



## Guideline Summary NGC-10436

### Guideline Title

**Management of obstructive sleep apnea using oral appliances.**

### Bibliographic Source(s)

AIM Specialty Health. Management of obstructive sleep apnea using oral appliances. Chicago (IL): AIM Specialty Health; 2014 May 20. 4 p. [12 references]

### Guideline Status

This is the current release of the guideline.

### Scope

#### Disease/Condition(s)

Obstructive sleep apnea (OSA)

#### Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

#### Clinical Specialty

Dentistry

Family Practice

Internal Medicine

Otolaryngology

Pulmonary Medicine

Sleep Medicine

#### Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dentists

Health Plans

Managed Care Organizations

Nurses

Physician Assistants

Physicians

#### Guideline Objective(s)

To provide indications for the appropriate use of oral appliances (OAs) in the management of obstructive sleep apnea (OSA)

#### Target Population

- Patients with mild or moderate obstructive sleep apnea (OSA) who are intolerant of positive airway pressure (PAP) therapy, those for whom PAP therapy is ineffective, and those who prefer to consider an oral appliance (OA) rather than

PAP as a first line therapy

- Patients with severe OSA when PAP is not well tolerated, is ineffective, or is contraindicated

### **Interventions and Practices Considered**

Oral appliances (OAs)

- Mandibular repositioning appliances (MRA)
- Tongue retaining devices (TRD)

### **Major Outcomes Considered**

- Reduction of apnea-hypopnea index (AHI)
- Refreshing night-time sleep
- Therapy compliance
- Reduction of airway collapse during sleep

## **Methodology**

### **Methods Used to Collect/Select the Evidence**

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### **Description of Methods Used to Collect/Select the Evidence**

#### **Review of AIM Guideline References**

The first screening process identified 52 AIM Specialty Health (AIM) guideline references relevant to the guideline. A full-text review retained 38 references and 1 article was added from reference list.

#### **Guidelines Search**

A manual search of the American Academy of Sleep Medicine (AASM) and American Thoracic Society (ATS) Web sites was conducted on February 3, 2014 yielding 9 systematic reviews and 17 guidelines. A National Guideline Clearinghouse search using the keywords "sleep apnea", "polysomnography", "sleep apnoea", "narcolepsy", and "positive airway pressure" was conducted on the same day, yielding 108 results. These searches resulted in 3 guidelines for full-text review. Two of these guidelines were added to the evidence tables.

#### **Scientific Literature Update Search**

A manual search of the Institute for Clinical Systems Improvement (ICSI), Blue Cross Blue Shield Health Technology Assessment (BCBS HTA), Oregon Health Evidence Review Commission, Washington HTA Program, National Health Service (NHS) HTA Programme and of the Institute for Clinical and Economic Review (ICER), the Agency for Healthcare Research and Quality (AHRQ), the Canadian Agency for Drugs and Technologies in Health (CADTH), California committee, and the Centers for Medicare and Medicaid Services (CMS) for grey literature on February 4, 2014 gave 1 result and 5 reports, respectively. Two reports had full-text review and were added to the evidence tables. A PubMed/MEDLINE update search on the same day for literature published from January 2012 to February 2014, using keywords and index terms for polysomnography, home sleep testing, positive airway pressure treatment, oral appliances, and narcolepsy yielded 767 results. Fifty-four had abstract review and 2 articles were added through ongoing surveillance. Thirty-one of these articles had full-text review and 19 of these were added to the evidence tables.

#### **Research Process**

The research and development process is primarily conducted by the lead physician author with staff support, including medical librarians, and is overseen by the AIM members of the Clinical Guidelines Committee (CGC). The resources considered during AIM Guidelines development can include but are not limited to:

- Professional Society Guidelines
- Professional Society Appropriateness Criteria
- Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Guidance
- The Centers for Medicare and Medicaid Services (CMS)
- Initiatives sponsored by Specialty Licensing Boards

Additional web-based searches for evidence-based clinical guidelines and appropriate use criteria may also be performed using the National Guideline Clearinghouse website. Searches of the primary literature for an AIM Guideline under review are also conducted using standard databases and clinical knowledge resources. Relevant evidence-based literature or information may be brought to AIM's attention at any time by providers, AIM's physician reviewers, committee members, or other interested parties. This additional information may warrant off-cycle review and modification to include clinically-important recommendations, in addition to the usual process as determined by the Chair of the CGC.

A database is used to track the various sources of information referenced. A digital copy of each source document, including primary literature, is stored. If the content license prohibits storing a digital copy, a print copy is stored. Quality data on actual case review by AIM's physician reviewers using the guidelines under consideration shall also be made available during the guideline review process.

### **Number of Source Documents**

## NUMBER OF SOURCE DOCUMENTS

Sixty-three references were in the evidence tables reviewed by expert panels. No guideline recommendation changes were made. For this guideline, 8 references were retained, 5 were removed, and 4 added during review.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Evidence tables were organized around key clinical questions, some applicable to multiple guidelines.

### Key Clinical Questions

1. What is the efficacy of oral appliances in the management of obstructive sleep apnea (OSA)?
2. In adults and children in whom positive airway pressure (PAP) has been recommended as treatment for OSA, what is the compliance rate?

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

### Guideline Development and Review Process

#### Review Process

When a new Guideline(s) is considered, the Chair of the Clinical Guidelines Committee (CGC) may choose to form a Specialty Panel to assist with the drafting and review of the Guideline. Similarly, the assigned AIM Medical Director may use a Specialty Panel to review and comment on proposed revisions to existing Guidelines.

In order for a new or revised Guideline to be approved for use by AIM, it must be reviewed by the Internal Panel of AIM physician reviewers. The Internal Panel considers supporting evidence as well as usability and validity within the education and adjudication process. The Internal Panel votes to forward recommendations to the Independent Physician Panel.

The Independent Physician Panel considers supporting evidence and the potential impact of draft AIM Guidelines on clinical outcomes and practice. The external panel votes to forward recommendations onto the CGC.

An AIM Medical Director is assigned to each program or solution for purposes of the guideline development and review process. These AIM Medical Directors are responsible for drafting new Guidelines as necessary and ensuring that every Guideline and the procedures for applying it, is reviewed and assessed for continued validity at least once annually. The assigned AIM Medical Directors are responsible for monitoring the clinical and regulatory environment with the support of AIM medical librarians to determine when Guideline revisions are necessary, based on new, potentially-relevant evidence and other factors. The assigned AIM Medical Directors are responsible for supporting the Vice President, Clinical Operations in facilitating education and training for the staff regarding the Guidelines.

#### Committee and Panel Operational Process

Review requires that the Guideline and any supporting materials be provided to members who are given sufficient time for review. The body then meets (either in person or telephonically) to discuss the proposed changes or enhancements. Approval of a Guideline is demonstrated by a vote of at least a majority of the members of that body who are present at the meeting (but in no event fewer than three [3] affirmative votes). If approval is received, then the Guideline can proceed to the next stage of the process. If committee approval is not received at any stage of the process, then the assigned AIM Medical Director shall be responsible for addressing committee member concerns and resubmitting the Guideline for committee review.

Minutes of all meetings are maintained as well as documentation of all proposed, approved and tabled Guidelines and changes to Guidelines. All input received during any level of review is recorded and noted in any subsequent review. Input received after approval of a Guideline is presented at the next regularly scheduled CGC meeting.

The AIM Quality Improvement Committee (QIC) reviews and accepts the Guidelines.

Ultimate responsibility and accountability for the development, review and updating of AIM's Guidelines are delegated to the CGC. No new or revised Guideline can be implemented without CGC approval.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

The Clinical Guidelines Committee (CGC) considers medical director feedback and Internal and External Panel recommendations. Data from guidelines use in appropriateness reviews, provider comments, and other feedback are also used in developing recommendation revisions. The CGC is the final and ultimate approving body.

The AIM Quality Improvement Committee (QIC) reviews and accepts the Guidelines.

## Recommendations

### Major Recommendations

**Treatment with oral appliances (OA) is appropriate for patients with severe obstructive sleep apnea (OSA) (apnea/hypopnea index [AHI] greater than 30) meeting at least one of the criteria (1-3) below:**

1. The patient is not a candidate for positive airway pressure (PAP) therapy; **or**
2. PAP therapy has not been effective despite a 45 day trial and participation in a PAP compliance program; **or**
3. The patient has tried continuous positive airway pressure (CPAP) but has not been compliant despite a 45 day trial and participation in a PAP compliance program.

**Treatment with OA is appropriate for patients with mild or moderate OSA meeting both of the following criteria (A and B) below:**

- A. At least one of the following:
  1. AHI greater than or equal to 15 and less than or equal to 30; **or**
  2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke;

#### **AND**

- B. At least one of the following:
  1. The patient is not a candidate for PAP therapy; **or**
  2. PAP therapy has not been effective despite a 45 day trial and participation in a PAP compliance program; **or**
  3. The patient has tried CPAP but has not been compliant despite a 45 day trial and participation in a PAP compliance program; **or**
  4. The patient prefers to use an OA rather than PAP as the initial therapy

### **Prefabricated Oral Appliances**

Prefabricated OA are not considered to be appropriate therapy for OSA in any clinical situation.

## Clinical Algorithm(s)

None provided

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The recommendations were based on a review of published literature. When evidence was unavailable, limited, unclear, or not directly generalizable to the patient populations under consideration, expert consensus was used to develop recommendations.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate use of oral appliances in the management of obstructive sleep apnea (OSA)

### Potential Harms

Not stated

## Qualifying Statements

### Qualifying Statements

- AIM Specialty Health (AIM) has developed proprietary diagnostic and treatment management clinical guidelines (together with any updates, referred to collectively as the "Guidelines"). The Guidelines are designed to evaluate and direct the appropriate management of sleep diagnostic testing and treatment scenarios. They are based on data from the peer-reviewed scientific literature, from criteria developed by specialty societies and from guidelines adopted by other health care organizations. Access to these guidelines is being provided for informational purposes only. AIM is under no obligation to update its Guidelines. Therefore, these Guidelines may be out of date.
- The Guidelines do not constitute medical advice and/or medical care, and do not guarantee results or outcomes. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The Guidelines do not address coverage, benefit or other plan specific issues.
- The Guidelines are provided "as is" without warranty of any kind, either expressed or implied. AIM disclaims all responsibility for any consequences or liability attributable or related to any use, non-use or interpretation of information contained in the Guidelines.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

## Identifying Information and Availability

### Bibliographic Source(s)

AIM Specialty Health. Management of obstructive sleep apnea using oral appliances. Chicago (IL): AIM Specialty Health; 2014 May 20. 4 p. [12 references]

### Adaptation

Not applicable: The guideline is not adapted from another source.

### Date Released

2014 May 20

### Guideline Developer(s)

AIM Specialty Health - Professional Association

### Source(s) of Funding

AIM Specialty Health

### Guideline Committee

Clinical Guidelines Committee (CGC)

### Composition of Group That Authored the Guideline

Board certified physicians, including three board-certified sleep medicine specialists

### Financial Disclosures/Conflicts of Interest

All members of any body are required to report and discuss any potential conflicts of interest. In the event that a member discloses a conflict of interest that may influence the Guideline development process or specific recommendations, the member must not participate in the vote specific to the relevant recommendation. Ongoing review and management of conflict of interest is the responsibility of the Clinical Guidelines Committee (CGC).

### Guideline Status

This is the current release of the guideline.

### Guideline Availability

Electronic copies: Available by request. Please contact AIM Specialty Health at [NGC-request@aimspecialtyhealth.com](mailto:NGC-request@aimspecialtyhealth.com).

#### **Availability of Companion Documents**

None available

#### **Patient Resources**

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on September 25, 2014. The information was verified by the guideline developer on October 23, 2014.

#### **Copyright Statement**

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