DATE: September 9, 2024

Docket Number: CMS-1807-P

Comments from the Alliance of Sleep Apnea Partners on the Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

The Alliance of Sleep Apnea Partners (ASAP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the proposed rulemaking. ASAP is a nonprofit patient-oriented advocacy organization dedicated to promoting and advocating for optimal health of those suffering from sleep apnea.

As an organization supporting patients living with sleep apnea and their caregivers, we take this opportunity to comment on several areas of this proposed rulemaking.

D.1.b.10 Caregiver Training

ASAP supports permanently adding Caregiving Training services (HCPCS 97550 and CPT 97551) to the Medicare Telehealth Services List. We would like to encourage CMS to consider including caregiver training in managing and maintenance of positive airway pressure (PAP) equipment as well as services to also include set up, cleaning and maintenance of CPAP, APAP, BIPAP, ASV or other pulmonary air pressure devices used in the treatment of sleep apnea.

D.1.e Audio-Only Communication Technology To Meet the Definition of "Telecommunications System"

ASAP supports allowing interactive audio-only telecommunications technology when any telehealth service is furnished to a beneficiary in their home and when the distant-site physician or practitioner is technically capable of using an interactive telecommunications system but the patient is not capable of, or does not consent to, the use of video technology. This would be very helpful for beneficiaries who do not have broadband capability (including rural or underserved populations) or technological skill to use video health technology. Audio-only communications should be allowed or payable when the care provider or practitioner deems that establishing a video connection is not feasible or is not needed.

D.1.b.3 Health and Well-Being Coaching

ASAP would be in support of CMS changing Health and Well-Being Coaching (CPT codes 0591T-0593T) from provisional to permanent to the Medicare Telehealth Services List. We look forward to CMS conducting a comprehensive review on this subject and obtaining public input.

J.1.C.6 Request for Information: Services Associated With Furnishing Oral Appliances Used for the Treatment of Obstructive Sleep Apnea

General comments regarding this RFI:

1. We request that oral appliances continue to be covered as DME under code E0486. We support no change to this action, as patients have successfully benefited from using oral appliances for the treatment of obstructive sleep apnea (OSA). Oral appliances can provide access to treatment, reduce out-of-pocket costs, and a medical insurance benefit (as opposed to being covered by dental insurance since many vulnerable populations may not have dental insurance).
2. ASAP respectfully requests that the "potentially by successive patients" DME criteria linked to "repeated use" be removed from applying to oral appliances fabricated for the treatment of OSA. To the best of our knowledge, oral appliances are not able to be used by successive patients. They are a single-use, custom-fabricated item and cannot be furnished as rental equipment. These custom-fabricated appliances are similar to a prosthetic designed and fabricated specifically for an individual patient, similar to limb replacement. Therefore, oral appliances should be coded and treated in a similar manner as prosthetics.
3. We thank CMS for recognizing that oral appliances when prescribed by a practitioner for the treatment of OSA are medically reasonable and necessary and therefore may be payable by Medicare.
4. We also agree that the payment for oral sleep apnea appliances would not fall within the payment policy for dental services but are instead services and supplies for the purposes of directly treating a medical condition such as sleep apnea (unrelated to teeth or structures directly supporting the teeth).
5. In order to protect patients' interests, we believe that the providers of oral appliance therapy (OAT) should be limited to DDS or DMD who have obtained additional specialized training in dental sleep medicine.
6. The American Academy of Dental Sleep Medicine (AADSM) provides the credential of qualified dentist to those who demonstrate competency in dental sleep medicine. These qualified dentists must renew their designation every two years. AADSM acknowledges the variable nature of DSM curricula within US dental schools; therefore, they have launched the AADSM Mastery Program in 2018. It is a standardized, evidence-based curriculum designed to meet the growing need for qualified dentists and to address access-to-care issues. Furthermore, it allows for postgraduate education for dentists in the proper screening of patients and the management/follow-up of OAT to maximize patient outcomes.[1]
7. We want CMS to be aware of new emerging therapies for OSA and encourage a dialogue with patient advocacy organizations such as ASAP to better prepare for patient-centered policies.
8. ASAP supports the theory of "Right Treatment for the Right Patient" to accommodate the growing number of treatment options for OSA and to acknowledge the potential need for combination therapies when considering personalized care for patients suffering from OSA.

ASAP is providing responses to the following questions asked by CMS regarding the services related to the furnishment of oral appliances used to treat obstructive sleep apnea:

[1] Levine M, Cantwell M, Postol K, Schwartz D. Dental sleep medicine standards for screening, treating, and management of sleep-related breathing disorders in adults using oral appliance therapy. J Dent Sleep Med. 2022;9(4).

- ***Patient eligibility criteria:*** **to whom is the service related to the furnishing of oral appliances being provided? How is the nuisance snorer differentiated from the medical condition of sleep apnea? What criteria are used to determine whether the provision of these services may be medically reasonable and necessary?**

  The local coverage determination (LCD) guidance ID 33661 "Oral Appliances for Obstructive Sleep Apnea" defines the beneficiary appropriately. There is also evidence to show that certain patient factors predict better treatment success, such as less disease severity, supine-predominant OSA, younger age, female gender and being less obese, along with certain anatomical characteristics.[2] A nuisance snorer is considered to have sleep disordered breathing and not necessarily OSA. However, a sleep study is recommended by a physician to determine whether a snorer has underlying OSA or simply primary snoring (without OSA). According to the 2015 joint clinical practice guidelines by the American Academy of Sleep Medicine (AASM) and AADSM, OAT has been recommended as a treatment for primary snoring. The guideline one explicitly states that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring.[3] Snoring can increase the risk of certain health conditions, including OSA, but a sleep physician can best determine whether a treatment is necessary for a particular individual. The guidelines also state that the sleep medicine physicians are required to conduct follow-up sleep testing to improve or confirm treatment efficacy for patients fitted with oral appliances, which we support.

- ***Practitioner type:*** **Who provides these services? What credentialing is required? Is supervision required? Who would be billing for these services? Would incident to payment policy rules apply?**

  ASAP believes that a treating practitioner referring or recommending OAT should be limited to an MD board-certified in sleep medicine. For effective OAT, the level of severity of the OSA; presence of other sleep disorders, such as insomnia or narcolepsy; and ruling out central or mixed apnea needs to be done. This level of medical expertise is not present in a general practitioner, NP, PA or other normal prescribing practitioners. Therefore, a valid prescription for OAT should be limited to ones signed or approved by an MD board-certified in sleep medicine. This can easily be accomplished in the recommendation for treatment in the diagnostic sleep study. These studies already must be evaluated by an MD board-certified in sleep medicine. Recommendations for treatment should include OAT if appropriate. ASAP agrees with both the AADSM and the AASM that the use of an oral appliance is and should be available to all patients with mild to moderate sleep apnea as a first-line treatment option.

- ***Services provided:*** **What is the service definition for oral sleep apnea appliances? Is a bundle of services provided? If yes, what services are included in the bundle? What does the process for evaluating, furnishing and fitting of oral sleep apnea appliances involve? What work is involved? Which elements of the services are essential (particularly in terms of what work is essential to**

[2] Sutherland K, Vanderveken OM, Tsuda H, et al. Oral appliance treatment for obstructive sleep apnea: an update. J Clin Sleep Med. 2014;10(2):215-227. Published 2014 Feb 15. doi:10.5664/jcsm.3460

[3] Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. J Clin Sleep Med. 2015;11(7):773-827. Published 2015 Jul 15. doi:10.5664/jcsm.4858

the effectiveness of the device)? What are the costs associated with providing these services? What are the payment amounts for these services?

ASAP supports the limitation of provision or payment of OAT services to patients who have a "Medicare Eligible" or qualifying diagnosis of sleep apnea. This should include:

a) A pre-evaluation by an appropriate medical practitioner for signs and symptoms of sleep apnea and to justify a sleep study.
b) A sleep study via home sleep test (HST) or polysomnography (PSG) performed according to AASM clinical practice parameters, scored appropriately, results reviewed and recommendations made by the MD board-certified in sleep medicine to a qualified dentist for treatment.

- ***Location of services:*** **Where and how are services for oral sleep apnea appliances provided? Are all services provided in an in-person setting? Does the patient have to be present for all elements of this service? Does the service involve direct contact with the patient in each instance?**

  The services will be provided in a dental office. ASAP believes services should be provided in an in-person setting, as it is crucial for the qualified dentist to examine, evaluate and create a customized fit for the oral appliance. Yes, there is a direct contact between the qualified dentist and the patient in each instance. The patient may need to visit the dental office to see the qualified dentist periodically to seek calibration of the oral appliance to ensure appropriate position needed for effective therapy.

- ***Considerations for telehealth:*** **Are any of these services provided, or capable of being provided, via telehealth?**

  Professional groups such as AADSM are better qualified to address the telehealth aspects of providing services related to dental examinations and impressions. However, we believe that telehealth should be a consideration for special populations, such as the underserved and those living in rural areas, for improving access to oral appliance therapy. Perhaps certain services, such as calibration or adjustment, can be provided via telehealth; these services, however, should be billable. But ASAP does not support payment for telehealth services when impressions are taken remotely to fabricate for oral appliances.

- ***Site of service:*** **Can services related to oral sleep apnea appliances be provided by hospital-based physicians?**

  We believe that oral sleep apnea appliances can be provided at the hospital as long as the hospital-based dentist is a qualified dentist and is able to provide the necessary service of creating impressions, fabrications and titrations of oral appliances. We emphasize that the prescribing hospital physician still has to be board-certified in sleep medicine and the DDS or DSM are trained in dental sleep medicine.

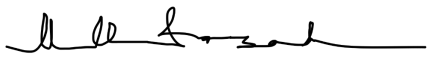
- ***Other considerations:*** **What billing procedures exist for these oral sleep apnea appliances? What existing and/or additional coding may currently describe these types of services? In addition to the HCPCS Level II codes described above (for example, E0485 and E0486), we**

believe that the CDT codes D9947 through D9957 may describe both the fabrication of the appliance, as well as services provided during and after fabrication.

We support the billing policies and processes laid out in LCD L33661 that guides the DME MACs. Additionally, ASAP believes that the inclusion of HCPCS Level II code K1037, "Docking station for use with oral device/appliance used to reduce upper airway collapsibility," to describe a docking station/power supply for an oral device/appliance should be included in the services that can be billed through Medicare. Safety-sensitive occupations such as commercial motor vehicle operators and commercial pilots have regulatory fitness for duty requirements. These include providing DOT medical examiners and FAA flight surgeons annual copies of treatment compliance. Adding K1037 code to Medicare billing may facilitate proper use and monitoring and may encourage private payor to cover for this service, since private payors often mirror or cite CMS.
Regarding the CDT codes D9947 and D9957, we believe that these codes only cover fabrication of a sleep appliance and screening of patients for sleep-related breathing disorders but do not cover the necessary comprehensive exam needed by qualified dentists. We once again emphasize here that although screening can be performed by dentists, the board-certified sleep medicine physicians should prescribe the oral appliance based on evaluation of patient needs. We further recommend that CMS have AADSM weigh in or provide further guidance or clarification on this use of CDT codes D9947 and D9957.

In conclusion, we emphasize the need for CMS to keep the oral appliances as part of DME and take our overall comments into consideration when making a decision regarding services associated with furnishing oral appliances used for treatment of OSA. We once again thank CMS for the opportunity to submit comments on the proposed rulemaking.

Sincerely,



Monica P. Mallampalli, PhD
Executive Director
Alliance of Sleep Apnea

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ASAP is a patient-oriented and led 501(c)(3) non-profit advocacy patient-oriented organization founded in 2018 with a mission to promote and advocate for optimal health of those suffering from sleep apnea. We are committed to providing patient education and resources, as well as advocacy on behalf of the patient community to advance the state of patient care and the life-long well-being of sleep apnea patients.