Select Health Medical Policies

Pulmonary Policies

Table of Contents

Select Health

MEDICAL POLICY

BRONCHIAL THERMOPLASTY FOR ASTHMA

Policy # 379

Implementation Date:8/16/07

Review Dates: 8/21/08, 8/13/09, 10/13/11, 11/29/12, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/20/18, 6/20/19, 6/18/20, 6/2/21, 5/19/22, 6/15/23, 6/17/24, 6/19/25

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Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Asthma is a chronic inflammatory disorder of the airways characterized by inflammatory airway changes and hypersensitivity-related bronchospasm of the bronchiolar smooth muscles

Current management of asthma is focused on reducing inflammation of the airways and reducing the smooth muscle spasm which triggers symptoms. Medications designed to control asthma ("Controllers") and prevent exacerbations include systemic and inhaled corticosteroids, leukotriene modifiers (e.g., montelukast/Singular), long-acting beta agonists, long-acting muscarinic receptor inhibitors, combination inhalers and xanthine derivatives such as theophylline. Acute management of asthma symptoms includes short-acting beta agonists, ipratropium, and oral or intravenous corticosteroids. For select patients with atopic asthma, therapy with omalizumab (Xolair), an injectable recombinant DNA-derived humanized IgG1k monoclonal antibody that specifically binds to IgE, is also used to treat their asthma.

Bronchial thermoplasty (BT) is one of several therapies designed to reduce the increased mass of smooth muscle in the asthmatic airway, with the goal of attenuating bronchoconstriction and airway hyperresponsiveness. BT refers to a technique of applying controlled radiofrequency waves to the airways during bronchoscopy, thereby heating and decreasing the amount of smooth muscle in the lungs. This minimally invasive bronchoscopic procedure is performed in three outpatient procedure visits, each treating a different area of the lungs and scheduled approximately three weeks apart. After all three procedures are performed, the BT treatment is complete. BT is routinely performed under moderate sedation or light anesthesia and the patient typically goes home the same day. BT is expected to complement asthma maintenance medications by providing long-lasting asthma control and improving asthma-related quality of life of patients with severe asthma.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers bronchial thermoplasty for asthma meeting specific coverage criteria. Use outside these criteria is considered experimental/investigational.

Coverage criteria for bronchial thermoplasty (BT): (must meet ALL the following):

1. Patient has severe persistent asthma defined by Expert Panel Report 3 (EPR3) criteria as:
   a. Continual symptoms limiting physical activity
   b. "Frequent" night-time symptoms requiring treatment with a short-acting agent (frequent is defined as at least 4 of each 7 nights weekly)

c. Abnormal pulmonary function tests performed in the last 6 months prior to the request for the procedure, which demonstrate the following:
   i. FEV_1 or PEF ≥ 60% of predicted
   ii. PEF variability > 30%

2. Evidence for use of both inhaled long-acting bronchodilator agents (LABA) and inhaled corticosteroids for the 6 months immediately prior to BT request, demonstrating a minimum of 80% compliance as defined by medical possession ratio (MPR) from pharmacy claims

And one of the following:

3. Required frequent or persistent steroid boluses to treat exacerbations; or
4. Experienced either a hospitalization or ER visit despite verified medication adherence

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Most of the information used to assess bronchial therapy is derived from three trials: the RISA, and the AIR and AIR2 trials. The focus of the evidence was studies published since October 2010. Early studies were of short duration, and follow-up, and failed to answer questions related to long-term safety and durability of the procedure. The evidence published since October 2010 has answered some of the concerns with the publication of additional intermediate to long-term data. However, this evidence has conflicting results. Hayes and NICE generally recommended the use of BT in patients with severe, persistent asthma. In every endpoint noted by NICE (quality of life, peak expiratory flow, severe exacerbations, and hospital admission), the BT group outperformed the sham or medical group at one year. However, for the two systematic reviews, both published in 2011 prior to the release of the 5-year AIR2 data, the recommendations were much more equivocal, stating that more trials need to be completed but that evidence does suggest safety and efficacy of the procedure in patients with moderate-to-severe asthma.

Many advocates of BT repeatedly point to the AIR2 trial as demonstrating the efficacy and safety of this therapy along with the durability. The trial included 288 adult subjects in a randomized, sham-controlled trial, who all underwent three bronchoscopy procedures. Asthma quality of life scores increased in the BT group as did hospitalizations in the six-week follow-up period. In the post-treatment period (6–52 weeks after BT), the BT group experienced fewer severe exacerbations, emergency department (ED) visits, and days missed from work/school compared with the sham group. Since the publication of this trial by Castro et al., several primary literature articles have been published both refuting and sustaining the findings of the AIR2 trial.

The six primary literature studies published since October 2010 have significant methodological limitations including lack of randomization, sham therapies, and small size with conflicting interpretations

of the safety and efficacy of BT. For example, Castro et al. reviewed the AIR2 trial and concluded that data demonstrate that patients with severe asthma, who are refractory to conventional treatment methods, had improved outcomes after BT. Whether Castro's close affiliation with the manufacturer colors these conclusions is hard to judge. However, Gupta et al. note that the AIR2 trial did not meet pre-defined endpoints, did not report CT and methacholine challenge test (which did not show an improvement over the BT group), and maintains the ability to induce harm. Four of the six publications are commentaries/reviews of the AIR2 trial and thus offer little new evidence. The majority (5/6, 83%) of the studies favor the use of BT for the treatment of patients with severe asthma who are refractory to standard approaches.

Finally, the 5-year results were published as an abstract of a poster presentation held at the American Thoracic Society Conference by Wechsler et al. in May 2013; though frequently quoted by advocates, bronchial thermoplasty has several limitations. Most notably this study relies on patient reported outcomes and infrequent clinical follow-up. There was also significant drop-off in participation compared to the AIR2 trial from which this was an extension (190 or 288 original AIR2 participants or 66%) with no attempt at an intention to treat analysis related to efficacy. This study's primary endpoints focused on efficacy measures such as ER visits and hospitalizations, but notes safety outcomes such as pulmonary function changes, which could be more indicative of long-term safety implications of this treatment being unchanged over the 5-year period. This study is also not yet published beyond an abstract of the poster presentation, so more detailed analysis is limited.

Except for the manufacturer sponsored AIR2 trial, the current body of evidence is inconsistent and maintains significant methodological conflicts, large drop-out rates, and is derivative of the AIR2 trial. This opens all other studies to the biases inherent in the manufacturer-sponsored AIR2 trial (Grade 2B).

Billing/Coding Information

CPT CODES

31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

DIAPHRAGMATIC/PHRENIC NERVE PACING

Policy # 273
Implementation Date:4/30/05
Review Dates: 5/4/06, 5/17/07, 4/24/08, 4/23/09, 4/12/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 9/18/18, 4/17/19, 4/15/20, 4/15/21, 3/18/22, 4/24/23, 4/12/24, 4/23/25
Revision Dates: 2/18/10, 4/11/11

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Description

Patients with a variety of conditions such as spinal cord injury, central nervous system disorders, stroke, encephalitis, amyotrophic lateral sclerosis (ALS), and pituitary dysfunction can experience ventilator insufficiency or ventilator failure due to congenital or acquired disruption of the neurophysiologic apparatus of breathing. Patients who do not have functional respiratory centers or who lack intact spinal connections to the phrenic nerves are dependent on mechanical ventilators or other mechanical systems to support their respiratory function. Mechanical ventilation that administers positive pressure airflow directly to the patient's airway has been the most common way of supporting ventilation. In addition, when patients are maintained on mechanical ventilators with a tracheostomy, close attention by caregivers is required, and the cost of care and supplies can be considerable. Some spinal cord injury patients can be trained to use the accessory muscles of the shoulders and neck to support adequate ventilation for limited periods of time, but mechanical or other support is generally needed. The loss of the ability to breathe in amyotrophic lateral sclerosis (ALS) patients is related to progressive muscle weakness. Ventilation in patients becomes a serious concern as the phrenic nerve loses its ability to operate the diaphragm.

An alternative to mechanical ventilation is diaphragmatic or phrenic (D/P) nerve stimulation, also called D/P pacing and electrophrenic respiration. An electrical stimulator provides stimulation to the phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). D/P stimulation allows patients to speak, since it does not interfere with sound production in the larynx. Pacing patients are at much lower risk of upper airway infections including ventilator-associated pneumonia (VAP) due to the reduction in suctioning, elimination of external humidifier and ventilator circuits, and the potential removal of the tracheostomy tube in appropriate patients.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers diaphragmatic/phrenic nerve pacing (e.g., NeuRx DPS) in patients with spinal cord injury. Current literature has demonstrated clinical effectiveness of this therapy in appropriately selected patients.

Select Health does NOT cover diaphragmatic/phrenic nerve pacing (e.g., NeuRx DPS) for any other indication, including but not limited to, amyotrophic lateral sclerosis. Use in these circumstances meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

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Summary of Medical Information

The current body of evidence on the safety and effectiveness of diaphragmatic/phrenic nerve stimulation for the treatment of chronic ventilator insufficiency is extensive, consistently positive, yet marginal in quality. This is due, at least in part, to the fact that the device (in its earliest versions) entered the market at a time when demands for evidence of outcomes was low; as well as the inherent difficulties in performing randomized, controlled trials on patients with life-threatening conditions who have few options.

Hayes, in their 2002 report on this technology, for the treatment of chronic ventilator insufficiency in patients whose remaining phrenic nerve, lung, and diaphragm function is sufficient to accommodate electrical stimulation was given a 'B' rating. Additionally, the American Thoracic Society, in an official statement on "Idiopathic Congenital Central Hypoventilation Syndrome - Diagnosis and Management," suggests that the possibility of diaphragm pacing by phrenic nerve stimulation should be considered in this population: "... to allow for increased mobility and improved quality of life."

In 2010, the manufacturer of the NeuRx DPS System received a humanitarian use device (HUD) approval for amyotrophic lateral sclerosis (ALS) which allowed it to be submitted for an HDE, enabling marketing for ALS. A Medical Technology Assessment performed in March 2011 identified literature from only one institution and one primary investigator, Dr. Raymond Onders. Of note, Dr. Onders has intellectual property rights involved with the diaphragm pacing system and equity in Synapse Biomedical, the device manufacturer, which might result in bias in his published works. In 2009, Dr. Onders published an article concluding, "In the SCI patients 96% were able to use DPS to provide ventilation replacing their mechanical ventilators and in the ALS studies patients have been able to delay the need for mechanical ventilation up to 24 months." This paper did not indicate that DPS was able to eliminate the need for mechanical ventilation but rather it was only able to delay the need for mechanical ventilation, in some patients, up to 2 years.

Aside from Dr. Onders' publications, only the publication by The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIPS) from 2010 provides insight into the evidence related to this technology and as a systematic review they remain subject to the potential biases present in Dr. Onders' publications. Despite these limitations, they concluded, "There is limited high level evidence available on the use of the laparoscopic DPS system. Case series evidence demonstrates that the laparoscopic procedure allows for safe implantation of the device in both SCI [spinal cord injury] and ALS patients. There were no serious complications reported. In most SCI patients, the device was effective in providing an alternative to mechanical ventilation (for at least four hours per day) and for ALS patients, the device has been shown to delay the need for mechanical ventilation. Additional studies in larger patient groups are required to provide further evidence of safety and effectiveness."

Only from Schmeising et al., in their article published in 2010 do we gain insight from the primary literature separate from Dr. Onders' 2 peer-reviewed papers. However, this article focuses on the surgical

technique of 3 patients and perioperative parameters which might impact surgical outcomes such as the presence of cardiomyopathy and which anesthetic agents should be used. No evidence related to short- or long-term morbidity or mortality was presented, and no evidence was presented related to quality of life.

In short, the current published evidence is limited and holds the potential for significant bias. It is apparent, however, from the literature that diaphragmatic pacing is a potential bridge for patients who will progress and either chooses mechanical ventilation or not. There remains a lack of evidence related to the cost-effectiveness of this technology in ALS patients and the impact on the quality of life of these patients. Also, the specific criteria for patient selection remain unclear and not fully defined.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

64580	Incision for implantation of neurostimulator electrode array; neuromuscular
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

HCPCS CODES

L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes Extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator

Not covered: Investigational/Experimental/Unproven for this indication

G12.21	Amyotrophic lateral sclerosis

Key References

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MEDICAL POLICY

ENDOBRONCHIAL VALVES

Policy # 613

Implementation Date:5/17/17
Review Dates: 6/26/18, 6/20/19, 6/18/20, 6/10/21, 5/19/22, 6/15/23, 6/17/24, 6/19/25
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Description

Accumulation of air in the pleural space is known as a pneumothorax. A pneumothorax can result from a variety of processes including trauma, high airway pressures induced during mechanical ventilation, lung surgery, and rupture of lung blebs or bullae which may be congenital or a result of chronic obstructive pulmonary disease (COPD).

Although an air leak from the lung into the pleural space may seal spontaneously, it often requires intervention. Techniques currently employed to attempt air leak closure include the following:

- Inserting a chest tube (tube thoracotomy) and employing a water seal or one-way valve to evacuate air collected in the pleural space and prevent it from reaccumulating
- For patients on mechanical ventilation who have pneumothorax, airway pressures are lowered
- Using autologous blood patches

An endobronchial valve is a synthetic device that permits one-way air movement. During inhalation, the valve is closed preventing air flow to the diseased area of the lung. The valve opens during exhalation to allow air to escape from the diseased area of the lung. When used to treat persistent air leak from the lung into the pleural space, the endobronchial valve theoretically permits less air flow across the diseased portion of the lung during inhalation aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy.

Endobronchial valves have also been investigated for use in severe emphysematous COPD. In emphysematous COPD peripheral lung tissue may form bullae. These diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. They also may rupture, causing a pneumothorax. Use of an endobronchial valve is thought to prevent hyperinflation of these bullae.

Consideration for the use of endobronchial valves in COPD is based on the improvement observed in patients who have undergone lung volume reduction surgery (LVRS). LVRS involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for patients undergoing lung volume reduction has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of diseased lung. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Endobronchial valves have been investigated as a nonsurgical alternative to LVRS.

In October 2008, the "IBV Valve System" (Spiration, Inc, Redmond, WA) was approved by the FDA under the Humanitarian Device Exemption for use in controlling prolonged air leaks of the lung or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). An air leak present on postoperative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for

treatment if it is continuous, present during normal inhalation phase of inspiration, or present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. IBV Valve System use is limited to 6 weeks per prolonged air leak.

The Zephyr Endobrochial Valve System is an implantable bronchial valve used to reduce over inflation of the lungs due to severe emphysema in adults. The device consists of a one-way silicone duckbill valve attached to a nickel-titanium (Nitinol) self-expanding retainer that is covered with a silicone membrane. In June 2018, the FDA approved the Zephyr Endobronchial Valve System for those patients with severe emphysema who have trouble breathing, and who have proven to be refractory to optimal medical management. The valve is the first minimally invasive device approved in the United States for treating such patients, according to Pulmonx (Redwood City, CA), the device manufacturer.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers FDA approved endobronchial valves (e.g., the Zephyr Valve System) for either of the following conditions:

1. For the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little-to-no collateral ventilation, and who have failed medical management and are severely impaired clinically, when ALL the following criteria are met:
   a) Emphysema confirmed by CT scan; and
   b) Smoking cessation for at least 4 months; and
   c) BMI less than 35; and
   d) Stable COPD on less than or equal to 20 mg of prednisone (or equivalent) daily; and
   e) FEV1 15 to 45% predicted; and
   f) TLC greater than or equal to 100% predicted; and
   g) RV greater than or equal to 175% predicted (Greater than or equal to 200% if homogenous emphysema); and
   h) Six-minute walk distance 100 to 500 m (150 to 500 m if homogenous emphysema); and
   i) Target lobe with little or no collateral ventilation as determined using both the StratX* and Chartis** system; and
   j) The device(s) used must be approved by the FDA and used according to FDA labeling.

   OR

2. For the treatment of bronchopleural fistulas refractory to other standard management.

*StratX is a cloud-based quantitative CT analysis service that is able to accept uploaded images and provide guidance on EBV placement for fissure completeness which would predict EBV success in lung volume reduction. This study should be a required element of evaluating the patient in the pre-operative setting prior to scheduling the bronchoscopy and EBV placement. StratX can create a prioritization of targets for EBV that would be confirmed by Chartis, see below, at time of bronchoscopy.

**Chartis is a catheter-based measurement performed at the time of bronchoscopy that uses airways resistance to measure collateral ventilation which might reduce effective lung volume reduction. This should be used to confirm the assessment of the StratX prior to endobronchial valve deployment.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Only case report data are available on the IBV Valve System (Spiration). Data on 4 patients with prolonged air leaks were submitted to the U.S. Food and Drug Administration (FDA) as part of the Humanitarian Device Exemption (HDE) process. In all 4 patients, there was an immediate decrease or complete resolution of the air leak after valve placement. Valves were removed without complication in 3 of the 4 cases; the fourth patient had not yet had valves removed at the time data were submitted.

In one large case series, Travaline et al. published a report in 2009 on 40 patients treated at 17 sites in the United States and Europe; 6 of the patients had been included in previously published case reports. Zephyr (Emphasys, now Pulmonx) endobronchial valves were used. Data were abstracted retrospectively from medical records. No specific eligibility criteria were reported, and patients did not need to demonstrate that they were refractory to other treatments. All patients in the series had prolonged pulmonary air leak (mean duration of 119 days, median of 20 days).

Twenty-five patients had continuous air leaks, 14 had expiratory air leaks, and 1 was unidentified. The most common co-morbidities were cancer and COPD. Prior to the procedure, 39 of the 40 patients had at least 1 chest tube. Five patients had other treatments (e.g., blood patch before valve placement). The mean number of valves placed per patient was 2.9 (standard deviation [SD]:1.9) overall. After valve placement, 19 patients (47.5%) had complete resolution of acute air leak, 18 (45%) had a reduction in air leak, 2 (5%) had no change, and data were not available for 1 patient. The mean time from valve placement to chest tube removal was 21 days, and the median time was 7.5 days (data from 2 patients were not available). Eight patients had the valves removed after the air leak ceased; in 32 patients, the clinician chose to leave the valves in place. Six patients experienced adverse effects related to valve placement, including valve expectoration, moderate oxygen desaturation, initial malpositioning of a valve, pneumonia, and *Staphylococcus aureus* colonization. The length of follow-up was highly variable, ranging from 5 to 1,109 days. At last follow-up, 16 patients were reported to have died; none of the deaths were attributed to the valve or the valve implantation procedure.

A case series was published in 2011 (Gillespie et al.), in which patients with pulmonary air leaks were treated with Spiration IBV valves. Procedures were performed on a total of 9 patients; target airways could not be identified in 2 patients, and valves were placed in 7 patients. One of the 7 had 2 procedures due to development of an additional air leak after the first one was treated and resolved. The median duration of air leaks in the 7 patients before valve placement was 4 weeks (range, 2 weeks to 5 months). Complete air leak cessation occurred in 6 of 8 procedures after a mean duration of 5.2 days. The other 2 procedures resulted in reduction of air leak. There were no operative or postoperative complications attributed to the bronchial valves. The valves were removed in 5 of the 7 patients at a mean of 37 days after placement (range, 14 to 55 days). Valves were not removed in one patient who entered hospice care, and one patient underwent 2 procedures because the patient declined removal.

The published literature consists of one RCT and several prior case series on the Zephyr valve and one published case series on the IBV valve. The RCT, called the Endobronchial Valve for Emphysema Palliation Trial (VENT), was published by Sciurba and colleagues in 2010. It was industry-funded, and data were collected at 31 centers in the United States. Key eligibility criteria were: diagnosis of heterogeneous emphysema, forced air expiratory volume in 1 second (FEV1) of 15–45% of the predicted value, total lung capacity of more than 100% of the predicted value, residual volume of more than 150% of the predicted value, and post-rehabilitation 6-minute walk distance of at least 140 meters. A total of 321 patients were randomly assigned on a 2:1 basis to receive Zephyr endobronchial valves (n=220) or standard medical care (n=101). Prior to randomization, all patients received 6−8 weeks of pulmonary

rehabilitation and medical management that was optimized at the discretion of the treating physician, using guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD). The mean number of valves placed in the endobronchial valve group was 3.8 per patient (range, 1 to 9). The primary effectiveness outcomes were percent change from baseline to 6 months in the FEV1 and distance on the 6-minute walk test.

A total of 42 of 220 (19.1%) in the endobronchial valve group and 28 of 101 (27.7%) in the control group had missing data for the primary efficacy outcomes. Of the 70 patients with missing data, 6 had died, 4 were too ill to participate, and 60 dropped out or did not have follow-up within the specified time window. The data analysis was intention-to-treat, and missing data were imputed. Primary outcome data at 6 months were as follows:

Outcome	**Endobronchial valve group (n =220)**	**Control group (n =101)**	**Between-group difference p-value**
FEV1			
Mean absolute percent change from baseline	4.3 (1.4-7.2)	-2.5 (-5.4 to 0.4)	6.8 (2.1 to 11.5) p =0.005
Distance on 6-minute walk test Median change from baseline (meters)	9.3 (-0.5 to 19.1)	-10.7 (-29.6 to 8.1)	19.1 (1.3 to 36.8) p =0.02
Median absolute percent change from baseline	2.5 (-1.1 to 6.1)	-3.2 (-8.9 to 2.4)	5.8 (0.5 to 11.2) p =0.04

Among the secondary outcomes reported at the 6-month follow-up, quality of life was measured using the St. George's Respiratory Questionnaire (SGRQ) which ranges from 0 to 100 with a higher score indicating a worse quality of life. At 6 months, the SGRQ score decreased -2.8 points (95% confidence interval [CI] =-4.7 to -1.0) in the endobronchial valve group and increased 0.6 points (-1.8 to 3.0) in the control group. The between-group difference was -3.4 (95% CI=-6.7 to 0.2) which was statistically significant (p =0.04) but was less than the 4 points generally considered to represent a clinically meaningful difference. According to body plethysmography, the mean change in total lung volume at 6 months was -1.2 (SD =10.6) in the endobronchial valve group and -0.4% (SD =13) in the control group; this difference was not statistically significant, p =0.41. Similarly, changes between groups in residual volume and inspiratory capacity were not statistically significant.

The primary safety variable was a composite measure consisting of 6 major complications (death, empyema, massive hemoptysis, pneumonia distal to valves, pneumothorax or air leak of more than 7 days' duration, or ventilator-dependent respiratory failure for more than 24 hours). The rate by 6 months was 6.1% in the endobronchial group and 1.2% in the control group. The between-group difference was 4.9% (95% CI =1.0 to 8.8) which was not statistically different (p =0.08) and fell within the pre-specified safety criteria. The adverse events to 6 months included 6 deaths (2.8%) in the endobronchial valve group and no deaths in the control group (p =0.19). Between 3 and 12 months, 25 of 214 (11.7%) patients in the endometrial valve group followed over this time experienced COPD exacerbations; 22 of these events resulted in hospitalization. Over the same time period, 8 of 87 (9.2%) patients in the control group had COPD exacerbations all of which resulted in hospitalization. The difference in number of exacerbations was not statistically significant. For hemoptysis (other than massive), between 3 and 12 months there were 13 (6.1%) cases in the endobronchial valve group and none in the control group (p =0.02). Among the 214 patients who received valves and were followed to 12 months, there were 6 cases (2.8%) of valve expectoration, aspiration or migration and 9 cases (4.2%) of bronchial granulation tissue. Valves were removed in 31 (14%) patients after 1 to 377 days; removal was based on investigators' discretion; there was no specific protocol.

A limitation of the study was lack of blinding which could have affected performance on the primary efficacy outcomes (e.g., it may have affected clinicians' coaching of patients and/or the degree of effort

exerted by patients). About 28% of the data were missing on the primary efficacy outcomes, most of this was due to lack of compliance rather than death or illness. Although there was a pre-specified plan for handling missing data, with this degree of missing data findings might not accurately represent outcomes in the population. In addition, there may have been insufficient power to detect meaningful differences for secondary outcomes, including safety outcomes. Even in the primary outcomes, there tended to be wide confidence intervals indicating an insufficiently large sample size. Moreover, some between-group differences, though statistically significant, may not be clinically significant (e.g., a 6.8% absolute change from baseline in FEV1). An editorial accompanying publication of the trial (Jones et al.) noted that the rate of complications such as COPD, were higher in the endobronchial valve group, albeit not statistically different. The editorial additionally criticized the study for not standardizing medical treatment for the control group, and for possibly providing suboptimal medical therapy for both groups. For example, only 57% of patients received recommended bronchodilators at the beginning of the study and that the medical therapy was not standardized.

An earlier uncontrolled study (Wan et al.), published in 2006, reported on 98 patients from 9 centers in 7 countries (not including the United States) who received Zephyr endobronchial valves for severe emphysema. Data were obtained from a prospectively collected multicenter registry (Anzeuto et al.) in 2010. Patients had symptomatic emphysema and shortness of breath on daily activities despite optimized medical therapy; most were candidates for lung volume reduction surgery at the participating centers. A mean of 4 (SD =1.6) valves were placed per patient (range of 1 to 8 valves). On average, there was statistically significant improvement in change from baseline to the 90-day follow-up in efficacy variables. For example, the mean absolute change in FEV1 was 0.06 liters (L) (SD =0.21) and the mean absolute change in the 6-minute walk test was 36.9 (SD =90) meters. The p-values for change from baseline were 0.007 and < 0.001, respectively. Among the 98 patients, there were 8 serious complications including one death and 30 patients had other complications including 17 exacerbations of COPD and 5 pneumonias in untreated lobes.

An uncontrolled study published in 2010 by Sherman and colleagues evaluated the IBV Valve for treatment of severe emphysema. Data were collected on 91 patients from 11 sites in the United States. All patients had heterogeneous upper-lobe predominant emphysema. The aim of the study was predominantly to study safety of the valve; the primary outcome was the rate of observed migration, erosion, or infection during the first 3 months after placement. Effectiveness and quality of life were secondary outcomes; patients were followed for up to 12 months.

A total of 609 valves were placed, with a mean of 6.7 valves per patient (range, 3–11). Seven patients withdrew from the study by 6 months; 5 of these withdrawals were due to adverse effects. Regarding the primary safety outcomes, there were no occurrences of valve migration or erosion during the 12-month follow-up. However, there were 2 instances of infection in the first 3 months, 1 episode each of pneumonia and bacterial bronchitis. Eight patients (8.8%) experienced bronchospasm (dyspnea and wheezing) after bronchoscopy; 2 patients had at least one valve removed due to bronchospasm. During the 12-month follow-up, 11 patients (12%) experienced pneumothorax. Three of these had pneumothorax with prolonged air leaks, and a total of 3 patients with pneumothorax died (one each on day 4, day 33 and day 113). There were no statistically significant improvements in the efficacy outcomes. The mean FEV1 was 0.87 liters at baseline (n=91) and 0.83 liters at 3 months (n=79). Among the 76 patients with data on the 6-minute walk test at 3 months, the mean distance walked had increased by 4 feet compared to baseline. However, there was improvement in quality of life, as assessed by the SGRQ. At 3 months, there was a mean decrease of 5.1 points (p=0.01), and 41 of 78 patients with available data (52.6%) were considered responders (a decrease in at least 4 points on the SGRQ).

In 2011, the British Thoracic Society (Du Rand et al.) published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults. The guidelines stated that sufficient evidence has not yet been demonstrated to recommend the routine use of endobronchial valves for treatment of emphysema.

The only available data on endobronchial valves for treating persistent air leaks are uncontrolled trials with small numbers of heterogeneous patients. Data on any FDA approved endobronchial valve device is particularly limited. A small case series using the FDA approved valves for treating air leaks reported on 9 patients; valves were successfully placed in 7 of them. This evidence is not adequate to determine a risk/benefit ratio for this procedure, nor does it provide any evidence on comparisons with alternatives. For patients with advanced emphysema, case series and a single unblinded RCT provide insufficient evidence that the technology improves the net health outcome. In the RCT, the magnitude of the

improvements was of uncertain clinical significance, and the statistical significance was marginal for most of the comparisons. In addition, the numerous adverse events experienced by patients who received endobronchial valves raise concerns about the safety of the treatment.

Billing/Coding Information

CPT CODES

31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure[s])

HCPCS CODES

No specific codes identified

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Endobronchial Valves, continued

Select Health

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MEDICAL POLICY

HIGH FREQUENCY CHEST WALL COMPRESSION

Policy # 128

Implementation Date: 7/1/02

Review Dates: 10/23/03, 11/18/04, 7/12/07, 6/19/08, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/8/19, 9/29/20, 10/26/21, 9/13/22, 10/16/23, 10/14/24

Revision Dates: 8/5/02, 2/2/05, 7/25/06, 7/13/09, 8/24/20, 11/15/23, 10/2/24

Related Medical Policies:

#246 Mechanical Insufflation-Exsufflation Therapy for the Clearance of Airway Secretions (Coughassist Device)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Some lung conditions have as a prominent component the difficulty in mobilizing secretions. These include conditions such as cystic fibrosis, bronchiectasis and some forms of chronic obstructive lung disease. In addition, patients with neuromuscular disorders may struggle with secretion mobilization for different reasons. Cystic fibrosis (CF) is an autosomal recessive disorder whose pulmonary manifestations include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. Bronchiectasis is a syndrome of chronic cough and the daily production of mucopurulent and tenacious sputum lasting months to years associated with airway dilatation and bronchial wall thickening. Multiple conditions are associated with the development of bronchiectasis, but all require an infectious insult plus impairment of drainage, airway obstruction, and/or a defect in host defense. Chronic obstructive pulmonary disease (COPD) though characterized by the presence of airflow obstruction may have a prominent component of chronic bronchitis is defined clinically as the presence of a chronic productive cough for 3 months during each of 2 consecutive years (other causes of cough being excluded). Neuromuscular disorders that have secretion issues include a variety of diverse disorders such as ALS, Muscular dystrophy, multiple sclerosis, myotonic disorders, acid maltase deficiency, other myopathic disorders, post-polio syndrome, and quadriplegia.

Patients with these conditions often require routine maintenance chest physical therapy (i.e., percussion and postural drainage [P/PD]) every day to assist in the removal of mucous secretions from the lung. P/PD may be administered by a physical therapist or another trained adult in the home, typically a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who wish to lead independent lifestyles. In addition, the neuromuscular patients may have weak cough and require additional cough help with cough assist devices.

The standard approach to aiding in removal of these thickened secretions is to use percussive therapy. This can be done manually using cupped hands and "pounding" on the chest/back in different positions and allowing the patient to then "drain" the secretions. This can also be done with manual electronic "pounders". Another method employed uses vibration of the air column in the conducting airways. One way in which this may be accomplished is to directly vibrate the chest wall at frequencies higher than the normal respiratory rate during deep breathing and coughing exercises. High-frequency chest wall compression (HFCWC) can be delivered using a device that fits over the patient's chest and back. The device consists of an inflatable vest connected to a small air-pulse generator by 2 tubes, which rapidly inflates and deflates the vest, compressing and releasing the chest wall up to 20 times per second. HFCWC with an inflatable vest was developed to improve consistency of care and treatment adherence and to reduce the manpower required to provide the care and to theoretically reduce cost of therapy. HFCWC therapy has been investigated for patients with impaired mucociliary clearance due to CF and other diseases in both outpatient and in hospital settings. A team-management approach is vital for

optimum treatment of conditions causing ineffective airway clearance. Patients living independently typically are trained to perform the therapy themselves. Hospitalized patients may require the assistance of a therapist to perform the procedures involved.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers high frequency chest compression therapy devices for patients with:

1. Cystic fibrosis (CF), or

2. Immotile cilia syndrome, or

3. Bronchiectasis, or

4. Neuromuscular disorders, when all the following are met (these criteria only apply to neuromuscular disorders):

   a) Well-documented failure of standard treatments to adequately mobilize retained secretions, with all the following:

      i) Failed chest PT, at least twice daily

      ii) A pattern of hospitalizations or significantly deteriorating clinical condition

      iii) Adequate cough to remove mobilized secretions or use of cough assist device

   b) Pulmonary evaluation or consultation

   c) Rental trial, prior to purchase (depending on plan)

Select Health does NOT cover high frequency chest wall compression therapy devices for any other medical conditions, including chronic obstructive lung disease (COPD) and other indications (e.g., alpha 1-antitrypsin deficiency, childhood atelectasis, cerebral palsy, coma, kyphosis, leukodystrophy, scoliosis, and stiff-person [stiff-man] syndrome; not an all-inclusive list) because their effectiveness for these indications has not been established. The available evidence is insufficient to determine efficacy of use of these devices for these conditions. This meets the plan's definition of experimental/investigational.

If coverage of high-frequency chest compression device is approved, chest physiotherapy (CPT) in the outpatient setting as a duplicate service will be denied.

Charges for set-up, training and/or extended warranty are not eligible for reimbursement, as payment for these services are included in the reimbursement made for the system itself. Charges for these services will be denied as a non-reimbursable.

Only one compressor device will be paid for by the plan over the member's lifetime.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

There are no studies with direct health outcomes that demonstrate that high frequency chest wall compression (HFCWC) therapy, including devices such as the vest, are equivalent or superior to other techniques designed to improve pulmonary clearance in patients with cystic fibrosis. However, in some situations, other methods of therapy, such as chest PT by a family member, are not available.

High-frequency chest compression devices have been shown to increase sputum mobilization in CF patients. CF is caused by abnormal chloride ion transport on the apical surface of epithelial cells in exocrine gland tissues. The abnormally composition of secretions from affected epithelial surfaces results in increased viscosity. It has been theorized that high-frequency chest compression devices are particularly effective in clearing the abnormal secretions of CF because vibratory shear forces facilitate expectoration by reducing the viscosity of these secretions, much in the same way that shaking Jello causes it to become fluid. However, high frequency chest compression vests have not been proven to be more effective than manual chest physiotherapy. It can be used in place of manual chest physiotherapy for patients with CF where manual chest physiotherapy is unavailable.

A December 2016 Technology Directory from Hayes identifying 18 studies on the procedure done on CF patients and gave the vest an overall rating of C. They found that the overall evidence was moderate in size, but low in quality, but recommended the vest as potential for treatment in patients with CF. Cochrane review (2019) states, “The evidence provided by this review is of variable quality, but suggests that all techniques and devices described may have a place in the clinical treatment of people with CF.” The data in non-CF bronchiectasis is more limited, however in a retrospective registry of over 2500 patients, Barto reported that there are less hospitalizations and antibiotic use in those using vests.

The evidence for use of these vests in neuromuscular disease is limited (Lechtzin). The studies tend to be small without randomization. A prospective cost analysis (Javanbakht) suggests cost is less due to decrease in hospitalization. Most clinics that deal with these patients feel that due to the precarious nature of their disease by the time these vests are instituted randomized trials at this point are not ethical.

The data is extremely limited for disorders such as COPD and does not support the use of this vest for this disorder (Alghamdi).

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment
E0480	Percussor, electric or pneumatic, home model
E0483	High frequency chest wall oscillation air-pulse generator system (includes hoses and vest), each

Select Health

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Revision History

Revision Date	Summary of Changes
11/15/23	For Commercial Plan Policy, added conditions to list of examples of exclusions.
10/2/24	For Commercial Plan Policy, added new criterion #2 (immotile cilia syndrome) to list of conditions that would qualify for coverage of this therapy.

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MEDICAL POLICY

HYPERBARIC OXYGEN THERAPY (HBO2/HBOT)

Policy # 129

Implementation Date:7/98

Review Dates: 1/4/00, 2/27/01, 4/10/02, 10/23/03, 11/18/04, 11/9/05, 12/18/08, 12/17/09, 4/25/13, 2/20/14, 3/19/15, 2/16/17, 2/15/18, 2/5/19, 2/11/20, 2/5/21, 1/16/22, 2/16/23, 2/19/24, 2/20/25

Revision Dates: 11/18/04, 7/26/06, 4/19/07, 11/12/07, 2/17/11, 3/6/12, 6/2/15, 2/3/16, 2/16/17, 11/1/19, 2/21/20, 3/11/20, 2/12/21, 10/8/21, 1/19/22, 9/27/22, 12/8/22, 1/4/23, 2/15/23

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Hyperbaric oxygen therapy (HBO2 or HBOT) provides a therapeutic dose of oxygen by creating a pressurized environment (a chamber) in which patients intermittently breathe 100% oxygen. To administer hyperbaric oxygen, the patient is placed inside a specially built pressurized chamber, and pure oxygen is delivered under pressure. Inside the chamber, the high pressure forces more oxygen into body tissues than is possible at normal pressures outside. The primary restorative effects of HBO2/HBOT are due to a combination of increased hydrostatic pressure and elevation of the tissue oxygen tension.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health does NOT cover topical hyperbaric oxygen therapy (HBO2/HBOT) for any indication as current evidence does not support the effectiveness of this therapy. This meets the plan's definition of investigational/experimental.

Select Health covers the initial hyperbaric oxygen (HBO2/HBOT) therapy treatment course under the following circumstances for the number of visits specified. Additional treatment visits can be requested but documentation must be submitted indicating substantial improvement in the underlying condition to justify additional visits. All requests for additional treatment visits after initial course must go to MD review.

HBO2/HBOT is covered for the following conditions:

Condition	# of treatment visits allowed
Acute Idiopathic Hearing Loss: Condition must be present for < 30 days, there must be formal audiometry testing demonstrating hearing loss of ≥ 41Dbl, the patient is on concomitant systemic or TM injected with steroids as determined by ENT consult.	**10 treatments initially, additional 10 treatments approvable,** if patient has demonstrated response of ≥ 20 Dbl improvement on audiogram at one or more frequencies or improvement in voice discrimination tests determined by the audiologist, documented after 10 initial treatments.
Actinomycosis: only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment	**15 treatments** maximum without MD review **30 treatments** if osteomyelitis is present without MD review; 60 treatments may be indicated but would require MD review

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Hyperbaric Oxygen Therapy (HBO_2/HBOT), continued

Brain abscess	**MD review**
Carbon monoxide (CO) intoxication, acute and severe with or without cyanide poisoning: exposure is confirmed, and symptoms are persistent. CoHb > 10% helps confirm exposure but should be assessed as soon as possible following the exposure. Levels > 5% in children or non-smokers may also help confirm exposure. COHb levels degrade with time and surface level oxygen treatment after removal from exposure, and therefore, may not be an absolute determination of severity of poisoning by itself. Other confirmation of exposure may come from the gas company or Fire Dept. tests for CO levels in the exposure area. Treatment is approved only if started less than 24 hours from CO poisoning.	**1–2 treatments**; Patients may need to be treated until they reach a clinical plateau. MD review required after 10 treatments
Central retinal artery occlusion. Patient must meet /the following criteria: 1) patient has diagnosis of central retinal artery occlusion 2) condition has been present ≤ 24 hours	**14 treatments** (BID for 1 week) with duration of 90 minutes per session
Chronic diabetic wounds Patient has type 1 or 2 diabetes and has a lower extremity wound (Wagner grade III or higher*) due to diabetes, and has failed an adequate dose of standard wound therapy (defined as 30 days of standard treatment including assessment and correction of vascular abnormalities, optimization of nutritional status and glucose control has been addressed, debridement, moist wound dressing, off-loading, and treatment of infection)	**20 treatments.** Increments of 20 visits may be indicated and will require MD review
Clostridial myonecrosis (gas gangrene)	**7 treatments**
Decompression illness (Caisson's disease) plus arterial gas embolism	**1–2 treatments**; Patients may need to be treated until they reach a clinical plateau. MD review required after 10 treatments
Gas/air embolism	**5 treatments**; up to 10 treatments may be indicated but requires MD review
Mucormycosis, Pneumatosis, Cystoides intestinales	**MD review**
Osteomyelitis, chronic refractory: only if unresponsive to conventional medical and surgical management	**40 initial treatments**; up to 60 treatments which will require documentation and MD review
Osteoradionecrosis: only as an adjunct to conventional therapy when the disease process is refractory to such therapies	**40 treatments**; 30 treatments before surgery and 10 treatments after. An additional 10−20 treatments may be indicated, but requires MD review
Radionecrosis, soft tissue: only as an adjunct to conventional therapy when the disease process is refractory to such therapies; including radiation myelitis, cystitis, enteritis, proctitis, or failing breast reconstruction or persistent pain from breast lymphedema due to radiation injury	**40 treatments**; 30 treatments before surgery and 10 treatments after. An additional 10−20 treatments may be indicated, but requires MD review
Skin grafts and flaps, compromised, preparation and preservation of: to be used in patients with	**20 treatments**; when preparing a recipient site for a flap or graft, after lack of response by standard

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local vascular compromise, previous radiation treatment, or in sites of previous graft failure	appropriate wound care, or after a flap or graft has been placed into its recipient site
Soft tissue infections acute, necrotizing, and progressive: used in conjunction with accepted, standard therapeutic measures when loss of function, limb, or life is threatened, and NOT as replacement therapy	**8 treatments**; additional treatments may be indicated but requires MD review
Thermal burns	**MD review**
Traumatic peripheral ischemia, acute ("crush injuries," compartment syndrome): only when used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened, and not as replacement therapy	**2 treatments a day up to 7 days**; beyond this time period, MD review is required

Select Health does NOT cover hyperbaric oxygen therapy (HBO2/HBOT) for the following conditions (this list is not all-inclusive). Use of HBO2/HBOT for these conditions is considered investigational:

1. Anemia/blood loss, severe
2. Arthritic diseases
3. Bone grafts
4. Brain or spinal cord injury, including but not limited to traumatic and "closed"
5. Brain syndromes, chronic; including but not limited to Alzheimer's, Pick's, Korsakoff's disease
6. Brown Recluse spider bites
7. Carbon tetrachloride poisoning
8. Cerebral edema
9. Fracture nonunion (healing)
10. Hepatic necrosis
11. Hydrogen sulfide poisoning
12. Infections/septicemia; aerobic, microaerophilic, or anaerobic; not Clostridia (unless specifically covered)
13. Leprosy
14. Lyme disease
15. Myocardial infarction (MI), cardiogenic shock
16. Migraine
17. Multiple sclerosis
18. Meningitis
19. Ophthalmic diseases; except for central retinal artery occlusion
20. Organ transplant, re-implantation, or storage
21. Peripheral arterial insufficiencies
22. Post-concussive syndrome/traumatic brain injury
23. Post-traumatic stress disorder
24. Pulmonary damage, acute thermal/chemical (e.g., carbon tetrachloride, hydrogen sulfide poisoning)
25. Pulmonary emphysema
26. Pseudomembranous colitis, intra-abdominal abscess
27. Pyoderma gangrenosum
28. Refractory mycoses other than actinomycosis

29. Renal artery insufficiency, acute
30. Raynaud's Phenomenon
31. Senility/dementia
32. Sickle cell crisis and/or hematuria
33. Sports injuries, soft tissue
34. Tetanus
35. Leg ulcers: cutaneous, decubitus, stasis, venous, arterial/ischemic

HBO2/HBOT is contraindicated in the following circumstances:

1. Treatment with doxorubicin, cisplatin, or disulfiram
2. Untreated pneumothorax

*Wagner Ulcer Grade Classification System

- Grade 0: Intact skin
- Grade 1: Superficial diabetic ulcer
- Grade 2: Ulcer extension involves ligament, tendon, joint capsule or fascia; no abscess or osteomyelitis
- Grade 3: Deep ulcer with abscess, infectious tendonitis, or osteomyelitis
- Grade 4: Gangrene to portion of forefoot
- Grade 5: Extensive gangrene of foot

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Utilization review will be required to send the case for medical necessity review if additional hyperbaric therapy is requested, once quantity limits as listed above have been achieved.

Summary of Medical Information

An HHS review in October 2000 concluded the following about HBO2: "Although our medical review did not attempt to independently evaluate the overall efficacy of HBO2, the benefits of hyperbarics, as evaluated by our medical review team, ranged from saving lives to no benefit at all. While a few are believed to have benefited to the extent that either life or limb was saved (0.7%), 13% of [Medicare] beneficiaries showed no improvement of their medical condition after treatment with HBO2."

"Of the beneficiaries appropriately treated with hyperbarics, 37% received treatments that likely did not yield the maximum benefit possible. We examined 2 proxy variables for quality of care: 1) insufficient progress to justify continuation of therapy, and 2) inappropriate or inadequate testing. Of beneficiaries treated for appropriate indications, 35% did not show sufficient documented progress to justify continuation of the therapy; and 15% did not have appropriate testing to confirm a diagnosis supporting the use of hyperbarics."

"According to our review, 18% demonstrated side effects as a result of the HBO2. Furthermore, there is no way to determine if those who do benefit would have seen improvement without the treatment or with other aggressive wound care. However, to acknowledge the risks, costs and variable outcomes does not necessarily disparage this procedure. Hyperbaric therapy is generally reserved as a last resort, when other treatment options are exhausted. The population targeted is generally elderly and very ill. The average age of a hyperbaric Medicare patient is 70. At least 45% are diabetic; and almost 30% have some form of heart disease. It also appears that about 18% are deceased within 2 years after treatment. Hyperbarics is often an end of life procedure and may provide a reprieve from painful non-healing wounds; and in some cases, it is credited with saving lives."

With regards to the use of hyperbaric oxygen therapy for the treatment of Raynaud's Phenomenon, only one paper was identified which had been published on this condition, and it was from 1967.The study included outcomes from 6 women who underwent 10 to 14 days of treatment (2 sessions per day, 2 hours per session). The study showed that improvements lasted for 1 month. However, the study was not randomized, blinded, prospective, or multi-centered, and limited by its small sample size. Thus, it is felt current published evidence is inadequate to reach conclusions on the safety, efficacy, or durability of this therapy for the treatment of Raynaud's Phenomenon.

With regards to acute idiopathic sudden sensory hearing loss (ISSHL), the Hyperbaric and Undersea Medicine Society listed this condition as an approved condition for which HBOT has demonstrated benefit in 2012. This was based on weak evidence and was more a consensus based on the weak evidence. A Cochrane Review by Bennett published in 2012 noted: "For people with acute ISSHL, the application of HBOT significantly improved hearing, but the clinical significance remains unclear. We could not assess the effect of HBOT on tinnitus by pooled analysis. In view of the modest number of patients, methodological shortcomings and poor reporting, this result should be interpreted cautiously. An appropriately powered trial is justified to define those patients (if any) who can be expected to derive most benefit from HBOT. There is no evidence of a beneficial effect of HBOT on chronic ISSHL or tinnitus and we do not recommend the use of HBOT for this purpose." Topuz, E., et al. (2004) similarly concluded the addition of HBO therapy to conventional treatment modalities significantly improves the outcome of ISSHL, especially at the frequencies of 250, 500, 1,000, and 4,000 Hz, and in hearing loss of above 61 dB. Furthermore, HBO therapy was found to be more effective in patients younger than 50 years. Additional small studies have suggested a probable benefit, though, the magnitude of the benefit is unclear. Some studies have also demonstrated limited benefit in older populations, and nearly all studies employed concomitant systemic steroids as part of the treatment protocols. Alsan et al. (2002) likewise concluded: "The addition of HBO therapy to the conventional treatment (betahistine hydrochloride, prednisone, and daily stellate ganglion block) significantly improves the outcome of SD, especially in patients younger than 50 years. Additional HBO therapy provides limited benefit in patients older than 50 years and no benefit in patients older than 60 years.

Carbon monoxide (CO) intoxication, acute and symptomatic, with or without cyanide poisoning, may be treated if exposure is confirmed and symptoms are persistent. CoHb > 10% helps confirm exposure but should be assessed as soon as possible following the exposure. CoHb levels > 5% in children or non-smokers may also help confirm exposure. COHb levels degrade with time, and surface level oxygen treatment after removal from exposure, and therefore, may not be an absolute determination of severity of poisoning by itself. Other confirmation of exposure may come from a gas company or fire department tests for CO levels in the exposure area. Treatment is approved, only if started less than 24 hours from CO poisoning.

Billing/Coding Information

CPT CODES

99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS CODES

G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
Not covered:	
A4575	Topical hyperbaric oxygen chamber, disposable

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Revision History

Revision Date	Summary of Changes
1/4/23	For Commercial Plan Policy, added arterial/ischemic ulcers to list of excluded conditions for this therapy.
2/15/23	For Commercial Plan Policy, clarified the exclusion of this therapy for the following ulcers is for ***leg*** ulcers: cutaneous, decubitus, stasis, venous, arterial/ischemic.

Select Health

Hyperbaric Oxygen Therapy (HBO_2/HBOT), continued

Select Health

Select Health

MEDICAL POLICY

HYPOGLOSSAL NEUROSTIMULATION (INSPIRE UPPER AIRWAY STIMULATION)

Policy # 608

Implementation Date:3/14/17

Review Dates: 7/25/18, 7/25/19, 6/18/20, 6/17/21, 5/19/22, 5/30/23, 6/5/24, 6/2/25

Revision Dates: 1/21/20, 5/28/20, 7/7/23, 2/28/24, 6/14/24, 6/23/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Obstructive sleep apnea (OSA) is a chronic disease that requires long-term, multidisciplinary management. The goals of therapy are to reduce or eliminate apneas, hypopneas, and oxyhemoglobin desaturation during sleep, and thereby improve sleep quality and daytime function. Potential benefits of successful treatment of OSA include improved quality of life, improved systemic blood pressure control, reduced healthcare utilization and costs, and possibly decreased cardiovascular morbidity and mortality.

Weight loss and continuous positive airway pressure (CPAP) therapy are the cornerstones of therapy. Both have been shown to improve outcomes in randomized trials. CPAP/BiPAP have demonstrated improvement in mortality, something no other therapy has demonstrated. Oral appliances are employed in patients who are intolerant to CPAP/BiPAP and have mild-to-moderate sleep apnea. Several surgical procedures are also employed as third-line therapy in some patients.

Hypoglossal nerve stimulation via an implantable neurostimulator device is a novel treatment strategy that is proposed in selected patients, with moderate-to-severe OSA. The Inspire Upper Airway Stimulation system (Inspire Medical Systems, Inc., Maple Grove, MN) is the first FDA Approved hypoglossal nerve stimulator for use in the treatment of obstructive sleep apnea. Inspire therapy is a small, fully implanted system that senses breathing patterns and delivers mild stimulation to maintain multilevel airway patency during sleep. Upper airway stimulation technology provides a first of its kind alternative for those suffering from obstructive sleep apnea who are unable to use or get consistent benefit from CPAP.

The Inspire system consists of three implanted components including a small generator, breathing sensor lead, and stimulation lead, all controlled with the small handheld Inspire sleep remote. Using a proprietary algorithm, Inspire therapy continuously monitors the patient's breathing patterns and delivers mild hypoglossal nerve stimulation during inspiration. The Inspire stimulation lead is designed to gently conform to a variety of hypoglossal (XII) nerve types. Securing the stimulation lead to the optimal location on the XII nerve facilitates stable, consistent stimulation of targeted airway muscles.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health will cover implantation of the Inspire stimulator when the following criteria are met:

1. Age ≥ 18 years old

Select Health

2. Moderate-to-severe OSA with AHI: 15 to 100 events per hour, and polysomnography or home sleep testing within 24 months of Inspire stimulator consult

3. Central and mixed sleep apnea accounted for < 25% of all AHI events

4. Recommendation for Inspire stimulator by both an ENT and a sleep specialist

5. Documentation which demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week); or documentation supports non-compliance for at least 6 months

6. No anatomical findings which would compromise the performance of the *Inspire* stimulator

7. BMI < 40 kg/meter squared

8. Dental appliance has been determined to not provide adequate control of the patient's sleep apnea or is not clinically appropriate

9. Inspire stimulator must be implanted by an ENT

B. Coverage for adolescents with Down Syndrome:

1. Age 13 to 18

2. Severe obstructive sleep apnea (as determined by an apnea-hypopnea index (AHI) of greater than or equal to 10 and less than or equal to 50)

3. No anatomical findings which would compromise the performance of the Inspire stimulator, including no evidence of complete concentric collapse at the soft palate, as determined by drug-induced sleep endoscopy

4. Have been considered for all other alternative/additional treatments that are considered the standard of care for this condition

5. Central and mixed sleep apnea accounted for < 25% of all AHI events

6. Documentation which demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week); or documentation supports non-compliance for at least 6 months

7. Recommendation for Inspire stimulator by both an ENT and a sleep specialist

8. Inspire stimulator must be implanted by an ENT

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The Inspire Upper Airway Stimulation (UAS) therapy for use in a subset of patients with moderate-to-severe obstructive sleep apnea (OSA) was FDA approved in 2014 for adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.

A review of published literature completed in March 2017 identified two systematic reviews and 11 primary studies related to hypoglossal nerve stimulation warranting coverage. Of the eleven primary studies, 7 were derived from the cohort of 126 patients enrolled in the STAR trial. Study size ranged from 8 to 126. The longest duration of follow-up was 48 months.

Hayes reviewed this therapy in 2016 and provides a good representation of the finding from most of the studies, except for some of the more recent studies published after March 2016. This systematic review noted the overall quality of evidence is low due to poor study design and inconsistency in findings across studies and the lack of clinically applicable endpoints. Many studies lacked an intention to treat analysis which may enhance perceived value of therapy.

Methodological issues identified in the studies include the lack of randomization in all studies, and none of the studies were comparative in nature to standard therapies. One study by Murphey et al. from 2016 was retrospective. The other studies were either prospective case series or cohort trials.

Outcomes were limited to measures such as sleep quality, AHI, ODI, and airflow mechanics with HGNS in patients with moderate-to-severe OSA. Those studies measuring AHI often found improvement, which was statistically significant, though, perhaps clinically inadequate given that patients often failed to achieve an AHI < 5. No studies were of duration or size to assess clinical endpoints such as impact on CV disease, rhythm disturbances, hypertension, or death.

The single cost-related study by Pietzsch et al., which was identified, is flawed by its comparison solely to untreated patients; this fact limits its utility.

The studies by Stolle, Soose, and Gillespie from 2015, 2016, and 2017, respectively, reports findings of the STAR trial at 18 months, 24 months, and 48 months. The studies assessed AHI and ODI as primary endpoints and identified statistically significant improvement, compared to no therapy, but again lack comparison to oral appliances or other methods to treat OSA. The serial studies suggest some level of effectiveness and safety of hypoglossal nerve stimulation as it relates to AHI, ODI, and sleep quality measures with some level of durability to these effects. However, these studies also suggest residual clinical disease which may reduce clinical impact of this therapy.

Overall, the current evidence is of low-level and is limited in volume. It suggests clinical benefit and limited safety concerns but given the number of members studied and the low-level of evidence [Grade 2B], this therapy still seems to be unproven.

Billing/Coding Information

CPT CODES

64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator

Select Health

Hypoglossal Neurostimulation (Inspire Upper Airway Stimulation), continued

64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64999	Unlisted procedure, nervous system (When specified as implantation of a hypoglossal nerve stimulator)

HCPCS CODES

L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

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Revision History

Revision Date	Summary of Changes
7/7/23	For Commercial Plan Policy, for general criteria, lowered age requirement from 22 years of age to 18 years of age; and added coverage criteria for adolescents with Down Syndrome (ages 13 to 18).
2/28/24	For Commercial Plan Policy, modified certain requirements in section A to align with updated FDA-approved indications: "2. Moderate-to-severe OSA with AHI: 15 to 100 events per hour [was previously 15 to 65 events per hour], and polysomnography within 24 months of Inspire stimulator consult; 7. BMI < 40 kg/meter squared [was previously < 35 kg/meter squared]."
6/14/24	For Commercial Plan Policy, modified criterion #A2: "Moderate-to-severe OSA with AHI: 15 to 100 events per hour, and polysomnography ***or home sleep testing*** within 24 months of Inspire stimulator consult."
6/23/25	For Commercial Plan Policy, modified requirements in both criterion #A-5 and #B-6: "Documentation which demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week***); or documentation supports non-compliance for at least 6 months***."

Hypoglossal Neurostimulation (Inspire Upper Airway Stimulation), continued

Select Health

MEDICAL POLICY

MECHANICAL INSUFFLATION-EXSUFFLATION THERAPY FOR THE CLEARANCE OF AIRWAY SECRETIONS (COUGHASSIST DEVICE)

Policy # 246

Implementation Date:10/15/04

Review Dates: 10/18/05, 10/13/06, 11/05/06, 12/20/07, 12/18/08, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 9/29/20, 10/26/21, 9/13/22, 10/16/23, 10/14/24

Revision Dates: 12/17/09, 9/29/14, 1/29/19, 12/30/19, 8/23/19, 8/24/21

Related Medical Policies:

#128 High Frequency Chest Wall Compression

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Patients who have ventilatory deficiencies due to a spinal cord injury or medical conditions which result in chest muscle weakness often require assistance to maintain an open airway, and thus, ensure adequate gas exchange for the lungs. The bronchial tubes can become plugged by mucous, particularly during respiratory tract infections that stimulate mucous production. Bronchial obstruction, or hypoventilation itself, may result in significant respiratory infections with marked increases in morbidity, mortality, and costs for the care of these patients. A common strategy for maintaining a clear airway is chest percussion alone, or in combination with proper positioning and postural drainage, which rely on gravity to assist the expectoration of airway secretions. However, these techniques may not mobilize secretions adequately. Although airway clearance may also be achieved by endotracheal suctioning, this is an invasive approach that may be poorly tolerated by patients. Other approaches to airway clearance involve enhancement of cough. In manually-assisted coughing, a care provider applies force to the chest and/or abdomen that is timed to increase expulsion of air. To increase the volume of air expulsed during a cough, ventilator-dependent patients can combine, or stack, insufflations provided by a ventilator or by glossopharyngeal breathing. Greater coughing force can be attained by these maneuvers, but manually-assisted coughing may not be appropriate for patients with stiff chest walls, fragile or osteoporotic ribs, or spinal disorders such as scoliosis.

Mechanical insufflation-exsufflation uses a device with a facemask that covers the nose and mouth, allowing air to be pumped into the lungs and then rapidly evacuated, facilitating the expulsion of secretions. Patients typically undergo multiple cycles of insufflation and exsufflation to improve airway clearance, with insufflation and exsufflation pressures adjusted to the maximum comfortable level for each patient. Mechanical insufflation-exsufflation therapy has been used on ventilator-dependent patients and those who have severe respiratory muscle weakness due to muscular dystrophy, poliomyelitis, spinal muscular atrophy, or amyotrophic lateral sclerosis.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers mechanical insufflation-exsufflation devices as medically necessary for patients with neuromuscular disorders, such as muscular dystrophy, amyotrophic lateral

sclerosis, spinal cord injuries, and myasthenia gravis; or for patients with significant impairment of chest wall and/or diaphragmatic movement resulting in difficulty clearing secretions. The medical literature has established that the use of these devices results in improved health outcomes for patients with ventilatory insufficiency and difficulty clearing secretions due to respiratory muscle weakness or chronic mechanical ventilation.

Select Health does NOT cover mechanical insufflation-exsufflation therapy for the clearance of airway secretions for patients not meeting the above coverage criteria and is contraindicated (and therefore, not covered) in the following patients:

1. History of bullous emphysema
2. Lung cysts
3. Presence or susceptibility to pneumothorax or pneumomediastinum (lung barotrauma injury)
4. Recent barotrauma

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Published data suggest that MI-E can improve the intermediate outcome of peak cough expiratory flow. Data regarding its role in the clinical management of the patient consist of case series. In some studies, patients have served as their own control, with a decreased incidence of hospitalization among patients who switch from tracheostomy to a non-invasive approach, which may include MI-E as one component. While controlled trials would ideally further delineate who is most likely to benefit from MI-E, particularly those who would benefit from having such a device in the home, such trials are logistically difficult. The heterogeneous nature of the patients, even among those with similar diseases, almost mandates a case-by-case approach for these patients. For example, the clinical utility of MI-E would not only depend on the physiologic parameters of lung function, but also, on the tempo of the disease course, the availability of home caregivers, and patient preference and motivation.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

No specific codes identified

HCPCS CODES

A7020 Interface for cough stimulating device, includes all components, replacement only

Mechanical Insufflation-Exsufflation Therapy For The Clearance Of Airway Secretions (Coughassist® Device), continued

E0482 Cough stimulating device, alternating positive and negative airway pressure

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Select Health

MEDICAL POLICY

MESOMARK TEST

Policy # 407
Implementation Date:8/18/08
Review Dates: 8/13/09, 8/19/10, 9/15/11, 11/29/12, 12/19/13, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/20/19, 6/18/20, 6/10/21, 5/19/22, 6/15/23, 6/17/24, 6/19/25
Revision Dates:

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Mesothelioma is an insidious neoplasm arising from the mesothelial surfaces of the pleural and peritoneal cavities, the tunica vaginalis, or the pericardium. Eighty percent of all cases are pleural in origin. The predominant cause of malignant mesothelioma is inhalational exposure to asbestos, with approximately 70% of cases of pleural mesothelioma being associated with documented asbestos exposure.

Malignant pleural mesothelioma most commonly presents in the fifth to seventh decades of life. The most frequent presenting symptoms of pleural mesothelioma are dyspnea and non-pleuritic chest pain. Common physical findings at the time of diagnosis include unilateral dullness to percussion at the lung base, palpable chest wall masses, and scoliosis towards the side of the malignancy.

Mesothelin is a glycoprotein that is expressed on the surface of normal mesothelial cells and highly is overexpressed in malignant mesothelioma. Soluble mesothelin-related peptides (SMRPs) are believed to be either cleaved peptide fragments of mesothelin, or abnormal variants of mesothelin that are unable to bind to membranes. These protein fragments may be released into a person's blood. Circulating SMRPs have been investigated as a potential early tumor marker for mesothelioma.

MESOMARK (Fujirebio Diagnostics, Inc., Malvern, PA) is a commercially available test that uses a two-step immunoassay to quantitate the presence of the SMRP in human serum using Enzyme Immunoassay technology with colorimetric detection in a standard ELISA microplate sandwich assay format. Two separate monoclonals are used (4H3 and OV569): one for capturing SMRP, the other for detection of SMRP. A direct relationship exists between the amount of SMRP in sample and the Optical Density (OD) detected by the spectrophotometric microtiter plate reader.

The test is administered through a simple blood draw. A sample of blood is drawn from the patient and added to specific chemicals in the MESOMARK test. Alternatively, diagnosis is established through obtaining tissues samples either through biopsy procedures or fluid extraction with immunohistochemistry analysis.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover the MESOMARK test for mesothelioma. Current evidence is inconclusive as to the clinical utility of the MESOMARK test, whether for diagnosis or monitoring of patients with mesothelioma.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

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please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A literature review of current studies involved the examination of lung samples from patients with histologically proven mesothelioma in comparison to patients with other lung disease. Generally, these studies reported that SMRP levels discriminate mesothelioma from other forms of lung cancer, benign lung disease, and healthy controls, including asbestos-exposed individuals. For example, Amati et al. examined 22 patients with mesothelioma, 94 asbestos-exposed subjects, and 54 healthy controls. The area under the curve for SMRPs was significant in discriminating asbestos-exposed from mesothelioma patients but not from healthy controls. A combination of SMRP with other biomarkers more reliably distinguished between the 3 subject groups. DeSerio et al. examined the role of SMRPs in 109 healthy subjects never exposed to asbestos, 26 healthy subjects exposed to asbestos, 33 patients with asbestosis, 33 with asbestos-related pleural plaques, 10 with non-malignant pleural diseases, 30 with lung cancer, and 24 with histological diagnosis of pleural mesothelioma. Using a cut off of 0.63 nmol/mL serum SMRP concentration distinguished patients with established pleural mesothelioma from healthy controls and patient groups.

Limited data exist regarding the use of SMRP for early detection or monitoring of patients with mesothelioma. No studies are published comparing SMRP counts to other established methods of diagnosing mesothelioma. Very few studies followed patients over time to determine the predictive value of SMRP counts for diagnostic purposes or for monitoring disease progression. Robinson et al. obtained serum samples from 44 patients with histologically proven mesothelioma; 68 matched healthy controls, 40 of whom had been exposed to asbestos; and 160 patients with other inflammatory or malignant lung and pleural diseases. Serum samples from 37 of 44 patients with established malignant mesothelioma had significantly higher concentrations of SMRP at all serum dilutions than did asbestos-exposed and non-asbestos exposed controls. Ten of the 228 comparison serum samples were positive, and 7 of these were in the asbestos-exposed healthy group. The SMRP assay had a sensitivity of 84% for mesothelioma (37/44 patients with mesothelioma being detected) and a specificity of 100% when compared with the other pleural diseases (38/38); 95% when compared with other lung tumors (21/22); and 83% when compared with asbestos exposed individuals (33/40).

SMRP concentrations were significantly higher in patients with the largest tumor mass (maximum tumor width > 3 cm) than in patients who had tumors with a maximum width of 1−3 cm or less than 1 cm. The sensitivity of the assay for the smallest tumors was 71% (15/21). The authors also reported a trend towards increasing SMRP concentrations in 6 patients with 3 or more serum samples during the course of the disease. Four patients with high SMRP concentrations underwent chemotherapy. None responded and SMRP levels remained stable throughout treatment. In contrast, 3 patients with mesothelioma underwent surgical debulking and their serum SMRP concentrations had fallen by 37.7%, 38.4%, and 46.8% when reassessed one month after the procedure.

The 40 asbestos-exposed individuals, 7 of whom had elevated SMRP concentrations, were followed for 8 years. Three of the 7 developed mesothelioma and 1 developed non-small-cell lung cancer. The remaining 3 remained asymptomatic at the last follow up. None of the remaining 33 asbestos-exposed individuals with normal SMR concentrations developed mesothelioma or other cancer in the 8 years of follow-up. Another 8 patients with mesothelioma and raised SMRP concentrations had sequential pre-diagnosis samples available. Two of these patients had increased SMRP concentrations at 12−48 months before presentation, and these 2 patients had very high SMRP concentrations with onset of their disease. No early SMRP increase was seen in the other patients. Finally, sequential samples from 6 individuals who had been exposed to asbestos but remained healthy showed no significant variation over a period of

about 5 years. In contrast to Robinson et al., there was no significant association between SMRP levels and mesothelioma risk when analyzed as continuous variables or as tertiles. SMRP levels < 10, 10−19 and ≥ 20 years before diagnosis were not significantly associated to mesothelioma risk.

These data suggest that SMRP measurement is a potentially useful test for distinguishing mesothelioma from other lung cancers and lung disease. Limited data suggest the test may also be useful in identifying individuals at risk for developing the disease and for monitoring treatment response. However, more data are needed in larger sample sizes to adequately determine the utility of this test for these applications.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

86316	Immunoassay for tumor antigen, other antigen, quantitative (e.g., CA 50, 72-4, 549), each
86945	Irradiation of blood product, each unit

HCPCS CODES

No specific codes identified

Key References

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Mesomark® Test, continued

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Select Health

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MEDICAL POLICY

RADIOFREQUENCY ABLATION (RFA) FOR PULMONARY TUMORS

Policy # 392

Implementation Date:3/3/08

Review Dates: 2/26/09, 2/18/10, 2/17/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/5/19, 2/3/20, 2/18/21, 1/18/22, 2/16/23, 2/7/24, 2/18/25

Revision Dates: 3/6/25

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Malignancies in the lungs may arise because of primary lung cancer and secondary or metastatic disease. Percutaneous imaging-guided radiofrequency ablation is a minimally invasive, non-surgical method to treat tumors that may be used as an adjunct to other treatments for lung cancer. Guided primarily by computed tomography (CT) scanning, a small needle electrode is inserted through the skin and directly into the tumor tissue. Radiofrequency energy, consisting of an alternating electrical current in the frequency of radio waves, is passed through the electrode. The energy causes the tissues around the needle electrode to heat up, killing nearby cancer cells, while minimizing damage to healthy surrounding tissue.

When done properly, RFA can destroy a tumor along with a thin rim of normal tissue at its edges without affecting most normal lung tissue. At the same time, heat from radiofrequency energy closes small blood vessels and lessens the risk of bleeding. If a large tumor is present, it may be necessary to do multiple ablations to be sure that no living tumor tissue is left behind. Scar tissue replaces the dead tumor cells and shrinks over time. Radiofrequency ablation usually causes little discomfort and is usually done as an outpatient procedure that does not call for general anesthesia; an application takes about 10−30 minutes.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Radiofrequency ablation may be considered medically necessary to treat an isolated peripheral non-small-cell lung cancer lesion that is no more than 3 cm in size when the following criteria are met:

   1. When surgical resection or radiotherapy with curative intent is considered appropriate based on stage of disease, however medical comorbidity renders the individual unfit for those interventions, and
   2. When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery, and the heart.

B. Radiofrequency ablation may be considered medically necessary to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when the following criteria are met:

Select Health

1. When it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status substantially; or
2. When the individual is not considered a surgical candidate and when there is no evidence of extra pulmonary metastases, and
3. When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery, and the heart.

- No more than 3 tumors per lung should be ablated
- Tumors should be amenable to complete ablation
- Twelve months should elapse before a repeat ablation is considered

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

The current literature identifies many studies focused primarily on feasibility of evaluating the ability of RFA to ablate pulmonary tumor tissue. By and large, these studies suggest that RFA is an effective means of destroying pulmonary malignancies of various types. Ambrogi et al., for example, reported complete necrosis of the tumor in 6 of 9 patients with adenocarcinoma (n = 5), and squamous cell carcinoma (n = 4). Akeboshi et al. found that RFA was effective in destroying 32 of 54 lung tumors in 31 patients with primary (n = 13) and metastatic (n = 42) lung cancer. In that study, RFA was more effective with small tumors, resulting in complete tumor necrosis in 69% in ≤ 3 cm vs. 39% of tumors > 3 cm. This size differential was a consistent finding in many studies. In 1 study, tumor size also predicted clinical outcomes. Simon et al. evaluated RFA in 153 patients with 189 lung metastases, tracking tumor growth over a 5-year period. Progression-free rates differed by tumor size (≤ 3cm vs. > 3 cm) over time: year 1 (83% vs. 45%), year 2 (64% vs. 25%), year 3 (57% vs. 25%), year 4 (47% vs. 25%), and year 5 (47% vs. 25%). However, questions as to the effectiveness of this therapy as primary management of lung tumors and subsequent change in clinical outcomes remain.

Studies assessing the durability of RFA on subsequent tumor growth over time varied. King et al., for example, used RFA in 19 patients with 44 lung metastases. Of those remaining at follow-up, at 6 months, 3 lesions had progressed, 25 metastases were stable or smaller, and 11 were no longer visible. At twelve months, 5 metastases had progressed, 11 were smaller or stable, and 9 were not visible. In Jin et al., 21 patients with primary lung cancer or metastatic disease, were treated with RFA and followed over 15 months. Among those with complete ablation after initial treatment (n=9), mean percentage of decrease in the size of ablated lesions relative to baseline at 3, 6, 9, 12, and 15 months was 5.7%, 11.4%, 14.3%, 40%, and 40%, respectively. A study by Pennathur et al. involved 19 patients with inoperable stage I non-small lung cancer who were offered RFA. Initial complete response was observed in 2 (10.5%) patients, a partial response in 10 (53%) patients, and stable disease in 5 (26%) patients. Early progression occurred in 2 (10.5%) patients. During follow-up, local progression occurred in 8 (42%) nodules, and the median time to progression was 27 months. In Hiraki et al., 27 patients with colorectal cancer metastases to the lung, had primary and secondary effectiveness rates at 1 year of 72% and 85%, 56% and 62% at 2 years, and 56% and 62% at 3 years. The overall survival rates after RFA were 96% at 1 year, 54% at 2 years,

and 48% at 3 years. Still, many of these studies did not identify a significant change in survival with use of this therapeutic tool.

Several studies evaluated clinical outcomes such as survival and procedure complications. Pneumothorax is the most common side effect of the procedure, up to 54% of cases in some reports, though, most do not require chest tube placement. Other reported adverse events included pleural effusion, up to 54% of cases in some reports, pneumonia/pneumositis, hemothorax, microemboli, and hemoptysis. In Pennathur et al., all-cause mortality was 32% during the average 29-month follow-up period. The probability of being alive at one year was 95%. In Hiraki et al., overall survival rates were 96% at 1 year, 54% at 2 years, and 48% at 3 years. In Herrera et al., death from metastatic disease occurred in 38% of patients with primary and secondary lung tumors during a mean follow-up of 6 months. After 1 year, in Belfiore et al.'s study of 33 patients treated with RFA, 8 patients had died of non-procedure-related causes. In Dupuy et al., 14 of 24 patients (58.3%) who had died, had died after an average of 26.7 months, with cumulative survival rates of 50% and 39% at the end of 2 years and 5 years, respectively; ten of the deaths were cancer related. Two patients had local recurrence (8.3%), while 9 patients had systemic metastatic disease. Statistically significant differences in overall survival, however, for individuals receiving this therapy as a primary therapeutic modality, compared to patients not receiving this therapy, were not identified.

Only 1 study examined quality of life following RFA. Of 29 patients available for follow-up in Belfiore et al., 12 reported improvement in symptoms at 6 months.

The bulk of the literature suggests RFA does effectively treat lung malignancies in the short-term, and data are emerging suggesting that these effects are maintained over time, particularly, in patients with tumors ≤ 3 cm. Gadaleta, perhaps, expressed it best in his 2006 study when he concluded: "Lung RFA is a very promising technique, minimally invasive and well-tolerated in the majority of patients; further investigation is required in order to define the optimal role of lung RFA in the multidisciplinary therapy of lung malignancies." Additional data are needed regarding the long-term effects of treatment on overall survival when this technology is employed as a primary therapy, as well as the quality of life when used in palliative situations.

Billing/Coding Information

Covered: For the indications outlined above

CPT CODES

32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
3/6/25	For Commercial Plan Policy, modified overall coverage criteria to align with current clinical guidelines, and added the following three bullet points as additional requirements for these procedures: "- No more than 3 tumors per lung should be ablated; - Tumors should be amenable to complete ablation; - Twelve months should elapse before a repeat ablation is considered"

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MEDICAL POLICY

SLEEP DISORDER EVALUATION AND TREATMENT

Policy # 625
Implementation Date: 3/14/19
Review Dates: 8/20/20, 8/19/21, 7/21/22, 12/15/23, 7/30/24
Revision Dates: 9/18/19, 12/27/22, 1/5/24, 5/7/24, 8/23/24, 1/2/25, 1/29/25, 7/3/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description
Continuous Positive Airway Pressure (CPAP) is a medical device that delivers one continuous positive pressure for the treatment of sleep apnea.

Bilevel Positive Airway Pressure (BiPAP) is a medical device that delivers two levels (one inhaled pressure and one exhaled pressure) of airway pressure for the treatment of sleep apnea.

Adaptive Servo Ventilation (ASV) is a medical device that utilizes positive airway pressure ventilatory support that is adjusted based on the detection of apnea or pauses during sleep.

CPAP/BiPAP/ASV are all proven therapeutic interventions for treatment of obstructive sleep apnea (OSA).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

I. Polysomnography testing in a member's home ('home sleep study') is covered when ALL the following criteria are met:

A. The member is at least 15 years of age; **and**
B. The member does not have any medical conditions that increase the risk of central sleep apnea, such as heart failure, neuromuscular disease, moderate-to-severe COPD, history of stroke, or chronic opioid medication use; **and**
C. The member does not have a seizure disorder, dementia, developmental delay, or morbid obesity (BMI ≥ 50); **and**
D. The physician performing the test is a diplomate of the American Board of Sleep Medicine (ABSM) or is sleep medicine certified through one of the following:

- American Board of Internal Medicine (ABIM)
- American Board of Family Medicine (ABFM)
- American Board of Pediatrics (ABP)
- American Board of Psychiatry and Neurology (ABPN)
- American Board of Otolaryngology – Head and Neck Surgery (ABOHNS)
- American Osteopathic Board of Neurology and Psychiatry (AOBNP)
- American Osteopathic Board of Family Medicine, (AOBFP)
- American Osteopathic Board of Internal Medicine, (AOBIM)
- American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO)
- American Board of Anesthesia (ABA) [*ABA certification not recognized by CMS*]

II. Continued CPAP rental or CPAP purchase is covered following an initial minimum 3-month rental period when ALL the following criteria are met:

A. A diagnosis of obstructive sleep apnea (OSA) confirmed or proven through formal polysomnography testing, or home sleep apnea testing, and at least one of the following:

1. The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI)* is ≥ 15 events per hour with minimum of 30 events; **or**

2. The AHI or RDI is ≥ 5 and ≤ 14 events per hour with minimum of 10 events and documentation of:

a. Excessive daytime sleepiness, impaired cognition, mood disorder, or insomnia; or
b. Hypertension, ischemic heart disease, or history of stroke; **or**

3. The patient has evidence of Upper Airways Resistance Syndrome diagnosed by polysomnography (with at least 5 respiratory-related arousals per hour), with any of the comorbid conditions listed in criterion #2b above.

AND

B. There is demonstrated adherence with use, defined as usage for at least 4 hours per night for 70% of nights in a consecutive 30-day period. Adherence must be assessed via direct download or visual inspection of usage data.

III. Continued BiPAP rental or BiPAP purchase is covered following an initial minimum 7-month rental period when ALL the following criteria are met:

A. A diagnosis of OSA confirmed or proven through formal polysomnography testing and at least one of the following:

1. The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI)* is ≥ 15 events per hour with minimum of 30 events; **or**

2. The AHI or RDI is ≥ 5 and ≤ 14 events per hour with minimum of 10 events and documentation of:

a. Excessive daytime sleepiness, impaired cognition, mood disorder, or insomnia; or
b. Hypertension, ischemic heart disease, or history of stroke.

AND

B. There is demonstrated adherence with use, defined as usage for at least 4 hours per night for 70% of nights in a consecutive 30-day period. Adherence must be assessed via direct download or visual inspection of usage data.

AND

C. CPAP (HCPCS code E0601) has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or a home setting. For CPAP to be considered ineffective, the treating physician must document that the following items were addressed prior to changing from CPAP to BiPAP:

1. **Interface fit and comfort**: an appropriate interface has been properly fit, and the member is using it without difficulty.

2. **CPAP pressure settings**: if pressure settings prevent the member from tolerating the therapy, and the lower pressure settings of the CPAP device were tried but failed due to:

    a. Inadequate control of the symptoms of OSA; or
    b. Lack of improvement in sleep quality; or
    c. Lack of reduction of AHI/RDI to acceptable levels.

IV. Continued ASV rental or ASV purchase is covered following an initial minimum 3-month rental period when BOTH of the following criteria (A and B) are met:

A. A diagnosis of central sleep apnea or complex sleep apnea/treatment-emergent sleep apnea has been confirmed or proven through polysomnography testing.

1. For central sleep apnea to be confirmed, polysomnography test results must show all the following:
    a. An AHI ≥ 5; and
    b. Sum central apnea plus central hypopnea > 50% of the total apneas and hypopneas; and
    c. Central apnea-central hypopnea index (CAHI**) ≥ 5 per hour; and
    d. Presence of either sleepiness, difficulty initiating or maintaining sleep, frequent awakening, or non-restorative sleep, awakening short of breath, snoring, or witnessed apneas; and
    e. No evidence of daytime or nocturnal hypoventilation.

OR

2. For complex sleep apnea/treatment-emergent sleep apnea to be confirmed, polysomnography test results must show all the following:

    a. Diagnostic polysomnography during use of continuous positive airway shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with both of the following:

        i. Five or more central respiratory events (central apneas or central hypopneas) per hour of sleep; and

        ii. The total number of central apneas plus central hypopneas is > 50% of the total number of apneas and hypopneas.

AND

B. There is demonstrated adherence with use, defined as usage for at least 4 hours per night for 70% of nights in a consecutive 30-day period. Adherence must be assessed via direct download or visual inspection of usage data.

**CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
Polysomnography Testing
Polysomnography (PSG) includes sleep staging, which requires items 1 through 3 below. Polysomnography is defined to minimally include, but is not limited to, the following:

1. A 1 to 4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp
2. Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye
3. A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions
4. Rhythm electrocardiogram (ECG)
5. Nasal and/or oral airflow via both thermistor and nasal pressure sensor
6. Respiratory effort by chest-wall and abdominal movement measured using respiratory inductive plethysmography, endoesophageal pressure or by intercostal EMG
7. Gas exchange (oxygen saturation [SpO2]) by oximetry or transcutaneous monitoring
8. Bilateral anterior tibialis muscle activity, motor activity-movement using EMG
9. Body positions by directly applied sensors or by direct observation

1) **Type I PSG** is used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
   - The most comprehensive is designated Type I attended facility-based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test where a technologist supervises during sleep time and has the ability to intervene, if needed. The following tests are included: electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO2).
   - Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over two nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

2) **Type II sleep testing devices** are used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
   - Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO2), this type of device monitors sleep staging, so AHI can be calculated.

3) **Type III sleep testing devices** are used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
   - Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation.

4) **Type IV sleep testing devices** measuring three or more channels, one of which is airflow, are used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
    - Type IV devices may measure one, two, three, or more parameters but do not meet all the criteria of a higher category device.
    - Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

5) **Split-Night Studies**
    a) For Continuous Positive Airway Pressure (CPAP) titration, a split-night study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night) is an alternative to one full night of diagnostic polysomnography, followed by a second night of titration for the treatment of obstructive sleep apnea (OSA):
        - Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

    b) A positive test for OSA is established using either the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI):

        - AHI or RDI greater than or equal to 15 events per hour with a minimum of 30 events;

        OR

        - AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
            - The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.
            - If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a 2-hour period.
        - CPAP titration is carried out for more than three hours;

        AND

        - Polysomnography documents that CPAP eliminates, or nearly eliminates, the respiratory events during REM and NREM sleep.

6) **Home Sleep Testing**
    - The physician services related to home sleep testing (G0398, G0399 and G0400) are for the purposes of testing a patient for the diagnosis of obstructive sleep apnea if the home sleep testing is reasonable and necessary for the diagnosis of the patient's condition and the physician who performs the service has sufficient training and experience to reliably perform the service.
    - A home sleep test is performed in conjunction with a comprehensive sleep evaluation and in patients with a high pretest probability of moderate-to-severe obstructive sleep apnea.
    - Home sleep testing is not intended for persons with comorbidities (moderate-to-severe pulmonary disease, neuromuscular disease, or congestive heart failure).

- Home Sleep studies are intended for the diagnosis of Obstructive Sleep Apnea. They are not intended for any other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy), or for screening asymptomatic persons.
- The sleep facility credentials are from the American Academy of Sleep Medicine (AASM), inpatient or outpatient;

Physician and Technician Qualifications for Sleep Studies and Polysomnography Testing

1) The physician performing the service meets one of the following:

a) be a diplomate of the American Board of Sleep Medicine (ABSM) or

b) have sleep credentials issued by **ONE** of the following:

- American Board of Internal Medicine (ABIM)
- American Board of Family Medicine (ABFM)
- American Board of Pediatrics (ABP)
- American Board of Psychiatry and Neurology (ABPN)
- American Board of Otolaryngology – Head and Neck Surgery (ABOHNS)
- American Osteopathic Board of Neurology and Psychiatry (AOBNP)
- American Osteopathic Board of Family Medicine, (AOBFP)
- American Osteopathic Board of Internal Medicine, (AOBIM)
- American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO)
- American Board of Anesthesia (ABA) [*ABA certification not recognized by CMS*]

AND

c) Be an active physician staff member of a credentialed sleep center or laboratory that have active physician staff members meeting the criteria above in **a or b.**

2) The technician performing the service meets one of the following:

- American Board of Sleep Medicine (ABSM),
- Registered Sleep Technologist (RST),
- Board of Registered Polysomnographic Technologists (BRPT),
- Registered Polysomnographic Technologist (RPSGT),
- National Board for Respiratory Care (NBRC),
- Certified Pulmonary Function Technologist (CPFT),
- Registered Pulmonary Function Technologist (RPFT),
- Certified Respiratory Therapist (CRT),
- Registered Respiratory Therapist (RRT);

Sleep Center or Laboratory Credentials (any place of service other than patient's home where sleep studies or recordings are performed).

The sleep facility is credentialed by one of the following:

1) the American Academy of Sleep Medicine (AASM), inpatient or outpatient; **OR**
2) The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sleep specific credentials for Ambulatory care sleep centers; **OR**
3) Accreditation Commission for Health Care (ACHC)
   - All centers billing sleep studies maintain proper certification documentation as defined above.
   - The sleep clinic is affiliated with a hospital or be under the direction and control of a physician (MD/DO), even though the diagnostic test may be performed in the absence of direct physician supervision. This information is documented and available upon request.
   -

Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be rendered in a hospital outpatient setting or in a freestanding facility, and meet the guidelines for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct supervision of a physician (CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70, D. Coverage of Therapeutic Services)

Sleep Disorder Evaluation and Treatment, continued

Billing/Coding Information

CPT CODES

94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

HCPCS CODES

E0601	Continuous positive airway pressure (CPAP) device
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

Accessories

A4604	Tubing with integrated heating element for use with positive airway pressure device

Sleep Disorder Evaluation and Treatment, continued

A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
A7030	Full face mask used with positive airway pressure device, each
A7031	Face mask interface, replacement for full face mask, each
A7032	Cushion for use on nasal mask interface, replacement only, each
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, nondisposable, used with positive airway pressure device
A7044	Oral interface used with positive airway pressure device, each
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each
A7047	Oral interface used with respiratory suction pump, each
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device

Key References

1. American Academy of Sleep Medicine. The Path to Sleep Medicine. Available at: https://aasm.org/professional-development/choose-sleep/the-path-to-sleep-medicine/
2. American Board of Internal Medicine. Sleep Medicine Policies. Available at: https://www.abim.org/certification/policies/internal-medicine-subspecialty-policies/sleep-medicine.aspx
3. CMS National Coverage Determination (NCD): Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)
4. CMS Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)
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9. UpToDate. (2018). Retrieved from https://www.uptodate.com/contents/central-sleep-apnea-treatment?search=asv&source=search_result&selectedTitle=2~15&usage_type=default&display_rank=2
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Revision History

Revision Date	Summary of Changes
1/5/24	For Commercial Plan Policy, added criterion #3 to section II as an additional qualifying factor: "The

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	patient has evidence of Upper Airways Resistance Syndrome diagnosed by polysomnography (with at least 5 respiratory-related arousals per hour), with any of the comorbid conditions listed in criterion #2b above."
5/7/24	For Commercial Plan Policy, changed minimum age requirement to qualify for a home sleep study in Section I, Criterion #A from 18 years to 15 years.
8/23/24	For Commercial Plan Policy, in Section I, Criterion #D; added sleep certified anesthesiologists (ABA certified) to also be considered as eligible physicians evaluating these studies.
1/2/25	For Commercial Plan Policy, modified wording of "CompSA" to clarify this is "complex sleep apnea" in section IV of criteria.
1/29/25	For Commercial Plan Policy, updated requirements pertaining to complex sleep apnea/treatment-emergent sleep apnea in criteria section IV: "For complex sleep apnea/treatment-emergent sleep apnea to be confirmed, polysomnography test results must show all the following: a. Diagnostic polysomnography during use of continuous positive airway shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with both of the following: i. Five or more central respiratory events (central apneas or central hypopneas) per hour of sleep; and ii. The total number of central apneas plus central hypopneas is > 50% of the total number of apneas and hypopneas."
7/3/25	For Commercial Plan Policy, clarified requirements in criterion #I-D: "D. The physician performing the test is a diplomate of the American Board of Sleep Medicine (ABSM) or is sleep medicine certified through one of the following: - American Board of Internal Medicine (ABIM) - American Board of Family Medicine (ABFM) - American Board of Pediatrics (ABP) - American Board of Psychiatry and Neurology (ABPN) - American Board of Otolaryngology – Head and Neck Surgery (ABOHNS) - American Osteopathic Board of Neurology and Psychiatry (AOBNP) - American Osteopathic Board of Family Medicine, (AOBFP) - American Osteopathic Board of Internal Medicine, (AOBIM) - American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO) - American Board of Anesthesia (ABA) [ABA certification not recognized by CMS]"

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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MEDICAL POLICY

SLEEP STUDIES: PEDIATRIC

Policy # 177

Implementation Date:5/7/01

Review Dates: 4/2/01, 3/29/02, 8/27/03, 8/26/04, 10/18/07, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 8/15/24

Revision Dates: 8/4/06, 10/31/06

Description

Obstructive sleep apnea syndrome (OSAS) in children is a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns. It has been estimated that approximately 7%–9% of children snore regularly with an estimated prevalence of OSAS at 0.7% in 4–5-year-old children. Clinical manifestations of OSAS in children include chronic mouth breathing, snoring, and restlessness during sleep, with or without frequent awakenings. Loud snoring that disturbs and concerns parents is a common indication for evaluation, though, testing in this setting must be compared with how it will alter the outcome. Clinical experience, however, suggests that some infants may have significant sleep apnea yet have little or no snoring. Less frequently, daytime hypersomnolence, failure to thrive, and cor pulmonale may be seen. The frequency of behavioral, personality, and learning problems with OSAS is unknown. Clinical experience suggests that the pathophysiology, clinical manifestations, diagnosis, and management of children with suspected obstructive sleep apnea is different from that of adults.

Full night polysomnography consists of 5–8 hours of monitoring, supervised by a sleep technician, while the patient sleeps. It is performed in a sleep lab and involves the following monitoring modalities: electroencephalogram (EEG) (to stage sleep and detect arousals), electro-oculogram (EOG) (to detect arousal and REM sleep) submental electromyogram, (EMG), electrocardiogram (EKG), 2 leg EMG, respiratory airflow and effort (to detect apnea), snoring, oxygen saturation, time, and position. In addition, a full night PSG may include additional monitoring modalities as indicated, such as esophageal pressure monitoring and blood pressure monitoring.

The first 3 elements listed above (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a "sleep study" does not include sleep staging. The actual components of the study will be dictated by the clinical situation. Typically, the evaluation of obstructive sleep apnea would include respiratory airflow and effort, electro-oculogram, and oxygen desaturation. An EEG may not be considered necessary to evaluate OSA, although it is required to evaluate UARS.

Split-night polysomnography utilizes the first 2 or 3 hours for evaluating the presence of sleep apnea and the second half to titrate and adjust CPAP. The same monitoring modalities used in full night PSG are used in split night study. In patients with severe obstructive sleep apnea, a reliable assessment of the respiratory disturbance index is possible with a partial night study. Half-night study for CPAP titration is reliable in selected cases of obstructive sleep apnea.

Split-night studies are appropriate in patients with severe sleep apnea syndrome. The decision to conduct a split-night study depends on the technical skill and experience of the staff, the initial sleep latency period, the severity and frequency of respiratory events, and patient compliance. Careful patient selection and education is required to conduct a successful split-night study.

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COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers polysomnography in children for any of the following conditions, if the study will alter the patient's treatment plan:

1. Obstructive sleep apnea syndrome
   a. To differentiate benign/primary snoring from pathologic snoring
   b. For the evaluation of the child with disturbed sleep patterns, excessive daytime sleepiness, cor pulmonale, failure to thrive or polycythemia unexplained by other factors or conditions
   c. As intensive postoperative monitoring in a child following adenotonsillectomy or other pharyngeal surgery with any of the following risk factors:
      1) > 10 obstructive events per hour of sleep
      2) SaO_2 < 70%
      3) Underlying neuromuscular disease
      4) Underlying craniofacial abnormalities especially if problem is mid-face hypoplasia or retro- or micrognathia
   d. Presence of laryngomalacia and associated failure to thrive or cor pulmonale
   e. Children with sickle cell disease and frequent veno-occlusive disease during sleep
   f. Persistent snoring or other symptoms of sleep disordered breathing >4 weeks postoperatively in patient previously diagnosed with OSAS
   g. For titration of CPAP/BiPAP therapy in patient diagnosed with OSAS who has previously undergone a diagnostic PSG
2. Bronchopulmonary dysplasia
   a. In patients with bronchopulmonary dysplasia PSG is allowed under the following circumstances:
      1) To detect upper airway obstruction when bradycardia is not without apnea
      2) If upper airway obstruction is suspected based on presence observation of snoring
3. Cystic fibrosis
      1) Patients with cystic fibrosis on supplemental oxygen and positive nocturnal oximetry who develop polycythemia, or cor pulmonale
      2) Patients with cystic fibrosis and hypercapnea while awake
4. Neuromuscular disease

   Children with a chronic neuromuscular impairment including muscular dystrophy, myotonic dystrophy, spinal muscle dystrophy, cerebral palsy, poliomyelitis, and congenital muscle diseases
5. Alveolar hypoventilation

   Children with alveolar hypoventilation syndrome as evidenced by measurements of CO_2 showing the patient to be hypercapneic and with associated hypoxia

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

In their practice guideline on diagnosing childhood obstructive sleep apnea syndrome, the American Academy of Pediatrics recommended a thorough diagnostic evaluation to include polysomnography. Polysomnography is the only method that quantifies ventilatory and sleep abnormalities and is recommended as the diagnostic test of choice. Other diagnostic techniques, such as videotaping, nocturnal pulse oximetry, and daytime nap studies, may be useful in discriminating between primary snoring and OSAS if results of polysomnography are positive. However, they do not assess the severity of OSAS, which is useful for determining treatment and follow-up. In any case, because of their high rate of false-negative results, polysomnography should be performed in the event of negative results of the other diagnostic techniques; additional study of audio taping is necessary.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95822	Electroencephalogram (EEG); recording in coma or sleep only

HCPCS CODES

No specific codes identified

Key References

1. "Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome." Pediatrics 109.4 (2002): 704-12.

Disclaimer

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Sleep Studies: Pediatric, continued

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