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|---------------------------------------------------------|--|-------------------------------------------|---------|
| <b>Subject: Home Apnea Monitoring for Infants</b>       |  | <b>Original Effective Date:</b>           | 12/6/07 |
| <b>Guidance Number:</b> MCG-044                         |  | <b>Revision Date(s):</b> 2/10/11, 6/29/12 |         |
| <b>Medical Coverage Guidance Approval Date:</b> 6/29/12 |  |                                           |         |

## PREFACE

*This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.*

## FDA INDICATIONS

The FDA has approved various medical devices for apnea monitors from various manufacturers.<sup>1</sup> The apnea monitor is designated as a class II device, but is now subject to special controls.<sup>2</sup> Any manufacturer submitting a 510(k) premarket notification for a newly proposed apnea monitor will need to address the issues covered in the special control guidance. The Special control guidance document outlines health risks, hardware/software validation and verification recommendations, feature and design suggestions, indicators for visible and audible alarms, mechanical and electrical safety, electromagnetic compatibility, performance testing, biocompatibility/sterility processes, clinical study and labeling requirements.

The FDA approvals are indicated for the continuous monitoring of respiration and heart rate of infant patients in the home or in the hospital. The monitor detects and alarms for periods of temporary interruption of breathing (central apnea) or low heart rates.

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

*The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.*

There is no National Coverage Determination or Local Coverage Determinations available for this topic.<sup>3</sup>

## INITIAL COVERAGE CRITERIA

Home apnea monitoring may be authorized in infants (defined as less than 12 months of age)\* that meet the following criteria:

- ☐ Prescribed by a Pediatrician, Neonatologist, or Pediatric Subspecialist; **AND**
- ☐ One of the following diagnosis/indications: **[ONE]**
  - o *Apnea of prematurity* in infants <37 weeks postmenstrual age<sup>\*\*</sup>.<sup>24,36</sup> with documentation of one of the following clinical manifestations: **[ONE]**

- ✧ Episodes of sudden cessation of breathing that lasts for at least 20 seconds; **OR**
    - ✧ Episodes of sudden cessation of breathing that lasts for > 10 seconds if accompanied by bradycardia (< 80-90);<sup>36,38,42</sup> **OR**
    - ✧ Episodes of oxygen saturation (< 85%)<sup>36</sup>

**Note:** There is no consensus regarding the duration of apnea, the degree of change in oxygen saturation, or severity of bradycardia that is considered pathologic.<sup>36,38</sup>

- o *Apparent life threatening events* in infants >37 weeks postmenstrual age<sup>\*\*</sup> or older with documented of the following symptoms:**[Combination of two or more]**
  - o Apnea (greater than 20 seconds),
  - o Color change (e.g., pallid or cyanotic but may be erythematous)
  - o marked change in muscle tone such as limpness choking or gagging

**\*\*Postmenstrual age is defined as gestational age plus chronological age.**<sup>55</sup>

- o
- o *Tracheostomy or anatomic abnormalities* in infants with documentation of increasing vulnerability to airway compromise
- o *Chronic lung disease (eg, bronchiopulmonary dysplasia)* in infants requiring:**[ONE]**
  - o supplemental oxygen; **OR**
  - o positive airway pressure; **OR**
  - o mechanical ventilatory support
- o *Neurologic or metabolic disorders* that have documented impact on respiratory control

**AND**

- ☐ All monitors should have event-recording (memory) capability to document events, to distinguish true apnea and bradycardia from false alarms, and to document compliance.<sup>10</sup>

**AND**

- ☐ Initial Authorization approval for 1 month of rental for apnea of prematurity or 2 month rental for all other indications

**\*NOTE:** Requests for apnea monitoring in children > 12 months requires review by a Medical Director for appropriateness. *AMR Peds Pulmonologist reviewer states “Yes, I have seen them (home apnea*

*monitoring) being used for older kids but this is inappropriate and should be discouraged. The need for this would be exceptionally rare. Maybe a central hypoventilation patient or a patient with brainstem tumor/traumatic injury might need this. However, this is very rare.”<sup>54</sup> January 2007, Board certified in Pediatrics and Pediatric Pulmonology.<sup>54</sup>*

#### CONTINUATION OF THERAPY

##### Apnea of Prematurity

Continuation of home apnea monitoring in infants < 12 months of age with **apnea of prematurity** may be authorized for subsequent 1 month intervals when:

- ☐ Provider submits documentation from event recorder download summary with continued episodes of apnea/bradycardia/desaturations: **[ONE]**
  - o Episodes of sudden cessation of breathing that lasts for at least 20 seconds; **OR**
  - o Episodes of sudden cessation of breathing that lasts for > 10 seconds if accompanied by bradycardia (< 80-90);<sup>36,38,42</sup> **OR**
  - o Episodes of oxygen saturation (< 85%)<sup>36</sup> exist

##### Discontinuation of Monitoring for Apnea of Prematurity

- ☐ Continuation of apnea monitoring for prematurity of apnea in infants < 12 months of age will not be authorized if one of the following criteria are met: **[ONE]**
  - o 8 continuous days or more have passed without apnea (greater than 20 seconds), bradycardia (less than 80 beats per minute), or oxygen desaturations (<85%), the monitor should be discontinued in an otherwise healthy infant, who is not using caffeine, theophylline, or other similar medications (must be off medication for 2 weeks prior to discontinuing); **OR**
  - o Infant reaches 43 weeks postmenstrual\*\* age without experiencing significant events

**\*\*Postmenstrual age is defined as gestational age plus chronological age.<sup>55</sup>**

##### Apparent life threatening events and all Other Indications

Continuation of home apnea monitoring in infants < 12 months of age with **apparent life threatening events and all other indications** may be authorized for subsequent 2 month intervals when:

- ☐ Provider submits documentation from event recorder download summary with continued episodes of apnea/bradycardia/desaturations: **[ONE]**
  - o Episodes of sudden cessation of breathing that lasts for at least 20 seconds; **OR**
  - o Episodes of sudden cessation of breathing that lasts for > 10 seconds if accompanied by bradycardia (< 80-90);<sup>36,38,42</sup> **OR**

- o Episodes of oxygen saturation ( $< 85\%$ )<sup>36</sup> exist; **OR**
- o Combination of two or more of the following documented symptoms:
  - o Apnea (greater than 20 seconds),
  - o Color change (e.g., pallid or cyanotic but may be erythematous)
  - o marked change in muscle tone such as limpness
  - o choking or gagging

#### Discontinuation of Monitoring for Apparent life threatening events and all Other Indications

Continuation of apnea monitoring in infants  $< 12$  months of age with ALTE or all other indications will not be authorized once the infant remains event free for 6 weeks.

**Notes:** Download summary reviews must include a review of the number of hours of daily usage along with a daily summary of events. Noncompliance with the use of the prescribed monitor will require a review by the Medical Director to determine if continuation of the monitor is warranted.

#### **COVERAGE EXCLUSIONS**

Home apnea monitoring for the prevention of sudden infant death syndrome (SIDS) or any other indication that is not listed in the above coverage criteria is considered ***experimental, investigational or unproven.***

Home apnea monitoring in infants  $>12$  months requires review by a Medical Director.

#### **DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

An apnea monitor is a complete medical device system intended to alarm primarily upon the cessation of breathing timed from the last detected breath.<sup>1</sup> The apnea monitor also includes indirect methods of apnea detection, such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration. The monitor has a built in memory capability that allows for downloading or printing of data for physician review and medical decision making purposes.

The standard for home monitoring device is transthoracic impedance combined with electrocardiogram (ECG) monitoring.<sup>46</sup> Impedance monitoring is an indirect technique for monitoring respiration in contrast to end-tidal carbon dioxide (CO<sub>2</sub>) monitoring and airflow monitoring. These devices directly measure central apnea by the lack of respiratory effort. They do not detect obstructive apnea in the absence of bradycardia.<sup>4</sup> The clinical utility of the monitor depends upon the pathophysiology of the underlying disorder. The monitor is more useful for infants at risk for central apnea or bradycardia (e.g., apnea of prematurity) than for disorders in which apnea or bradycardia are late consequences of hypoxemia. Devices with oxygen saturation measurements may provide somewhat earlier recognition of events in infants with primary respiratory disease (e.g., neuromuscular or tracheostomy disease).

#### **GENERAL INFORMATION**

##### Summary of Medical Evidence

The efficacy of home cardiorespiratory monitoring (CR) has not been established through randomized-control trials for any category of patients partially due to ethical issues regarding establishing a treatment group versus

a control group.<sup>4,34</sup> A major issue in assessing the role of CR monitors to prevent infant death is that clinical efficacy cannot be established.<sup>4</sup> Randomized controlled trials are impractical because death is a rare event in these infants, and families are unlikely to consent to randomization.

There are no reports of scientifically designed studies regarding the effectiveness of home monitoring for an apparent life-threatening event (ALTE), for subsequent siblings of SIDS victims, premature infants or for other pathological conditions. SIDS annual mortality rates have not declined as a result of the use of home monitoring. Home use of the apnea monitor has been initiated for more than 30 years and has become a standard of care in the United States and internationally regardless of the paucity of evidence regarding efficacy.<sup>34</sup> Home apnea monitors are designed with the purpose of protecting an infant by identifying central apnea or heart rate extremes and signaling for caregiver intervention (e.g., mouth-to-mouth resuscitation, cardiac compressions, stimulation) to prevent death. Data recording devices are also used to provide a mechanism for the health-care provider to review and interpret the data for developing a course of action. High mortality diagnoses such as severe bronchiopulmonary dysplasia may warrant home monitoring but supportive data are lacking.<sup>1</sup>

#### Preterm Infants with apnea of Prematurity

*Apnea of prematurity* is defined as the sudden cessation of breathing that lasts for at least 20 seconds or > 10 seconds if accompanied by bradycardia (< 80-90)<sup>36,38,42</sup> or oxygen saturation (< 85%)<sup>36</sup> in an infant younger than 37 weeks postmenstrual age.<sup>24,36</sup> There is no consensus regarding the duration of apnea, the degree of change in oxygen saturation, or severity of bradycardia that is considered pathologic.<sup>36,38</sup> Apnea occurs in more than 50% of premature infants;<sup>36</sup> and is almost standard in infants who are < 1000 grams at birth. the frequency decreases with increasing maturity.<sup>29</sup> Apnea usually resolves before 37 postmenstrual weeks in infants delivered after 28 weeks gestation.<sup>28</sup> Apnea frequently continues after postmenstrual age in infants born prior to 28 weeks.<sup>32,33</sup>

There are three classifications of apnea depending on the presence of continued inspiratory efforts and upper airway obstruction while respiratory airflow is absent follows<sup>28</sup>:

- *Central apnea*- absence of inspiratory effort or breathing
- *Obstructive apnea*- airway obstruction with persistent inspiratory efforts
- *Mixed apnea*- Central apnea occurs in addition to periods of airway obstruction with continued inspiratory effort

The majority of apnea episodes in premature infants are mixed or central as demonstrated in a study of 2082 apneic episodes in 46 infants; 20 percent were mixed, 40 percent were central, and 11 percent were obstructive.<sup>31</sup>

Outpatient home monitoring studies have demonstrated that apnea, bradycardia, and desaturation continue in convalescing preterm infants after discharge.<sup>38</sup> The use of conventional impedance home cardiorespiratory monitors showed that 79% of 29 preterm infants who had persistent apnea and bradycardia at the time of discharge continued to demonstrate significant events, defined as apnea lasting 20 seconds or longer or age-

related bradycardia, after discharge. Most events occurred in the first month after discharge. Bradycardia, with and without central apnea, was the most prevalent event recorded.

The Collaborative Home Infant Monitoring Evaluation (CHIME) study enrolled 443 preterm infants of less than 34 weeks' gestation, a birth weight less than 1750 g, and age less than 120 days at the time of discharge into two groups: 76 (17%) symptomatic preterm infants and 367 (83%) asymptomatic preterm infants. "Symptomatic" was defined as clinically observed apnea and bradycardia associated with cyanosis in the NICU within 5 days of discharge.<sup>13</sup> Both symptomatic and asymptomatic preterm infants continued to have conventional and extreme events that decreased over time. The rate of extreme events was higher in both preterm groups than in healthy term infants through 43 weeks postmenstrual age. A key finding of the CHIME study is that after discharge asymptomatic preterm infants continued to have events, with 20% of asymptomatic preterm infants experiencing at least one extreme event. With the use of respiratory inductance plethysmography (RIP) monitors, a high frequency of obstructed breathing was noted, with at least three obstructed breaths found in 50% of conventional events of apnea lasting at least 20 seconds and in 70% of extreme events of apnea lasting longer than 30 seconds. RIP monitors detect obstruction as well as central apnea whereas impedance monitors central apnea and heart rate only.

Both in-hospital and at-home studies have shown that convalescing preterm infants continue to have cardiorespiratory patterns with both central and obstructive apnea, heart rate decelerations, and bradycardia and episodes of desaturation. These episodes continue to occur even though the infants have achieved a period of cardiorespiratory stability and clinically seem to be asymptomatic and ready for discharge.

#### Home Monitoring Prior to Discharge from a Hospital of Infants with Apnea of Prematurity

There is limited information available regarding when to discontinue apnea monitoring prior to discharge from a hospital.<sup>38-40</sup> Completion of apnea and bradycardia free periods is the common criterion for discharge without a home cardiorespiratory monitor.<sup>38</sup> In one study of 91 premature infants, no apnea occurred more than eight days after an apnea-free interval except in the presence of a specific cause such as sepsis.<sup>30</sup> A survey of 252 neonatologists demonstrated that 67% used an apnea-free interval of 5 to 7 days as a criterion for discharge without a home cardiorespiratory monitor.<sup>39,40</sup> UpToDate recommends home monitoring until infants reach 34 to 36 weeks postmenstrual age and no apnea is detected for five to seven days.<sup>28</sup>

A number of monitoring studies have been performed in an attempt to determine a convalescing preterm infant's cardiorespiratory stability (or instability) before discharge. An early study performed in-hospital recordings in 83 infants (mean gestational age at birth, 30 weeks) who had a history of cyanosis, apnea, and bradycardia and who were ready for discharge at 36 to 44 weeks' Postconceptional age (PCA).<sup>47</sup> Stability was defined as having needed no nursing intervention for the past week. Rare episodes of brief bradycardia lasting several seconds (not defined further) and not associated with color change or intervention did not exclude discharge. In-hospital recordings demonstrated abnormalities of apnea lasting 20 seconds or longer, excessive periodic breathing, or bradycardia lower than 80 bpm in 92% of the "asymptomatic" infants. Recorded events did not correlate with subsequent clinical events.

A second study also identified abnormal findings by predischarge multichannel recordings among 187 infants at a mean postconceptional age (PCA) of 37.4 weeks (mean gestational age at birth, 27 weeks) who were

identified as ready for discharge.<sup>48</sup> Apnea lasting 12 seconds or longer (usually between 12 and 19 seconds and often obstructive and mixed) or apnea associated with a 10% drop in heart rate or a 10-point fall in hemoglobin saturation were demonstrated in 91% of recordings. The findings in 12 healthy, asymptomatic infants were so severe, frequent, or prolonged that their discharge was delayed. No relationship was found between pre-discharge recordings and clinical outcomes. In contrast, pre-discharge recordings among 106 infants considered stable for discharge on caffeine therapy (31 weeks' mean gestational age at birth) were performed at a younger mean PCA of 35 weeks.<sup>49</sup> These studies demonstrated abnormalities of apnea lasting 20 seconds or longer or bradycardia lower than 80 bpm for longer than 5 seconds in 30% of infants. This subset of infants was discharged on home recording monitors and had more postdischarge complications and pathologic apnea recorded. The infants without pre-discharge abnormalities were discharged on caffeine without home monitoring.

Although data are limited, discontinuation of home monitoring appears to be safe if there is no significant recorded event or when the patient reaches 43 weeks of corrected age.<sup>13</sup> In 2003, the American Academy of Pediatrics released a recommendation that if home monitoring is utilized, it usually can be discontinued after 43 weeks postmenstrual age or after cessation of extreme episodes, whichever occurs last.<sup>10</sup>

Sixty-four preterm infants with apnea of prematurity (AOP) discharged with cardiorespiratory home monitoring were prospectively followed.<sup>41</sup> For each monitor alarm the parents recorded the occurrence of apnea, bradycardia or color change, and the type of assistance provided. The mean gestational age at birth was 28.8 (26–34) weeks, and the mean birth weight was 1,180 (730–2,390) g. The parents of 61/64 infants (95%) reported a total of 185 true AOPs with a mean of 3 (1–12) events/infant. The mean postconceptional age (PCA) at the last apnea was 41.0 (37–44) weeks. In 80%, AOP terminated between 40 and 44 weeks PCA. There was no correlation between the degree of prematurity and the PCA of the last apnea.

### Apparent Life Threatening Events (ALTE)

An *apparent life-threatening event* is defined as an episode that is frightening to the observer and is characterized by some combination of apnea, color change, marked change in muscle tone, choking or gagging.<sup>24</sup> An ALTE is not a specific diagnosis but a description of a chief complaint that brings an infant medical attention.<sup>51</sup> There are many differential diagnoses associated with these events. The most common include neurological problems (e.g., breath-holding spells, seizures, ventricular hemorrhage, hydrocephalus), gastroesophageal reflux, infection, upper airway obstruction, inborn errors of metabolism, child abuse, prematurity, and respiratory issues.<sup>38,51,52</sup> Approximately 50% of these events are considered idiopathic with no cause determined.<sup>52</sup>

There is limited evidence available for home monitoring studies in infants who experience an idiopathic apparent life-threatening event.<sup>38</sup> The available evidence is from case series. Home monitoring for ALTE has been recommended for certain idiopathic ALTE. Monitors would be less helpful for infants with presumed obstructive pathophysiology than for those with central apnea.<sup>4</sup> Home monitors only detect chest wall movement and heart rate. Pulse oximetry for monitoring oxygen saturation may be more appropriate for suspected obstructive apnea.<sup>51</sup>

Earlier studies are available in patients who experienced an idiopathic ALTE using home monitoring without event recording making clinical correlation difficult.<sup>38</sup> Studies using home monitoring with memory capability have assisted in establishing a diagnosis in infants who experience idiopathic ALTE when the initial evaluation

was unremarkable.<sup>43,44</sup> In both case series, infants who experienced recurrent severe ALTEs, cardiorespiratory monitoring as well as monitoring of oxygenation allowed the diagnosis of seizures, suffocation, and Munchausen's syndrome by proxy. It has been concluded that home monitoring with memory capability can assist in identifying underlying mechanisms and clarify the natural history and frequency of recurrence of ALTE in infants.<sup>38,43,44</sup>

In a program using monitors with memory capability, subsequent significant events occurred in 33% of the 73 infants who experienced an ALTE.<sup>45</sup> Most of the significant events were recorded in the first month of monitoring. Sixty percent of 134 documented significant events were not associated with any reported clinical symptoms; conversely, only 61% of the 144 reported clinical events had significant documented apnea and/or bradycardia. As with AOP, these findings question the threshold of significance for apnea and bradycardia and highlight the difficulty in correlating recorded significant events with clinical events observed by the caregivers. Term (n= 5 /107) and preterm (n= 5 /45) infants who had experienced an idiopathic ALTE were enrolled as two groups in the CHIME study that enrolled 1079 infants overall.<sup>13</sup> Although all infants being monitored for an idiopathic ALTE had an increased risk for repeated extreme events, the difference was statistically significant only for the preterm infants who experienced an ALTE. Of the 116 term and preterm infants who had at least one extreme event, 51.7% had a second event; 57.3% of the infants who experienced a second event had a third event; and 80% of the infants who had a third event experienced a fourth event. Most subsequent events occurred within 6 weeks of the prior event.

### Sudden Infant Death Syndrome

*Sudden Infant Death Syndrome (SIDS)* is defined as the sudden death of an infant under one year of age that remains unexplained despite a thorough investigation, including autopsy, examination of the death scene, and review of the clinical history.<sup>26</sup> SIDS is the leading cause of infant mortality between 1 month and 1 year of age in the United States. The risk of SIDS in the United States is <1 per 1000 live births.<sup>25</sup> Increased rates (two to three times the national average) are reported in black and American Indian/Alaskan native children. Disproportionately high rates (15 to 20 percent) of SIDS cases occur in child care settings. The risk of SIDS is slightly increased in boys (multivariate OR 1.49 (95%CI 1.14-1.83) in one large European case-control study).<sup>27</sup>

There is no available data to support the therapeutic use of cardiorespiratory monitoring to reduce the risk of SIDS in asymptomatic infants regardless of risk factors that may be present (e.g., prematurity or prior sibling death).<sup>4</sup> Epidemiologic studies and years of clinical data have been unsuccessful at showing an effect of CR monitors in decreasing the incidence of SIDS in at risk infants.<sup>10-12</sup> Several case-control and observational studies have been performed which have not found apnea of prematurity to be a risk factor for the development of SIDS. SIDS risk factors identified through these studies include: prone sleeping condition, no prenatal care or delayed care, low birth weight with or without preterm birth, maternal smoking or exposure to smoke, young maternal age, maternal alcohol consumption, infant care (e.g., overheating, prone positioning, <3 well-child visits, soft surface sleeping, bed sharing).<sup>18-23</sup>

The National Institute of Child Health and Human Development SIDS Cooperative Epidemiologic Study reported that 93% of SIDS victims experienced no apnea prior to death.<sup>13</sup> Studies using plethysmographic monitors that detect both obstructive and central apnea in infants presumed to be at risk for SIDS exhibited a high frequency of obstructed breathing that would not be detected with conventional monitoring.<sup>13</sup> Data obtained from death tracings following infant deaths with home monitoring devices in place demonstrate that bradycardia occurs first followed by terminal apnea.<sup>5,6,9</sup> It is hypothesized that hypoxia precedes the recorded

bradycardia. There is currently no data to support the therapeutic use of cardiorespiratory monitoring to decrease the risk for SIDS in asymptomatic infants regardless of risk factors.<sup>4</sup>

The American Academy of Pediatrics launched the “Back to Sleep” campaign encouraging supine sleeping in 1992.<sup>14</sup> The SIDS rate has decreased by more than 40 percent since the initiation of this program.<sup>16,17</sup>

The Collaborative Home Infant Monitoring and Evaluation Study demonstrated that infants with monitored respiratory events were frequently (70%) having obstructive events that are not detected by standard monitors.

### Other indications

In infants with underlying diseases predisposing to respiratory failure, home CR monitoring have facilitated rapid recognition of central apnea, airway obstruction, respiratory failure, interruption of supplemental oxygen supply, or failure of mechanical respiratory support.<sup>10</sup> Infants with the following conditions are candidates for monitoring:

- Tracheostomy or airway abnormalities
- Neurologic or metabolic disorders affecting respiratory control
- Chronic lung disease (e.g., bronchiopulmonary dysplasia), especially those requiring supplemental oxygen, positive airway pressure, or mechanical ventilatory support
- In some infants, oxygen saturation monitoring alone, or in conjunction with a CR device may provide more useful diagnostic information than a CR monitor alone. None of the currently available home CR monitors reliably detects obstructive apnea<sup>13</sup>.

The end point of monitoring varies based upon the indication for monitoring.<sup>4</sup> Six to eight weeks of normal downloads with no clinical events has been documented by UpToDate as sufficient.

### Professional Organizations

The AAP SIDS Task Force 2005 policy statement reiterates the recommendation made in 1985 and 2000 regarding home apnea monitoring, stating, “Do not use home monitors as a strategy to reduce the risk of SIDS. Electronic respiratory and cardiac monitors are available to detect cardiorespiratory arrest and may be of value for home monitoring of selected infants who are deemed to have extreme cardiorespiratory instability. However, there is no evidence that use of such home monitors decreases the incidence of SIDS.”<sup>22</sup>

According to the AAP policy statement, Apnea, Sudden infant Death Syndrome, and Home Monitoring (2003), home cardiorespiratory monitoring may be warranted for the following groups of infants, not because of increased risk of SIDS but because of other factors that increase the risk of sudden death:<sup>10</sup>

- ☐ premature infant with history of apnea accompanied by bradycardia or oxygen desaturation (cyanosis)
- ☐ infant who has experienced an ALTE, defined as some combination of the following:
  - central or obstructive apnea

- o color change
- o marked change in muscle tone (i.e., flaccid or hypotonic)
- o choking or gagging
- ☐ infant with a tracheostomy or anatomic abnormalities increasing vulnerability to airway compromise
- ☐ infant with neurologic or metabolic disorders affecting respiratory control
- ☐ infant with chronic lung disease (e.g., bronchopulmonary dysplasia), particularly when supplemental oxygen, continuous positive airway pressure (CPAP) or mechanical ventilation is required

If monitoring is recommended, the monitor should be equipped with an event recorder. Parents should be advised that home monitoring has not been proven to prevent sudden unexpected infant death and should be made aware of the proven practices to reduce the risk of SIDS.<sup>10</sup> These practices include supine sleeping, safe sleeping environments and elimination of exposure to tobacco smoke both before and after birth.

#### CODING INFORMATION

| CPT   | Description                                                                                                                                                                                                                                                                                                                          |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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, physician review, interpretation, and preparation of a report [Codes reported by the physician for home health agency to provide monitor and downloads] |
| 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) [Home health agency and nurse connect the patient and do teaching, no physician initiation]                      |
| 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 [Home health downloads and converts for physician interpretation, no physician initiation]               |
| 94777 | Pediatric home apnea monitoring event recording including respiratory rate, pattern and heart rate per 30-day period of time; physician review, interpretation and preparation of report only                                                                                                                                        |

| HCPCS | Description                                                   |
|-------|---------------------------------------------------------------|
| E0618 | Apnea monitor, without recording feature <b>(NOT COVERED)</b> |
| E0619 | Apnea monitor, with recording feature                         |

| ICD-9  | Description                                                      |
|--------|------------------------------------------------------------------|
| 277.9  | Unspecified disorder of metabolism affecting respiratory control |
| 748.0- | Congenital anomalies of the respiratory system                   |

|               |                                                                                                 |
|---------------|-------------------------------------------------------------------------------------------------|
| 748.9         |                                                                                                 |
| 756.6         | Congenital anomaly of the diaphragm                                                             |
| 765.00-765.09 | Extreme Fetal Immaturity                                                                        |
| 765.10-765.19 | Other Preterm Infants                                                                           |
| 765.21-765.29 | Use this additional code for weeks of gestation                                                 |
| 769           | Respiratory distress syndrome                                                                   |
| 770.7         | Chronic respiratory disease arising in the perinatal period including brochopulmonary dysplasia |
| 770.81        | Primary apnea of newborn                                                                        |
| 770.82        | Other apnea of newborn                                                                          |
| 770.83        | Cyanotic attacks of newborn                                                                     |
| 770.84        | Respiratory failure of newborn                                                                  |
| 770.89        | Other respiratory problems after birth                                                          |
| 770.9         | Unspecified respiratory condition of fetus and newborn                                          |
| 779.81        | Neonatal bradycardia                                                                            |
| 781.99        | Other symptoms involving nervous and musculoskeletal systems affecting respiratory control      |
| V44.0         | Tracheostomy status                                                                             |
| V46.11        | Dependence on respirator, status                                                                |

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