Clinical Policy Title: Apnea monitors for infants — in-home use

Clinical Policy Number: 11.02.00

Effective Date: October 1, 2014
Initial Review Date: March 19, 2014
Most Recent Review Date: April 27, 2016
Next Review Date: April 2017

Policy contains:
- Apnea monitors.
- Infants.

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of apnea monitors for infants to be clinically proven and, therefore, medically necessary durable medical equipment (DME) when any of the following criteria are met:

- Infants who have experienced any apparent life-threatening events (ALTEs) until the infants remain event-free for six weeks.
- Infants diagnosed with pertussis with positive cultures, upon discharge from acute care facility. If monitored for pertussis, use of an apnea monitor is considered medically necessary for up to one month post-diagnosis.
- Infants with tracheostomies or anatomic abnormalities that make them vulnerable to airway compromise.*
- Infants with neurologic or metabolic disorders affecting respiratory control, including central sleep apnea.*
- Infants with chronic lung disease (i.e., bronchopulmonary dysplasia), especially those requiring supplemental oxygen, continuous positive airway pressure or mechanical ventilation.*
- Infants at high risk of recurrent episodes of prolonged apnea with duration greater than 20 seconds, bradycardia (heart rate less than 80 beats per minute) and hypoxemia (oxygen saturation below 90 percent) after hospital discharge, until the infant remains event-free for six weeks.
• Infants with gastroesophageal reflux disease that results in apnea, bradycardia or oxygen desaturation, until the infants remain event-free for six weeks.
• Infants with apnea accompanied by marked hypotonia; use of an apnea monitor until the infants remain event-free for six weeks.
• The use of home cardiorespiratory monitoring for infants with apnea of prematurity, defined as sudden cessation of breathing that lasts for at least 20 seconds or at least 10 seconds if accompanied by bradycardia or hypoxemia in infants younger than 37 weeks’ gestational age. Continued use is considered medically necessary until infants are past post-conceptional age of 43 weeks and are event-free for six weeks.

* Except as specified for certain indications noted in this policy, infant apnea monitors are usually considered medically necessary for approximately three months. Continued use of an apnea monitor, during the course specified as medically necessary, is considered medically necessary for the durations noted in this policy, even when infants reach age 12 months. Apnea monitoring for children beyond 12 months old requires physician documentation supporting the continuation of monitoring (e.g., continued alarms, documented apnea, bradycardia, or hemoglobin desaturation).

Limitations:

All other uses for apnea monitoring for infants are not medically necessary.

• The use of apnea monitors for remote infrared sensor for the detection of infant sleep apneas is not medically necessary because its effectiveness has not been established.
• Home cardiorespiratory monitoring is intended in part to alert caregivers to intervene at the time of an event in patients with apnea and is not medically necessary to diagnose sleep-disordered breathing (central or obstructive).

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

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

E0618 - Apnea monitor, without recording feature

Alternative covered services:

Increased network physician office visits and evaluation.

Background
Apnea monitors were introduced in the mid-1960s for the management of apnea of prematurity in hospital settings. Subsequently, cardiorespiratory monitoring became widely used in the care of infants with a variety of acute and chronic disorders. There are three types of infant apnea:

- **Central apnea** — Both the inspiratory effort and airflow cease simultaneously (absence of chest wall movement and airflow).
- **Obstructive apnea** — Airflow is absent in the presence of inspiratory efforts (presence of chest wall movement, but no airflow).
- **Mixed apnea** — Central apnea is preceded or followed by airway obstruction.

**Apnea of prematurity:**

Apnea of prematurity (AOP) is the most common and frequently recurring problem in very low birth weight infants. Generally, babies who are born at less than 35 weeks of gestation have periods of stopped breathing or bradycardia. The lower the infant's weight and the greater the level of prematurity at birth, the more likely the infant will have AOP. AOP usually ceases by 37 weeks of post-menstrual age but may persist for several weeks beyond term, especially in infants born before 28 weeks of gestation. The most recent data indicate that extreme episodes usually cease at approximately 43 weeks of post-conceptional age.

The American Academy of Pediatrics (AAP) defines clinically significant apnea in infants as breathing pauses that last for greater than 20 seconds or greater than 10 seconds if associated with bradycardia (e.g., < 80 beats per minute) or oxygen desaturation (e.g., \(O_2\) saturation < 80 percent – 85 percent) (Finer, 2006). This definition may vary depending on geographic location or the infant's symptomatology. Moreover, there is no consensus about the duration of apnea that should be considered pathologic, and there is no agreement regarding the degree of change in oxygen saturation or severity of bradycardia that constitutes an important apnea event.

The hypothesis that apnea is the pathophysiologic precursor to sudden infant death syndrome (SIDS) was first proposed in 1972. Apnea documented by cardiorespiratory monitoring during prolonged hospitalizations was reported for two infants, both of whom were siblings of three infants who had died suddenly at home. Both siblings subsequently died unexpectedly after discharge from the hospital. More than 20 years later, evidence suggested infanticide for all five infants in the original report. The apnea theory has never been proven despite extensive independent research in the several decades since that report. Nevertheless, the home cardiorespiratory monitoring industry, fueled by increasing demand from parents concerned about the risk of SIDS, rapidly developed products aimed at preventing SIDS. Despite the absence of a scientific foundation or evidence of efficacy, home cardiorespiratory monitoring continues to be a common practice in this country.

In 1975, the AAP Committee on Infant and Preschool Children recommended that home monitoring to prevent SIDS should be limited to ongoing research studies. Subsequently, in the early 1980s, AAP formed the Task Force on Prolonged Infantile Apnea to evaluate the evidence for the theory that apnea is a precursor to SIDS. The task force concluded in a 1985 statement that “a causal relationship between prolonged apnea and SIDS has not been established.” The recommendations left the use of home cardiorespiratory monitoring in individual situations to physician judgment.
The risk of sudden death in siblings of infants who died of SIDS is unclear. The rarity of a SIDS death and the more extreme rarity of the subsequent SIDS death of a sibling make it difficult to complete a definitive clinical trial to establish efficacy. Many studies that reported an increased risk for siblings were performed before the current understanding of the epidemiology involved. The roles of infant sleep position and sleeping environment, smoking in the household and death scene investigation to exclude infanticide are now recognized as significant factors in understanding the causes of SIDS. There is a body of evidence, although inconclusive, that suggests the existence of a genetic susceptibility to SIDS, though the risk of recurrence in siblings, if present, is most likely exceedingly low.

**Efficacy of home cardiorespiratory monitoring:**

Epidemiologic studies have failed to document any impact of home cardiorespiratory monitoring for apnea and/or bradycardia on the incidence of SIDS. There is no evidence that the presence of apnea and/or bradycardia identifies a group at increased risk of SIDS, that home cardiorespiratory monitoring can provide warning in time for intervention to prevent sudden death, or that intervention would be successful in preventing unexpected death. Given the lack of evidence that home cardiorespiratory monitoring has any impact on SIDS, prevention of SIDS is not an acceptable indication for home cardiorespiratory monitoring.

Evidence exists that preterm infants are at a greater risk of extreme apnea episodes than are term infants. This risk decreases with time, ceasing at approximately 43 weeks of post-menstrual age. There are no studies correlating long-term neurodevelopmental outcome with such episodes. Home cardiorespiratory monitoring after hospital discharge may be prescribed for some preterm infants with an unusually prolonged course of recurrent, extreme apnea (as defined previously). The physician, together with the parents, should consider the potential advantages and disadvantages of home cardiorespiratory monitoring. Current evidence suggests that if such monitoring is elected, it usually may be discontinued after 43 weeks of post-menstrual age, although extreme apnea may persist beyond that time in some infants. Using a monitor with event recording can be helpful in determining the appropriate time for discontinuance.

When cardiorespiratory monitoring in the hospital or home is prescribed, the physician should also establish a specific plan for periodic review and termination. Should monitoring beyond 43 weeks of post-menstrual age be recommended, clear documentation of the reasons for continuing monitoring is necessary.

Many monitors are available, and it is the physician’s responsibility to prescribe equipment with specific capabilities. Cardiac and respiratory activity should be monitored simultaneously. Monitors capable of event recording should be used for downloading and retrospective analysis of true versus false alarms. None of the current monitors available for home uses reliably detect obstructive apnea. Most home infant apnea monitors measure chest movements and heart rate. Normally, the monitor’s alarm is set to go off if the infant stops breathing for 20 seconds or if the heart rate falls below 80 beats per minute.

**Searches:**

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on February 18, 2016. Search terms were: “apnea, prematurity,” and “home pneumogram monitoring [Mesh].”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

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, the AAP guidelines has 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 and chronic lung disease). These conditions identified by the AAP as benefiting from home apnea monitoring may therefore be recommended. Current evidence suggests if such monitoring is elected, it usually may be discontinued after 43 weeks of post-menstrual age, although extreme apnea may persist beyond that time in some infants. Using a monitor with event recording can help determine the appropriate time for discontinuance.

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perfect Sychowski S, et al. (2001)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| *Home apnea monitor use in preterm infants discharged from newborn intensive care units.* | • Purpose: To identify current factors associated with home apnea monitor use in preterm infants and to determine whether home monitor use was associated with a shorter length of hospital stay.  
• Setting: We evaluated neonates who were < or = 34 weeks estimated gestational age and admitted for neonatal intensive care. We excluded neonates with congenital anomalies, neonates transferred out before discharge and neonates who died.  
• Methods: Using a database created with a computer-assisted tool that generates hospital notes, we reviewed the epidemiology of monitor use. Differences between neonates sent home with an apnea monitor and those who were not were evaluated by using stepwise logistic regression analysis to identify which factors were independently associated with a neonate being discharged with a monitor.  
• Results: We studied 14,532 neonates; 1,588 (11 percent) were sent home with monitors and 12,944 (89 percent) were not. The most important variables associated with being discharged with a monitor were site of care and a diagnosis of apnea. Site variation remained significant when adjusted for gestational age, diagnosis of apnea, and a history of use of methylxanthines. When corrected for gestational age, monitor use was
Citation | Content, Methods, Recommendations
--- | ---
• Conclusion: The data suggest that monitor use is more dependent on physician preference than medical indication, and is not associated with earlier hospital discharge.

**Key points:**
• A large cohort of infants (8,998) at high risk for sudden and unexpected death was followed with home cardiorespiratory monitoring over a five-year period. These infants included premature infants (23 – 36 weeks of post-conceptual age), SIDS siblings and infants who experienced an ALTE.
• The overall SIDS rate in this high-risk population was 0.55/1,000, a rate significantly less than the 0.85 deaths/1,000 reported in the “general population” of Georgia over this same time period.
• In addition, they report their experience with using home monitors as a diagnostic tool, and how monitors can actually be cost-effective.
• Editorial opinions and lay press summaries of the CHIME study (JAMA, May 2, 2001) imply that home cardiorespiratory monitors are of little value. Although the study never made this claim, many clinicians are now referring to this study as evidence that home monitoring is ineffective and not needed.
• This article disputes those misconceptions about home cardiorespiratory monitors based on experience with a large high-risk population of infants.

**Glossary**

**Actigraphy** — A method of monitoring activity with a portable device or actimeter that can be used while patients are sleeping. Actigraph devices include a small accelerometer typically fixed to a patient’s wrist to record movement (AASM, 2007).

**Apparent life-threatening event (ALTE)** — An episode characterized by some combination of apnea, color change, marked change in muscle tone, choking or gagging.

**Obstructive sleep apnea syndrome (OSAS)** — A potentially serious sleep disorder in which breathing repeatedly stops and starts during sleep. Several types of sleep apnea exist, but the most common type is obstructive sleep apnea, which occurs when your throat muscles intermittently relax and block your airway during sleep.

**Polysomnogram (PSG)** — The continuous and simultaneous recording of multiple physiologic variables during sleep: electroencephalogram, electrooculogram, electromyogram (these are the three basic stage-scoring parameters), electrocardiogram, respiratory air flow, respiratory movements, leg movements and other electrophysiologic variables (AASM, 2001).

**Post-conceptual age** — Gestational age at birth plus age in weeks from birth. According to AAP, this is more accurately designated as “post-menstrual age.”

**Sudden infant death syndrome (SIDS)** — The sudden death of an infant under age 1 year.


References

Professional society guidelines/other:


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on February 18, 2016, using terms pediatric home apnea monitoring | Open Studies. One study found, one relevant.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>94774</td>
<td>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.</td>
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<tr>
<td>94775</td>
<td>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).</td>
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<td>94776</td>
<td>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.</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>A37.00</td>
<td>Whooping cough due to Bordetella pertussis without pneumonia</td>
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<tr>
<td>A37.01</td>
<td>Whooping cough due to Bordetella pertussis with pneumonia</td>
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<td>A37.10</td>
<td>Whooping cough due to Bordetella parapertussis without pneumonia</td>
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<td>A37.11</td>
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<td>A37.80</td>
<td>Whooping cough due to other Bordetella species without pneumonia</td>
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<td>A37.81</td>
<td>Whooping cough due to other Bordetella species with pneumonia</td>
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<td>K21.9</td>
<td>Gastro-esophageal reflux disease without esophagitis</td>
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<td>P27.1</td>
<td>Bronchopulmonary dysplasia originating in the perinatal period</td>
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<tr>
<td>P28.2</td>
<td>Cyanotic attacks of newborn</td>
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<tr>
<td>P28.3</td>
<td>Primary sleep apnea of newborn</td>
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<tr>
<td>P28.4</td>
<td>Other apnea of newborn</td>
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<tr>
<td>P29.12</td>
<td>Neonatal bradycardia</td>
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<tr>
<td>Q31.0</td>
<td>Web of larynx</td>
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<td>Q31.1</td>
<td>Congenital subglottic stenosis</td>
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<td>Q31.5</td>
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<td>Q39.1</td>
<td>Atresia of esophagus with tracheo-esophageal fistula</td>
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<td>Q39.2</td>
<td>Congenital tracheo-esophageal fistula without atresia</td>
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<td>Esophageal web</td>
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<td>Q39.8</td>
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<td>Z93.0</td>
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<tr>
<td>Z99.81</td>
<td>Dependence on supplemental oxygen</td>
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<td>A4557</td>
<td>Lead wires (e.g., apnea monitor), per pair.</td>
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<td>E0618</td>
<td>Apnea monitor, without recording feature.</td>
<td>One per month (rental)</td>
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<tr>
<td>E0619</td>
<td>Apnea monitor, with recording feature.</td>
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