

**Oral Appliances for Obstructive Sleep Apnea  
Response to Comments**

1. There are no randomized, controlled crossover trials that show efficacy of any prefabricated oral appliance. As the literature only supports the use of custom appliances, we urge the complete removal of the paragraph giving preference to E0485 (prefabricated appliances).

Response: Agree. Because of the lack of proven efficacy, prefabricated appliances will be denied as not reasonable and necessary.

2. It is an anatomic impossibility for an oral appliance to be hinged or jointed in the back. We propose the following CODING GUIDELINES be considered:
  - a. They meet the general coverage requirements for durable medical equipment.
  - b. They have a mechanism that is hinged or jointed on the sides, front, or palate.
  - c. They have a mechanism that allows the mandible to be advanced.

Response: Agree.

3. Some patients have insufficient numbers of healthy teeth or acute TMJ disorders that preclude mandibular advancement. This population, all too prominent in the elderly population, often benefit from use of a tongue-retaining appliance. By design, tongue retainers do not utilize mandibular advancement.

Response: Disagree. We were unable to identify sufficient published clinical literature demonstrating the effectiveness of oral appliances used for the treatment of obstructive sleep apnea other than mandibular advancement devices.

4. Consideration should be given as to whether reimbursement for the oral appliance will cover only the physical appliance or also include 90 days of adjustments/ modification/ patient management/ appliance titration. These visits would be billable to Medicare B if it is ultimately determined that only the physical appliance is included in the code. Oral appliance therapy is a process that involves gradual mandibular advancement typically over a number of months. The first 90 days are a critical period with the most concentrated need for professional assistance.

Response: Reimbursement for DME items includes all payment necessary for proper fitting, adjustment, and use of the item during the first 90 days. No separate reimbursement is allowed for these services during this time period. Even after 90 days, there is no separate payment by the DME MAC for professional services, including but not limited to adjustments modifications, and appliance titration.

5. Custom oral appliances are durable. However, they can be subject to heavy bruxism and rhythmic masticatory muscle activity during sleep. Oral appliances can be expected to last 2-5 years on average. Recommended replacement of an oral appliance should be every 3 years without going through the appeal process.

Response: The statutory reasonable useful lifetime for durable medical equipment is 5 years. Replacement due to wear and tear sooner than that is Statutorily noncovered.

6. Appliance repairs will sometimes be needed.

Response: Repairs are allowed for medically necessary DME.

7. The published guidelines from the American Academy of Sleep Medicine (Reference 14 in the proposed LCD) includes the following language:

“Oral appliances (OAs) are indicated for use in patients with mild to moderate OSA who prefer them to continuous positive airway pressure (CPAP) therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before considering OAs.”

Oral appliances are accepted as first line treatment of mild-moderate sleep apnea. Oral appliances are accepted as second line treatment, after CPAP, in those patients with severe sleep apnea (AHI >30). It is proposed that the Indications and Limitations of Coverage and/or Medical Necessity be modified to read:

- a. A, B, D – unchanged
- b. C If the AHI >30 and RDI >30: The patient is not able to tolerate a positive airway pressure (PAP) device or the treating physician determines that the use of a PAP device is contraindicated. A CPAP trial is not required if the AHI ≤ 30 or RDI ≤ 30.

Response: Agree

8. Regarding the requirement of board certification in Sleep Medicine or the equivalent for the interpretation of sleep tests, the members of the American Board of Sleep Medicine include the American Board of Internal Medicine, American Board of Pediatrics, American Board of Otolaryngology, American Board of Family Medicine and the American Board of Psychiatry and Neurology. Physicians who are board certified by one of these ABMS approved boards have sufficient expertise to interpret sleep tests.

Response: Disagree. These organizations are part of the sleep medicine sub-specialty certification board. Their participation in that certification demonstrates their recognition of the need for specialized training.

9. The current LCD language recognizes that the dental role is subsequent to a physician referral. However, there should be more specificity to indicate that the referring physician should be an individual who is fully qualified to "assess the patient for obstructive sleep apnea."

Response: We agree that the primary responsibility for diagnosis and treatment of OSA rests with the physician. However, we feel that no additional credentialing or certification need be placed upon the referring MD/DO.

10. Additional language emphasizing the key role of the physician in the treatment of OSA by means of an oral appliance should be incorporated into the LCD. The rationale for this treatment modality is outlined in Guideline 3.4.4 of the *Practice Parameters*:

"Patients with OSA who are treated with oral appliances should return for periodic follow-up office visits with the referring clinician. The purpose of follow-up is to assess the patient for signs and symptoms of worsening OSA. Close communication with the dental specialist is most conducive to good patient care. An objective reevaluation, of respiration during sleep is indicated if signs or symptoms of OSA worsen or reoccur."

The absence of language in the LCD addressing follow up visits with the referring physician undermines patient care.

Response: We agree that good follow-up is important to proper care; however, this LCD addresses reimbursement for a device. It is outside of the jurisdiction of the DME MACs to address follow-up physician services.

11. Language should be included in the LCD mandating a patient follow-up visit, including polysomnography testing, with the referring physician after the oral appliance has been fitted. Guideline 3.4.2 of *Practice Parameters* states the following:

"To ensure satisfactory therapeutic benefit from OAs [oral appliances], patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the oral appliance in place after final adjustments of fit have been performed"

In discussing this, the *Practice Parameters* goes on to state:

"Subsequent data has shown that even relatively low AHIs [Apnea-Hypopnea Index] are associated with adverse health outcomes, especially in patients with comorbid diseases or risk factors. Since the rate of treatment success is not predictably high with OAs, treatment should be assessed for efficacy with *objective* testing."

Response: We agree that good follow-up is important to proper care; however, this LCD addresses reimbursement for a device. It is outside of the jurisdiction of the DME MACs to address follow-up care.

12. One of the proposed criteria included in the "Indications and Limitations of Coverage and/or Medical Necessity" section states that "the patient has a face-to-face clinical evaluation by the treating physician (MD or DO) prior to the sleep test to assess the patient for obstructive sleep apnea." We believe that this proposed criterion could lead to unnecessary visits that inconvenience the patient and increase costs. It is common for a general internist to refer a patient with an abnormal screening overnight oximetry to a pulmonologist (or other specialist) for a sleep study. We are unclear as to the implications the proposed criterion would have in this situation. For instance, we are unclear as to whether this criterion:
- a. Affects the ability of the general internist to refer the patient and/or order a sleep study;
  - b. Requires the pulmonologist to have a face-to-face (F2F) encounter with the patient before ordering a sleep study for a patient referred by the general internist; and/or
  - c. Requires the pulmonologist to see the patient in person before interpreting the home sleep test study results.

We ask that the DME MACs clarify this criterion.

Response: The F2F requirement pertains to documenting the justification for sleep testing. It is not the intent of this LCD to interfere with referral relationships between physicians. Either the referring physician or the pulmonologist (or other specialist) can perform the F2F.

13. We believe that based on the existing literature and current practice; there is less evidence for the value of oral appliance therapy than for PAP therapy. Therefore, the devices should NOT be first line therapy. We are unaware of any convincing studies where oral devices were used as first-line therapy in the Medicare population.

Response Disagree. There are studies in the dental literature demonstrating the effectiveness of oral appliances in the treatment of obstructive sleep apnea.

14. We suggest the following addition to the coverage criteria:

"The patient has a face-to-face clinical evaluation by the treating physician (MD or DO) prior to the sleep test to assess the patient for obstructive sleep apnea. A dentist is not the treating physician for the purpose of this clinical examination, only the treating physician may order the oral device."

Response: Agree

15. The policy requires that a dentist fit the device. We believe the dentist should also be enrolled as a provider of the DME to avoid the conflict of interest between the provider of sleep testing and provider of the oral appliance, even though it is "fitted" by a dentist. The definitions and limitations surrounding in-facility sleep studies and home sleep tests should be consistent between this LCD and the LCD for PAP devices.

Response: Agree

16. The LCD should ensure that "provider" means that the dentist is actually the biller for the DME and not linked directly to the sleep test provider. We are unsure if the current language is clear enough.

Response: Agree

17. Do not change the requirement for an adjustment mechanism (e.g. maintain original condition). The oral appliance should have a mechanism that allows the mandible to be advanced.

Response: Agree

18. The device must be able to protrude the mandible beyond the front teeth to maximum protrusion. Two features of an oral appliance determines efficacy: adjustability to maximum mandibular protrusion and ability for the patient to adjust the device.

Response: Agree

19. The appliance should be adjustable in increments of 1 mm or less. Devices that move the mandible more than 1 mm at a time are unable to specifically position and retain the jaw at maximum protrusion. An increase of 1 mm or more often triggers temporomandibular disorders (TMD).

Response: Agree