Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP201

Section: Medical Benefit Policy

Subject: Obstructive Sleep Apnea

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Obstructive Sleep Apnea

II. Purpose/Objective:

To provide a policy of coverage regarding Obstructive Sleep Apnea

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

Apnea: Cessation of airflow at the nostrils and mouth lasting at least ten seconds. There are three types of apnea: obstructive, central and mixed. Obstructive apnea is secondary to an upper airway obstruction; central apnea is associated with a cessation of all respiratory movements; mixed apnea has both central and obstructive components.
Hypopnea: An abnormal respiratory event lasting at least ten seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.
Apnea Hypopnea Index (AHI): The number of apneas plus hypopneas (obstructive, central or mixed) per hour of sleeps; also referred to as the respiratory disturbance index (per AASM Practice Parameters).
Interface: Interface includes all items that allow the passage of positive pressure between the CPAP machine and an airway.
Respiratory-Disturbance Index (RDI): The number of apneas plus hypopneas (obstructive, central or mixed) per hour of sleep; also referred to as the apnea-hypopnea index.
Continuous Positive Airway Pressure Devices (CPAP) a non-invasive provision of air pressure through an interface and flow generator system to prevent collapse of the oropharyngeal walls during sleep.
Auto-or Self-titrating Positive Airway System (APAP) utilizes an algorithm that uses a pressure transducer and micropressure to monitor the airway for vibration pattern and then makes air pressure adjustments based on the incidence of apnea/absence of vibration.

Obstructive Sleep Apnea Syndrome (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The sequence of events leading to airway obstruction is as follows:

1. Decreased upper airway muscle activity with sleep-onset leads to pharyngeal narrowing;
2. Increased negative intraluminal pressures result, producing further pharyngeal narrowing;
3. Ineffective activation of upper airway muscles relative to the respiratory pump muscles fails to counteract the negative intraluminal pressure; AND
4. Pharyngeal closure results.

The Plan considers the diagnosis and treatment of obstructive airway disease medically necessary according to the criteria below:

Diagnosis

For information related to the diagnosis and management of sleep-related disorders, please see **MP 217 Polysomnography and Sleep Studies** for coverage criteria

Treatment

Treatment of snoring in the absence of documented obstructive sleep apnea is considered not medically necessary and is NOT COVERED.

A. *Positive Airway Pressure (PAP) Systems and for the Treatment of OSA*

Coverage for these items is subject to the terms, conditions and limitations of the Durable Medical Equipment benefits as outlined in the applicable benefit document.

A request for coverage requires a pre-certification through Medical Management Department or Designee. Equipment must be obtained through contracted Durable Medical Equipment vendors. Equipment or supplies provided at a sleep testing site without pre-certification may be denied with no member liability.

CPAP and/ or APAP may be considered medically necessary for the treatment of obstructive sleep apnea when the following qualifying criteria are met:

1. For ages 8 years or less, documented apnea or refractory hypoxemia**; or**
2. For ages 8 years or more, diagnosis of Obstructive Sleep Apnea *accordance with **MP 217 – Polysomnography and Sleep Studies.***

And

3. Member must satisfy Criteria a or b and one of the following criteria
   a AHI/RDI greater than 15 events per hour; **or**
   b AHI/RDI greater than 5 and less than 14 with documented symptoms of one of the following:
      (i) Symptomatic excessive daytime sleepiness (EDS) as in an elevated Epworth sleepiness scale score of 11 or more; **or**
      (ii) Documented evidence of impaired cognition or mood disorders or insomnia; **or**
      (iii) Documented hypertension, cor pulmonale, ischemic heart disease; **or**
      (iv) Documented evidence of non-arteritic anterior ischemic optic neuropathy (NAION); **or**
      (v) Body mass index of 35 or greater; **or**
      (vi) History of stroke

CPAP and/ or APAP may be considered medically necessary for the treatment of Upper Airway Resistance Syndrome (UARS) without significant oxygenation desaturation, apneas, or hypopneas but with fragmented sleep leading to excessiveness day-time sleepiness.

* **For the Medicare and Medicaid Business Segments Only** - Additional coverage may be available through the applicable CMS mandates and/or the Coverage with Evidence Development (CED) when enrolled in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial.

Bi-level Positive Airway pressure devices may be considered medically necessary when a standard CPAP is not tolerated or when nocturnal oxygen saturation is not raised sufficiently with standard CPAP.

The Plan covers bi-level positive airway pressure (BiPAP) as medically necessary for the treatment of OSA with coexisting central hypoventilation or for those who require, but prove intolerant to, high pressures of CPAP, C-Flex or APAP.

AUTHORIZATION DETERMINATION CPAP, APAP and Bi-PAP equipment will be initially rented for a three - month time period. By the end of the first three months, the computerized, smartcard technology will be downloaded to assess if continued compliance criteria was met. Non-compliance will result in medical director review to determine medical necessity. Extenuating circumstances that affect compliance will be taken into consideration.

For continued coverage:
Compliance with the returning of the Smartcard technology and with the use of the CPAP, APAP or Bi-PAP unit is required in order to receive continued coverage. Noncompliance is defined as use of the CPAP equipment less than the required minimum of 4 hours per 24 hour period at least 70% of the time as recorded on the Smartcard download.

B. *Oral appliances*

Mandibular advancement appliances and/or tongue-retaining devices are considered to be medically necessary for members who have a sleep study documenting one of the following:

a AHI/RDI greater than 15 events per hour; or
b AHI/RDI greater than 5 and less than 14 with documented symptoms of one of the following:
   (i) Symptomatic excessive daytime sleepiness (EDS) as in an elevated Epworth sleepiness scale score of 11 or more; or
   (ii) Documented evidence of impaired cognition or mood disorders or insomnia; or
   (iii) Documented hypertension, cor pulmonale, ischemic heart disease; or
   (iv) Documented evidence of non-arteritic anterior ischemic optic neuropathy (NAION); or
   (v) Body mass index of 35 or greater; or
   (vi) History of stroke

c AHI/RDI greater than 30 and:
   (i) the member cannot tolerate a positive pressure device; or
   (ii) a positive pressure device is medically contraindicated

C. *Surgical Management for the Treatment of OSA*

1. **Uvulopalatophayrngoplasty (UPP) and Laser-assisted Uvulopalatoplasty (LAUP)** procedures may be considered *m*edically *necessary* for the treatment of clinically significant sleep apnea (OSA) or upper airway resistance syndrome (UARS) when they met the following criteria:
   a. A full polysomnogram performed in a sleep disorders laboratory that rules out non-obstructive causes of sleep apnea; **and**
   b. CPAP is not tolerated or when nocturnal oxygen saturation is not raised sufficiently with standard CPAP; **and**
   c. A pre-surgical physical evaluation which confirms the site of obstruction as being the oropharynx [palate] and/or hypopharynx [base of tongue]

   *Tonsillectomy and/or adenoidectomy procedures may be performed in conjunction with and in addition to LAUP, at the time of surgery.

D. Hypoglossal Nerve Stimulation - Unilateral (eg, Inspire) and Bilateral(eg, Genio)

Unilateral hypoglossal nerve stimulation using an FDA-approved device is considered medically necessary for the treatment of obstructive sleep apnea when ALL of the following criteria are met:

~~1.~~ The member is 22 years of age or older; **OR**
2. The member is between 18 and 22 years of age and one of the following is met:
   a. Member has had an adenotonsillectomy; or
   b. An adenotonsillectomy is contraindicated for the member.

   and
2. Body mass index (BMI) is less than 35 kg/m^2; **and**
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and
4. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
5. AHI is 15 to 65 events per hour; **and**
6. Member has documentation that 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 the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert: **and**
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

Hypoglossal nerve stimulation is considered medically necessary for the treatment of obstructive sleep apnea in adolescents and young adults with Down syndrome when **ALL** of the following criteria are met:

- The member has a diagnosis of Down syndrome; and
- The member is 10 through 21 years of age; and
- Body mass index (BMI) less than or equal to 95th percentile for age; and
- Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and
- Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
  - AHI 5 or greater for ages 10 through 17; OR
  - AHI is 15 to 65 events per hour age 18 through 21
  - and
- Member has documentation that demonstrates CPAP failure defined as at least one of the following:
  - Noncompliance; OR
  - Undesirable side effects; OR
  - Persistent symptoms despite compliant use; OR
  - A documented unwillingness or refusal to use CPAP therapy

EXCLUSIONS:

The **Plan** does not provide coverage for ANY of the following procedures or services for the treatment of OSA because they are considered **experimental, investigational or unproven**: (This list may not be all inclusive):

- Radiofrequency Volumetric Tissue Reduction (Somnoplasty™) ***(See Also MP40 – Somnoplasty/Coblation)***

- Coblation ***(See Also MP40 – Somnoplasty/Coblation)***
- Cautery-assisted Palatal Stiffening Operation (CAPSO)
- Pillar ™ Palatal Implant System
- Repose Bone Screw System
- AIRvance Tongue Suspension Advance System (adjustable tongue advancement device)
- Winx therapy system/oral pressure therapy
- NMES tongue muscle (eXciteOSA)
- Injection Snoreplasty™
- Flexible Positive Airway Pressure
- Intranasal expiratory resistance valve
- Electronic positional OSA treatment devices

The Plan **does NOT provide coverage** for the use of NMES to the tongue base as a treatment for obstructive sleep apnea because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The use of oral appliances for the treatment of socially disruptive snoring in the absence of documented OSA is considered to be not medically necessary, and **NOT COVERED.**

The use of oral appliances for the treatment of upper airway resistance syndrome is considered to be experimental, investigational or unproven, and **NOT COVERED.**

The use of implantable neurostimulation (aka Phrenic Nerve Stimulation) devices for the treatment of Central Sleep Apnea (CSA) is considered to be unproven and **NOT COVERED**. There is insufficient evidence of safety and/or efficacy in the published peer-reviewed medical literature.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Associated Coding: Obstructive Sleep Apnea

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

Covered Services:

30999 Unlisted procedure, nose
41512 Tongue base suspension, permanent suture technique
41530 Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session
42145 Palatopharyngoplasty (eg. Uvulopalatopharyngoplasty, uvulopharyngoplasty)
42160 Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42890 Limited pharyngectomy
42299 Unlisted procedure, palate, uvula
42999 Unlisted procedure, pharynx, adenoids or tonsils
64582 Hypoglossal nerve neurostimulator implantation; open
64583 Hypoglossal nerve neurostimulator revision or replacement
64584 Hypoglossal nerve neurostimulator removal
64568 Open implantation of cranial nerve (eg, vagal or hypoglossal) neurostimulator electrode array and pulse generator *{Inspire V single lead HNS}*
64582 Open implantation of hypoglossal neurostimulator array, pulse generator, and distal respiratory sensor electrode array *{Inspire IV HNS}*
94660 Continuous positive airway pressure ventilation (CPAP), initiation and management

95803 Actigraphy testing, recording, analysis, interpretation and report (minimum of 72 hours to 14 consecutive days of recording)
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, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist
95807 Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808 Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810 Sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811 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
A7027 Combination oral/nasal mask, used with CPAP
A7030 Full face mask used with positive airway pressure device, each
A7031 Full face mask interface, replacement for full face mask, each
A7032 Replacement cushion for nasal application device, each
A7033 Replacement pillows for nasal application device, 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
A7039 Filter, non-disposable, used with positive airway pressure device
A7044 Oral interface used with positive airway pressure device, each
A7049 Expiratory positive airway pressure intranasal resistance valve
C9727 Insertion of palate implants
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 backup 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)
E0485 Oral Device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment.
E0486 Oral Device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment.
E0490 Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491 Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0561 Humidifier, non-heated, used with positive airway pressure device
E0562 Humidifier, heated, used with positive airway pressure device
E0601 CPAP continuous airway pressure device
K1001 Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
K1027 Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
K1028 Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029 Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
S2080 Laser-assisted uvulopalatoplasty (LAUP)

0424T Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)
0425T Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only
0426T Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead

only
0427T Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only
0428T Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only
0429T Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only
0430T Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only
0431T Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only
0434T Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea
0435T Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
0436T Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study
0466T Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
0467T Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
0468T Removal of chest wall respiratory sensor electrode or electrode array
C9727 Insertion of implants into the soft palate; minimum of three implants

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

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Revised: 7/08, 8/09(added add'l CPAP indication), 10/10, 10/11 (added indication); 6/16 (added exclusion); 5/17 (revised criteria for oral appliance), 11/19 (revised criteria); 2/1/02 (update Medicare coverage of HNS); 2/21 (add criteria for HNS); 2/22 (add exclusions), 2/23 (add exclusion language), 2/24 (expand HNS criteria)

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Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.