Name of Policy:
Home Apnea Monitoring

Policy #: 408
Category: DME
Latest Review Date: March 2014
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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 that patient’s illness, injury or disease.
Description of Procedure or Service:
Home apnea monitors generally monitor 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 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 at detecting obstructive sleep apneas. False alarms due to movement artifact are common with pulse oximeters, and these devices are not intended for the diagnosis of sleep-disordered breathing in a child.

Sudden infant death syndrome (SIDS) refers to the sudden death of an infant younger than one year of age; the circumstances are unexplained after a thorough investigation that includes autopsy, examination of the death scene, and review of the family history. As a means to decrease the incidence of SIDS, in the 1970s, cardiorespiratory monitoring was suggested. However over time, scientific medical studies have failed to establish that the use of home monitoring reduces the incidence of SIDS. In 2011, the American Academy of Pediatrics (AAP) Task Force on Sudden Infant Death Syndrome reiterated the recommendations of its previous policy statements that home monitoring should not be used as a strategy to prevent SIDS. Instead, the AAP recommends that proven practices should be promoted to reduce the incidence of SIDS, which includes 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 (NICHD) and the Maternal Child Health Bureau of Human Resources and Services Administration, American Academy of Pediatrics (AAP). The campaign is a national process to educate healthcare professionals, parents, and caregivers about the significance of placing infants in the supine sleeping position to reduce SIDS. The incidence of SIDS in the U.S. decreased dramatically between 1992 and 2001, especially in the years after the first supine sleep position recommendations were issued. The incidence of SIDS has remained relatively constant since 2001, and SIDS remains a major cause of infant mortality in the U.S.

Policy:
Effective for dates of service on or after April 9, 2010:
Home cardiorespiratory (pneumogram) monitoring meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in infants less than 12 months of age in the following situations:

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

**Home cardiorespiratory (pneumogram) monitoring does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **not medically necessary** in infants with any who do not meet the above criteria but have a siblings with a history of sudden infant death syndrome (SIDS).

**Home cardiorespiratory monitoring (pneumogram)** in all other conditions, including but not limited to the diagnosis of obstructive sleep apnea, **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

*An apparent life-threatening event is defined as an episode that is characterized by some combination of apnea, color change, marked change in muscle tone, choking, or gagging, and is frightening for the parent or caretaker to observe.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
This policy is based on a 2003 policy (reaffirmed in 2007) statement by the American Academy of Pediatrics regarding home cardiorespiratory monitoring (i.e., apnea monitoring).

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

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

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

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

The AAP policy statement also 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 that have:

- Experienced an apparent life-threatening event
- Tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise
- Neurologic or metabolic disorders affecting respiratory control
- Chronic lung disease (i.e., bronchopulmonary dysplasia), particularly those requiring supplemental oxygen; continuous positive airway pressure; or mechanical ventilation.

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

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

Summary
There is insufficient evidence from published studies and a lack of support from national guidelines for home apnea monitoring to prevent SIDS. For other respiratory conditions, there is also a lack of published evidence; however national guidelines published by the American Academy of Pediatrics 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, etc.). These conditions identified by the AAP as benefiting from home apnea monitor may therefore be considered medically necessary.

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

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

Key Words:
Apnea, Infant, Home Monitoring, Monitoring, Siblings of SIDS Victims, Sudden Infant Death Syndrome (SIDS)

Approved by Governing Bodies:
A number of infant apnea monitors have been cleared for marketing by the FDA.
Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT codes:
The following CPT codes may be used:

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  ;monitor attachment only (includes hook-up, initiation of recording and disconnection)
94776  ;monitoring, download of information, receipt of transmission(s) and analyses by computer only
94777  ; 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
E0618  Apnea monitor, without recording feature
E0619  Apnea monitor, with recording feature

References:


Policy History:
Medical Policy Group, February 2010 (3)
Medical Policy Administration Committee, February 2010
Available for comment February 23-April 8, 2010
Medical Policy Group, March 2012 (3): 2012 Update-Policy Statement defining infants that “do not meet criteria”, Key Points, Approved by Governing Bodies, References
Medical Policy Group, December 2012 (3): 2013 Coding Updates – Verbiage change to codes 94774 & 94777 – added “by a physician or other qualified health care professional”.
Medical Policy Panel, April 2013
Medical Policy Group, April 2013 (3): 2013 Update to Description, Key Points and References; no change in policy statement
Medical Policy Panel, March 2014
Medical Policy Group, March 2014 (3): 2014 Updates to Description, Key Points & References; no change in policy statement – did remove the word “(pneumogram)” from policy statements

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.