

Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Nonsurgical Treatments



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Noninvasive Home Ventilators

Orthognathic Surgery

Related Documents

Please refer to [CMS website](#) for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories
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Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Nonsurgical Treatments

			Contractors (MACs)	
Internet-Only Manuals (IOMs)	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15	§110 Durable Medical Equipment – General		
NCD	Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)	240.4		
LCA	Billing and Coding: Oral Maxillofacial Prosthesis	A53497	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCA	Billing and Coding: Independent Diagnostic Testing Facilities (IDTF)	A58559	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Oral Appliances for Obstructive Sleep Apnea Standard Documentation Requirements for All Claims Submitted to DME MACs	L33611 A52512 A55426	DME A - Noridian Healthcare Solutions, LLC (DME MAC) DME B - CGS Administrators, LLC (DME MAC) DME C - CGS Administrators, LLC (DME MAC) DME D - Noridian Healthcare Solutions, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT IL, IN, KY, MI, MN, OH, WI AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea	L33718 A52467	DME A - Noridian Healthcare	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT

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	Standard Documentation Requirements for All Claims Submitted to DME MACs	A55426	<p>Solutions, LLC (DME MAC)</p> <p>DME B - CGS Administrators, LLC (DME MAC)</p> <p>DME C - CGS Administrators, LLC (DME MAC)</p> <p>DME D - Noridian Healthcare Solutions, LLC (DME MAC)</p>	<p>IL, IN, KY, MI, MN, OH, WI</p> <p>AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI</p> <p>AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands</p>
LCD LCA	<p>Respiratory Assist Devices</p> <p>Standard Documentation Requirements for All Claims Submitted to DME MACs</p>	<p>L33800</p> <p>A52517</p> <p>A55426</p>	<p>DME A - Noridian Healthcare Solutions, LLC (DME MAC)</p> <p>DME B - CGS Administrators, LLC (DME MAC)</p> <p>DME C - CGS Administrators, LLC (DME MAC)</p> <p>DME D - Noridian Healthcare Solutions, LLC (DME MAC)</p>	<p>CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT</p> <p>IL, IN, KY, MI, MN, OH, WI</p> <p>AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI</p> <p>AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands</p>

Description

Obstructive sleep apnea (OSA) is a common sleep disorder in which the muscles of the soft palate and throat intermittently relax during sleep, creating an obstruction that blocks the upper airway. This causes breathing to become difficult and noisy (snoring). Individuals with OSA experience cessation of breathing from 10 to 60 seconds at a time, which can occur up to 120 times an hour during sleep. As a result, oxygen levels in the bloodstream decrease, which may lead to high blood pressure, stroke, heart attack and/or abnormal heart rhythms.

Central sleep apnea (CSA) is a disorder characterized by repetitive cessation or decrease of both airflow and ventilatory effort during sleep. It can be primary (eg, idiopathic CSA) or secondary. Examples of secondary CSA include CSA associated with Cheyne-Stokes breathing, a medical condition, a drug or substance or high-altitude periodic breathing. CSA associated with Cheyne-Stokes breathing is particularly common, especially among individuals who have heart failure or have had a stroke.

Depending on which type of sleep study is conducted (facility-based polysomnogram [PSG] or home sleep apnea test [HSAT]), there will be different measurements provided to aid in the diagnosis of OSA, CSA or other sleep related breathing disorders as well as to gauge the severity. Those measurements may include apnea-hypopnea index (AHI), respiratory disturbance index (RDI) and respiratory event index (REI).

Nonsurgical treatments for OSA and other sleep related breathing disorders include, but may not be limited to, the following:

Positive Airway Pressure (PAP) Therapy

There are a number of variations for the devices used to deliver PAP. All devices work similarly by utilizing an air compressor, which forces a flow of air through the nose and into the airway, by way of a light mask worn over the nose during sleep. This prevents collapse of the oropharyngeal passage, which can cause an obstruction of airflow during sleep. Therefore, the goals of PAP therapy are to allow for unobstructed breathing and to improve sleep quality and/or duration.

The original and most utilized treatment is **continuous positive airway pressure (CPAP)**. A CPAP device provides the air flow at a constant, preset pressure; however, the settings can be manually changed by a health care professional.

A **bilevel positive airway pressure (BiPAP)** device blows air at a higher pressure for inhaling and a lower pressure for exhaling. This can be used for individuals who cannot tolerate the high constant pressure with CPAP. The settings, like with CPAP, can be manually titrated.

An **auto-titrating continuous positive airway pressure (AutoPAP or APAP)** device continuously modifies the positive pressure level during the night, allowing for a decrease in pressure when spells of apnea and hypopneas disappear and an increase in pressure level when they return. APAP can be used to determine an optimal fixed level of CPAP for long term treatment with conventional CPAP.

Claustrophobia, discomfort or other issues may contribute to poor PAP therapy adherence. Pressure relief technology (A-Flex, Bi-Flex, C-Flex and C-Flex +) has been developed for APAP/BiPAP/CPAP devices and

provides pressure relief at critical points in the breathing cycle. This technology has become widely used in PAP devices and is purported to increase comfort and compliance with therapy. Some devices have smartcards which can be used to view or verify compliance data of an individual to evaluate the treatment's overall effectiveness.

A **demand positive airway pressure (DPAP)** device responds to the individual's changing oxygen demands based on an analysis of each individual breath. It may be used after a trial of CPAP or BiPAP has been ineffective.

A **variable positive airway pressure device (VPAP)** allows bilevel PAP with higher pressure for inhaling and a lower pressure for exhaling, but differs from a regular BiPAP by synchronizing the timing of inspiration and expiration with the individual's breathing. The amount of pressure does not vary. This may be used for individuals who cannot tolerate the constant pressure of CPAP or who have other sleep related respiratory disorders such as CSA or nocturnal hypoxemia related to severe chronic obstructive pulmonary disease (COPD).

The Somnera System, approved by the US Food & Drug Administration (FDA) as a potential alternative to CPAP, uses a proprietary SmartValve which purportedly generates pressure, not airflow. The airbox regulates the back pressure level providing air and back pressure to the individual's airway in the event of incipient apnea or hypopnea. With hopes of facilitating greater compliance than standard PAP devices, there are some unique features including no humidification, quieter sound while operating, smaller diameter of tubing (9 mm compared to traditional CPAP devices which typically measure 22 mm), various personalization settings and a virtual support program.

Regular PAP maintenance and cleaning are important, however currently no home, over-the-counter CPAP cleaning devices that use ozone gas or UV light have been approved by the FDA. The FDA has not determined whether CPAP cleaning devices are safe, nor does it have evidence whether CPAP cleaning devices are effective to clean or disinfect CPAP equipment of germs or allergens. SoClean is an example of this type of device.

Oral Appliance Therapy

Oral appliances (splints), sometimes called dental appliances, may be a treatment option for mild to moderate OSA and are intended to maintain an open airway. There are two major types of oral appliances: mandibular advancement splints (MAS) and tongue retaining devices. MAS, also referred to as mandibular repositioning appliances or mandibular advancement devices (MAD), push the lower jaw forward and are the most commonly used oral appliance. Tongue retaining devices prevent the tongue from falling back over the airway. Many oral appliances are custom-made, offering individuals the best fit and treatment outcomes.

New technology is being introduced for 3D printing of oral appliances. Examples of these devices include, but may not be limited to, Respire Clear and Slow Wave DS8. At this time, there is no evidence that demonstrates these are equivalent to traditional, custom-made appliances.

Oral surgical splints are typically fabricated and used to offer perioperative and/or postoperative support to ensure satisfactory surgical outcomes during orthognathic surgery.

Some oral appliances have been developed for the treatment of snoring alone. An example of one of these devices is the Snore Guard which resembles an athletic mouthpiece. Suggested as a treatment for snoring, it uses normal body reflexes to maintain an open airway. The device fits snugly on the upper teeth. When the lower jaw closes, the lower teeth close onto the lower ramp of the Snore Guard. This keeps the jaw in a normal position, rather than sagging open and back. In addition, the tongue reflexively seeks the small center orifice between the upper and lower ramp. This reflex keeps it from sagging back into the throat. Another example of such a product is the ZYPAH Anti-Snoring Mouthpiece.

Other Nonsurgical Treatment Devices

Daytime oral alignment devices have been introduced to allegedly help an individual perform isometric exercises to return the mandible back to its pretreatment position or help maintain proper mouth alignment after using an overnight sleep apnea device. Some of these devices may require custom fitting and/or other tests may be ordered (eg, laryngeal function studies) to ensure the proper fit. Examples include, but may not be limited to, the SomMorning Repositioner and AM Aligner.

Expiratory positive airway pressure (EPAP) is suggested as a treatment for OSA that utilizes the individual's own breathing to create PAP to prevent obstructed breathing. Bongo Rx, Optipillows EPAP Mask and ULTepap are examples of removable appliances that are placed just inside the nostril and increase pressure inside the nose during exhalation to maintain an open airway during sleep. These appliances may also be referred to as nasal dilators or nasal valve devices.

Nonsurgical electric muscular stimulation via the eXciteOSA device, a daytime option for the treatment of mild OSA, delivers electrical stimulation through a mouthpiece that sits around the tongue. The mouthpiece has four electrodes, two located above the tongue and two located below the tongue. It is used for 20 minutes, once a day, for a period of 6 weeks and once each week thereafter. eXciteOSA purportedly works by improving tongue muscle endurance and responsiveness preventing upper airway collapse during sleep.

Oral pressure therapy (OPT) is comprised of a bedside console, a soft polymer mouthpiece and a flexible tube connecting the mouthpiece to the console. The console creates a vacuum pulling of the soft palate anteriorly and purportedly stabilizes the tongue to reduce obstruction during sleep. The iNAP One Sleep Therapy System is an example of OPT.

Positional sleep therapy devices (eg, NightBalance, Night Shift Positioner, Zzoma) have been developed for individuals who have positional obstructive sleep apnea (POSA). The goal of NightBalance and Night Shift Positioner is to purportedly detect when an individual is sleeping on their back and send a tactile vibration to a strap positioned around the chest or neck in an effort to prompt the individual to change their sleep position. Zzoma is a device that is worn on an individual's back with adjustable Velcro straps that are secured anteriorly on the upper chest. This device purportedly keeps an individual positioned on their side and prevents the individual from laying in a supine position.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **obstructive sleep apnea and other sleep related breathing disorders nonsurgical treatments**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

[Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Nonsurgical Treatments](#)

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
21085	Impression and custom preparation; oral surgical splint	
21089	Unlisted maxillofacial prosthetic procedure	
92520	Laryngeal function studies (ie, aerodynamic testing and acoustic testing)	
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management	
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments

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A4604	Tubing with integrated heating element for use with positive airway pressure device	
A7002	Tubing, used with suction pump, each	
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	
A7049	Expiratory positive airway pressure intranasal resistance valve	
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	
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)	

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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 nonadjustable, prefabricated, includes fitting and adjustment	
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment	
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application	
E0493	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	
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type	
E0561	Humidifier, nonheated, used with positive airway pressure device	
E0562	Humidifier, heated, used with positive airway pressure device	
E0600	Respiratory suction pump, home model, portable or stationary, electric	
E0601	Continuous positive airway pressure (CPAP) device	
E1399	Durable medical equipment, miscellaneous	
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	

References

1. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and coding: independent diagnostic testing facilities (IDTF) (A58559). <https://www.cms.gov>. Published April 1, 2021. Updated October 1, 2023. Accessed November 8, 2023.
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3. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Standard documentation requirements for all claims submitted to DME MACs (A55426). <https://www.cms.gov>. Published January 1, 2017. Updated January 1, 2023. Accessed November 8, 2023.
4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Oral appliances for obstructive sleep apnea (L33611). <https://www.cms.gov>. Published October 1, 2015. Updated August 8, 2021. Accessed November 8, 2023.
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6. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Respiratory assist devices (L33800). <https://www.cms.gov>. Published October 1, 2015. Updated August 8, 2021. Accessed November 8, 2023.
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8. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) (240.4). <https://www.cms.gov>. Published March 13, 2008. Accessed November 8, 2023.

Change Summary

- 01/01/2024 New Policy.