22/2013	Coding Update
06/30/2015	Coding Update Policy revision without position change
08/31/2015	Policy title change from Home Apnea Monitors Policy revision without position change
02/01/2017	Policy title change from Home Apnea Monitoring Policy revision without position change
08/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
08/01/2023	Policy reactivated. Previously archived from 07/01/2020 to 07/31/2023.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p><b>Reactivated Policy</b></p> <p><b>Policy Statement:</b> N/A</p>	<p><b>Home Cardiorespiratory Monitoring 1.01.06</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Home cardiorespiratory monitoring may be considered <b>medically necessary</b> when initiated in infants younger than 12 months of age in <b>any</b> of the following situations (see Policy Guidelines):               <ol style="list-style-type: none"> <li>A. Those with tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise</li> <li>B. Those with neurologic or metabolic disorders affecting respiratory control, including central apnea and apnea of prematurity</li> <li>C. Those with chronic lung disease (i.e., bronchopulmonary dysplasia; see Policy Guidelines)</li> </ol> </li> <li>II. Home cardiorespiratory monitoring is considered <b>investigational</b> when used as a strategy to reduce the risk of Sudden Infant Death Syndrome (SIDS).</li> <li>III. Home cardiorespiratory monitoring is considered <b>investigational</b> when used for cardiopulmonary evaluation in lower-risk infants following a brief resolved unexplained event (BRUE), which was previously known as an apparent life threatening event (ALTE) (see Policy Guidelines for further discussion of BRUE risk).</li> <li>IV. Home cardiorespiratory monitoring in all other conditions, including but not limited to, the diagnosis of obstructive sleep apnea, is considered <b>investigational</b>.</li> </ol>