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## Home Cardiorespiratory Monitoring

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None

### Disclaimer

#### **Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Legislative Mandates

**EXCEPTION: For Illinois only:** Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

### Coverage

Home cardiorespiratory monitoring **may be considered medically necessary** for premature infants who are at high risk of recurrent episodes of apnea, bradycardia, and hypoxemia, for up to three months after hospital discharge or after the cessation of serious episodes for 14 consecutive days, whichever comes last.

Home cardiorespiratory monitoring **may be considered medically necessary** in infants younger than 12 months of age in the following situations:

- 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 (i.e., bronchopulmonary dysplasia), particularly those requiring supplemental oxygen, continuous positive airway pressure, or mechanical ventilation.

Home cardiorespiratory monitoring is **considered not medically necessary** when used as a strategy to reduce the risk of sudden infant death syndrome (SIDS).

Home cardiorespiratory monitoring is **considered not medically necessary** 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 **NOTE 1**).

Home cardiorespiratory monitoring in all other conditions, including but not limited to the diagnosis of obstructive sleep apnea, is **considered experimental, investigational and/or unproven**.

A back-up electrical system and/or alterations to the living quarters required for the monitor are **considered not medically necessary** as they are considered to be convenience.

The following services are considered part of the rental/purchase fee for the monitor:

- Retrieval of recorded data from the monitor event recorder;
- Parental training sessions (e.g., cardiopulmonary resuscitation [CPR] classes and/or instructions on monitor use).

## Policy Guidelines

**NOTE 1:** The 2016 clinical practice guideline from the American Academy of Pediatrics reported by Tieder et al. (2016) (3) on BRUE and evaluation of lower-risk infants identified the following patient factors as determining a lower risk:

- Age > 60 days;
- Prematurity: gestational age  $\geq$ 32 weeks and postconceptional age  $\geq$ 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 (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 (e.g., general appearance, growth variables, vital signs, skin, head, eyes, ears, nose and mouth, neck, chest, heart, abdomen, genitalia, extremities, neurologic).

**NOTE 2:** Home cardiorespiratory monitors should be equipped with an event recorder whenever possible.

**NOTE 3:** The physician should perform monthly review and provide medical necessity for continuing monitoring.

**NOTE 4:** This policy does not address the use of an unattended (unsupervised) home sleep study for the diagnosis and management of obstructive sleep apnea.

**NOTE 5:** This policy applies only to the use of U.S. Food and Drug Administration (FDA)-approved home monitoring systems.

## 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.

### 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 will sound 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. (1) Instead, the 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 the 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. (2) 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.

### **Brief Resolved Unexplained Event (BRUE)**

The 2016 AAP clinical practice guideline published by Tieder et al. (3) 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), (4) 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. (5) 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.

### **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 patients with home noninvasive or invasive ventilator use or chronic lung

disease.

### **Bronchopulmonary Dysplasia (BPD)**

The diagnosis of 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). (6)

**Table 1. Diagnosis of Bronchopulmonary Dysplasia**

Diagnosis	Gestational Age	
	<32 Weeks	≥32 Weeks
Time point of assessment	36 weeks PMA or discharge to home, whichever comes first.	>28 days but <56 days postnatal age or discharge to home, whichever comes first.
<b>Treatment with Oxygen &gt;21% for at Least 28 Days Plus</b>		
Mild BPD	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.
Moderate BPD	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.
Severe BPD	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). (6)

BPD: bronchopulmonary dysplasia; PMA: postmenstrual age.

### **Brief Resolved Unexplained Event (BRUE) 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) (3) 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 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 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.

### **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, Respiration), 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.

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.

### **Rationale**

This medical policy was created in 1990 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through April 17, 2023.

Medical policies 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. 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.

## **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 policy.

#### *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.

### 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. (7) 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. (8) 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 post-conceptual 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. (8)

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) (9) are consistent with the 2022 AAP literature review. (7) 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 policy.

#### *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.

#### Brief Resolved Unexplained Event (BRUE)

##### *Systematic Reviews*

In a 2016 systematic review that supported the AAP 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. (3) 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) (10) 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, 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. (11)

### 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.

### **Summary of Evidence**

For individuals with risk of respiratory failure in infancy who receive home cardiorespiratory monitoring for prevention of sudden infant death syndrome (SIDS), the evidence includes a systematic review and large epidemiological studies, including the Collaborative Home Infant Monitoring Evaluation (CHIME) study. Relevant outcomes are overall survival and morbid events. The systematic review and epidemiological studies consistently found that the use of home cardiorespiratory monitors did not decrease the incidence of SIDS. 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 (e.g., tracheostomies, chronic lung disease). These conditions identified by AAP as benefiting from home cardiorespiratory monitoring may therefore be considered medically necessary.

For individuals with risk of respiratory failure in infancy who receive home cardiorespiratory monitoring for other respiratory conditions, the evidence includes a systematic review and several observational cohort studies. Relevant outcomes are overall survival and morbid events. For lower-risk infants following a brief resolved unexplained events, (BRUE), which was previously known as an apparent life-threatening event (ALTE), the systematic review and observational cohort 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Practice Guidelines and Position Statements**

### American Academy of Pediatrics (AAP)

#### *Sudden Infant Death Syndrome*

In 2016, the AAP (reported by Moon et al.) issued a policy statement on sudden infant death syndrome (SIDS) and other sleep-related infant deaths (12) 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. (1)

#### *Brief Resolved Unexplained Events*

In 2016, the AAP issued clinical practice guidelines on brief resolved unexplained events (BRUE), which address the use of home cardiorespiratory monitoring for low-risk infants. (3, 13) 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. (4) The 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 cardiorespiratory 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.”

### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in May 2023 did not identify any ongoing or unpublished trials that would likely influence this medical policy.

### **Coding**

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	94774, 94775, 94776, 94777
<b>HCPCS Codes</b>	A4556, A4557, E0618, E0619

\*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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## **Centers for Medicare and Medicaid Services (CMS)**

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
08/15/2024	Reviewed. No changes.
12/01/2023	Document updated with literature review. The following change was made to Coverage: Notes 1 through 5 were moved to the Policy Guidelines section, coverage intent unchanged. Added references 1, 6 and 7.
01/01/2023	Reviewed. No changes.
01/15/2022	Document updated with literature review. Coverage substantially edited to improve overall readability and increase clarity of the policy coverage statements which are unchanged. References 2, 4, and 5 added; some updated and others removed.
08/15/2020	Reviewed. No changes.
09/15/2019	Document updated with literature review. The following NOTES were added to Coverage: 1) "This policy does not address the use of an unattended (unsupervised) home sleep study for the diagnosis and management of obstructive sleep apnea"; and 2) "This policy applies only to the use of U.S. Food and Drug Administration (FDA)-approved home monitoring systems." No new references added.
01/15/2019	Reviewed. No changes.
04/15/2018	Document updated with literature review. The following changes were made to Coverage: 1) The medical necessity statement on home cardiorespiratory monitoring in infants younger than 12 months of age who experience an apparent life-threatening event was modified to: "Those who have experienced a brief resolved unexplained event (BRUE) (previously known as apparent life-threatening event) (See NOTE 1) and are not considered lower risk following clinical evaluation", and 2) Added NOTE 1 regarding the American Academy of Pediatrics definition of "brief resolved unexplained event". Title changed from "Home Apnea Monitor".
10/01/2016	Document updated with literature review. Coverage unchanged.
07/15/2015	Reviewed. No changes.
10/01/2014	Document updated with literature review. Coverage unchanged. However, the following edits were made: 1) The term "(pneumogram)" was removed from the coverage statements; 2) The example "central sleep apnea" was changed to "central apnea"; 3) The example "apnea of prematurity" was added. In addition, the Rationale was completely revised.
12/15/2012	Document updated with literature review. The following was added: 1) Home cardiorespiratory monitoring (pneumogram) may be considered medically necessary in infants younger than 12 months of age for those with chronic lung disease (i.e., bronchopulmonary dysplasia), particularly those requiring supplemental oxygen, continuous positive airway pressure, or mechanical ventilation; and "including central sleep apnea" was added to neurologic or metabolic disorders affecting respiratory control; 2) Home

	cardiorespiratory monitoring (pneumogram) in all other conditions, including but not limited to the diagnosis of obstructive sleep apnea, is considered experimental, investigational and unproven. Rationale and Description were completely revised.
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
07/01/2007	Revised/updated entire document
03/01/2005	Revised/updated entire document
10/24/2003	Coverage revised
04/01/2003	CPT/HCPCS code(s) updated
11/01/2000	Revised/updated entire document
05/01/1996	Revised/updated entire document
05/01/1990	New medical document