



Medical Coverage Determination

Sleep Apnea

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- I. **Title:** Sleep Apnea
- II. **Description:** Medically Necessary Coverage Sleep Apnea for Clinical Centers of Excellence (CCE) and Nationwide Provider Network (NPN) Members
- III. **Coverage Overview**

Sleep apnea is a common sleep disorder characterized by brief interruptions of breathing during sleep. The most common type of sleep apnea is obstructive sleep apnea (OSA). OSA occurs when the upper airway collapses or becomes blocked during sleep, thus reducing or stopping airflow.¹ Central sleep apnea (CSA) is caused by irregularities in the brain's normal signals to breathe. Most people with sleep apnea will have a combination of both types.²

Sleep apnea may be covered by the WTC Health Program in three different ways: as a certified WTC-related health condition included on the List of WTC-Related Health Conditions (List), as a health condition medically associated with a certified WTC-related condition, or where medically necessary to treat certain certified WTC-related health conditions.

Under the Zadroga Act, sleep apnea exacerbated by or related to one of the aerodigestive disorders on the List of WTC-Related Health Conditions (List) is a Listed condition itself eligible for certification.³ To be certified as a WTC-related health condition, the sleep apnea must be exacerbated by or related to the following certified WTC-related aerodigestive conditions: Interstitial lung diseases, chronic respiratory disorder—fumes/vapors, asthma, reactive airways dysfunction syndrome (RADS), WTC-exacerbated chronic obstructive pulmonary disease (COPD), chronic cough syndrome, upper airway hyperreactivity, chronic rhinosinusitis, chronic nasopharyngitis, chronic laryngitis, and gastroesophageal reflux disorder (GERD).⁴ The Program may certify OSA or combined CSA/OSA as a WTC-related health condition only when the sleep apnea meets the certification requirements outlined below and one of these eleven aerodigestive disorders has also been certified by the Program.⁵

¹ See National Institutes of Health, at <http://www.nlm.nih.gov/health/health-topics/topics/sleepapnea/>.

² See National Institutes of Health, "Sleep Apnea Information Page," at: <https://www.nlm.nih.gov/Disorders/All-Disorders/Sleep-Apnea-Information-Page>.

³ See sections 3312(a)(3)(A)(xii) and 3322(b)(1)(L) of the Zadroga Act.

⁴ See sections 3312(a)(3)(A)(i)-(xi) and 3322(b)(1)(A)-(K) of the Zadroga Act.

⁵ A co-occurring aerodigestive certification which is pending processing must meet criteria for certification approval in order for the sleep apnea to be eligible for certification, and must be certified prior to certification of the sleep apnea.

Sleep apnea may be certified as a health condition medically associated with a certified WTC-related health condition when the sleep apnea results from the treatment or progression of a certified WTC-related health condition, as evidenced by published, peer-reviewed scientific literature.

Sleep apnea that does not meet certification criteria may be eligible to be covered as an ancillary condition when it is determined that treatment of the sleep apnea is medically necessary to treat the member's certified WTC-related mental health condition of post-traumatic stress disorder, depression, and/or chronic anxiety. Certification is not generated when the sleep apnea is considered an ancillary condition⁶ to these certified mental health conditions; however, the member must still comply to all treatment adherence requirements, as described below in Section VIII.A.

Sleep apnea that is solely occurring as CSA may arise from non WTC-related health conditions, including heart failure, stroke, acromegaly, and mitochondrial diseases. Accordingly, the WTC Health Program will only consider certification of CSA as a WTC-related health condition when a CCE/NPN Clinical Director submits a request to the Program which includes evidence from published, peer reviewed studies that CSA may be exacerbated by or related to one of the eleven aerodigestive conditions listed above. For a CSA submitted as a health condition medically associated with a certified WTC-related condition, the CCE/NPN Clinical Director must submit evidence from published, peer-reviewed studies that the CSA arises from treatment or progression of a certified WTC-related health condition. Additionally, CSA that does not meet certification criteria may be eligible to be covered as an ancillary condition as above.

The WTC Health Program uses sleep studies to diagnose sleep apnea by recording the number of episodes of slow or stopped breathing detected per hour of the member's sleep. If the member meets certification criteria for sleep apnea, then breathing devices such as continuous positive air pressure (CPAP) devices, bilevel positive airway pressure (BIPAP), and other oral dental devices may be covered if the member meets all of the applicable requirements described in this medical coverage determination (MCD).

IV. Sleep Apnea Certification Requirements

The following must be included in the Certification (WTC-3) Request:

- Selection of sleep apnea as a WTC-related condition with co-occurring certified WTC-related condition or as a medically associated condition
 - **For sleep apnea as a related condition:** Attestation from Physician describing co-occurring certified WTC-related condition
 - **For sleep apnea as a medically associated condition:** Attestation from Physician describing how sleep apnea results from treatment or progression of the health condition medically associated to the certified WTC-related health condition
- Narrative describing and Attestation to Sleep apnea-related symptoms
 - **For mild sleep apnea only:** documentation that other likely causes of fatigue and sleepiness have been ruled out or treated in the patient
 - **For mild sleep apnea with cardiovascular exacerbation:** documentation from a cardiologist or other appropriate medical specialist
- Evidence of Sleep Study: In-Lab Polysomnography (PSG) or Home Sleep Apnea Test (HSAT)

⁶ Ancillary condition is defined as a chronic health condition co-occurring with a certified WTC-related or medically associated health condition that, if left untreated, would interfere with reasonable treatment (i.e., manage, ameliorate, or cure) of a certified WTC-related health condition.

- Including detailed score results as outlined in Section V below.
- PSG or HSAT results
- Physician Statement
- *Optional: Epworth Sleepiness Score (preferred) or Functional Outcomes of Sleep Questionnaire (FOSQ) and/or Fatigue Severity Scale (FSS)*

V. Sleep Apnea Diagnostic Requirements

The WTC Health Program may cover diagnostic testing via in-lab polysomnography (PSG) or home sleep apnea testing (HSAT) for members with high pretest probability of moderate to severe uncomplicated sleep apnea. PSG and HSAT vendors⁷ must be certified by the American Academy of Sleep Medicine (AASM) to assure quality performance of study and high-quality interpretation of results.⁸

The Apnea-Hypopnea Index (AHI) should be used during diagnostic testing to indicate sleep apnea severity. The AHI score is equivalent to the number of apneas and hypopneas⁹ recorded during the sleep study per hour of sleep. Severity using the AHI scale is categorized as follows:

- Low: AHI < 5
- Mild: AHI ≥ 5, but < 15 per hour
- Moderate: AHI ≥ 15, but < 30 per hour
- Severe: AHI ≥ 30 per hour

If the member has a low AHI, the Respiratory Disturbance Index (RDI) may also be used to diagnose sleep apnea. The RDI measures apneas and hypopneas, as well as respiratory effort-related arousal (RERAs) and other respiratory events per hour of sleep.

- Mild: RDI ≥ 5, but < 15 per hour
- Moderate: RDI ≥ 15, but < 30 per hour
- Severe: RDI ≥ 30 per hour

Members with a low AHI may be diagnosed with mild sleep apnea if their RDI score is greater than 15 and the member has excessive daytime sleepiness with no other attributable cause.¹⁰ Hypoxias or arrhythmias during sleep study would also increase the severity level to allow for certification.

If the member is diagnosed with mild sleep apnea, the WTC Health Program provider must attest to sleep apnea-related symptoms and submit an MD statement as to why treatment of the mild sleep apnea is medically necessary. The WTC Health Program provider must also attest that there are no other causes for the mild sleep apnea, that other likely causes of fatigue and sleepiness have been ruled out or treated in the member.¹¹

⁷ WTC Health Program providers should instruct testing centers to attest to certifications on sleep study results. To enroll a sleep testing center, the WTC Health Program may require that certifications be verified for credentialing.

⁸ The lab will need to send copies of their AASM certification for HSTs and for the equipment they use for HSTs

⁹ See <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=19&fromdb=true> for the CMS definition of hypopnea, utilizing the American Academy of Sleep Medicine (AASM) Rule 1B scoring criteria: <https://aasm.org/aasm-clarifies-hypopnea-scoring-criteria/>.

¹⁰ Guilleminault, C. & Bassiri, A. (2005). *Clinical Features and Evaluation of Obstructive Sleep Apnea-Hypopnea Syndrome and Upper Airway Resistance Syndrome*. Principles and Practice of Sleep Medicine (pp. 1043-1052). Doi: [10.1016/B0-72-160797-7/50094-X](https://doi.org/10.1016/B0-72-160797-7/50094-X). See <https://www.sciencedirect.com/topics/medicine-and-dentistry/respiratory-disturbance-index>.

¹¹ The Epworth Sleepiness Score (ESS) is determined by a self-administered questionnaire with 8 questions which is shown to provide a measurement of the patient's general level of daytime sleepiness. See <https://epworthsleepinessscale.com/about-the-ess/>. Scale: 0-5:

A. Home Sleep Apnea Test (HSAT)

A Prior Authorization Level 2 (PA2) is required for HSAT services. HSAT is recommended for those members **with no significant comorbidity** such as severe cardiopulmonary disease, significant psychiatric issues, periodic limb movements of sleep (PLMS) and/or significant neurologic issues that could affect diagnosis or treatment.

The WTC Health Program may provide coverage of a Type III¹² unattended home sleep test with a Type III portable monitor and four channels: two that measure respiratory movement and airflow, one that takes electrocardiogram (ECG) and/or heart rate, and one that determines oxygen saturation.¹³

The HSAT may also be measured by the Respiratory Event Index (REI), which correlates with the AHI and RDI when recording time includes at least four hours of sleep. The REI records the number of events per hour of recording time, rather than total sleep time. The REI uses the following rating scale to determine severity:

- Mild: REI \geq 5, but $<$ 15 per hour¹⁴ (5-14)
- Moderate: REI \geq 15, but $<$ 30 per hour (15-29)
- Severe: REI \geq 30 per hour (30 or more)

Members with a low REI may be diagnosed with mild sleep apnea if their RDI score is greater than 15 and the member has excessive daytime sleepiness with no other attributable cause.¹⁵ Hypoxias or arrhythmias during sleep study would also increase the severity level to allow for certification.

WatchPAT Technology¹⁶ may also be used for the HSAT. The Peripheral Arterial Tone (PAT) signal measures the arterial pulsatile volume to identify respiratory events. The WatchPAT uses both the AHI and the RDI rating scales referenced above, as denoted by pAH and pRDI to indicate use of WatchPAT technology during the HSAT.

Lower Normal Daytime Sleepiness; 6-10: Higher Normal Daytime Sleepiness; 11-12: Mild Excessive Daytime Sleepiness; 13-15: Moderate Excessive Daytime Sleepiness; 16-24: Severe Excessive Daytime Sleepiness.

¹² Note that the WTC Health Program does not cover Type II or Type IV sleep tests. Type II HSATs only utilize 2-3 leads, and Type IV HSATs has 10 leads often leading to decrease in accuracy due to user error. Type III HSATs have a minimum of 4 monitored channels including ventilation or airflow, heartrate or ECG, and oxygen saturation.

¹³ See Medicare Coverage Database Decision Memo for Sleep Testing for Obstructive Sleep Apnea at [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=11&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+\(OSA\)&CoverageSelection=National&Keyword=sleep+testing&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAACAAEAAA&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=11&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+(OSA)&CoverageSelection=National&Keyword=sleep+testing&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAACAAEAAA&).

¹⁴ If the member has no apneas and only hypopneas, mild may be classified as 5-15 per hour REI.

¹⁵ Guilleminault, C. & Bassiri, A. (2005). *Clinical Features and Evaluation of Obstructive Sleep Apnea-Hypopnea Syndrome and Upper Airway Resistance Syndrome*. Principles and Practice of Sleep Medicine (pp. 1043-1052). Doi: [10.1016/B0-72-160797-7/50094-X](https://doi.org/10.1016/B0-72-160797-7/50094-X). See <https://www.sciencedirect.com/topics/medicine-and-dentistry/respiratory-disturbance-index>.

¹⁶ See Medicare Coverage Database at [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=11&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+\(OSA\)&CoverageSelection=National&Keyword=sleep+testing&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAACAAEAAA&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=11&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+(OSA)&CoverageSelection=National&Keyword=sleep+testing&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAACAAEAAA&); See also WatchPAT CMS Decision Memo at [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=7&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+\(OSA\)&year=2009&DocType=NCA%7cCAL&bc=AgAAAQAAEAAA&&fromdb=true](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=227&ver=7&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+(OSA)&year=2009&DocType=NCA%7cCAL&bc=AgAAAQAAEAAA&&fromdb=true).

To ensure HSAT vendor¹⁷ quality control, a sleep medicine board-certified physician is necessary for study interpretation. Major medical centers and private sleep offices or respiratory therapy companies may provide HSAT if they meet the below requirements:¹⁸

- American Academy of Sleep Medicine (AASM) certification is required for these vendors.¹⁹ The AASM standards are designed to assure quality performance of studies, as well as high quality interpretation of results.²⁰
- The interpreting physician should be a Board Certified or Board Eligible Sleep specialist and reports should be provided to the ordering CCE clinician, in order to have appropriate data to judge the quality of the study and the interpretation.
- The vendor performing the test should also have an in-lab center that they own or are responsible for (not merely a referral relationship). By owning or running an in-lab center, the Program has a higher confidence that they understand and provide high quality HSAT.²¹
- Upon request, the sleep center should be able to provide sleep apnea patients with clinical follow-up care of their sleep issues and treatment adherence issues. This clinical follow-up care will require authorization by the CCE.

For those members diagnosed with sleep apnea by HSAT, an in-lab titration study may follow if the member requires treatment initiation and education, is anticipated to have a difficult titration, or is not tolerating treatment (if previously treated). For those whom HSAT was performed and is negative, inconclusive, or technically inadequate, and a clinical suspicion remains for sleep apnea, an in-lab polysomnography may be performed.

B. In-Lab Polysomnography (PSG)

A Prior Authorization Level 2 (PA2) is required for In-Lab PSGs. A PSG is recommended for members **with significant comorbidity** such as severe cardiopulmonary disease, and/or significant neurologic issues that could affect diagnosis or treatment. If positional sleep apnea is suspected, PSG is also preferred.

PSG is measured with the AHI rating scale as outlined above. While the RDI scale is not recommended during PSG, it may be an optional consideration in addition to the AHI. However, if AHI <5 but RDI >15, member should be diagnosed with mild sleep apnea. Any hypoxia or arrhythmias during the sleep study may prompt treatment for mild sleep apnea.

The member must also report and the provider must document fatigue and sleepiness as measured by the Epworth Sleepiness Scale (preferred) or other tools such as the Functional Outcomes of Sleep Questionnaire (FOSQ) and/or Fatigue Severity Scale (FSS).

¹⁷ Companies that dispense CPAP devices or other sleep-related durable medical equipment (DME) for member treatment are encouraged to not be used for HSAT due to potential conflict of interest. If this is not possible due to lack of HSAT availability from non-DME vendors, then an independent review process by a board certified/eligible sleep specialist is required.

¹⁸ In the case that a testing center does not meet all requirements, the center may enroll in the Program and the CCE may decide to utilize the center on a case-by-case basis.

¹⁹ The CCEs will instruct testing centers to attest to certifications on sleep study results. In order to enroll a sleep testing center, the WTC Health Program may require certifications to be verified for credentialing.

²⁰ The lab will need to send copies of their AASM certification for HSTs and for the equipment they use for HSTs

²¹ If rural companies providing HSAT do not have an in-lab center, the CCE should consider mailing devices or using WatchPAT Direct.

VI. Covered Services

Covered services under the WTC Health Program include HSAT and PSG diagnostic services, as well as treatment for:

1. symptomatic mild sleep apnea,
2. mild sleep apnea that exacerbates a certified WTC-related mental health condition,
3. certified WTC-related mild sleep apnea when the only symptom is cardiovascular in nature, and
4. moderate to severe sleep apnea.

Covered treatments include CPAP/BIPAP, positional devices, and certain mandibular advancement devices as medically necessary. These covered services are permitted only when in accordance with Program guidelines.²² Refer to the WTC Health Program Codebook for a full list of covered medical services, procedures, and diagnosis codes.

VII. Coverage Guidelines – General Eligibility Requirements for Medically Necessary Sleep Apnea Services for CCE and NPN Members

All sleep apnea services must meet the coverage guidelines given below.

A. Coverage of Symptomatic Mild Sleep Apnea

WTC Health Program members with mild, symptomatic sleep apnea may be eligible for treatment of the following symptoms:

1. Symptom: Sleepiness and/or Fatigue

If the member has reported symptoms of sleepiness and/or fatigue due to or exacerbated by sleep apnea and meets all certification requirements, the member may receive a treatment trial with a positive pressure device if it is documented that other likely causes of fatigue and sleepiness have been ruled out or treated in the member. If the member reports no symptomatic improvement after six months, then the machine must be returned.

Symptomatic improvement is measured by a significant change in sleepiness or fatigue.²³ If there is no improvement, the DME provider must be informed that the Program payments will cease in month seven. The CCE/NPN must monitor this and maintain documentation through case management. All documentation is subject to audit by the WTC Health Program.

2. Symptom: Exacerbation of a Cardiovascular Condition

If the member has diagnosed cardiovascular symptoms (e.g., hypertension, arrhythmias, etc.) due to or exacerbated by sleep apnea²⁴ and meets all certification requirements, the member may receive a treatment trial with a positive pressure device. Comprehensive evaluation and management of cardiac or cardiovascular disease, including symptoms that

²² See generally WTC Health Program Administrative Manual for a full description of Program guidelines, policies, and procedures, at <https://www.cdc.gov/wtc/ppm.html>.

²³ This may be measured by the Epworth or Fatigue Severity Scores (i.e., pre-treatment 10 or greater and post-treatment fewer than 10). If significant symptomatic improvement occurs then continued use should be authorized by the WTC Health Program.

may be related to mild sleep apnea, is not a covered benefit of the WTC Health Program. When the clinical scenario suggests the management of mild sleep apnea is necessary to optimize a non-covered cardiovascular or cardiac condition, documentation from a cardiologist or other appropriate medical specialist is required, and must be included on the certification request or in the medical record if the symptom arises after certification of mild symptomatic sleep apnea.

These members should continue to adhere to other prescribed standards of cardiac and cardiovascular care external to the Program²⁵ while receiving mild sleep apnea benefits from the WTC Health Program. Attestation to the member receiving cardiac care external to the Program must be included in the WTC-3.

If the member reports no symptomatic improvement after six months, then the machine must be returned. Symptomatic improvement would be measured by quantifiable improvement in cardiovascular symptoms.²⁶ If no improvement is documented, the DME provider will need to be informed that the Program payments will cease in month seven. The CCE/NPN must monitor this and maintain documentation. All medical and claims documentation is subject to audit by the WTC Health Program.

B. Coverage of Mild Sleep Apnea Exacerbating Certain Certified Mental Health Conditions

If the member has a certified, WTC-related active mental health condition of post-traumatic stress disorder, depression, and/or chronic anxiety and their mild sleep apnea is determined to be exacerbating the mental health condition(s),²⁷ the member may receive a treatment trial with positive pressure device if a licensed clinical mental health provider (e.g., psychiatrist) documents that it is likely that:

1. Exacerbation of WTC mental health symptoms and sleep apnea are associated or functionally related;²⁸ and
2. Other likely causes for worsened symptoms have been ruled out or treated.

If the member reports no symptomatic improvement after six months, then the machine must be returned. Symptomatic improvement would be measured by a significant change in mental health symptoms.²⁹ If no improvement, the DME provider will need to be informed that the Program payments will cease in month seven. The CCE/NPN must monitor this and maintain documentation through case management. All documentation is subject to audit by the WTC Health Program.

²⁵ The cardiovascular care external to the Program for a member with mild symptomatic sleep apnea should be co-managed by the CCE/NPN Case Management and the member's primary private or public health insurance in order to ensure benefits are coordinated appropriately. See Policy and Procedures for Coordination of Benefits for Treatment Costs for Non-Work-Related, Certified WTC-Related Health Conditions: Coordination with Health Insurance <https://www.cdc.gov/wtc/policies.html#recoupment>.

²⁶ This may be measured by a written attestation from a licensed cardiologist or other appropriate medical specialist. If significant symptomatic improvement occurs, then continued use should be authorized by the WTC Health Program.

²⁷ Under these circumstances, sleep apnea is considered ancillary, or medically necessary to manage, ameliorate, or cure the WTC-related mental health condition, and does not meet requirements for certification.

²⁸ Gupta, M. A., & Simpson, F. C. (2015). Obstructive sleep apnea and psychiatric disorders: a systematic review. *Journal of Clinical Sleep Medicine*, 11(02), 165-175, <https://jcsm.aasm.org/doi/10.5664/jcsm.4466>.

²⁹ This may be measured by a written attestation from a licensed mental health provider. If quantifiable and objective significant symptomatic improvement occurs then continued use should be authorized by the WTC Health Program.

C. Coverage of Moderate to Severe Sleep Apnea

Members with moderate to severe sleep apnea may be eligible for CPAP/BIPAP treatment (preferred), oral dental devices, or, where deemed clinically appropriate, combination therapy (CPAP + oral dental device). Improvement is measured by significant change in sleepiness or fatigue (using accepted measures such as the Epworth or Fatigue Severity Scale). For sleepiness, the pre-treatment Epworth score is 10 or greater and post-treatment the Epworth Score is decreased to far fewer than 10. Improvement can also be measured by a moderate decrease in AHI from baseline (PSG) on the usage report.³⁰ Treatment will continue to be covered as long as the member continues to be adherent to CPAP/BIPAP treatment and all prior authorization requirements are met.

D. Positional OSA

If a member meets diagnostic criteria for positional OSA³¹, the WTC Health Program provider may determine positional contributor through PSG (preferably) or HSAT. Devices or software that include positional data include Noxturnal, WatchPAT, and AREHST devices, while commercial positioning devices include Zzomba (with compliance chip) and Slumber Bump. A PA2 is required to obtain a device related to positional OSA. For detailed Prior Authorization procedures, see instructions found in the WTC Health Program's Administrative Manual.³²

³⁰ Treatment may be allowed to continue if the member is compliant even if there is no objective improvement in AHI or EEDS.

³¹ The AHI is often twice as high when an individual is supine, as opposed to other sleep positions. See <https://www.sleepassociation.org/sleep-apnea/positional-sleep-apnea/>.

³² WTC Health Program Administrative Manual, [Chapter 4, Section 3.4], at https://www.cdc.gov/wtc/ppm.html#medical_prior.

VIII. Treatment Considerations and Adherence – CPAP/BIPAP Treatment and Oral Devices

All sleep apnea treatment services require either a PA2 or PA3.

A. CPAP/BIPAP Treatment – Prior Authorization Level 2 (PA2)

Eligible members may receive a 6-month treatment trial with an approved CPAP/BIPAP device³³. Members must demonstrate adherence to the treatment regimen to be eligible for continued treatment after the 6-month trial period. Adherence³⁴ is defined as CPAP/BIPAP use of at least 3-4 hours per night for at least four days per week over the first 6-month adherence trial period. The WTC Health Program provider may terminate the trial at an earlier point if the member and provider agree that there is no possibility of improved adherence. The CPAP/BIPAP device must be returned to the DME vendor.

The CCE/NPN must develop a protocol to review CPAP/BIPAP adherence reports.

If the member was adherent and the CPAP/BIPAP treatment is unsuccessful or the member could not tolerate the CPAP/BIPAP device, the member may be referred to a qualified dentist for fitting of an oral device. The dentist must be certified by the American Academy of Dental Sleep Medicine and enrolled in the WTC Health Program provider network.

1. Program Coverage and Coordination of Benefits

The WTC Health Program may provide coverage for CPAP/BIPAP rentals³⁵ that do not exceed a period of continuous use longer than 13 months (with the exception of oxygen and supplies). The WTC Health Program will approve the purchase of CPAP/BIPAP for a member if use is expected to exceed a 13-month rental period, or if the purchase price is more cost-effective than the rental price. The CCE/NPN will make the decision of purchasing versus renting.

For survivors, if the primary payer is only covering through month three, the WTC Health Program will cover months four through six as primary payer. At six months of treatment, the CCE/NPN must determine if adherence (and improvement for those with mild sleep apnea) has been achieved.

³³ See CMS Adherence Standards at <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ver=20&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=PAP&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&>

³⁴ Typically, DME companies identify noncompliance after PAP therapy prescription on a regular basis, especially in the first 3 months. They identify non-compliant patients and bring them to the sleep MD's attention. Sleep MD and DME compliance address any issues that are causing noncompliance immediately. This may require clinic visit with sleep MD. DME companies contact patients when they notice adherence problems but, the treating physician or sleep specialist should be ultimately responsible for ascertaining adherence, trying to improve it, or sustain it as needed, and determine failure.

³⁵ See Program coverage of Durable Medical Equipment at https://www.cdc.gov/wtc/ppm.html#medical_dme.

B. Oral Dental Device Treatment – Prior Authorization Level 2 (PA2)

The WTC Health Program may provide coverage for custom-made (not over the counter), titratable mandibular advancement devices (MAD)³⁶ (or oral dental device) for members with moderate to severe sleep apnea. Oral dental devices are not covered for mild sleep apnea, even if the member is symptomatic, but may be considered on a case-by-case basis. Coverage is also excluded for any dental issues that may arise during the evaluation or fitting for an oral dental device.

Eligible members may receive a 6-month treatment trial with an oral dental device that contains an adherence chip to measure treatment compliance.³⁷ Members must demonstrate adherence to the treatment regimen to be eligible for continued treatment after the 6-month trial period. Adherence is defined as at least 3-4 hours per night for at least 4 days per week, over the first 6-month adherence trial period, unless the WTC Health Program provider and the member decide to terminate the trial at an earlier time point. Follow-up post-diagnostic studies are required after an oral dental device is in place. Follow-up care is to be performed as needed during the fitting, adjustment, and efficacy testing phases every 3-6 months during the first year and every 6-12 months thereafter.

C. Combination Therapy Treatment— Prior Authorization 3 (PA3)

The WTC Health Program may provide coverage for combination therapy (CPAP + oral dental device) where clinically appropriate for members with moderate to severe sleep apnea.^{38 39 40} Combination therapy, using an oral dental device and CPAP, may be effective in decreasing respiratory disturbances in those with obstructive sleep apnea; this therapy may also promote comfort and compliance and may be considered for members who are found to be intolerant to higher pressures of CPAP alone. Combination therapy is not currently covered for members with mild sleep apnea.

The PA3 request must include documentation by the sleep specialist indicating that combination therapy is medically necessary to treat the member's certified sleep apnea, sleep apnea medically associated with a certified WTC-related health condition, or sleep apnea that is medically necessary to treat the member's certified WTC-related mental health condition of post-traumatic stress disorder, depression, and/or chronic anxiety.

³⁶ Coverage for the oral appliance (OA) only extends to dental evaluations (initial and subsequent related to its creation and effectiveness) and the oral appliance itself. Coverage does not extend to significant dental issues that might exist prior to the crafting of the OA; such dental issues are not WTC-related and must be covered by the member/personal insurance. Further, any dental issues arising from oral device treatment must be covered by the member and not by the WTC Health Program. The risk of potential dental issues should be carefully explained to the member by the dentist (and by the WTC Health Program) so that the member understands that related future dental costs will be borne by them.

³⁷ Note that an adherence chip failure is also treated as non-compliance. Dental providers must provide a high-quality device with low rates of chip failure.

³⁸ See De Vries, Grietje E. MSc; Doff, Michiel H.J., DMD, PhD; Hoekema, Aarnoud, MD, PhD; Kerstjens, Huib A.M., MD, PhD; Wijkstra, Peter J., MD, PhD (2016). Continuous Positive Airway Pressure and Oral Appliance Hybrid Therapy in Obstructive Sleep Apnea: Patient Comfort, Compliance, and Preference: A Pilot Study, *Journal of Dental Sleep Medicine*, <https://aadsm.org/docs/JDSM.03.01.5.pdf>.

³⁹ See also Vanderveken, MD, PhD, Olivier M. (2015). Combination Therapy for Obstructive Sleep Apnea in Order to Achieve Complete Disease Alleviation: from Taboo to New Standard of Care? *Journal of Dental Sleep Medicine*, <https://aadsm.org/docs/JDSM.02.01.7.pdf>.

⁴⁰ See also El-Solh, Ali A.; Moitheennazima, Binusha; Akinnusi, Morohunfolu E.; Churder, Paul M.; Lafornara, Anthony M. (2011). <https://pubmed.ncbi.nlm.nih.gov/21063793/>.

In accordance with the CPAP and oral device treatment guidance, eligible members may receive a 6-month treatment trial period and must demonstrate adherence to the treatment regimen.

IX. Prior Authorization Request Submission Requirements

Any sleep apnea services with a PA2 must be signed and authorized by the CCE/NPN Clinical Director, and maintained in the member's medical record. The CCE/NPN Clinical Director will maintain documentation that demonstrates MCD criteria has been met in the member's medical record, as well as documentation related to the PA2. Sleep apnea services requiring a PA2 may be audited by the WTC Health Program no less than annually, unless otherwise agreed upon.

Any sleep apnea services with a PA3 must be signed by the requesting CCE/NPN Clinical Director and submitted to the Health Program Support (HPS) contractor through the Secure File Transfer Protocol (SFTP) server. The WTC Health Program will decide whether to authorize the service and will inform the HPS contractor, who will subsequently inform the CCE/NPN of the decision. The CCE/NPN will maintain documentation that demonstrates MCD criteria has been met in the member's medical record, as well as documentation related to the PA3 Request. Incomplete or inaccurate requests will be returned to the requesting CCE/NPN for additional information.

The CCE/NPN Clinical Director may complete a PA2/PA3 for sleep apnea services retrospectively only when an urgent need for sleep apnea services arises. The retrospective PA3 Request must be submitted within 14 calendar days of the start date of sleep apnea services.

All documentation for completed sleep apnea services authorizations are subject to audit by the WTC Health Program.

X. Certification and Coverage Exclusions

The WTC Health Program no longer certifies the following:

Asymptomatic Mild OSA: Includes members who meet AHI/REI requirements for mild OSA but have no symptoms.

The WTC Health Program does not cover the following:

Inspire Device: Includes any device for hypoglossal nerve stimulation for those unable to tolerate CPAP/BIPAP or other first-line treatments.⁴¹

Distilled Water or any other CPAP/BIPAP cleaning or disinfectant supplies⁴².

Surgery: Sleep apnea surgery (such as uvulopalatopharyngoplasty) is not covered under the WTC Health Program unless the member has not benefitted from other therapy, has a life-threatening disease (e.g., pulmonary hypertension, right heart failure, respiratory failure, etc.), and the CCE/NPN Clinical Director approves the surgery via a PA2.

⁴¹ Exclusion is based on lack of coverage within CMS National Coverage Determination guidelines, which exclude this device per available peer-reviewed literature, though this device is considered standard of care covered by other federal plans like the Veterans Administration (VA).

⁴² See WTC Health Program Administrative Manual, Chapter 12, Section 7.6 at https://www.cdc.gov/wtc/ppm.html#pharmacy_otcDrugs.

XI. Billing/Coding Guidelines

All applicable codes are listed in the WTC Health Program Codebook, located on the Secure Access Management services (SAMs) portal.

For consideration of codes that are not currently included in the WTC Health Program Codebook, please submit a WTC-5 Medical Code Request form to the Health Program Support (HPS) Contractor via the standard WTCMedCode@csra.com mailbox process.

XII. Revision History

- a. Added allowance for diagnosis with RDI level from HSATs with specific conditions (page 4).
Added exclusion – sleep apnea surgery (page 10). April 01, 2021
- b. Added coverage for combination therapy (CPAP and oral dental device) with a PA3 requirement (page 10). Adjusted the prior authorization requirement for stand alone oral dental device from a PA3 to a PA2 (page 9). Added the requirement to audit oral dental device PA2s annually (page 10). December 1, 2021