

## Out of Committee: Medical Devices and Drugs Update on Oral Appliances for Obstructive Sleep Apnea

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**O** bstructive Sleep Apnea (OSA) is a highly prevalent disease, associated with cardiovascular morbidity, mortality, and reduced quality of life. While Positive Airway Pressure (PAP) is efficacious for resolving the airway obstructions that define OSA, many patients are unable to adhere to PAP therapy. Surgical reconstruction can reduce the Apnea Hypopnea Index (AHI), improve quality of life and survival, but many patients defer surgery. Oral appliance therapy has emerged as an efficacious, non-invasive treatment modality for OSA, often preferred to PAP.

Oral appliances that advance the mandible have been shown to be effective for OSA treatment. The mechanism of action includes upper-air dilation and stabilization that occurs via tongue advancement and pharyngeal wall lateralization. In recent studies, oral appliances effectiveness was demonstrated for reduction of the AHI and sleepiness, improvement of quality of life and driving performance, and cardiovascular event reduction, even for those with severe OSA (Anandam, *Respirology* 2013; Doff, *Sleep* 2013; Holley, *Chest* 2011; Phillips, *AJRCCM* 2013). Clinical outcomes were comparable to those achieved with CPAP but AHI reduction was greater with CPAP therapy.

### New Technologies

Two recent technologies may improve outcome for oral appliance therapy. A

limitation of appliances for OSA is that the optimal mandibular advancement distance for a patient is not known. Thus, to test treatment efficacy, the patient usually undergoes a polysomnogram or home sleep study once symptoms improve at a given advancement setting. If the result is inadequate, the test may need to be repeated after further adjustment. For some appliances and in certain sleep centers, during the sleep study the technician enters the room and advances the appliance once or twice to determine the better position. Thus, efficacy is determined only *after* appliance delivery and somewhat imprecisely. A device called MATRx (Zephyr Sleep Technologies) was developed for use at the sleep center, advancing the mandible using an oral tray that stays in the patient's mouth during sleep. The device is remote-controlled to advance the mandible in fine increments in order to determine the precise protrusion distance for efficacy and whether jaw advancement would be effective at all, prior to production of a costly custom-fitted appliance.

The assessment of oral appliance therapy has also been limited by the absence of *objective compliance monitoring*. Objective monitoring is now available. A tiny data-recording device that attaches to an oral appliance, called DentiTrac (Braebon Medical), allows for assessment of compliance using temperature and position sensors. The manufacturer states that extensive anti-deception algorithms are utilized in data processing so that, for example, placing the device in a bath would be detected. Additional companies are seeking approval at present for other compliance monitoring devices. Compliance monitoring for oral appliances may increase their acceptance as an OSA treatment modality by the transportation industry that requires adherence monitoring for its drivers.

### Coding

Commercial insurance carriers usually cover treatment of OSA with oral appliances. Most policies allow for oral appliances to be used as primary therapy, based on patient preference over CPAP, for patients with mild to moderate OSA, as defined by an AHI between five and 30 events per hour. For patients with severe OSA, as noted by AHI >30/hour, CPAP must be tried first, but oral appliances are usually covered for CPAP intolerant patients.

Oral appliances may be billed under two HCPCS codes: E0485 and E0486.

E0485 is used for prefabricated, commonly thermoplastic appliances, which are heated and molded to the patient's dentition in the office. The CMS definition is below:

*"A prefabricated oral appliance (e0485) is one, which is manufactured in quantity without a specific beneficiary in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary (i.e., custom-fitted). Any appliance that does not meet the definition of a custom-fabricated oral appliance is considered prefabricated. E0485 is used for all prefabricated oral appliances used for the treatment of OSA including, but not limited to, mandibular advancement devices, tongue positioning appliances, etc."*

E0486 is used for a custom-made appliance, laboratory manufactured for a specific patient. This appliance requires taking dental impressions for production and after production is custom-fitted in the office. The CMS definition is below:

*A custom fabricated oral appliance (E0486) is one that is individually and uniquely made for an individual beneficiary. It involves taking an impression of the beneficiary's teeth and*



# Out of Committee: Hearing and Equilibrium Standards for the Diagnosis and Evaluation of Therapy in Meniere's Disease

## Communication from the Committee on Equilibrium

The 1995 Committee on Hearing and Equilibrium Guidelines for the Diagnosis and Evaluation of Therapy in Meniere's Disease established a practical and useful framework for the reporting of results in Meniere's treatment and outcomes research, by comparing the frequency of definite attacks for the period six months before treatment compared with the interval occurring between 18 and 24 months after treatment (ref1). Class A-F results were defined, based on a comparison of the frequency of spells (see Table 1). Class F outcome was reported if secondary treatment was initiated due to disability from vertigo. As Meniere's disease has evolved from a "disease" to Meniere's syndrome, and as treatment options have changed since the initial publication in 1995, the Committee on Equilibrium has prepared this document to serve as an assessment and publication standard for current and future reporting on Meniere's syndrome.

With the advent of intratympanic therapy for Meniere's syndrome, the accurate application of the prior guidelines to reports including intratympanic therapy as a treatment was impossible, since intratympanic therapy is often performed repeatedly, dependent on symptom severity. As such, the committee suggests considering intratympanic therapies as "intent to treat" events. The patient would enter the "intratympanic steroid treatment" or "intratympanic gentamicin treatment" arm, and irrespective of the number of treatments, outcome at 18 months to 24 months could be compared to other treatments, such as medical management or surgery. Progression to a secondary treatment other than the original "intent to treat" arm would still be considered a class F event. Patients

More information regarding the severity of attacks would be useful in evaluating therapies.

in the "intratympanic steroid intent to treat" arm would be classified as class F if they entered the "intratympanic gentamicin intent to treat" arm.

The frequency of intratympanic treatment could also be reported in any publication, and would add additional relevant detail to the evaluation of this treatment.

The committee considered whether outcome reporting based totally on frequency of attacks was an optimal strategy. The current A-F reporting guidelines are based solely on frequency of attacks, are in wide use, and have been a standard of comparability in the literature. However, more information regarding the severity of attacks would be useful in evaluating therapies.

The committee recommended the following five-point scale of daily vertigo severity, with acknowledgement that other daily vertigo severity scales are also in use:

- 0—No vertigo.
- 1—Mild attack—brief episode of vertigo lasting less than 20 minutes and/or vague sense of disequilibrium lasting less than two hours.
- 2—Moderate attack—vertigo lasting between 20 to 60 minutes and/or disequilibrium lasting greater than two hours with reduction in daily activities from 0 percent to 50 percent.
- 3—Severe attack—vertigo lasting more than one hour with or without accompanying nausea and vomiting, with or without lingering disequilibrium lasting greater than two hours with reduction in daily activities between 50 percent to 100 percent.
- 4—Extreme attack—vertigo lasting more than one hour with nausea and vomiting and persistent lingering severe disequilibrium requiring bed rest the entire day.

Table 1. 1995 AAO-HNS Classification Description

Numerical Value	
0	Class A
1-40	Class B
41-80	Class C
81-120	Class D
>120	Class E
Secondary treatment initiated because of disability from vertigo	Class F

The numerical value is the ratio of the average number of vertigo spells during the pretreatment period divided by the average number of vertigo spells for the same number of months at the end of the reporting period.

Class A indicates complete control of definite spells. **b**

### References

1. Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Meniere's disease *Otolaryngol Head Neck Surg* 1995;113:181-5.
2. Monsell, E. New and revised reporting guidelines from the Committee on Hearing and Equilibrium *Otolaryngol Head Neck Surg* 1995;113:176-8.



making a positive model of plaster or equivalent material. Basic materials are cut, bent, and molded using the positive model. It requires more than trimming, bending, or making other modifications to a substantially prefabricated item. A custom fabricated oral appliance may include a prefabricated component (e.g., the joint mechanism).

### The Otolaryngologist's Role

A qualified otolaryngologist can take impressions, fit, and bill for an oral appliance with most commercial insurance carriers. For CMS, however, when oral appliance therapy became a covered service in 2012, language was introduced specifying that the appliance needs to be provided and billed for by a licensed *dentist* (DDS or DMD). CMS covers oral appliances for treatment of OSA in patients with mild OSA (AHI five to 15) who have symptoms or cardiovascular comorbidities, for patients with moderate OSA (AHI between 15 and 30), and for those with severe OSA (AHI > 30) if CPAP is not tolerated or contraindicated.

The device needs to be "ordered by the treating *physician* following review of the report of the sleep test." There is a 90-day global period for fitting any adjustments. Oral appliances fall under the DME category.

When a qualified otolaryngologist provides the oral appliance for an OSA patient with a commercial insurance policy that covers oral appliance therapy, patients will usually be able to afford oral appliance therapy. Most dentists do not take commercial insurance as payment or do not participate with CMS, thus patient access to this therapy is often limited due to prohibitive cost.

Otherwise, the otolaryngologist can collaborate with a treating dentist. Patients who use oral appliances need to have a patent nasal airway, as the appliance obstructs their oral airway. The otolaryngologist can assist by optimizing the nasal airway for therapy.

### FDA Approval

There are more than 70 FDA-approved oral appliances. Unfortunately, the device code LRK, "Device, anti-snoring,"

includes devices for both treatment of primary snoring and OSA. It is therefore important to check a given oral appliance's approved indications prior to use. Oral appliances are not FDA-approved for use in severe OSA, and thus their use for severe OSA patients would represent an off-label use.

One can check a given device for FDA approval status at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>, or obtain a list of devices where their indications may be checked by searching the web page under product code "LRK" and "LQZ."

*Disclosures: Dr. Jacobowitz is an otolaryngologist who is board certified in sleep medicine. He does not have any commercial or competing interests in the devices mentioned above. Dr. Devaiah*

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This is another in a series of articles being produced by the Medical Devices and Drugs Committee, written by committee members, consultants, and invited guests for the AAO-HNS membership. Do you have a question or topic we can address, which may fall under the committee's charge? Do you have a comment about an article? Email our coordinator, Harrison Peery, at [hpeery@entnet.org](mailto:hpeery@entnet.org) and the chair, **Anand Devaiah, MD**, at [anand.devaiah@bmc.org](mailto:anand.devaiah@bmc.org), with the subject line "MDDC question/article," so we can identify and answer your query. We may ask your permission to publish your note, in anonymous or edited form, if it becomes the inspiration for a *Bulletin* article. 

