Coverage Guidelines

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 titled Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

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

- CMS COVID-19 Fact Sheet
- Physicians and Other Practitioners (PDF)


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:

**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 table for Oximetry Services (Pulse Oximetry).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the Palmetto LCD/LCA for Respiratory Therapy and Oximetry Services (L33446).

Note: After checking the Oximetry Services (Pulse Oximetry) table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
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:

- 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.
- 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.
- Refer to 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.
- 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 table for Home Sleep Studies or Polysomnography.

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:
  - 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
- 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:
  - 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).


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

- Coverage Summary titled Experimental Procedures and Items, Investigational Devices and Clinical Trials.
- NCD for Continuous Positive Airway Pressure CPAP Therapy For Obstructive Sleep Apnea (OSA) (240.4). (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. Refer to the DME MAC LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718). (Accessed March 5, 2021)

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


**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).

**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).
**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 Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base.

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

Note: After checking the Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

**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 for all states/territories and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Implantable Hypoglossal Nerve Stimulation (HGNS).

**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 table for Other Surgical Treatments of Obstructive Sleep Apnea (OSA).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled **Obstructive 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.

**Supporting Information**

**Important Note:** When searching the Medicare Coverage Database, if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

<table>
<thead>
<tr>
<th>LCD/LCA ID</th>
<th>LCD/LCA Title</th>
<th>Contractor Type</th>
<th>Contractor Name</th>
<th>Applicable States/Territories</th>
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<tbody>
<tr>
<td>L33923</td>
<td>Noninvasive Ear or Pulse Oximetry For Oxygen Saturation (L33923)</td>
<td>Part A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<tr>
<td>L35434</td>
<td>Oximetry Services</td>
<td>Part A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<tr>
<td>L33446</td>
<td>Respiratory Therapy and Oximetry Services</td>
<td>Part A and B MAC</td>
<td>Palmetto GBA</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
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**Back to Guidelines**
### Radiofrequency Submucosal Ablation of the Soft Palate and/or Tongue Base
Accessed March 5, 2021

<table>
<thead>
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<tr>
<td>L34526 (A56905)</td>
<td><strong>Surgical Treatment of Obstructive Sleep Apnea (OSA)</strong></td>
<td>Part A MAC</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
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### Other Surgical Treatments of Obstructive Sleep Apnea (OSA)
Accessed March 5, 2021

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<td><strong>Surgical Treatment of Obstructive Sleep Apnea (OSA)</strong></td>
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<td>Wisconsin Physicians Service Insurance Corporation</td>
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<tr>
<td>L34526 (A56905)</td>
<td><strong>Surgical Treatment of Obstructive Sleep Apnea (OSA)</strong></td>
<td>Part B MAC</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
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### Home Sleep Studies or Polysomnography
Accessed March 5, 2021

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<tr>
<th>LCD/LCA ID</th>
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<tr>
<td>L36902 (A57049)</td>
<td><strong>Polysomnography and Other Sleep Studies</strong></td>
<td>Part A and B MAC</td>
<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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<tr>
<td>L33405 (A57496)</td>
<td><strong>Polysomnography and Sleep Testing</strong></td>
<td>Part A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<tr>
<td>A53019</td>
<td><strong>Polysomnography and Sleep Studies – Medical Policy Article</strong></td>
<td>Part A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>CT, IL, ME, MA, MN, NH, NY, RI, VT, WI</td>
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<tr>
<td>L34040 (A57698)</td>
<td><strong>Polysomnography and Other Sleep Studies</strong></td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>L36861 (A57697)</td>
<td><strong>Polysomnography and Other Sleep Studies</strong></td>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>L35050 (A56923)</td>
<td><strong>Outpatient Sleep Studies</strong></td>
<td>Part A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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### Home Sleep Studies or Polysomnography

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<tr>
<td>L36839 (A56903)</td>
<td>Polysomnography and Other Sleep Studies</td>
<td>Part B MAC</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>IA, IN, KS, MI, MO, NE</td>
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</table>

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.

### Implantable Hypoglossal Nerve Stimulation (HGNS)

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<tr>
<td>L38307</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
<td>Part A and B MAC</td>
<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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<tr>
<td>L38398</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
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<td>First Coast Service Options, Inc.</td>
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<td>L38387</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
<td>Part A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>CT, IL, ME, MA, MN, NH, NY, RI, VT, WI</td>
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<tr>
<td>L38310</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>L38312</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
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### Implantable Hypoglossal Nerve Stimulation (HGNS)

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<td>Novitas Solutions, Inc.</td>
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<td>Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea</td>
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<td>L38528</td>
<td>Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</td>
<td>Part B MAC</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
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### Policy History/Revision Information

**Date** | **Summary of Changes**
--- | ---
05/01/2021 | **Template Update**
  - Reformatted policy; transferred content to new template

02/16/2021 | **Implantable Hypoglossal Nerve Stimulation (HGNS) [Inspire® Upper Airway Stimulation and the aura6000™ Sleep Therapy System] (CPT codes 64568, 64569, 64570, 0466T, 0467T and 0468T)**
  - Revised language pertaining to applicable Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) to indicate LCDs/LCAs exist for all states/territories and compliance with these policies is required where applicable
  - Removed default guidelines for states/territories with no LCDs/LCAs
  **Supporting Information**
  - Updated LCD/LCA Availability Grids to reflect the most current reference links
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.

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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