A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health of Pennsylvania</th>
<th>Re-Submission Date: 06/01/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 0339</td>
<td>Effective Date:</td>
</tr>
<tr>
<td></td>
<td>Revision Date: 05/24/2017</td>
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<tr>
<td>Policy Name: Pulse Oximetry for Home Use</td>
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<tr>
<td>Type of Submission – Check all that apply:</td>
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<tr>
<td>☑ New Policy</td>
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<tr>
<td>☑ Revised Policy*</td>
<td></td>
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<tr>
<td>☐ Annual Review – No Revisions</td>
<td></td>
</tr>
</tbody>
</table>

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

**CPB 0339 - Pulse Oximetry for Home Use**

This CPB has been revised to state that the use of home pulse oximetry is considered experimental and investigational for predicting the need of adenotonsillectomy in children.

Name of Authorized Individual (Please type or print): Chandra A. Kee, MD

Signature of Authorized Individual: [Signature]
Pulse Oximetry for Home Use

Number: 0339

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers a pulse oximeter for home use medically necessary durable medical equipment (DME) for members with chronic lung disease, severe cardiopulmonary disease or neuromuscular disease involving muscles of respiration, and any of the following indications:

A. To determine appropriate home oxygen liter flow for ambulation, exercise, or sleep; or

B. To monitor individuals on a ventilator at home; or

C. Short-term (one month) monitoring when a change in the individual’s physical condition requires a physician-directed adjustment in the liter flow of their home oxygen needs; or

D. When weaning the individual from home oxygen; or

E. For interstage monitoring of children undergoing the Norwood procedure for hypoplastic left heart syndrome.
For information on the use of pulse oximetry in periodically re-assessing the need for long-term oxygen in the home, see CPB 0002 - Oxygen (.../1_99/0002.html). Pulse oximetry can be used in conjunction with infant home apnea monitoring; for information on infant apnea monitors, see CPB 0003 - Apnea Monitors for Infants (.../1_99/0003.html).

Home pulse oximetry for indications other than those listed above may be considered medically necessary upon medical review.

II. Aetna considers the use of home pulse oximetry experimental and investigational for all other indications, including the following because its effectiveness for these indications has not been established:

A. Asthma management
B. Diagnosing nocturnal hypoventilation associated with neuromuscular disorders
C. Evaluating and teaching continuous positive airway pressure (CPAP)
D. Maintenance or continuous monitoring (other than for persons on a ventilator)
E. Predicting the need of adenotonsillectomy in children
F. When used alone as a screening/testing technique for suspected obstructive sleep apnea.

See also CPB 0004 - Obstructive Sleep Apnea in Adults (.../1_99/0004.html), CPB 0479 - Respiratory Devices: Incentive Spirometers and Intermittent Positive Pressure Breathing Machines (.../400_499/0479.html), and CPB 0572 - Home/Ambulatory Spirometry (.../500_599/0572.html).

Background
Oximeters are noninvasive monitors that measure the oxygen saturation of blood. They are often also referred to as "pulse oximeters" because they also measure and record an individual's heart rate. A sensor is placed on a finger, toe or ear and uses light to estimate the oxygen saturation in the arterial blood; the sensor is connected by a wire to a monitor, which then displays both the oxygen saturation (O2 sat) and the heart rate.
Home oximetry may be used to monitor the O2 sat in the blood of individuals with known or suspected heart disease or many other circulatory or lung disorders. It may be considered medically necessary to assist the physician in determining the correct flow of supplemental oxygen, monitor changes in O2 sat during exercise and assist with management of home ventilators. The units used in the home are usually small, portable hand-held devices, though they can be larger, stationary machines.

For patients on long-term oxygen therapy, pulse oximetry arterial oxygen saturation (SaO2) measurements are unnecessary except to assess changes in clinical status, or to facilitate changes in the oxygen prescription. Home pulse oximetry is also indicated when there is a need to monitor the adequacy of SaO2 or the need to quantitate the response of SaO2 to a therapeutic intervention.

A National Heart, Lung and Blood Institute/World Health Organization Global Asthma Initiative Report concluded that pulse oximetry was not an appropriate method of monitoring patients with asthma. The report explained that, during asthma exacerbations, the degree of hypoxemia may not accurately reflect the underlying degree of ventilation-perfusion (V-Q) mismatch. Pulse oximetry alone is not an efficient method of screening or diagnosing patients with suspected obstructive sleep apnea (OSA). The sensitivity and negative predictive value of pulse oximetry is not adequate to rule out OSA in patients with mild to moderate symptoms. Therefore, a follow-up sleep study would be required to confirm or exclude the diagnosis of OSA, regardless of the results of pulse oximetry screening.

Home overnight pulse oximetry (OPO) has been used to evaluate nocturnal desaturation in patients with chronic obstructive pulmonary diseases (COPD). However, Lewis et al (2003) found that nocturnal desaturation in patients with COPD exhibited marked night-to-night variability when measured by home OPO. A single home OPO recording may be insufficient for accurate assessment of nocturnal desaturation. Gay (2004) stated that for COPD patients who exhibit more profound daytime hypercapnia, polysomnography is preferred over nocturnal pulse oximetry to rule out other co-existing sleep-related breathing disorders such as OSA (overlap syndrome) and obesity hypoventilation syndrome.

In a retrospective case-series study, Bauman et al (2013)
Pulse Oximetry for Home Use
determined the utility of home-based, unsupervised transcutaneous partial pressure of carbon dioxide (tc-Pco(2)) monitoring/oxygen saturation by pulse oximetry (Spo(2)) for detecting nocturnal hypoventilation (NH) in individuals with neuromuscular disorders. Subjects (n = 35, 68.6% men; mean age of 46.9 yrs) with spinal cord injury (45.7%) or other neuromuscular disorders underwent overnight tests with tc-Pco(2)/Spo(2) monitoring. Fifteen (42.9%) were using nocturnal ventilatory support, either bilevel positive airway pressure (BiPAP) or tracheostomy ventilation (TV). A respiratory therapist brought a calibrated tc-Pco(2)/Spo(2) monitor to the patient’s home and provided instructions for data collection during the subject’s normal sleep period. Forced vital capacity (FVC), body mass index (BMI), and exhaled end-tidal Pco(2) (ET-Pco(2)) were recorded at a clinic visit before monitoring. Main outcome measure was detection of NH (tc-Pco(2) greater than or equal to 50 mmHg for greater than or equal to 5% of monitoring time). Data were also analyzed to determine whether nocturnal oxygen desaturation (Spo(2) less than or equal to 88% for greater than or equal to 5% of monitoring time), FVC, BMI, or daytime ET-Pco(2) could predict the presence of NH. Nocturnal hypoventilation was detected in 18 subjects (51.4%), including 53.3% of those using BiPAP or TV. Nocturnal hypoventilation was detected in 43.8% of ventilator-independent subjects with normal daytime ET-Pco(2) (present for 49.4% +/- 31.5% [mean +/- SD] of the study period), and in 75% of subjects with an elevated daytime ET-Pco(2) (present for 92.3% +/- 8.7% of the study period). Oxygen desaturation, BMI, and FVC were poor predictors of NH. Only 3 attempted monitoring studies failed to produce acceptable results. The authors concluded that home-based, unsupervised monitoring with tc-Pco(2)/Spo(2) is a useful method for diagnosing NH in neuromuscular respiratory failure (NMRF). The findings of this small retrospective case-series study need to be validated by well-designed studies.

Nardi et al (2012) noted that pulse oximetry alone has been suggested to determine which patients on home mechanical ventilation (MV) require further investigation of nocturnal gas exchange. In patients with neuromuscular diseases, alveolar hypoventilation (AH) is rarely accompanied with ventilation-perfusion ratio heterogeneity, and, therefore, oximetry may be
less sensitive for detecting AH than in patients with lung disease. These investigators examined if Spo(2) and tc-Pco(2) during the same night were interchangeable or complementary for assessing home MV efficiency in patients with neuromuscular diseases. Data were collected retrospectively from the charts of 58 patients with chronic NMRF receiving follow-up at a home MV unit. Spo(2) and tc-Pco(2) were recorded during a 1-night hospital stay as part of standard patient care. These researchers compared AH detection rates by tc-Pco(2), Spo(2), and both. Alveolar hypoventilation was detected based on tc-Pco(2) alone in 24 (41%) patients, and based on Spo(2) alone with 3 different cut-offs in 3 (5%), 8 (14%), and 13 (22%) patients, respectively. Using both tc-Pco(2) and Spo(2) showed AH in 25 (43%) patients. The authors concluded that pulse oximetry alone is not sufficient to exclude AH when assessing home MV efficiency in patients with neuromuscular diseases. Both tc-Pco(2) and Spo(2) should be recorded overnight as the first-line investigation in this population.

Also, UpToDate reviews on "Respiratory muscle weakness due to neuromuscular disease: Clinical manifestations and evaluation" (Epstein, 2013a); "Respiratory muscle weakness due to neuromuscular disease: Management" (Epstein, 2013b); "Continuous noninvasive ventilatory support for patients with neuromuscular or chest wall disease" (Bach, 2013), and "Types of noninvasive nocturnal ventilatory support in neuromuscular and chest wall disease" (Hill and Kramer, 2013) do not mention the use of home pulse oximetry.

Studies have demonstrated improvements in survival of infants undergoing the Norwood procedure for hypoplastic left heart syndrome with interstage monitoring with home pulse oximetry (Ghanayem et al, 2003; Dobrolet et al, 2011; Hansen et al, 2012).

In a feasibility study, Cross et al (2012) noted that strategies to reduce inter-stage morbidity and mortality for patients with single ventricle following stage I palliation included standardized care protocols, focused high-risk outpatient clinics, dedicated teams that focus on the unique needs of these fragile patients and use of home surveillance monitoring. Use of telemedicine
devices for home monitoring has been shown to improve outcomes in adults. These devices allow for a more automated approach to home monitoring that have many advantages. These researchers described their program that utilizes a web-based telemedicine device to capture and transmit data from the homes of their patients during the inter-stage period. The authors stated that their early data suggested that home telemedicine is feasible, provides a more systematic data review and analysis and supports the assertion that patients using home surveillance have significantly better nutritional status than those not using home monitoring.

Ohman et al (2013) stated that shunt occlusion is a major cause of death in children with single ventricle. These investigators evaluated whether one daily measurement of oxygen saturation at home could detect life-threatening shunt dysfunction. A total of 28 infants were included in this study. Parents were instructed to measure saturation once-daily and if less than or equal to 70% repeat the measurement. Home monitoring was defined as positive when a patient was admitted to Queen Silvia Children's Hospital because of saturation less than or equal to 70% on repeated measurement at home. A shunt complication was defined as arterial desaturation and a narrowing of the shunt that resulted in an intervention to relieve the obstruction or in death. Parents' attitude towards the method was investigated using a questionnaire. A shunt complication occurred out of hospital 8 times in 8 patients. Home monitoring was positive in 5 out of 8 patients. In 2 patients, home monitoring was probably life-saving; in 1 of them, the shunt was replaced the same day and the other had an emergency balloon dilatation of the shunt. In 3 out of 8 patients, home monitoring was negative; 1 had an earlier stage II and survived, but 2 died suddenly at home from thrombotic shunt occlusion. On 7 occasions in 3 patients, home monitoring was positive but there was no shunt complication. The method was well accepted by the parents according to the results of the questionnaire. The authors concluded that home monitoring of oxygen saturation has the potential to detect some of the life-threatening shunt obstructions between stages I and II in infants with single-ventricle physiology.
Also, an UpToDate review on “Management and outcome of heterotaxy (isomerism of the atrial appendages)” (Lowental et al, 2014) states that “Single ventricle physiology is predominant in RAI [right atrial isomerism], as patients usually have a hypoplastic left ventricle. These patients also typically have asplenia, as the spleen is a left side abdominal organ. In general, patients with RAI most often present during the neonatal period with cyanosis due to right-to-left shunting as a result of pulmonary outflow obstruction and septal defects between the atria and ventricles. In severely affected neonates, survival is dependent on maintaining a patent ductus arteriosus. In other cases, respiratory distress may develop because of pulmonary congestion due to pulmonary venous obstruction .... Single ventricle palliation -- Similar to other univentricular conditions, palliative management beginning in the neonate generally consists of a series of staged procedures, which vary with the underlying lesions .... Initial neonatal shunting -- Follow-up visits are frequent for neonates who undergo palliative shunting to secure either pulmonary blood flow or systemic blood flow. At each visit, the clinical status is evaluated with a focus on the adequacy of oxygen saturation and somatic growth. As many of these single ventricle patients have ventricular overload and abnormal atrioventricular valves, surveillance echocardiograms are performed on a monthly basis to monitor for the development of atrioventricular insufficiency”. Moreover, this review does not mention the use of home pulse oximetry as a management tool.

In a Cochrane review, Welsh et al (2015) examined if pulse oximeters used as part of a personalized asthma action plan for people with asthma are safer and more effective than a personalized asthma action plan alone. These investigators searched the Cochrane Airways Group Specialised Register (CAGR), which includes reports identified through systematic searches of bibliographic databases including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Allied and Complementary Medicine Database (AMED) and PsycINFO, and by hand-searching. They also searched ClinicalTrials.gov and the World Health
Organization (WHO) trials portal. These researchers planned to include randomized controlled trials (RCTs). Participants would have included adults, children or both with a diagnosis of asthma. They planned to include trials in which investigators compared participants who used pulse oximeters to monitor oxygen levels at home during an asthma exacerbation as part of a personalized asthma action plan (PAAP) versus those who used a PAAP without a pulse oximeter. They planned to include studies involving people receiving any treatment regimen provided that no medicine was included as part of the randomization schedule. The authors planned to use standard methods as recommended by The Cochrane Collaboration. They found no studies and no evidence to support or refute the use of home pulse oximetry in self-management of asthma; thus, they could not make any recommendations about use of a pulse oximeter as part of a PAAP. The authors concluded that they found no reliable data to support or refute patient use of pulse oximeters to monitor oxygen saturation levels when experiencing an asthma attack. They stated that individuals should not use a pulse oximeter without seeking advice from a qualified healthcare professional. They identified no compelling rationale for home monitoring of oxygen levels in isolation for most people with asthma. Some people have a reduced perception of the severity of their own breathlessness when exposed to hypoxia. If trials on self-monitoring of oxygen levels in the blood by pulse oximeter at home by people with asthma are conducted, the pulse oximeter must be given as part of a personalized asthma action plan.

*Predicting the Need of Adenotonsillectomy in Children:*

Pavone and colleagues (2017) stated that nocturnal pulse oximetry has a high positive predictive value for polysomnographically diagnosed OSA in children. When significant adenotonsillar hypertrophy is diagnosed, adenotonsillectomy (T&A) represents a common treatment for OSA in children. These investigators examined the role of pulse oximetry in predicting those patients, referred for suspected OSA, who subsequently needed T&A. At-home nocturnal pulse oximetry was performed on 380 children (65.7% males), median age of 4.1 (IRQ 3.0 to 5.6) years, referred for suspected OSA, and
data were retrospectively analyzed. For each recording McGill Oximetry Score (MOS) was categorized. Mean pulse rate (PR) z-score and pulse rate variability (PRV)-corrected (PRSD/mean PR) were significantly higher in children with abnormal MOS. Both parameters were significantly higher in subjects who underwent T&A compared with those not surgically treated. Both DI4 and PRV corrected showed a negative correlation with the elapsed time between pulse oximetry recordings and T&A. The logistic regression model showed a strong effect of an abnormal MOS as a predicting factor for T&A (adjusted odds ratio [OR] of 19.7). The authors concluded that children with OSA who subsequently needed T&A showed higher PRV compared to those without surgical indication. Children with abnormal MOS were nearly 20 times more likely to undergo T&A. They stated that nocturnal pulse oximetry had a high positive predictive value for polysomnographically diagnosed OSA in children. When significant adenotonsillar hypertrophy is diagnosed, adenotonsillectomy represents a common treatment for OSA in children. Moreover, they noted that an abnormal pulse oximetry highly predicted the indication for adenotonsillectomy. They suggested that the use of at-home pulse oximetry as a method to predict prescription of adenotonsillectomy, and this may be useful in contexts where polysomnography is not readily available.

<table>
<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
</tr>
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</table>

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>CPT codes covered if selection criteria is met:</th>
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</thead>
<tbody>
<tr>
<td>94760 Noninvasive ear or pulse oximetry for oxygen saturation; single determination</td>
</tr>
<tr>
<td>94761 multiple determinations (e.g., during exercise)</td>
</tr>
<tr>
<td>94762 by continuous overnight monitoring (separate procedure)</td>
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</table>

CPT codes related to the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>94660</td>
<td>Continuous positive airway pressure ventilation (CPAP), initiation and management [Pulse oximetry is not covered when performed in home for evaluating and teaching on CPAP use]</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**

- **A4606** Oxygen probe for use with oximeter device, replacement
- **E0445** Oximeter device for measuring blood oxygen levels non-invasively

**Other HCPCS codes related to the CPB:**

- **E0424 - E0444, E0455 - E0484** Oxygen and related respiratory equipment

**ICD-10 codes covered if selection criteria are met (not all-inclusive):**

- **D75.1** Secondary polycythemia
- **E84.0 - E84.9** Cystic fibrosis
- **G70.9** Myoneural disorder, unspecified [neuromuscular disease]
- **I20.1 - I20.9** Angina pectoris
- **I27.0 - I27.9** Other pulmonary heart diseases
- **I50.20 - I50.9** Congestive heart failure
- **I73.9** Peripheral vascular disease, unspecified
- **J34.0 - J43.9** Emphysema
- **J44.9** Chronic obstructive pulmonary disease, unspecified
- **J47.0 - J47.9** Bronchiectasis
- **J80** Acute respiratory distress syndrome
- **J84.10** Pulmonary fibrosis, unspecified
- **J95.1 - J95.3, J95.821 - J95.822** Pulmonary insufficiency following trauma and surgery
- **J96.00 - J96.92** Respiratory failure [neuromuscular disease]
<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J98.4</td>
<td>Other disorders of lung [neuromuscular disease]</td>
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<td>J98.6</td>
<td>Disorders of diaphragm [neuromuscular disease]</td>
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<tr>
<td>P22.0</td>
<td>Respiratory distress syndrome of newborn</td>
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<tr>
<td>P22.1</td>
<td>Other respiratory conditions of fetus and newborn</td>
</tr>
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<td>P28.9</td>
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<tr>
<td>Q23.4</td>
<td>Hypoplastic left heart syndrome [for interstage monitoring of children undergoing the Norwood procedure]</td>
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<tr>
<td>R06.81</td>
<td>Apnea, not elsewhere classified</td>
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<tr>
<td>R09.02</td>
<td>Hypoxemia</td>
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<tr>
<td>Z99.11</td>
<td>Dependence on respirator [ventilator] status</td>
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<tr>
<td>Z99.81</td>
<td>Dependence on supplemental oxygen</td>
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**ICD-10 codes not covered for indications listed in the CPB (not all inclusive):**

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<th>Code</th>
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<tr>
<td>F51.8</td>
<td>Other sleep disorders not due to a substance or known physiological condition</td>
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<tr>
<td>G47.00</td>
<td>Sleep disorders</td>
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<td>J45.20</td>
<td>Asthma</td>
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<td>J45.998</td>
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<tr>
<td>Z13.83</td>
<td>Encounter for screening for respiratory disorder, not elsewhere classified</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


2. National Heart, Lung and Blood Institute (NHLBI) and World...


26. Epstein SK. Respiratory muscle weakness due to neuromuscular disease: Clinical manifestations and evaluation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013a.

27. Epstein SK. Respiratory muscle weakness due to neuromuscular disease: Management. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013b.

28. Bach JR. Continuous noninvasive ventilatory support for patients with neuromuscular or chest wall disease. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013.

29. Hill NS, Kramer NR. Types of noninvasive nocturnal ventilatory support in neuromuscular and chest wall disease. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013.


34. Welsh EJ, Carr R. Pulse oximeters to self monitor oxygen saturation levels as part of a personalised asthma action plan for people with asthma. Cochrane Database Syst Rev. 2015;9:CD011584.

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Amendment to
Aetna Clinical Policy Bulletin Number:
0339 - Pulse Oximetry for Home Use

There are no amendments for Medicaid.