

## Coverage Summary

### Sleep Apnea: Diagnosis and Treatment

<b>Policy Number:</b> S-003	<b>Products:</b> UnitedHealthcare Medicare Advantage Plans	<b>Original Approval Date:</b> 08/23/2007
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<b>Approved by:</b> UnitedHealthcare Medicare Benefit Interpretation Committee	<b>Last Review Date:</b> 10/20/2020
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**Related Medicare Advantage Policy Guidelines:**

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| <ul style="list-style-type: none"> <li>• <a href="#">Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (NCD 240.4)</a></li> <li>• <a href="#">Electrosleep Therapy (NCD 30.4)</a></li> </ul> | <ul style="list-style-type: none"> <li>• <a href="#">Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1)</a></li> <li>• <a href="#">Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a></li> </ul> |
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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.**

*There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).*

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## I. COVERAGE

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

**DME Face to Face Requirement:** Effective July 1, 2013, 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 for Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#).

**COVID-19 Public Health Emergency Waivers & Flexibilities:** In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain respiratory services. For details, see the following Coronavirus Waivers/Flexibilities:

- [CMS COVID-19 Fact Sheet](#)
- [Physicians and Other Practitioners \(PDF\)](#)

For a comprehensive list of Coronavirus Waivers & Flexibilities, refer to <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.

(Accessed October 13, 2020)

### **Guidelines/Notes:**

1. Diagnosis of obstructive sleep apnea (OSA) is covered. Examples of covered diagnostic services include, but are not limited to:
  - a. **Oximetry Testing**
    - Medicare does not have a National Coverage Determination (NCD) for oximetry testing.
    - 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 [LCD/LCA Availability Grid \(Attachment A\)](#).
    - For coverage guidelines for states/territories with no LCDs/LCAs, see the [Palmetto LCD/LCA for Respiratory Therapy and Oximetry Services \(L33446\)](#). (**IMPORTANT NOTE:** After checking the LCD/LCA Availability Grid and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the above referenced policy.)
    - **Committee approval date: September 15, 2020**
    - Accessed October 20, 2020
  - b. **Polysomnography and Sleep Studies**

Effective for claims with dates of service on and after March 3, 2009, the following tests are considered reasonable and necessary:

    - 1) 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.
    - 2) 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.
    - 3) 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.
    - 4) 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.

- See the [NCD for Sleep Testing for Obstructive Sleep Apnea \(OSA\) \(240.4.1\)](#). (Accessed September 2, 2020)
  - Local Coverage Determinations exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.
- 5) **Home Sleep Studies (HCPCS codes G0398, G0399 and G0400; 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 [LCD/LCA Availability Grid \(Attachment D\)](#).
  - **Committee approval date: September 15, 2020**
  - Accessed October 20, 2020

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

a. **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:

- 1) 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.
- 2) 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.
- 3) A confirmed diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
  - Attended polysomnography (PSG) performed in a sleep laboratory; or
  - Unattended home sleep test (HST) with a Type II home sleep monitoring device; or
  - 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
- 4) The sleep test must have been previously ordered by the patient's treating physician and furnished under appropriate physician supervision.
- 5) 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:

- 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 [Guideline 2.a.1](#) above for the description and criteria for the initial 12-week trial period for CPAP.

- 6) 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.
- 7) 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.
- 8) 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 & 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 & 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 <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/CPAP.html>. (Accessed September 2, 2020)*

*For payment rules for NCDs requiring CED, see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).*

*See the [NCD for Continuous Positive Airway Pressure CPAP Therapy For Obstructive Sleep Apnea \(OSA\) \(240.4\)](#). (Accessed September 2, 2020)*

*Also see the [Medicare Benefit Policy Manual, Chapter 15, Section 70, Sleep Disorder Clinics](#). (Accessed September 2, 2020)*

*Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) for all states/territories exist and compliance with these LCDs/LCAs is required where applicable. See the DME MAC [LCD for Positive Airway Pressure \(PAP\) Devices for the Treatment of Obstructive Sleep Apnea \(L33718\)](#). (Accessed October 20, 2020)*

*Also see the DME MAC [Positive Airway \(PAP\) Devices – Supplier Frequently Asked](#)*

*Questions:*

- CGS Administrators at <https://www.cgsmedicare.com/jc/pubs/news/2009/0909/cope10618b.html>. (Accessed October 20, 2020)
- Noridian Healthcare Solutions at <https://med.noridianmedicare.com/web/jddme/dmepos/pap>. (Accessed October 20, 2020)

b. **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 [LCD for Respiratory Assist Devices \(L33800\)](#).
- **Committee approval date: September 15, 2020**
- Accessed October 20, 2020

c. **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 [LCD for Oral Appliances for OSA \(L33611\)](#).
- **Committee approval date: September 15, 2020**
- Accessed October 20, 2020

d. **Electrosleep Therapy**

Until scientific assessment of this technique has been completed and its efficacy is established, no program payment may be made for electrosleep therapy. *see the [NCD for Electrosleep Therapy \(30.4\)](#)*. (Accessed September 2, 2020)

e. **Surgical Treatment**

1) **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 [LCD/LCA Availability Grid \(Attachment B\)](#).
- **For coverage guidelines for states/territories with no LCDs/LCAs, see the [UnitedHealthcare Commercial Medical Policy for Obstructive Sleep Apnea Treatment](#)**. (**IMPORTANT NOTE:** After checking the LCD/LCA Availability Grid and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the above referenced policy.)
- **Committee approval date: September 15, 2020**
- Accessed October 20, 2020

2) **Implantable Hypoglossal Nerve Stimulation (HGNS) [Inspire® Upper Airway Stimulation and the aura6000™ Sleep Therapy System] (CPT codes 64568, 64569, 64570, 0466T, 0467T and 0468T)**



- 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 and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the [LCD/LCA Availability Grid \(Attachment E\)](#).
- For coverage guidelines for states/territories with no LCDs/LCAs, see the [UnitedHealthcare Commercial Medical Policy for Obstructive Sleep Apnea Treatment](#). (**IMPORTANT NOTE:** After checking the LCD/LCA Availability Grid and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the above referenced policy.)
- **Committee approval date: September 15, 2020**
- Accessed October 20, 2020

### 3) Other Surgical Treatments

- 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 [LCD/LCA Availability Grid \(Attachment C\)](#).
- For coverage guidelines for states/territories with no LCDs/LCAs, see the [UnitedHealthcare Commercial Medical Policy for Obstructive Sleep Apnea Treatment](#). (**IMPORTANT NOTE:** After checking the LCD/LCA Availability Grid and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the above referenced policy.)
- **Committee approval date: September 15, 2020**
- Accessed October 20, 2020

## II. DEFINITIONS

## III. REFERENCES

## IV. REVISION HISTORY

### 10/20/2020 Coverage Statement

- Updated notation pertaining to **COVID-19 Public Health Emergency Waivers & Flexibilities** to indicate:
  - In response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services (CMS) has updated some guidance for certain respiratory services; for details, see the following Coronavirus Waivers & Flexibilities:
    - [COVID-19 Fact Sheet](#)

## V. ATTACHMENTS

### Attachment A – LCD/LCA Availability Grid

#### Oximetry Services (Pulse Oximetry)

CMS website accessed October 20, 2020

ID #	Title	Contractor Type	Contractor	States/Territories
L33923 (A57113)	<a href="#">Noninvasive Ear or Pulse Oximetry For Oxygen Saturation (L33923)</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L35434 (A57205)	<a href="#">Oximetry Services</a>	A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L33446 (A56730)	<a href="#">Respiratory Therapy and Oximetry Services</a>	A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV

End of Attachment A

### Attachment B – LCD/LCA Availability Grid

#### Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base

CMS website accessed October 20, 2020

ID #	Title	Contractor Type	Contractor	States/Territories
L34526 (A56905)	<a href="#">Surgical Treatment of Obstructive Sleep Apnea (OSA)</a>	MAC Part A	Wisconsin Physicians Service Insurance Corporation	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
L34526 (A56905)	<a href="#">Surgical Treatment of Obstructive Sleep Apnea (OSA)</a>	MAC Part B	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MS, NE

End of Attachment B

### Attachment C – LCD/LCA Availability Grid

#### Other Surgical Treatments of Obstructive Sleep Apnea (OSA)

CMS website accessed October 20, 2020

ID #	Title	Contractor Type	Contractor	States/Territories
L34526 (A56905)	<a href="#">Surgical Treatment of Obstructive Sleep Apnea (OSA)</a>	MAC Part A	Wisconsin Physicians Service Insurance Corporation	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
L34526 (A56905)	<a href="#">Surgical Treatment of Obstructive Sleep Apnea (OSA)</a>	MAC Part B	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MS, NE

End of Attachment C

### Attachment D – LCD/LCA Availability Grid

#### Home Sleep Studies or Polysomnography

CMS website accessed October 20, 2020

ID #	Title	Contractor Type	Contractor	States/Territories
L36902 (A57049)	<a href="#">Polysomnography and Other Sleep Studies</a>	A and B MAC	CGS Administrators, LLC	KY, OH
L33405 (A57496)	<a href="#">Polysomnography and Sleep Testing</a>	MAC Part A and B	First Coast Service Options, Inc.	FL, PR, VI

**Attachment D – LCD/LCA Availability Grid**

**Home Sleep Studies or Polysomnography**

CMS website accessed October 20, 2020

A53019	<a href="#">Polysomnography and Sleep Studies – Medical Policy Article</a>	MAC Part A and B	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
L34040 (A57698)	<a href="#">Polysomnography and Other Sleep Studies</a>	A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36861 (A57697)	<a href="#">Polysomnography and Other Sleep Studies</a>	A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV
L35050 (A56923)	<a href="#">Outpatient Sleep Studies</a>	A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L36839 (A56903)	<a href="#">Polysomnography and Other Sleep Studies</a>	MAC Part A	Wisconsin Physicians Service Insurance Corporation	AK*, AL, AR, AZ*, CA*, CO*, CT*, DE*, FL*, GA, HI, IA, ID*, IL*, IN, KS, KY*, LA*, MA*, MD*, ME*, MI, MO, MS*, MT*, NC, ND*, NE, NH*, NJ*, NM*, NV, OH*, OK*, OR*, PA*, RI*, SC, SD*, TN, TX*, UT*, VA, VT*, WA*, WI*, WV, WY*  <i>(Note: States notated with an asterisk should follow the other available state-specific LCD listed on this grid. This WPS LCD only applies to states without asterisk.)</i>
L36839 (A56903)	<a href="#">Polysomnography and Other Sleep Studies</a>	MAC Part B	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MS, NE

**End of Attachment D**

**Attachment E – LCD/LCA Availability Grid**

**Implantable Hypoglossal Nerve Stimulation (HGNS)**

CMS website accessed October 20, 2020

<b>ID #</b>	<b>Title</b>	<b>Contractor Type</b>	<b>Contractor</b>	<b>States/Territories</b>
L38307 (A57149)	<a href="#">Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	A and B MAC	CGS Administrators, LLC	KY, OH
L38398 (A56953)	<a href="#">Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L38387 (A57092)	<a href="#">Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	MAC Part A and B	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
L38310 (A57948)	<a href="#">Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV
L38312 (A57949)	<a href="#">Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY



**Attachment E – LCD/LCA Availability Grid**  
**Implantable Hypoglossal Nerve Stimulation (HGNS)**

CMS website accessed October 20, 2020

L38385 (A56938)	<a href="#">Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	MAC Part A and B	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
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**End of Attachment E**