Challenges and Opportunities for Oral Appliance Therapy as a Non-PAP Treatment Alternative for Obstructive Sleep Apnea
Prepared by SomnoMed

Obstructive sleep apnea (OSA) is a common sleep disorder occurring in approximately 170 million people in North and South America. It is estimated that 81 million adults, or 18% of the population, suffer from moderate to severe OSA with only ~20% of them being diagnosed and treated.¹ The most common treatment for OSA is CPAP therapy.²,³ Non adherence to CPAP therapy overall remains a tremendous road block to solve and work through.⁴⁻⁶ Studies have shown that a significant amount of PAP users use their treatment half the time with as low as 17% CPAP usage after five years, and only ~50% of patients using CPAP ≥ 4 h per night after 6 months.⁷⁻¹¹ While CPAP therapy continues to be a key non-invasive therapy for those who can tolerate and use it throughout the night, alternative therapies, including oral appliance therapy must be considered with a patient-centered approach to effective OSA treatment.

Formal guidelines from the American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) have followed the growing evidence supporting OATs use.¹²

<table>
<thead>
<tr>
<th>Recommendation Statement</th>
<th>Strength of Recommendation</th>
<th>Quality of Evidence</th>
<th>Benefits versus Harms/ Burdens Assessment</th>
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</thead>
<tbody>
<tr>
<td>The Use of Oral Appliances for Treatment of Primary Snoring in Adults</td>
<td>STANDARD</td>
<td>High</td>
<td>Benefits clearly outweigh harms</td>
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<td>We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea).</td>
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The Use of Oral Appliances for Treatment of Obstructive Sleep Apnea in Adults

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<td>When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices.</td>
<td>GUIDELINE</td>
<td>Low</td>
<td>Benefits clearly outweigh harms</td>
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<td>We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy.</td>
<td>STANDARD</td>
<td>Moderate</td>
<td>Benefits clearly outweigh harms</td>
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<td>We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence.</td>
<td>GUIDELINE</td>
<td>Low</td>
<td>Benefits clearly outweigh harms</td>
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<td>We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances.</td>
<td>GUIDELINE</td>
<td>Low</td>
<td>Benefits clearly outweigh harms</td>
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<td>We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician.</td>
<td>GUIDELINE</td>
<td>Low</td>
<td>Benefits clearly outweigh harms</td>
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These guidelines are supported by a wide body of clinical evidence that recognizes CPAP as offering greater efficacy, but limited by compliance and adherence, whereby other non-PAP therapies such as custom OAT may offer lower efficacy but much greater compliance and adherence.¹³,¹⁴,¹⁵
Despite these evidence-based guidelines and the significant adherence and compliance issues related to PAP therapy, fewer than 10% of diagnosed OSA patients are treated with oral appliance therapy.

In 2013, Sharma et al.\textsuperscript{17} pointed to the challenges associated with the particularly fragmented delivery of OSA treatment care contributing to historical underutilization of oral appliance therapy for which they offered a "Sleep Medicine Care Under One Roof" model as a remedy. However, while significant gains have been made since then, including Joint (AASM/AADSM) Practice Guidelines established in 2015, broader commercial reimbursement, and a greater number of dentists trained in oral appliance therapy (200 in 2013; 1,700 today), truly integrated oral appliance treatment models between dentistry and medicine remain the exception by far, with little central coordination of clinical and insurance-related benefits.\textsuperscript{18}

In a recent Sleep Research Society focus group panel of key sleep researchers and practitioners, the use of oral appliance therapy as a first-line treatment of OSA was unanimously supported. However, many of the same barriers to integrated care models as identified by Sharma et al. in 2013 were again identified as continued challenges to patient-centered integrated care between physicians and dentists. Barriers identified include:
• State-specific scope of practice regulations that hinder formal co-treatment collaboration and coordination of benefits, between dentists and physicians and/or DMEs when dentists are often denied in-network status with payers. And...

• Patient and payer economics that require significant pre-treatment expense commitment with no assurance of future treatment efficacy and adherence. “There’s a problem of cost. Payers should have the right to require evidence that something works and is being used before paying for it” suggesting that predictive trial devices and adherence monitoring technologies, if reimbursed, would lead to significantly greater implementation of oral appliance therapy.

To address these and other non-science-based barriers standing in the way of greater implementation of a clinically accepted therapy, it was suggested that a better understanding of these barriers from a combined multi-professional society group would enable solutions to be presented to regulatory agencies and payers that would clear the way for treatment of more OSA patients more successfully.

SomnoMed is committed to fostering continued discussion and patient care collaborations between our robust network of credentialed dentists and the sleep medicine community to ensure the greatest opportunity for OSA treatment success with SomnoMed custom oral appliances that offer the greatest level of patient comfort for successful life-long treatment of obstructive sleep apnea.

Reference:

4. Weaver TE, Kribbs NB, Pack AI, et al. Night-to-night variability in CPAP use over the first three months of treatment. Sleep 1997;20; 278-83

