

## UnitedHealthcare® Medicare Advantage Coverage Summary

## **Sleep Apnea Diagnosis and Treatment**

Policy Number: MCS087.09 Approval Date: March 1, 2024

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## **Related Medicare Advantage Policy Guideline**

Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1)

## **Coverage Guidelines**

The diagnosis and treatment of obstructive sleep apnea are covered when Medicare coverage criteria are met.

DME Face to Face Requirement: Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including respiratory assist devices). For DME Face to Face Requirement information, refer to the Coverage Summary titled <u>Durable Medical Equipment (DME)</u>, <u>Prosthetics</u>, <u>Orthotics (Non-Foot Orthotics)</u>, <u>Nutritional</u> Therapy, and Medical Supplies Grid.

#### Diagnosis of Obstructive Sleep Apnea (OSA)

Diagnosis of obstructive sleep apnea (OSA) is covered. Examples of covered diagnostic services include, but are not limited to:

#### Polysomnography and Sleep Studies

The following tests are considered reasonable and necessary:

- Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
- Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients 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 IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients 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.
- Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients 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.

Refer to the NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1).

Local Coverage Determinations exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. (Accessed March 20, 2024)

## Home Sleep Studies (HCPCS Codes G0398, G0399, and G0400 and CPT Codes 95800, 95801, and 95806)

Medicare does not have a National Coverage Determination (NCD) specifically for home sleep testing or polysomnography. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Home Sleep Studies or Polysomnography</u>.

#### Treatment of OSA

Treatment of sleep apnea include, but are not limited to:

#### Continuous Positive Airway Pressure (CPAP)

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 OSA.

The use of CPAP is covered when used in adult patients with diagnosis of under the following situations:

- The use of CPAP is covered when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period
  to identify patients diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered
  only for those patients diagnosed with OSA who benefit from CPAP during this 12-week period.
- The provider of CPAP must conduct education of the patient prior to the use of the CPAP device to ensure that the patient has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the patient 's home and willing and able to safely operate the CPAP device.
- A confirmed diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
  - o Attended polysomnography (PSG) performed in a sleep laboratory; or
  - Unattended home sleep test (HST) with a Type II home sleep monitoring device; or
  - o Unattended HST with a Type III home sleep monitoring device; or
  - Unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.
- The sleep test must have been previously ordered by the patient's treating physician and furnished under appropriate physician supervision.
- An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:
  - o AHI or RDI greater than or equal to 15 events per hour; or
  - AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms
    of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension,
    ischemic heart disease, or history of stroke.

Refer to Continuous Positive Airway Pressure (CPAP) above for the description and criteria for the initial 12-week trial period for CPAP.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected). If the AHI or RDI is calculated based on less than two 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 two-hour period.

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

### Coverage with Evidence Development (CED)

Medicare provides limited coverage for CPAP in adult patients who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a patient who is an enrolled subject in that study must address one or more of the following questions:

- In Medicare aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III and IV HST in identifying subjects with OSA who will respond to CPAP?
- In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III and IV HST, does CPAP cause clinically meaningful harm?

The study must meet the additional standards outlined in the NCD for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4).

The list of Medicare approved clinical trials is available at <a href="http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/CPAP.html">http://www.cms.gov/Medicare/Coverage-with-Evidence-Development/CPAP.html</a>.

For payment rules for NCDs requiring CED, refer to the:

- Medicare Managed Care Manual, Chapter 4, §10.7.3 Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
- NCD for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)
- Medicare Benefit Policy Manual, Chapter 15, Section 70, Sleep Disorder Clinics

Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) for all states/territories exist and compliance with these LCDs/LCAs is required where applicable. Refer to the DME MAC <u>LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)</u>.

Also refer to the DME MAC Positive Airway (PAP) Devices - Supplier Frequently Asked Questions:

- CGS Administrators at <a href="https://www.cgsmedicare.com/jc/pubs/news/2009/0909/cope10618b.html">https://www.cgsmedicare.com/jc/pubs/news/2009/0909/cope10618b.html</a>
- Noridian Healthcare Solutions at <a href="https://med.noridianmedicare.com/web/jddme/dmepos/pap">https://med.noridianmedicare.com/web/jddme/dmepos/pap</a> (Accessed March 20, 2024)

## Respiratory Assist Devices including Bilevel Positive Airway Pressure (BiPAP)

Medicare does not have a National Coverage Determination (NCD) for respiratory assist devices. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the DME MAC <u>LCD for Respiratory Assist Devices (L33800)</u>. (Accessed March 20, 2024)

## Mandibular Devices/Oral Appliances

Medicare does not have a National Coverage Determination (NCD) for mandibular devices/oral appliances for the treatment of OSA. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the DME MAC <u>LCD for Oral Appliances for Obstructive Sleep Apnea (L33611)</u>. (Accessed March 20, 2024)

#### Surgical Treatment

### Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base (CPT Code 41530)

Medicare does not have a National Coverage Determination (NCD) for radiofrequency submucosal ablation of the soft palate and/or tongue base. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Obstructive and Central Sleep Apnea Treatment.

**Note**: After checking the <u>Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed March 20, 2024)

# Implantable Hypoglossal Nerve Stimulation (HGNS) [Inspire® Upper Airway Stimulation and the aura6000™ Sleep Therapy System] (CPT Codes 64569, 64570, 64582, 64583, and 64584)

Medicare does not have a National Coverage Determination (NCD) for implantable Hypoglossal Nerve Stimulation (HGNS); also known as Inspire Upper Airway Stimulation. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Implantable Hypoglossal Nerve Stimulation (HGNS)</u>.

## Other Surgical Treatments (CPT Codes 21685, 41512, 41599, and 42145)

Medicare does not have a National Coverage Determination (NCD) for other surgical treatments of OSA. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Other Surgical Treatments of Obstructive Sleep Apnea (OSA).

For coverage guidelines for states/territories with no LCDs/LCAs, refer the UnitedHealthcare Commercial Medical Policy titled Obstructive and Central Sleep Apnea Treatment.

**Note**: After checking the Other Surgical Treatments of Obstructive Sleep Apnea (OSA) table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed March 20, 2024)

## **Supporting Information**

Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base  Accessed March 20, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L34526 (A56905)	Surgical Treatment of Obstructive Sleep Apnea (OSA)	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, MO, NE
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Other Surgical Treatments of Obstructive Sleep Apnea (OSA)  Accessed March 20, 2024					
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories	
L34526 (A56905)	L34526 Surgical Treatment of Part A and B MAC Wisconsin Physicians IA, IN, KS, MI, MO, NE				
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	Home Sleep Studies or Polysomnography  Accessed March 20, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories	
L36902 (A57049)	Polysomnography and Other Sleep Studies	Part A and B MAC	CGS Administrators, LLC	KY, OH	
L33405 (A57496)	Polysomnography and Sleep Testing	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI	
A53019	Polysomnography and Sleep Studies - Medical Policy Article	Part A and B MAC	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI	
L34040 (A57698)	Polysomnography and Other Sleep Studies	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	

Home Sleep Studies or Polysomnography  Accessed March 20, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L36861 (A57697)	Polysomnography and Other Sleep Studies	Part A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV
L35050 (A56923)	Outpatient Sleep Studies	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L36593 (A56995)	Polysomnography	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L36839 (A56903)	Polysomnography and Other Sleep Studies	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
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	Implantable Hypoglossal Nerve Stimulation (HGNS)					
	Accessed March 20, 2024					
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories		
L38307 (A57149)	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea	Part A and B MAC	CGS Administrators, LLC	KY, OH		
L38398 (A56953)	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI		
L38387 (A57092)	Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea	Part A and B MAC	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI		
L38310 (A57948)	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV		
L38312 (A57949)	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY		
L38385 (A56938)	Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX		
L38276 (A58075)	Hypoglossal Nerve Stimulation for	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV		

	Implantable Hypoglossal Nerve Stimulation (HGNS)  Accessed March 20, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories	
	Obstructive Sleep Apnea				
L38528 (A57944)	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE	
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## **Policy History/Revision Information**

Date	Summary of Changes
03/01/2024	<ul> <li>Supporting Information</li> <li>Updated lists of applicable Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) to reflect the most current information; modified reference information for:         <ul> <li>Home Sleep Studies or Polysomnography</li> <li>Implantable Hypoglossal Nerve Stimulation (HGNS)</li> </ul> </li> </ul>
	Administrative
	Archived previous policy version MCS087.08

## **Instructions for Use**

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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