

# VA/DoD Clinical Practice Guidelines

## THE MANAGEMENT OF CHRONIC INSOMNIA DISORDER AND OBSTRUCTIVE SLEEP APNEA



**VA/DoD Evidence-Based Practice**

**Provider Summary**

Version 1.0 | 2019



# **VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF CHRONIC INSOMNIA DISORDER AND OBSTRUCTIVE SLEEP APNEA**

**Department of Veterans Affairs**

**Department of Defense**

**Provider Summary**

## **QUALIFYING STATEMENTS**

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at [www.tricare.mil](http://www.tricare.mil) or by contacting your regional TRICARE Managed Care Support Contractor.

**Version 1.0 – 2019**

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## Introduction

The Department of Veterans Affairs (VA) and Department of Defense (DoD) Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the Health Executive Committee (HEC) “...on the use of clinical and epidemiological evidence to improve the health of the population...” across the Veterans Health Administration (VHA) and Military Health System (MHS), by facilitating the development of clinical practice guidelines (CPGs) for the VA and DoD populations.<sup>[1]</sup> This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with sleep disorders, specifically chronic insomnia disorder and obstructive sleep apnea (OSA), thereby leading to improved clinical outcomes.

An effort to create the Chronic Insomnia Disorder and OSA CPG was initiated in 2018. The Chronic Insomnia Disorder and OSA CPG includes objective, evidence-based information on the management of selected sleep disorders (chronic insomnia disorder and OSA). It is intended to assist healthcare providers in all aspects of patient care, including, but not limited to, screening, assessment, treatment, and follow-up. The system-wide goal of evidence-based guidelines is to improve patient health and well-being by guiding health providers who are taking care of patients with chronic insomnia disorder and/or OSA along management pathways that are supported by evidence. The expected outcome of the successful implementation of this guideline is to:

- Assess patient condition and determine, in collaboration with the patient, the best treatment method(s)
- Optimize patient health outcomes and improve quality of life
- Minimize preventable complications and morbidity
- Emphasize the use of patient-centered care (PCC)

## Recommendations

The following recommendations were made using a systematic approach considering four domains as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. These domains include confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability). GRADE is detailed in the full text Chronic Insomnia Disorder and OSA CPG in the Methods section and Appendix A.

Topic	Sub-topic	#	Recommendation	Strength <sup>a</sup>	Category <sup>b</sup>
Diagnosis and Assessment of Obstructive Sleep Apnea and Insomnia Disorder		1.	For patients who report sleep complaints, we suggest using the STOP questionnaire to stratify the risk of obstructive sleep apnea.	Weak for	Reviewed, New-added
		2.	We suggest that providers assess for sleep disordered breathing in patients with a history of cardiovascular or cerebrovascular events, congestive heart, and chronic prescription opioid use.	Weak for	Reviewed, New-added
		3.	Among patients with a high pretest probability for obstructive sleep apnea, we suggest a manually-scored type III home sleep apnea test (unattended portable monitor) using an event index (i.e., respiratory disturbance index, apnea-hypopnea index) $\geq 15$ events per hour to establish the diagnosis of moderate to severe obstructive sleep apnea.	Weak for	Reviewed, New-added
		4.	For patients with a high pretest probability for obstructive sleep apnea and a non-diagnostic home sleep apnea test (i.e., technically inadequate or apnea-hypopnea index $< 5$ ), we recommend repeat (home sleep apnea testing or lab-based polysomnography) testing for obstructive sleep apnea.	Strong for	Reviewed, New-added
		5.	For evaluating patients suspected of having insomnia disorder, we suggest using the Insomnia Severity Index or Athens Insomnia Scale as part of a comprehensive sleep assessment.	Weak for	Reviewed, New-added
		6.	There is no available evidence to recommend for or against additional diagnostic testing for patients with chronic insomnia disorder who do not respond to cognitive behavioral therapy for insomnia (CBT-I) or pharmacotherapy.	Neither for nor against	Reviewed, New-added
Treatment and Management of Obstructive Sleep Apnea		7.	We recommend that patients with obstructive sleep apnea on positive airway pressure therapy use this treatment for the entirety of their sleep period(s).	Strong for	Reviewed, New-added
		8.	We suggest continuing positive airway pressure therapy for patients with obstructive sleep apnea even if the patient is using this treatment for $< 4$ hours per night.	Weak for	Reviewed, New-added
		9.	In patients with obstructive sleep apnea, including those at high-risk for poor positive airway pressure adherence, such as those with posttraumatic stress disorder, anxiety, or insomnia, we recommend educational, behavioral, and supportive interventions to improve positive airway pressure adherence.	Strong for	Reviewed, New-added
		10.	We suggest that patients with obstructive sleep apnea and concurrent diagnoses/symptoms of posttraumatic stress disorder, anxiety, or insomnia be offered interventions to improve positive airway pressure adherence upon initiation of therapy.	Weak for	Reviewed, New-added
		11.	In appropriate patients with mild to moderate obstructive sleep apnea (apnea-hypopnea index $< 30$ per hour), we suggest offering mandibular advancement devices, fabricated by a qualified dental provider, as an alternative to positive airway pressure therapy.	Weak for	Reviewed, New-added
		12.	Among patients with anatomical nasal obstruction as a barrier to positive airway pressure use, we suggest evaluation for nasal surgery.	Weak for	Reviewed, New-added
		13.	For patients with obstructive sleep apnea with an apnea-hypopnea index of 15 – 65 per hour and a body mass index $< 32$ kg/m <sup>2</sup> who cannot adhere to positive airway pressure therapy, we suggest evaluation for surgical treatment with hypoglossal nerve stimulation therapy.	Weak for	Reviewed, New-added
		14.	For patients with severe obstructive sleep apnea who cannot tolerate or are not appropriate candidates for other recommended therapies, we suggest evaluation for alternative treatment with maxillomandibular advancement surgery.	Weak for	Reviewed, New-added

Topic	Sub-topic	#	Recommendation	Strength <sup>a</sup>	Category <sup>b</sup>
Treatment and Management of Obstructive Sleep Apnea (cont.)		15.	For patients with obstructive sleep apnea who cannot tolerate or who have declined all other recommended treatments, we suggest offering alternative/salvage therapies.	Weak for	Reviewed, New-added
		16.	We suggest against oxygen therapy as a standalone treatment for patients with obstructive sleep apnea who cannot tolerate other recommended therapies.	Weak against	Reviewed, New-added
		17.	For patients without nasal congestion, we suggest against the routine use of topical nasal steroids for the sole purpose of improving positive airway pressure adherence.	Weak against	Reviewed, New-added
		18.	Due to the lack of clinically significant benefit, we cannot recommend for or against: <ul style="list-style-type: none"> <li>• auto-titrating positive airway pressure when compared to fixed positive airway pressure, or</li> <li>• the use of flexible pressure delivery (e.g., C-Flex®, expiratory pressure relief)</li> </ul> to improve positive airway pressure adherence.	Neither for nor against	Reviewed, New-added
Treatment and Management of Chronic Insomnia Disorder	Behavioral and Psychological Treatments	19.	We recommend offering CBT-I for the treatment of chronic insomnia disorder.	Strong for	Reviewed, New-added
		20.	We suggest offering brief behavioral therapy for insomnia (BBT-I) for the treatment of chronic insomnia disorder.	Weak for	Reviewed, New-added
		21.	There is insufficient evidence to recommend for or against group versus individual CBT-I for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		22.	There is insufficient evidence to recommend for or against internet-based CBT-I as an alternative to face-to-face based CBT-I for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		23.	For patients diagnosed with chronic insomnia disorder, we suggest CBT-I over pharmacotherapy as first-line treatment.	Weak for	Reviewed, New-added
		24.	We suggest offering CBT-I for the treatment of chronic insomnia disorder that is comorbid with another psychiatric disorder.	Weak for	Reviewed, New-added
		25.	There is insufficient evidence to recommend for or against mindfulness meditation for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		26.	We suggest against sleep hygiene education as a standalone treatment for chronic insomnia disorder.	Weak against	Reviewed, New-added
	Complementary & Integrative Health Treatments	27.	We suggest offering auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder.	Weak for	Reviewed, New-added
		28.	There is insufficient evidence to recommend for or against acupuncture other than auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		29.	There is insufficient evidence to recommend for or against aerobic exercise, resistive exercise, tai chi, yoga, and qigong for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		30.	We suggest against cranial electrical stimulation for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added



Topic	Sub-topic	#	Recommendation	Strength <sup>a</sup>	Category <sup>b</sup>
Treatment and Management of Chronic Insomnia Disorder (cont.)	Over-the-counter Treatments	31.	We suggest against the use of diphenhydramine for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added
		32.	We suggest against the use of melatonin for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added
		33.	We suggest against the use of valerian and chamomile for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added
		34.	We recommend against the use of kava for the treatment of chronic insomnia disorder.	Strong against	Reviewed, New-added
	Pharmacotherapy	35.	In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest use of low-dose (i.e., 3 mg or 6 mg) doxepin.	Weak for	Reviewed, New-added
		36.	In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest the use of a non-benzodiazepine benzodiazepine receptor agonist.	Weak for	Reviewed, New-added
		37.	There is insufficient evidence to recommend for or against the use of ramelteon for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		38.	There is insufficient evidence to recommend for or against the use of suvorexant for the treatment of chronic insomnia disorder.	Neither for nor against	Reviewed, New-added
		39.	We suggest against the use of antipsychotic drugs for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added
		40.	We suggest against the use of benzodiazepines for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added
		41.	We suggest against the use of trazodone for the treatment of chronic insomnia disorder.	Weak against	Reviewed, New-added

<sup>a</sup> For additional information, please refer to the section on Grading Recommendations in the full text Chronic Insomnia Disorder and OSA CPG.

<sup>b</sup> For additional information, please refer to Appendix A in the full text Chronic Insomnia Disorder and OSA CPG.

Abbreviations: BBT-I: brief behavioral therapy for insomnia; CBT-I: cognitive behavioral therapy for insomnia; STOP: Snoring, Tiredness, Observed apnea, and high blood Pressure


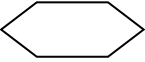
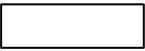
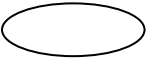


## Algorithm

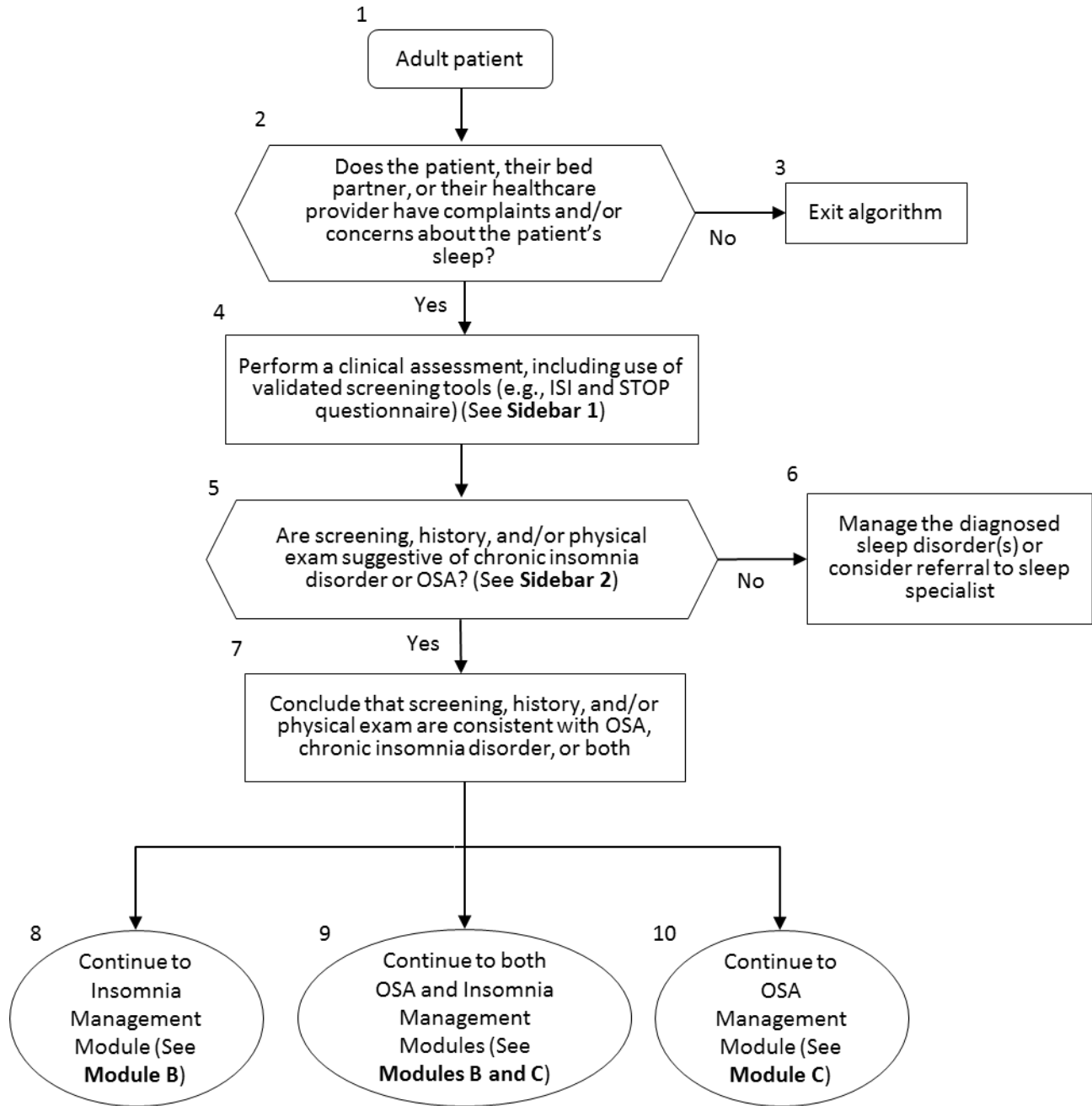
This algorithm is designed to inform providers of the recommended interventions and appropriate timing of each of the interventions for patients with chronic insomnia disorder and/or OSA. The interventions included in the algorithm are paired with the corresponding recommendation in the VA/DoD CPG for the Management of Chronic Insomnia Disorder and OSA. The use of the algorithm format as a way to represent patient management was chosen based on the understanding that such a format may promote more efficient diagnostic and therapeutic decision making and has the potential to change patterns of resource use. Although the Work Group recognizes that not all clinical practices are linear, the simplified linear approach depicted through the algorithm and its format allows the provider to assess the critical information needed at the major decision points in the clinical process. It includes:

- An ordered sequence of steps of care
- Recommended observations and examinations
- Decisions to be considered
- Actions to be taken

For each VA/DoD CPG, there is a corresponding clinical algorithm that is depicted by a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm, and arrows connect the numbered boxes indicating the order in which the steps should be followed.<sup>[2]</sup>

Shape	Description
	Rounded rectangles represent a clinical state or condition
	Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No
	Rectangles represent an action in the process of care
	Ovals represent a link to another section within the guideline

**Module A: Screening for Sleep Disorders**



Abbreviations: ISI: Insomnia Severity Index; OSA: obstructive sleep apnea; STOP: Snoring, Tiredness, Observed apnea, and high blood Pressure

### Sidebar 1: Clinical Features of OSA and Chronic Insomnia Disorder

**OSA (for detailed ICSD-3 diagnostic criteria, see [ICSD-3 Diagnostic Criteria](#) [also Appendix D in the full CPG]):**

- Sleepiness
- Loud, bothersome snoring
- Witnessed apneas
- Nightly gasping/choking
- Obesity (BMI >30 kg/m<sup>2</sup>)
- Treatment resistant hypertension

**Chronic Insomnia Disorder (for detailed ICSD-3 diagnostic criteria, see [ICSD-3 Diagnostic Criteria](#) [also Appendix D in the full CPG]):**

- Difficulty initiating sleep, difficulty maintaining sleep, or early-morning awakenings
- The sleep disturbance causes clinically significant distress or impairment in important areas of functioning
- The sleep difficulty occurs at least 3 nights per week
- The sleep difficulty has been present for at least 3 months
- The sleep difficulty occurs despite adequate opportunity for sleep
- The insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder
- The insomnia is not attributable to the physiological effects of a substance
- Coexisting mental disorders and/or medical conditions do not adequately explain the predominant complaint of insomnia

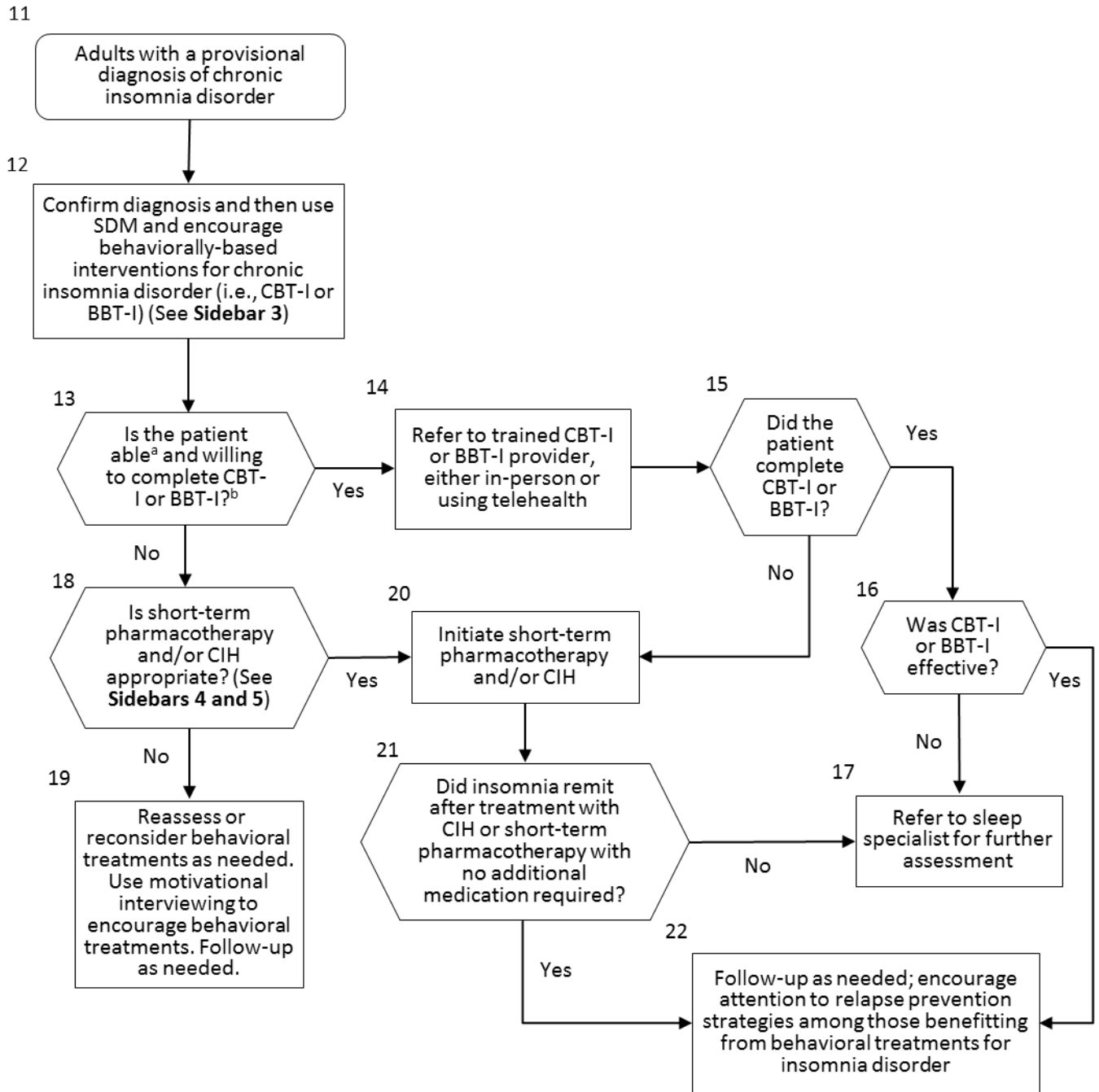
Abbreviations: BMI: body mass index; ICSD-3: International Classification of Sleep Disorders, 3<sup>rd</sup> edition; kg/m<sup>2</sup>: kilograms per meter squared; OSA: obstructive sleep apnea

### Sidebar 2: Other Sleep Disorders

- Insufficient sleep syndrome
- Restless legs syndrome
- Narcolepsy/idiopathic CNS hypersomnia
- Nightmare disorder
- REM sleep behavior disorder
- Circadian rhythm sleep disorders
- NREM parasomnias – sleepwalking/sleep eating
- Central sleep apnea

Abbreviations: CNS: central nervous system; NREM: non-rapid eye movement; REM: rapid eye movement

**Module B: Management of Chronic Insomnia Disorder**



<sup>a</sup> In cases where the patient requires immediate intervention, providers may exercise clinical judgment to determine if pharmacotherapy may be safely initiated.

<sup>b</sup> CBT-I and BBT-I are not equivalent, and there is more robust evidence for CBT-I. While this algorithm uses CBT-I and BBT-I similarly, providers referring patients for these treatments should consider availability of the treatment, the complexity and comorbidities of the patient, and the training of the provider.

Abbreviations: BBT-I: brief behavioral therapy for insomnia; CBT-I: cognitive behavioral therapy for insomnia; CIH: complementary and integrative health; SDM: shared decision making

### Sidebar 3: Components of Sleep Education, Overview of Behavioral Interventions, and Contraindications

#### Patient education and SDM:

- General information on insomnia disorder
- Education about behavioral treatment options
- Discussion of treatment options (risks, benefits, preferences, and alternatives)

#### Behavioral treatment components (CBT-I and BBT-I):

- Sleep Restriction Therapy: Limits time in bed to actual sleep duration to increase sleep drive; time in bed extended across treatment
- Stimulus Control: Strengthens bed as a cue for sleep rather than wakefulness
- Relaxation: Reduces physiological arousal and promotes optimal conditions for sleep
- Sleep Hygiene Education: Counseling regarding behaviors that interfere with sleep
- Cognitive Restructuring (CBT-I only): Addresses cognitive arousal (busy or racing mind) by challenging unhelpful thoughts and beliefs about sleep, a natural result of the struggle with insomnia

#### Conditions requiring tailored or delayed CBT-I:

- Medically unstable
- Active alcohol or drug use disorder
- Excessive daytime sleepiness
- Engagement in exposure-based PTSD treatment
- Uncontrolled seizure disorder
- Bipolar disorder
- Current acute mental health symptoms

Abbreviations: BBT-I: brief behavioral therapy for insomnia; CBT-I: cognitive behavioral therapy for insomnia; PTSD: posttraumatic stress disorder; SDM: shared decision making

### Sidebar 4: Pharmacotherapy Considerations for Chronic Insomnia Disorder

#### Before starting short-term pharmacotherapy, review sleep history, and evaluate contraindications for pharmacotherapy:

- Evaluate for other sleep disorders (e.g., apnea, NREM parasomnias), daytime sleepiness, respiratory impairment, cognitive impairment, substance abuse history, and medication interactions
- Encourage non-pharmacologic approaches (e.g., CBT-I or BBT-I)

#### When short-term pharmacotherapy is appropriate, consider the following:

- Low-dose doxepin; or
- Non-benzodiazepine benzodiazepine receptor agonists (all patients offered treatment with a non-benzodiazepine benzodiazepine receptor agonist should be specifically counseled regarding the risk of complex sleep-related behaviors)

**The use of antipsychotic agents is NOT suggested for treatment of chronic insomnia disorder.**

**Consider sleep specialist referral in patients who do not respond to pharmacotherapy.**

Abbreviations: BBT-I: brief behavioral therapy for insomnia; CBT-I: cognitive behavioral therapy for insomnia; NREM: non-rapid eye movement

### Sidebar 5: Other Approaches

**CIH treatments suggested for chronic insomnia disorder:**

- Auricular acupuncture with seed and pellet

**Other treatments NOT suggested chronic insomnia disorder:**

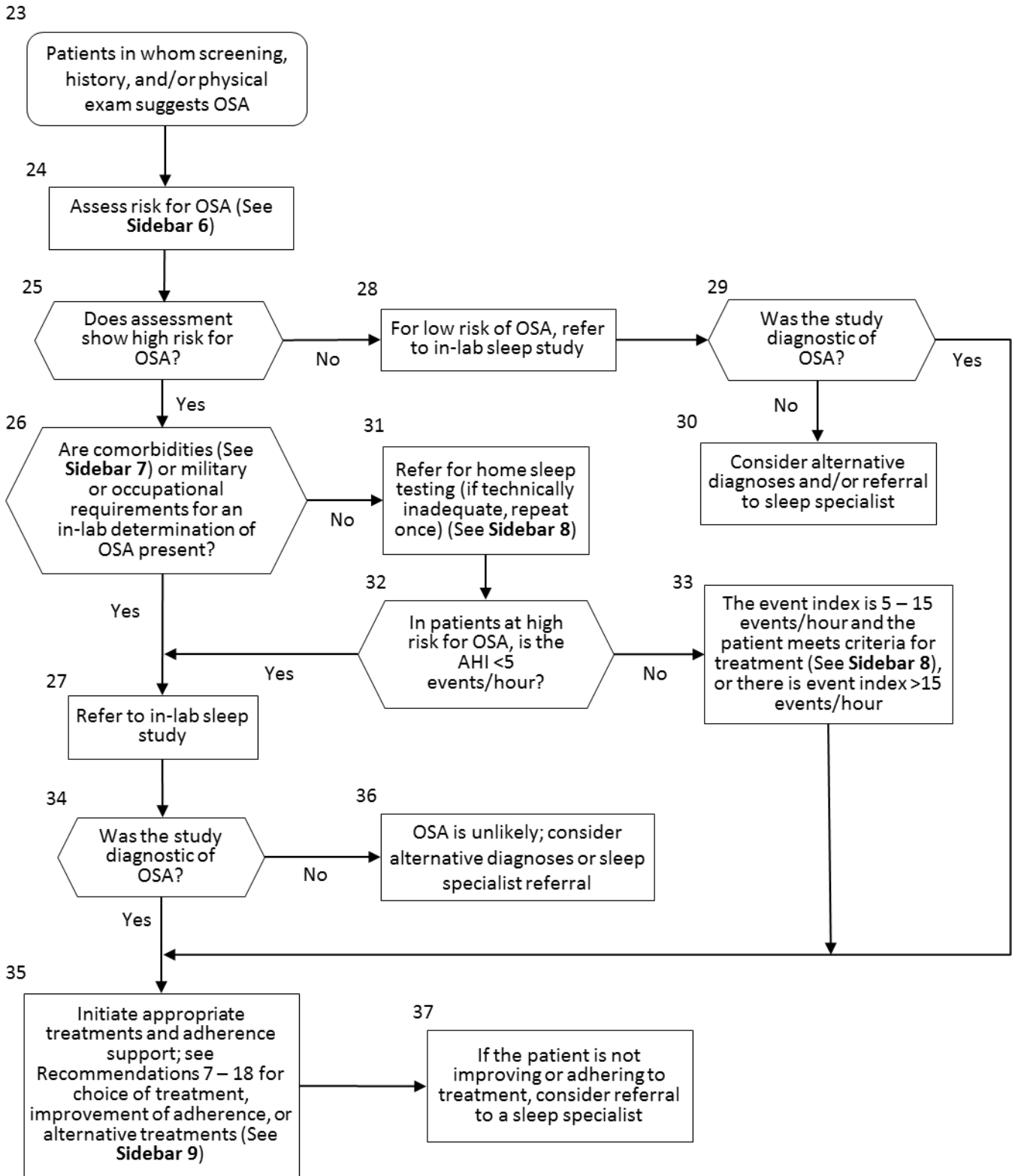
- Alpha-stim
- Cranial electrical stimulation
- Diphenhydramine
- Melatonin
- Chamomile
- Valerian

**Other treatments NOT recommended for chronic insomnia disorder:**

- Kava

Abbreviations: CIH: complementary and integrative health

**Module C: Management of Obstructive Sleep Apnea**



Abbreviations: AHI: apnea-hypopnea index; OSA: obstructive sleep apnea



### Sidebar 6: Risk of OSA\*

#### Consider using STOP questionnaire for risk stratification:

1. Snoring loudly
2. Tired, fatigue, sleepy in daytime
3. Observed to stop breathing
4. Treated for hypertension

**High risk if  $\geq 2$  items are answered “yes”**

**Low risk if  $< 2$  items are answered “yes”**

**STOP questionnaire should not replace clinical judgment; clinical assessment should include:**

**BMI  $> 30$  kg/m<sup>2</sup>, age  $> 50$ , menopausal status, neck circumference, family history, and crowded oropharynx**

\*i.e., high risk or high pretest probability of OSA

Abbreviations: BMI: body mass index; kg/m<sup>2</sup>: kilograms per meter squared; OSA: obstructive sleep apnea; STOP: Snoring, Tiredness, Observed apnea, and high blood Pressure

### Sidebar 7: Comorbidities

- Significant cardiorespiratory disease
  - Cardiovascular comorbidities including congestive heart failure
  - Pulmonary comorbidities that impact baseline oxygen saturation (or requiring oxygen therapy) including chronic obstructive pulmonary disease: GOLD Stage III or IV
- Stroke
- Respiratory muscle weakness
- Hypoventilation/suspected hypoventilation due to neuromuscular or pulmonary disorder
- Opioid use
- Chronic insomnia
- PTSD

Abbreviations: GOLD: Global Initiative for Chronic Obstructive Lung Disease; PTSD: posttraumatic stress disorder

### Sidebar 8: AHI 5 – 15 on HSAT

1. Treatment for OSA is recommended for symptomatic patients with an AHI or REI of 5 – 15 events per hour
2. For patients who will have limitations to their work and/or lifestyle, definitive testing with an in-lab PSG is recommended
3. For the general population without such restrictions, an AHI of 5 – 15 events per hour on HSAT should be treated as OSA

Abbreviations: AHI: apnea-hypopnea index; HSAT: home sleep apnea testing; OSA: obstructive sleep apnea; PSG: polysomnogram; REI: respiratory event index

### Sidebar 9: Treatment of OSA

1. For patients with severe OSA (i.e., AHI  $\geq 30$  events per hour), the recommended initial therapy is PAP
2. For patients with mild to moderate OSA (i.e., AHI 5 –  $< 30$  events per hour), either PAP or MAD therapy can be considered for initial therapy; choice of treatment should be based on clinical evaluation, comorbidities, and patient preference
3. Educational, behavioral therapy, and supportive interventions should be offered to improve PAP adherence
4. Weight loss and a comprehensive lifestyle intervention program should be encouraged in all patients with OSA who are overweight or obese; while weight loss alone is typically insufficient as therapy for OSA, weight loss may result in improvement of AHI
5. In those OSA patients who are not adherent to PAP and/or MAD therapy or have persistent symptoms despite adequate therapy, referral to a physician with expertise in sleep medicine is recommended

Abbreviations: AHI: apnea-hypopnea index; MAD: mandibular advancement device; OSA: obstructive sleep apnea; PAP: positive airway pressure.

## Scope of the CPG

Ideally, any patient in the healthcare system should have access to the interventions that are recommended in this guideline regardless of the setting and after taking into consideration the patient's specific circumstances.

Guideline recommendations are intended to be patient-centered. Thus, treatment and care should take into account a patient's needs and preferences. Good communication between healthcare professionals and the patient is essential and should be supported by evidence-based information tailored to the patient's needs. An empathetic and non-judgmental approach facilitates discussions sensitive to gender, culture, ethnic, and other differences. The information that patients are provided about treatment and care should be culturally appropriate and also available to people with limited literacy skills. It should also be accessible to people with additional needs, such as physical, sensory, or learning disabilities. Family involvement should be considered, if appropriate.

This CPG is designed to assist providers in managing or co-managing adult patients with chronic insomnia disorder and/or OSA, as those are the most prevalent sleep disorders. Moreover, the patient population of interest for this CPG is adults with OSA and/or insomnia who are eligible for care in the VA and DoD healthcare delivery systems. It includes Veterans as well as deployed and non-deployed active duty Service, Guard, and Reserve Members and their dependents.

## Methods

The methodology used in developing the 2019 CPG follows the *Guideline for Guidelines*,<sup>[3]</sup> an internal document of the VA and DoD EBPWG that was updated in January 2019. The *Guideline for Guidelines* can be downloaded from <http://www.healthquality.va.gov/policy/index.asp>. This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the VA and DoD, known as the Work Group and, ultimately, the development and submission of the new Chronic Insomnia Disorder and OSA CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical practice recommendations and writing and publishing a guideline document to be used by providers within the VA/DoD healthcare systems as well as those within the community who treat military personnel or Veterans. Specifically, the Champions and Work Group members for this guideline were responsible for identifying the key questions (KQs) of the most clinical relevance, importance, and interest for the management of patients with chronic insomnia disorder and/or OSA. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified four clinical leaders, Susmita

Chowdhuri, MD, MS, FAASM and Christi Ulmer, PhD, CBSM, DBSM from the VA, and COL Vincent Mysliwiec, MD, FAASM and Christopher Spevak, MD, MPH, JD from the DoD, as Champions for the 2019 CPG.

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in January 2018, with participation from the contracting officer's representative (COR), leaders from the VA Office of Quality, Safety and Value, the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review (SR) about the management of patients with chronic insomnia disorder and/or OSA. The group also identified a list of clinical specialties and areas of expertise important and relevant to the management of chronic insomnia disorder and/or OSA, from which Work Group members were recruited. The specialties and clinical areas of interest included: pulmonology, neurology, psychiatry, psychology, behavioral sleep medicine, pharmacology, dental, ear, nose, and throat, surgery, and primary care.

The guideline development process for the 2019 CPG consisted of the following steps:

1. Formulating and prioritizing KQs and defining critical outcomes
2. Convening patient focus group
3. Conducting the systematic evidence review
4. Convening a face-to-face meeting with the CPG Champions and Work Group members
5. Drafting and submitting a final CPG on the management of chronic insomnia disorder and/or OSA to the VA/DoD EBPWG

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## **A. Grading Recommendations**

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The Champions and Work Group used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence base and assign a strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:[\[25\]](#)

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence
- Patient or provider values and preferences
- Other implications, as appropriate, e.g.,:
  - Resource use
  - Equity
  - Acceptability
  - Feasibility
  - Subgroup considerations

Using these four domains, the Work Group determined the relative strength of each recommendation (“Strong” or “Weak”). A “Strong” recommendation generally indicates high confidence in the quality of the available scientific evidence, a clear difference in magnitude between the benefits and harms of an intervention, similarity among patient or provider values and preferences, and the apparent influence of other implications (e.g., resource use, feasibility). If the Work Group has less confidence after the assessment across these domains and believes that additional evidence may change the recommendation, it generally assigns a “Weak” recommendation. It is important to note that the GRADE terminology used to indicate the assessment across the four domains (i.e., Strong versus Weak) should not be confused with the clinical importance of the recommendation. A “Weak” recommendation may still be important to the clinical care of a patient with insomnia disorder and/or OSA.

Occasionally, instances may occur when the Work Group believes there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong for (or “We recommend offering this option ...”)
- Weak for (or “We suggest offering this option ...”)
- No recommendation for or against (or “There is insufficient evidence ...”)
- Weak against (or “We suggest not offering this option ...”)
- Strong against (or “We recommend against offering this option ...”)

The grade of each recommendation made in the 2019 CPG can be found in the section on [Recommendations](#). Additional information regarding the use of the GRADE system can be found in Appendix A in the full Chronic Insomnia Disorder and OSA CPG.

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## Patient-centered Care

VA/DoD CPGs encourage clinicians to use a PCC approach that is individualized based on patient needs, characteristics, and preferences. Regardless of the setting, all patients in the healthcare system should be able to access evidence-based care appropriate to that patient. When properly executed, PCC may decrease patient anxiety, increase trust in clinicians,<sup>[4]</sup> and improve treatment adherence.<sup>[5]</sup> Improved patient-clinician communication and a PCC approach convey openness and support disclosure of current and future concerns.

As part of the PCC approach, clinicians should review the outcomes of previous healthcare experiences of patients with chronic insomnia disorder and/or OSA. Providers should ask each patient about any concerns he or she has or any perceived barriers to high quality care. In addition, they should educate the patient about the actions that need to be taken and any decisions that need to be made and should involve the individual in decision making regarding the management of chronic insomnia disorder and/or OSA.

## Shared Decision Making

Throughout this VA/DoD CPG, the authors encourage clinicians to focus on shared decision making (SDM). The SDM model was introduced in *Crossing the Quality Chasm*, an Institute of Medicine (IOM) (now called the National Academy of Medicine [NAM]) report, in 2001.<sup>[6]</sup> It is readily apparent that patients, together with their clinicians, make decisions regarding their plan of care and management options. Patients with chronic insomnia disorder and/or OSA require sufficient information and time to be able to make informed decisions. Clinicians must be adept at presenting information to their patients regarding individual treatments, expected outcomes, and levels and/or locations of care. Clinicians are encouraged to use SDM to individualize treatment goals and plans based on patient capabilities, needs, goals, and preferences.

## Diagnosis and Assessment of Obstructive Sleep Apnea and Insomnia Disorder

### 1. For patients who report sleep complaints, we suggest using the STOP questionnaire to stratify the risk of obstructive sleep apnea. (*Weak for; Reviewed, New-added*)

- Using an apnea-hypopnea index (AHI) (defined as the number of apneas and hypopneas per hour of sleep)  $\geq 5$  events per hour on polysomnography (PSG) as the gold standard test to define OSA, our evidence review yielded data on diagnostic accuracy for only the Berlin Questionnaire (BQ), STOP-BANG questionnaire (Snoring, Tiredness, Observed apnea, high blood Pressure, Body mass index, Age, Neck circumference, male Gender), STOP questionnaire (Snoring, Tiredness, Observed Apnea and high blood Pressure), and Epworth Sleepiness Scale (ESS).<sup>[7]</sup>
- The Work Group agreed that, considering all these performance measures, none of these questionnaires has sufficient accuracy in establishing a diagnosis of OSA. Because confirmatory objective testing is a requirement after screening, focusing on sensitivity as the metric of choice will increase the likelihood of detecting cases while minimizing the false negative cases. With that in mind, among these four screening tools, the sensitivities for STOP and STOP-BANG were the highest, and similar to each other. Given their performance similarities and its simpler administration, STOP was included in our recommendation.

- The Work Group’s confidence in the quality of the evidence was moderate.[\[7\]](#) Although it could introduce some inefficiency and possible false positive cases, the Work Group determined the benefits of OSA screening outweigh its harms or burdens. The Work Group acknowledged that implementing screening would require additional resources and that these resources may not be available to all providers. Owing to variability in resource availability, the Work Group determined that a “Strong for” recommendation could impose an unintended burden on providers with limited access to resources. Thus, the Work Group decided upon a “Weak for” recommendation.

**2. We suggest that providers assess for sleep disordered breathing in patients with a history of cardiovascular or cerebrovascular events, congestive heart, and chronic prescription opioid use. (Weak for; Reviewed, New-added)**

- We reviewed the evidence supporting the key clinical factors that contribute to sleep disordered breathing (SDB), a term encompassing both obstructive and central sleep apnea (CSA) because the two conditions may present with similar clinical features and are pathophysiologically linked.[\[8,9\]](#) Therefore, their measure of apnea severity (i.e., AHI, obstructive apnea index, and central apnea index [CAI]) are often reported concurrently in the epidemiology literature. The available evidence suggests that individuals who have cardiovascular disease (CVD), cerebrovascular disease, congestive heart failure (CHF), or a history of using prescription opioids are at increased risk of obstructive, central, or both forms of SDB.[\[10-16\]](#)
- In a prospective cohort study of middle-aged and older adults, patients with incident CVD had greater levels of both obstructive and central apnea indices compared with participants without incident CVD.[\[11\]](#) The evidence also suggested patients on opioid therapy for chronic spinal pain had an increased prevalence of OSA (13.8%) compared to patients without prescription opioids or benzodiazepines (10.5%).[\[12\]](#) It also noted a significant correlation of OSA diagnosis with multiple comorbid conditions (e.g., a history of CHF, stroke, atherosclerotic CVD, increasing body mass index [BMI]). Additionally, a large study from a national sample of United States (U.S.) Veterans reported that male gender and chronic prescription opioid use were associated with two times greater risk of CSA diagnosis compared with controls.[\[16\]](#)
- The Work Group’s confidence in the quality of the evidence is very low, though the risks of assessment for SDB were small.[\[10-16\]](#) The Work Group determined there were few harms associated with assessing these high-risk patients for SDB, though there might be some cost involved. There is likely some variation in patient values and preferences (e.g., some patients may not want to undergo clinical assessment for SDB or be asked about usage of opioid medications).

**3. Among patients with a high pretest probability for obstructive sleep apnea, we suggest a manually-scored type III home sleep apnea test (unattended portable monitor) using an event index (i.e., respiratory disturbance index, apnea-hypopnea index)  $\geq 15$  events per hour to establish the diagnosis of moderate to severe obstructive sleep apnea. (Weak for; Reviewed, New-added)**

**4. For patients with a high pretest probability for obstructive sleep apnea and a non-diagnostic home sleep apnea test (i.e., technically inadequate or apnea-hypopnea index  $< 5$ ), we recommend repeat**



**(home sleep apnea testing or lab-based polysomnography) testing for obstructive sleep apnea.  
(Strong for; Reviewed, New-added)**

- The Work Group reviewed data on the validity of portable monitoring (PM) devices with a focus on the sensitivity and specificity of PMs compared to in-lab PSG.[\[17\]](#) Largely based on concerns regarding specificity of type III devices in this study at the 5 events per hour cutoff, the Work Group recommends applying a cutoff of 15 events per hour for a definitive diagnosis of OSA on home sleep apnea tests (HSATs). For patients who undergo home testing and have a reported event index (AHI, respiratory disturbance index, or respiratory event index [REI]) of 5 to 15 events per hour, a clinical decision integrating the patient’s event index, symptoms, occupation, and comorbid disorders should be used to render an appropriate diagnosis. If there is a question, either repeat testing or a referral to a sleep specialist should be considered. If the initial HSAT is non-diagnostic of OSA (event index of <5 per hour), either a repeat HSAT or in-lab PSG should be performed.
- Because all patients appropriately selected for evaluation with PM should have a high pretest probability for OSA, negative, non-diagnostic HSATs, and technically inadequate studies should prompt further evaluation to ensure the absence of SDB. Depending on the results of the initial HSAT, this repeat evaluation can be either a repeat HSAT or an in-lab PSG.
- Because of the risk of significant harm related to undiagnosed (and therefore untreated) OSA in this pre-selected population at high risk for the disease, the Work Group determined it was important for this guideline to explicitly state the need for repeat testing in patients for whom an HSAT does not confirm a diagnosis of OSA. Although not included in the systematic evidence review and, thus, independent from the strength of this recommendation, there is significant evidence suggesting harm in patients with undiagnosed or untreated OSA. Patients with untreated OSA have a threefold increased risk of MVCs compared to the general population [\[18\]](#) and have a higher risk of personal injury related to those MVCs.[\[19,20\]](#) An SR of nine studies of patients with moderate to severe OSA by Treager et al. (2010) noted that treatment with PAP reduces crash risk and relieves excessive daytime sleepiness among these patients.[\[21\]](#) Elevated AHI is associated with an increased likelihood of hypertension, stroke, coronary artery disease, and heart failure, even after adjustment for other cardiovascular risk factors.[\[22,23\]](#) An AHI >20 events per hour confers a higher risk of stroke [\[24\]](#) and >30 events per hour confers a higher risk of dysrhythmias and all-cause mortality.[\[25,26\]](#)
- The Work Group’s confidence in the quality of the evidence for Recommendation 3 is moderate.[\[17\]](#) Regarding Recommendation 4, the Work Group’s confidence in the quality of the evidence is low.[\[17,27\]](#) However, the Work Group believed that the risk of significant harm related to undiagnosed OSA as a result of a non-diagnostic test in a patient with high pretest probability significantly outweighed concern about the negligible harm or minor patient inconvenience of repeat testing. OSA is a serious medical disorder and undiagnosed OSA is associated with accidents (e.g., motor vehicle, industrial, work-related), adverse cardiovascular outcomes, and, in severe disease, worsened all-cause mortality. Due to this risk of significant harm related to undiagnosed OSA in a high risk population, repeat testing is recommended to ensure the absence of OSA. Thus, the Work Group decided upon a “Strong for” recommendation.

- 5. For evaluating patients suspected of having insomnia disorder, we suggest using the Insomnia Severity Index or Athens Insomnia Scale as part of a comprehensive sleep assessment. (Weak for; Reviewed, New-added)**
- Self-report measures for the assessment of insomnia disorder are an important part of a larger comprehensive assessment. Diagnosing insomnia disorder requires a sleep history and detailed medical, substance, and psychiatric history, and self-reported measures are recommended as part of this process for both evaluation and differential diagnosis.[\[28\]](#)
  - Based on the questionnaire length, complexity of the scoring process, and intended purpose of each measure, the Work Group determined that the Insomnia Severity Index (ISI) and Athens Insomnia Scale (AIS) have greater clinical utility and chose to recommend them over the Pittsburgh Sleep Quality Index (PSQI) for insomnia disorder screening.
  - The ISI and the AIS [\[29\]](#) have high diagnostic accuracy for insomnia. In an SR conducted by Chiu et al. (2016), both measures were found to be both sensitive and specific for accurately classifying individuals with insomnia.[\[30\]](#)
  - Based on limitations in the body of evidence (e.g., publication bias, patient selection, reference standards, study quality), the Work Group’s confidence in the quality of the evidence is low.[\[30\]](#) Owing to the brevity and high accuracy of the recommended measures, the Work Group concluded that the benefits of their use outweigh any harms/burdens.
- 6. There is no available evidence to recommend for or against additional diagnostic testing for patients with chronic insomnia disorder who do not respond to cognitive behavioral therapy for insomnia (CBT-I) or pharmacotherapy. (Neither for nor against; Reviewed, New-added)**
- Additional diagnostic testing for patients with chronic insomnia disorder who do not respond to cognitive behavioral therapy for insomnia (CBT-I) or pharmacotherapy was included in the evidence search; however, there was no available evidence to make a recommendation for or against additional diagnostic testing, such as home sleep apnea testing or laboratory PSG, in this patient population.
  - As treatment for refractory insomnia is increasingly recognized and many patients with insomnia disorder have other suspected sleep disorders (e.g., OSA), the Work Group acknowledged that further evaluation of the patient, as part of an SDM process, to include consideration of a referral to a sleep medicine specialist, should be considered.

## Treatment and Management of Obstructive Sleep Apnea

- 7. We recommend that patients with obstructive sleep apnea on positive airway pressure therapy use this treatment for the entirety of their sleep period(s). (Strong for; Reviewed, New-added)**
- 8. We suggest continuing positive airway pressure therapy for patients with obstructive sleep apnea even if the patient is using this treatment for <4 hours per night. (Weak for; Reviewed, New-added)**
- Evidence supports an association between increasing positive airway pressure use and improved outcomes.[\[31-34\]](#) Several studies have reported benefits with positive airway pressure (PAP) use of <4 hours per night.[\[33,35,36\]](#)

- PAP therapy’s safety has been established across multiple studies. PAP therapy has been associated with nasal congestion, oronasal dryness, mask discomfort, and nocturnal awakenings.[34] Although not included in the systematic evidence review and, therefore, independent from the strength of this recommendation, the weight gain associated with PAP use appears to be modest and was not associated with adverse metabolic effects.[37]
- For Recommendations 7 and 8, the Work Group’s confidence in the quality of the evidence is moderate.[31-34] Based on the evidence that longer duration of nightly PAP use is associated with greater improvements in patient-centric outcomes, we recommend that patients with OSA on PAP use PAP for the entirety of their sleep periods. However, some PAP therapy is better than no PAP therapy for improving outcomes (i.e., sleepiness, functional status, and quality of life).

**9. In patients with obstructive sleep apnea, including those at high-risk for poor positive airway pressure adherence, such as those with posttraumatic stress disorder, anxiety, or insomnia, we recommend educational, behavioral, and supportive interventions to improve positive airway pressure adherence. (Strong for; Reviewed, New-added)**

- A Cochrane Review found that educational, behavioral, and supportive interventions improve adherence to PAP (i.e., hours of use per night) among patients with SDB.[38] This review primarily included studies of PAP-naive patients at the beginning of treatment and concluded that supportive strategies, educational therapy, and behavioral interventions were associated with significant improvements in mean hours of PAP use per night and in the proportion of patients who used PAP more than four hours per night, as compared to control conditions (typically usual care).
- The Work Group’s confidence in the quality of the evidence for this recommendation is moderate.[38] Other considerations relevant to this recommendation included the benefits of improved adherence to a known effective therapy that has no identified harms, patient values and preferences for these interventions, and acceptability of the intervention by providers.

**10. We suggest that patients with obstructive sleep apnea and concurrent diagnoses/symptoms of posttraumatic stress disorder, anxiety, or insomnia be offered interventions to improve positive airway pressure adherence upon initiation of therapy. (Weak for; Reviewed, New-added)**

- There was general consistency in the evidence demonstrating lower PAP adherence rates among individuals with insomnia, posttraumatic stress disorder (PTSD), or anxiety. Evidence from one randomized controlled trial (RCT) supported that patients with OSA and anxiety had lower adherence to PAP than patients without anxiety.[39] Moreover, one SR of three observational studies found that regular use of PAP and number of hours used per night were lower among Veterans with comorbid PTSD compared to Veterans with OSA alone.[40]
- There is no evidence for additional harms or reduced benefits of supportive, educational, or behavioral interventions to improve PAP adherence among patients with these comorbid conditions; however, there may be additional burden associated with identifying these comorbid conditions so that patients can be targeted for early access.
- The Work Group’s confidence in the quality of the evidence for this recommendation was low for PTSD (based on small sample sizes) and moderate for comorbid anxiety and insomnia.[38-40]

Other considerations included indirectness of evidence; challenges in screening SDB patients for comorbid conditions; the benefits of improved adherence to a known effective therapy with no identified harms; patient values and preferences that indicate many patients would desire these interventions; and acceptability of the intervention by providers.

**11. In appropriate patients with mild to moderate obstructive sleep apnea (apnea-hypopnea index <30 per hour), we suggest offering mandibular advancement devices, fabricated by a qualified dental provider, as an alternative to positive airway pressure therapy. (*Weak for; Reviewed, New-added*)**

- The Work Group reviewed studies comparing PAP and mandibular advancement device (MAD) therapy and found that while MAD may be less efficacious in reducing the AHI, the increased usage of MAD, in part based on patient preference and acceptance, can result in more effective treatment.[\[41-45\]](#) Although all studies concluded that PAP therapy was superior in AHI reduction, none found a significant difference in improvement of daytime sleepiness, cognitive function, vigilance, hypertension, or quality of life measures. One randomized cross-over trial of Veterans diagnosed with OSA and PTSD reported significantly higher patient preference for and adherence to MAD over PAP therapy.[\[43\]](#)
- Based on the relative lack of RCTs with an adequate sample size, proper blinding, objective measurements, and mitigated risk of bias, the Work Group's confidence in the quality of the evidence for this recommendation is low.[\[41-45\]](#) However, the 30-plus year body of evidence was acceptable to render a recommendation. Other considerations included the requirement for adequate dentition (i.e., 8 – 10 teeth in both arches) and supporting bone/periodontium, patient desire or need for non-PAP alternatives, benefits of patient comfort with MAD, and the requirement for a follow-up sleep study in patients with moderate to severe OSA treated with MAD. The Work Group also considered the importance of ensuring a qualified dentist was involved in MAD selection, delivery, and follow-up care.

**12. Among patients with anatomical nasal obstruction as a barrier to positive airway pressure use, we suggest evaluation for nasal surgery. (*Weak for; Reviewed, New-added*)**

- Upper airway surgery has been shown to improve PAP adherence in patients with OSA who are struggling to tolerate this therapy. Camacho et al. (2015) demonstrated that after sinonasal surgery to improve nasal breathing, the proportion of patients regularly using PAP increased from 39% to 90%.[\[46\]](#) Similarly, Ayers et al. (2016) found a mean increase in nightly PAP use of 0.62 hours after upper airway surgery.[\[47\]](#)
- While there is consistent evidence supporting upper airway surgery to improve PAP tolerance, this treatment's effectiveness may be limited based on the known variability in provider and patient preferences. Patients' and providers' desire to pursue surgery could be based on prior experiences with surgery. Also, operative procedures can come at a significant financial cost to the patient and the healthcare system. Furthermore, access to a qualified surgeon could be a limiting factor, especially in rural or remote areas. In addition, not every patient is a good candidate for surgical treatment, based on comorbidity profile and general health status.
- The Work Group's confidence in the quality of the evidence for this recommendation is very low.[\[46,47\]](#) This is largely because most studies included in the SRs are observational studies or

case series of small numbers of patients. However, because the evidence was consistent in showing benefit and the risk of adverse events is small, the benefits were deemed to slightly outweigh the risks.

**13. For patients with obstructive sleep apnea with an apnea-hypopnea index of 15 – 65 per hour and a body mass index <32 kg/m<sup>2</sup> who cannot adhere to positive airway pressure therapy, we suggest evaluation for surgical treatment with hypoglossal nerve stimulation therapy. (*Weak for; Reviewed, New-added*)**

- Since as many as half of patients prescribed PAP therapy for the treatment of OSA will not be adherent long-term, there is a need for alternative treatment options.[\[48-51\]](#) Kompelli et al. (2018) found statistically and clinically significant benefits in both objective (AHI and oxygen desaturation index [ODI]) management of OSA and subjective (ESS and Functional Outcomes of Sleep Questionnaire [FOSQ]) improvement of daytime sleepiness and quality of life measures.[\[52\]](#) In the longest prospective cohort trial completed to date, a mean AHI reduction from 32 events per hour to 12.4 events per hour was demonstrated five years after device implantation, with 71 of the original 126 patients completing the follow-up PSG at five years.[\[53\]](#)
- The Work Group acknowledged that many factors can limit this treatment’s utility. There is known variability in provider and patient preferences regarding surgery and implantable devices. Moreover, the Work Group considered the cost of surgery and the device, as well as the need for a specially trained surgeon. Furthermore, this therapy has mostly been tested in a specific population of patients (i.e., those who could not adhere to PAP therapy) based on strict exclusion criteria. In addition, not every patient is a good surgical candidate based on comorbid conditions and general health status. Compatibility of the device with magnetic resonance imaging (MRI) should also be considered.
- The Work Group’s confidence in the quality of the evidence for this recommendation is low because the individual studies are all either retrospective or prospective cohort studies with a small number of subjects that lack reporting on confounding variables.[\[52,53\]](#) However, as the evidence was consistent in showing benefit, and the known risk of adverse events is low, the benefits were deemed to outweigh the risks for this treatment. Patient values and preferences regarding this treatment were considered to be somewhat varied.

**14. For patients with severe obstructive sleep apnea who cannot tolerate or are not appropriate candidates for other recommended therapies, we suggest evaluation for alternative treatment with maxillomandibular advancement surgery. (*Weak for; Reviewed, New-added*)**

- Altering the facial skeleton can have a profound impact on the diameter and collapsibility of the upper airway. The literature base regarding maxillomandibular advancement surgery (MMA) for OSA supported statistically significant improvements in several critical outcomes, including AHI, ESS scores, and FOSQ scores.[\[54-62\]](#) An SR including 234 patients found a mean reduction in AHI of 87% with MMA surgery in patients with a baseline mean AHI of 54 events per hour.[\[54\]](#) ESS score improvement was also significant, from a preoperative mean of 17.8 to 4.7 postoperatively. Limited information was available on adverse events, although 1 – 2% of patients experience life-threatening complications.[\[54\]](#)

- The Work Group acknowledged that many factors can limit the utility of this treatment. While the available evidence supporting the treatment of OSA with MMA surgery is consistent regarding improvement in critical outcomes, some variability is expected in provider and patient preferences regarding this extensive surgical procedure. This variability can be based on a patient's or a provider's experience with surgery. Other implications considered were the resources required for this treatment, specifically the cost of surgery, as well as the need for a specially trained surgeon. Furthermore, this surgical treatment has inherent exclusion criteria based on patient factors such as age, comorbid conditions, status of dentition, and facial anatomy.
- The Work Group's confidence in the quality of the evidence for this recommendation is very low because the individual studies were all cohort studies with a small number of subjects that lacked a comparator group and reporting on confounding variables.[54-62] Patient values and preferences regarding this treatment were considered to be somewhat varied. The evidence was consistent in showing benefit, and the benefits were deemed to slightly outweigh the potential intraoperative and postoperative risks.

**15. For patients with obstructive sleep apnea who cannot tolerate or who have declined all other recommended treatments, we suggest offering alternative/salvage therapies. (*Weak for; Reviewed, New-added*)**

- Several non-surgical alternative therapies for OSA exist for those patients who cannot tolerate PAP or a MAD. If alternative/salvage therapies are being considered, consultation with a sleep specialist is recommended to optimize treatment. The Work Group reviewed evidence for positional therapy,[63] myofunctional therapy (MT),[64,65] exercise,[66,67] and expiratory positive airway pressure (EPAP) [68] and found generally positive outcomes for these therapies. There was insufficient evidence for weight loss as monotherapy for OSA, though treatments for weight loss (e.g., dietary intervention, bariatric surgery) should be pursued as adjunctive therapy in overweight or obese patients.
- The Work Group's confidence in the quality of the evidence is low.[63-69] There were significant limitations in the study designs. It should also be noted that none of these therapies were directly compared to PAP or other recommended therapies and the evidence did not study patients who had previously failed such therapies. However, as the evidence showed benefit of alternative/salvage therapies in the treatment of OSA, and the risk of adverse events is small, the benefits were deemed to outweigh the potential harms or burden. Additionally, these treatments may not always be feasible because of the lack of resources or training and patients with certain ailments (e.g., back/shoulder pain for positional therapy, nasal congestion for EPAP) may not be able to tolerate treatment.

**16. We suggest against oxygen therapy as a standalone treatment for patients with obstructive sleep apnea who cannot tolerate other recommended therapies. (*Weak against; Reviewed, New-added*)**

- Oxygen, which may be used as a supplemental therapy in patients on PAP with residual hypoxia, lacks sufficient evidence as a stand-alone treatment for OSA. Mehta et al. (2013) evaluated the use of oxygen therapy as an alternative treatment in patients with OSA who do not adhere to



continuous positive airway pressure (CPAP).<sup>[70]</sup> This study concluded that while oxygen therapy improves oxygen saturation, it also increases the duration of apnea-hypopnea events.

- Although not included in the systematic evidence review and, therefore, independent from the strength of this recommendation, the largest study on oxygen therapy versus CPAP, which was conducted in patients with OSA and CVD or cardiovascular risk factors, revealed that CPAP but not nocturnal oxygen resulted in a significant reduction in blood pressure.<sup>[71]</sup> Other studies demonstrated benefit in nocturnal hypoxemia with oxygen therapy in patients with OSA but no reduction in AHI or improvement in daytime functioning.<sup>[72,73]</sup>
- The Work Group’s confidence in the quality of the evidence for this recommendation is low.<sup>[70]</sup> The use of home oxygen carries the small risk of adverse events, including combustion/explosion and fire. The risk of harm or burden with stand-alone oxygen therapy was deemed to outweigh potential benefits. Patient values and preferences were considered varied because some patients may be unwilling to use oxygen therapy. It also may be difficult to obtain oxygen therapy without evidence of nocturnal hypoxemia.

**17. For patients without nasal congestion, we suggest against the routine use of topical nasal steroids for the sole purpose of improving positive airway pressure adherence. (*Weak against; Reviewed, New-added*)**

- Although topical steroids are an acceptable therapy for patients with OSA and nasal congestion due to rhinitis or nasal polyps, evidence reviewed by the Work Group demonstrated that, in the absence of these associated disorders, topical nasal steroids did not improve PAP adherence. Chakhorn et al. (2017) demonstrated no improvement in either average duration of CPAP use per night or percentage of nights of CPAP use with the use of topical steroid treatment (specifically fluticasone propionate dosed at 50 micrograms twice daily) when compared to usual care.<sup>[74]</sup> Evidence also indicates some level of harm (e.g., epistaxis, nasal burning, nasal dryness) associated with nasal steroid use.
- The Work Group determined that there is some variability in provider and patient preferences regarding this treatment. In patients with chronic nasal obstructive symptoms, therapy with topical nasal steroids to augment PAP adherence remains a reasonable approach.
- The Work Group’s confidence in the quality of the evidence for this recommendation is moderate.<sup>[74]</sup> The body of evidence did not have concerning limitations. Other considerations include the lack of proven benefit for PAP adherence and the small potential harm of adverse events in patients without nasal congestion.

**18. Due to the lack of clinically significant benefit, we cannot recommend for or against:**

- **auto-titrating positive airway pressure when compared to fixed positive airway pressure, or**
- **the use of flexible pressure delivery (e.g., C-Flex<sup>®</sup>, expiratory pressure relief)**

**to improve positive airway pressure adherence. (*Neither for nor against; Reviewed, New-added*)**

- There are two primary PAP modalities that are most often used to treat OSA: auto-titrating positive airway pressure (APAP) and continuous or fixed PAP. While APAP significantly increased adherence (usage of PAP) by 11 minutes compared to CPAP, this was not clinically



significant.[75] As both APAP and CPAP effectively treat OSA, there is a balance between the potential benefits and harms (i.e., the evidence showed that neither modality was more efficacious). When determining if APAP or CPAP is more appropriate, these factors should be considered: patient preference; ability to start therapy sooner; cost of the machine; and availability of resources (e.g., access to a sleep laboratory for PAP titration).

- The flexible pressure delivery modalities are relatively similar in that they decrease PAP upon exhalation and return to the therapeutic pressure by the start of inspiration. Bakker and Marshall (2011) assessed whether flexible pressure delivery improved adherence and found no significant improvement in compliance when flexible pressure delivery was used.[76] In determining if flexible pressure therapy is used in conjunction with either APAP or CPAP therapy, patient preference should be considered. The presence or absence of comorbid diseases, especially severe obstructive lung diseases, should also be considered because these patients may have increased expiratory time, leading to potential under-treatment of upper airway events.
- The Work Group’s confidence in the quality of the evidence for this recommendation is low.[75,76] Other considerations regarding this recommendation included the benefits of increased patient comfort, decreased patient time to start treatment, and decreased resources required with APAP versus CPAP. The Work Group determined potential for harm from adverse events was unlikely if used in appropriately selected patients. Patient values and preferences were deemed to be consistent.

## Treatment and Management of Chronic Insomnia Disorder

### A. Behavioral and Psychological Treatments

**19. We recommend offering CBT-I for the treatment of chronic insomnia disorder. (*Strong for; Reviewed, New-added*)**

**20. We suggest offering brief behavioral therapy for insomnia (BBT-I) for the treatment of chronic insomnia disorder. (*Weak for; Reviewed, New-added*)**

**21. There is insufficient evidence to recommend for or against group versus individual CBT-I for the treatment of chronic insomnia disorder. (*Neither for nor against; Reviewed, New-added*)**

- Two SRs examined the efficacy of CBT-I.[77,78] Brasure et al. (2015) included 59 trials comparing psychological interventions (e.g., CBT-I, brief behavioral therapy for insomnia [BBT-I]) with passive controls. It reported outcomes favoring CBT-I, including statistically significant improvements in certain sleep outcomes in the general adult, older adult, and adult with comorbid pain populations.[77] Brasure et al. (2015) also reported on three RCTs comparing multicomponent behavioral therapies or BBT-I versus passive controls in older adults and found significant changes favoring BBT-I.[77] There was insufficient evidence to indicate the optimal frequency of appointments. Johnson et al. (2016) reviewed eight trials comparing CBT-I to waitlist control in individuals with a comorbid cancer diagnosis and found significant effects favoring CBT-I over passive treatments for improvements in certain sleep outcomes.[78]

- The evidence reviewed comparing individual versus group CBT-I consisted of one non-RCT study, Yamadera et al. (2013).[\[79\]](#) The study demonstrated a statistically significant improvement in sleep efficiency and sleep quality at four weeks for individual CBT-I over group CBT-I. There were no statistically significant differences in daytime functioning, sleep onset latency, total sleep time, and wake after sleep onset between individual and group CBT-I. Attrition rates were comparable in both arms.
- For Recommendations 19 and 20, the Work Group’s confidence in the quality of the evidence for CBT-I and BBT-I is moderate.[\[77,78,80\]](#) Brasure et al. (2015) had some limitations (e.g., allocation concealment and blinding, lack of intention-to-treat [ITT] analysis in some studies, attrition).[\[77\]](#) CBT-I and BBT-I must be delivered by professionals trained specifically in the delivery of these treatments, and the Work Group considered access inequality due to lack of provider availability. Additionally, the relatively frequent (e.g., weekly) visits may be burdensome to patients, who may prefer a different treatment approach. Other considerations included the benefits of the intervention seen across multiple sleep outcomes and no significant harms except for transient sleepiness that may result from sleep restriction caused by CBT-I or BBT-I. Given these considerations, the Work Group decided upon a “Strong for” recommendation for CBT-I. Because there is a much smaller literature base on BBT-I and the evidence on BBT-I evaluates its effect on older adults only, the Work Group decided upon a “Weak for” recommendation for BBT-I.
- For Recommendation 21, the Work Group’s confidence in the quality of the evidence is very low based on a lack of randomization or allocation concealment in studies.[\[79\]](#) The Work Group considered the evidence to be insufficient to recommend for or against group versus individual CBT-I for chronic insomnia disorder. Either individual or small group (i.e., fewer than 10 patients) approaches can be considered as appropriate based on patient preferences and local service delivery considerations.

**22. There is insufficient evidence to recommend for or against internet-based CBT-I as an alternative to face-to-face based CBT-I for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- Taylor et al. (2017) concluded that six weekly sessions of self-directed internet-delivered CBT-I was as effective as face-to-face CBT-I when studied in a military population.[\[81\]](#) However, while subjective sleep efficiency improved in both CBT-I groups, objective measures of sleep efficiency were no different from the control group. Lancee et al. (2016) studied a Dutch civilian population comprised primarily of females, so its findings are not necessarily generalizable to the active duty military or Veteran population.[\[82\]](#) However, it found that a guided form of internet-based CBT-I, which improved sleep efficiency and insomnia severity, was less effective than face-to-face CBT-I. In addition to internet-based treatments, telephonic CBT-I has also been studied in a very small pilot trial.[\[83\]](#) Because of the very low quality of studies reviewed, there was insufficient evidence to make a recommendation on the effectiveness of internet-based CBT-I relative to face-to-face treatment.
- The Work Group’s confidence in the quality of the evidence is very low.[\[81-85\]](#) The body of evidence suffered from inconsistency, imprecision, and indirectness.[\[82,85\]](#) Patient values and

preferences were somewhat varied with the possibility of a generational difference (i.e., younger patients preferring virtual treatment and older patients preferring face-to-face therapy). While the concept of guided or unguided internet-based CBT-I is attractive, particularly in underserved or rural areas, the magnitude of the benefit is unclear. Internet-based CBT-I does seem to have evidence showing benefit over no treatment, and the decision to utilize this treatment delivery modality should be informed by the presence or absence of high quality face-to-face treatment in the local area.

**23. For patients diagnosed with chronic insomnia disorder, we suggest CBT-I over pharmacotherapy as first-line treatment. (*Weak for; Reviewed, New-added*)**

- Mitchell et al. (2012) found CBT-I was favored over several pharmacotherapies of comparison.[\[86\]](#) The authors noted that reports of adverse events from medications, which could include both subjective and objective measures, was limited. When compared to pharmacotherapy for chronic insomnia disorder, CBT-I may appear equivalent in short-term results (i.e., two to four weeks); however, CBT-I was superior in long-term outcomes.
- The potential benefits of CBT-I outweigh the potential harms/burden of pharmacotherapy as there are fewer potential side effects. There is a lack of clear safety data for the majority of pharmacologic sleep treatment options beyond brief treatment periods (i.e., two to four weeks), which raises concerns about the potential for increased risks associated with longer periods of pharmacotherapy. In contrast, there are lesser concerns for harms associated with CBT-I, as treatment-related symptoms (e.g., sleepiness during the initial phase of sleep restriction therapy) resolve quickly as treatment continues.
- Although not included in our systematic evidence review and, thus, independent from the strength of this recommendation, two studies provide information related to potential concerns with this treatment. Smith and Perlis (2006) found CBT-I may not be appropriate, or may need to be delayed, for select patient groups (e.g., patients with a history of mania, seizure disorder, current suicidal ideation).[\[87\]](#) Other potential concerns for participation in CBT-I include high-risk work duties that require sustained attention while driving or use of weapons in military training activities. However, these concerns refer to a specific component of CBT-I, sleep restriction therapy, and pertain to the potential for an associated temporary increase in sleepiness.[\[88\]](#) Modifications to this component within a comprehensive CBT-I treatment plan can mitigate these potential harms.
- The Work Group's confidence in the overall quality of the evidence is low.[\[86\]](#) The body of evidence had limitations (e.g., small sample sizes, wide variation in the follow-up periods across the included studies). Since improvements from pharmacotherapy may manifest sooner and because CBT-I requires more frequent visits with a provider, patient values and preferences were somewhat varied. Access to trained CBT-I providers was also considered by the Work Group.

**24. We suggest offering CBT-I for the treatment of chronic insomnia disorder that is comorbid with another psychiatric disorder. (*Weak for; Reviewed, New-added*)**

- CBT-I has been found to reduce insomnia severity, sleep onset latency, and wake after sleep onset and to increase sleep efficiency and sleep quality in patients with chronic insomnia

disorder that is comorbid with another mental health disorder.[\[89-91\]](#) Based on an SR conducted by Okajima et al. (2018), treatment with CBT-I was associated with improvements in ISI, sleep efficiency, sleep onset latency, wake after sleep onset, and sleep quality in patients with chronic insomnia disorder comorbid with mental disorders including bipolar disorder, depression, PTSD, alcohol dependence, and mixed psychiatric disorders.[\[90\]](#) An RCT conducted in individuals with insomnia disorder comorbid with a schizophrenia spectrum diagnosis found improvements in insomnia severity, sleep onset latency, and sleep quality.[\[89\]](#) There is evidence for improvement in a range of sleep measures, but some studies included individuals receiving other sleep treatments in addition to CBT-I.

- There was insufficient evidence to include any recommendation regarding the treatment of chronic insomnia disorder in individuals with comorbid traumatic brain injury (TBI). Although there is no evidence of harm from CBT-I in patients with comorbid mental disorders, Smith and Perlis (2006) found certain medical and mental health conditions require either delaying CBT-I or a tailored treatment approach.[\[87\]](#) Adherence to mood stabilizing pharmacotherapy in patients with bipolar disorder would need to be closely monitored in order to avoid precipitating hypomania or mania with sleep restriction, a component of CBT-I. Similarly, some evidence suggests that sleep restriction may precipitate seizures in those with seizure disorders.[\[87\]](#) Delayed treatment is appropriate among those endorsing current suicidal ideation and those currently engaged in exposure-based PTSD treatments. Smith and Perlis (2006) was not included in our systematic evidence review and, thus, did not influence the strength of this recommendation.
- The Work Group’s confidence in the quality of the evidence for this recommendation varied from low to moderate.[\[89-91\]](#) The body of evidence had some deficiencies, including limited information about patient age and gender and specifics pertaining to mental disorders.[\[90\]](#) Other considerations regarding the Work Group’s recommendation included the benefits outweighing the potential for adverse events, which was small. Patients may have different values and preferences, and the feasibility of offering CBT-I may be limited by provider availability.

**25. There is insufficient evidence to recommend for or against mindfulness meditation for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- The available research does not demonstrate the utility of mindfulness meditation for the purpose of treating chronic insomnia disorder and other, more effective insomnia-focused behavioral interventions (e.g., CBT-I) should take precedence. This review focused on the effect of mindfulness meditation on insomnia because there was insufficient literature to examine the effects of other forms of meditation (e.g., transcendental meditation). An SR by Gong et al. (2016) found mindfulness meditation was not superior to comparison interventions for improving insomnia severity, sleep efficiency, or sleep quality.[\[92\]](#) However, mindfulness meditation resulted in significant improvements in both self-reported sleep quality and subjective total wake time. Mindfulness-based therapy for insomnia (MBTI) showed the greatest precision for targeting insomnia symptoms.[\[92\]](#) MBTI produced significant improvements in insomnia severity and long-term remission rates, and responses for MBTI were better than those for mindfulness-based stress reduction (MBSR).

- The Work Group’s confidence in the quality of the evidence is very low based on diagnostic imprecision among the various interventions considered.[92] Patient preferences for mindfulness meditation likely vary. Mindfulness meditation requires a considerable time commitment from patients, including home practice and approximately two months of face-to-face sessions. Although no direct harms were identified, patients who do not realize improvements from this intervention may forgo other, more effective insomnia-focused behavioral interventions (e.g., CBT-I). Thus, the harms of engaging in mindfulness meditation for treating chronic insomnia disorder instead of CBT-I may slightly outweigh the benefits. Further, few providers have received mindfulness meditation training and the intervention requires a considerable investment of resources from patients and providers. Given the available evidence, resources devoted to the treatment of chronic insomnia disorder would be better directed to CBT-I training as the first-line insomnia treatment (see [Recommendation 23](#) and [Recommendation 24](#)).

**26. We suggest against sleep hygiene education as a standalone treatment for chronic insomnia disorder. (Weak against; Reviewed, New-added)**

- This recommendation pertains to sleep hygiene education as a stand-alone approach and does not apply to its use as a component of CBT-I. An SR by Chung et al. (2018) reviewed studies comparing sleep hygiene education as monotherapy to CBT-I for the treatment of poor sleep or insomnia.[93] Analyses favored CBT-I over sleep hygiene education in areas of sleep onset latency, wake after sleep onset, sleep efficiency, and PSQI and ISI scores. In addition, an RCT by Morgan et al. (2012) compared self-help CBT-I (e.g., six weekly booklets that provided information on components of CBT-I) to advice on sleep hygiene. The former group demonstrated significant improvements in insomnia severity, sleep efficiency, and sleep quality.[94]
- Although the evidence supports CBT-I over sleep hygiene education, the Work Group acknowledges that CBT-I and BBT-I require trained professionals who may not always be readily available. In addition, patient interest in referral for CBT-I or BBT-I may vary, and multiple appointments may be burdensome to patients. Thus, providers may feel that they are left with the option of sleep hygiene education or no treatment at all. In those circumstances, providers should seek out CBT-I resources or alternative strategies (e.g., BBT-I or self-help or internet-based CBT-I programs) (see [Recommendation 19](#), [Recommendation 20](#), and [Recommendation 22](#)). Additionally, providers should use a patient-centered, motivational interviewing approach to encourage reluctant patients to engage in CBT-I or BBT-I. Providers can do this by providing an accurate description of the treatments, relating the treatments to the patient’s own history and experience with insomnia, and relating the treatments to the patient’s values and circumstances. Sleep hygiene education may promote healthful sleep practices and prevent the development of poor sleep habits, but it may be ineffectual and, in fact, harmful when offered alone. Patients who have received only sleep hygiene education may be less likely to accept a referral for additional behavioral treatments (e.g., CBT-I, BBT-I), believing these treatments will also be ineffectual.

- The Work Group’s confidence in the quality of the evidence is low.[93,94] Chung et al. (2018) had some limitations (i.e., allocation concealment, blinding of participants and study personnel), as did Morgan et al. (2012) (i.e., allocation concealment, lack of ITT analysis, and attrition).[94]

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## **B. Complementary and Integrative Health Treatments**

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### **27. We suggest offering auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder. (Weak for; Reviewed, New-added)**

- An SR and meta-analysis of 15 RCTs by Lan et al. (2015) compared the effect of auricular acupuncture to sham acupuncture using standard points, sham auris-points methods and stimulations, pseudo plasters, and the medications estazolam or diazepam.[95]
- The meta-analysis of seven RCTs comparing seed and pellet auricular acupuncture to sham auris-points found increased total sleep time to six or more hours in both subjective and objective measures. In one of the seven studies, subjective PSQI results found middle age and older age persons reported improvements in sleep quality, quantity, and sleep efficiency (80%) with auricular acupuncture compared to sham interventions. Auricular acupuncture was compared to the medications estazolam and diazepam in eight studies. Results suggested auricular acupuncture improved sleep onset latency, sleep efficiency, decreased awakenings, and increased total sleep time (>6 hours) when compared to the medications. The auricular acupuncture intervention group had significantly fewer adverse effects (2.3%) than the comparison control group which received medications (27.4%).[95]
- The Work Group’s confidence in the quality of the evidence is low.[95] Primary insomnia was not clearly defined in the studies and participants may have not met International Classification of Diseases, 10<sup>th</sup> Version (ICD-10) criteria. The evidence had other limitations, including indirectness for the outcomes of sleep efficiency, sleep duration, sleep quality, and sleep latency. Considerable differences in methodologies, follow-up, acupuncture techniques, and points made it difficult to compare outcomes across studies. Considerations regarding patient values and preference were recognized. Feasibility may be an issue as there may not be enough trained clinicians available, and the benefits slightly outweigh harms or burdens.

### **28. There is insufficient evidence to recommend for or against acupuncture other than auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- An SR of 30 RCTs by Shergis et al. (2016) compared the effects of acupuncture versus sham acupuncture, placebo acupuncture, benzodiazepines, zopiclone, trazodone, and CBT-I for the treatment of primary insomnia.[96] Acupuncture was found to have very low to low evidence for improving chronic insomnia disorder outcomes of subjective sleep onset latency, total sleep time, wake after sleep onset, and insomnia severity as well as sleep efficiency measured by actigraphy.[96] Acupuncture was shown to be slightly superior to sham treatment. Acupuncture provided the best results when compared to pharmacotherapy, with a statistically superior effect over medication.



- An SR of 18 RCTs, Dong et al. (2017), compared acupuncture, sham or placebo acupuncture, and medication to evaluate the effectiveness of acupuncture for depression-related insomnia and reported variable results.[\[97\]](#)
- The Work Group’s confidence in the quality of the evidence is very low.[\[96,97\]](#) Results of both studies are limited by risk of bias, heterogeneity, and serious study limitations (e.g., inconsistency, imprecision, lack of details or outcome data available for review). Patient values and preferences with respect to acupuncture may vary widely. Acupuncture is not always accessible, and while some primary care providers are trained in this, it diverts their time from other treatment.

**29. There is insufficient evidence to recommend for or against aerobic exercise, resistive exercise, tai chi, yoga, and qigong for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- Aerobic exercise, resistive exercise, tai chi, and qigong have all been studied in patients with insomnia symptoms.[\[98-100\]](#) An SR by Yang et al. (2012), which evaluated exercise training programs, did not show a significant improvement in sleep duration, sleep efficiency, or daytime functioning in middle-aged or older adults, although subjective sleep latency was decreased.[\[98\]](#)
- Exercise is very important for general health, and although there is a small risk of injury, it is generally not associated with harms. As such, exercise should be considered an important aspect of overall health maintenance; however, the available evidence is insufficient to make a recommendation regarding exercise as a primary treatment for insomnia disorder. There is likely variability in provider and patient preference regarding this treatment. Some patients may be resistant to the idea of exercise as a treatment for sleep conditions or may already be engaged in an exercise regimen.
- The Work Group’s confidence in the quality of the evidence for this recommendation is very low.[\[98,100\]](#) The body of evidence had numerous limitations, including inconsistent definitions of sleep disorders and highly variable exercise programs. The populations studied were not necessarily generalizable to Veteran and active duty patients, as Yang et al. (2012) focused on female middle-aged and older adults.[\[98\]](#)

**30. We suggest against cranial electrical stimulation for the treatment of chronic insomnia disorder. (Weak against; Reviewed, New-added)**

- Cranial electrical stimulation (i.e., microcurrents delivered by the proprietary device Alpha-Stim through clips worn on the earlobes) was found to increase total sleep time in patients with insomnia in Lande and Gragnani (2013),[\[101\]](#) the only RCT included within the SR by Shekelle et al. (2018) that studied this intervention.[\[102\]](#) It is not known whether there may be adverse effects of this treatment other than mild skin irritation. Some patients may like the ease of administering this treatment (without scheduling office visits), but others may be skeptical. The device used to deliver the treatment is expensive and, thus, may not be accessible for most patients.
- The Work Group’s confidence in the quality of the evidence is very low.[\[102\]](#) The evidence had significant limitations, including small sample size, uncertainty about participants’ diagnoses, and a very short follow-up period (i.e., five days). The potential for adverse events is unclear.



Patient values and preferences are likely to be varied. The cost of the device could be prohibitive for most patients. In addition, offering patients this treatment may direct them away from another treatment with demonstrated effectiveness. Although there is insufficient evidence to determine the effectiveness of Alpha-Stim, the Work Group decided upon a “Weak against” recommendation because of the cost of the device.

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## C. Over-the-counter Treatments

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### 31. We suggest against the use of diphenhydramine for the treatment of chronic insomnia disorder. *(Weak against; Reviewed, New-added)*

- The systematic evidence review conducted for this CPG did not identify any evidence that met inclusion criteria regarding the use of antihistamines in treating chronic insomnia disorder. The Work Group acknowledged, however, that first-generation antihistamines, many of which are included in cold and headache combination products, are often considered for treating insomnia because of their sedating/drowsiness properties. Diphenhydramine and doxylamine succinate are often “prescribed” by providers as a nighttime sleep aid. However, there are no rigorous data supporting the use of these agents and other antihistamines for treating chronic insomnia disorder.
- While no studies that met this guideline’s inclusion criteria examined antihistamines for treating chronic insomnia disorder, other studies have researched the use of antihistamines in patients with primary insomnia or experiencing “sleep problems.” For instance, one SR evaluated diphenhydramine 50 mg compared to placebo.[\[103\]](#) All the studies were short in duration (5 – 28 days) and included adult patients with primary insomnia per Diagnostic and Statistical Manual of Psychiatric Disorders, 4<sup>th</sup> edition (DSM-IV) or predominately experiencing difficulty falling asleep. Of the analyzable outcomes, including sleep latency, total sleep time, number of awakenings, and sleep efficiency, all four studies using diphenhydramine resulted in mixed outcomes, with the majority not being statistically different compared to placebo.
- Safety data using first-generation antihistamines long-term for chronic insomnia disorder is not available. Because these antihistamines also have antagonistic properties at the muscarinic receptor, one can expect dry eyes, dry mouth, constipation, urinary retention, and confusion to be the reason why the 2019 Beers Criteria carries a strong recommendation to avoid using these agents in older adults.[\[104\]](#) Tolerance to the sedative effects of these agents has been noted after three to four days of continuous use, limiting its benefit even for short-term treatment of insomnia. Because of the known harms of diphenhydramine and the lack of evidence for potential benefits, the Work Group decided upon a “Weak against” recommendation.

### 32. We suggest against the use of melatonin for the treatment of chronic insomnia disorder. *(Weak against; Reviewed, New-added)*

- A meta-analysis by Ferracoli-Oda et al. (2013) demonstrated an approximately seven-minute reduction in sleep onset latency, an eight-minute increase in total sleep time, and a very small improvement in sleep quality (all statistically significant) favoring melatonin. However, the clinical significance of these findings was unclear.[\[105\]](#) Moreover, there are no acceptable dose guidelines for melatonin related to the different sleep disorders. Doses included in the evidence

ranged from 0.1 mg – 5 mg, which makes a comparison of results difficult. It is also difficult to assess efficacy and harms because of the various formulations used, lack of reporting of the time melatonin was ingested in relation to bedtime, and the recognized, age-related decrease in melatonin production in the elderly.

- The Work Group had several concerns regarding the balance of desirable and undesirable outcomes. Although not included in the systematic evidence review and, thus, independent from the strength of this recommendation, Keijzer et al. (2014) found that when melatonin is not administered correctly, it may fail to produce the desired results or even produce opposite effects and perpetuate sleep disorders.[106] Also, the potential harms are largely unknown and over-the-counter (OTC) melatonin composition may vary. Further, patients may perceive melatonin as safe because it is marketed as an herbal or dietary supplement.
- The Work Group’s confidence in the overall quality of the evidence is low.[105] The evidence available suffered from a substantial risk of bias. The small improvement in some of the measures did not outweigh the Work Group’s concern about purity/contaminants in OTC preparations and the potential for undesired circadian consequences. The Work Group acknowledged it was not addressing the use of melatonin in other sleep disorders, where it may be an indicated therapy.

**33. We suggest against the use of valerian and chamomile for the treatment of chronic insomnia disorder. (*Weak against; Reviewed, New-added*)**

- The evidence supporting this recommendation is derived from Leach and Page (2015), an SR that evaluated the efficacy and safety of three herbal medicines (valerian, kava, and chamomile) for the management of insomnia.[107] Comparisons included valerian versus placebo, subspecies of valerian versus oxazepam, chamomile individually versus placebo, and kava. They found no significant between-group differences in daytime functioning, insomnia severity, sleep efficiency, sleep onset latency, total sleep time, wake after sleep onset, and sleep quality with either valerian or chamomile for treatment of insomnia disorder.[107]
- Patient and provider preferences for use of herbal supplements for insomnia may be highly variable. While some patients may consider supplements as natural therapy, the patient focus group acknowledged some stigma with using herbal supplements for insomnia. Moreover, patients who prefer to take OTC supplements may not report significant benefit after using them. There are also concerns about the purity and composition of these herbal supplements; however, there were no reported side effects with chamomile.
- The Work Group’s confidence in the quality of the evidence is very low.[107] The evidence had serious limitations, including risk of bias given the small sample size and serious imprecision. Evidence also indicates some potential harm with valerian, and there are concerns about lack of purity of both supplements. Thus, there is very low quality evidence with no proven clinical efficacy for the treatment of insomnia symptoms with valerian and chamomile, and the harms attributed to valerian likely outweigh the benefits. Moreover, patient preferences and values pertaining to herbal supplements for insomnia are likely to be variable.

**34. We recommend against the use of kava for the treatment of chronic insomnia disorder. (*Strong against; Reviewed, New-added*)**

- The evidence supporting this recommendation is derived from one SR by Leach and Page (2015) (very low quality of evidence) that evaluated the efficacy and safety of three herbal medicines (valerian, kava, and chamomile) for the management of insomnia.[107] One RCT with 391 patients with insomnia evaluated the effects of kava (containing 100 mg total kavalactones) and found no differences between kava and placebo for insomnia severity, sleep onset latency, and nocturnal awakenings. No other outcomes (e.g., sleep efficiency, sleep onset latency, sleep duration [total sleep time], wake after sleep onset, sleep quality) were reported.
- The U.S. Food and Drug Administration (FDA) has issued an advisory about the risk of liver damage associated with kava.[108] The Work Group also noted that patient preferences may be highly variable regarding the use of herbal supplements for insomnia. While some patients may view supplements as natural therapy, others may acknowledge stigma associated with supplement use or be concerned about safety or effectiveness, which may impact their preferences over the long-term. Furthermore, patients may not be aware of the potentially serious adverse effects of kava.
- The Work Group’s confidence in the quality of the evidence for the use of kava in the treatment of chronic insomnia disorder is very low.[107] The body of evidence had serious limitations, including risk of bias and imprecision. The reviewed studies showed no benefit of using kava to treat chronic insomnia disorder compared to placebo, and there is a known risk for acute fatal liver toxicity with kava.[108] Considering the serious potential harm of liver failure and death, the Work Group decided upon a “Strong against” recommendation.

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## **D. Pharmacotherapy**

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**35. In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest use of low-dose (i.e., 3 mg or 6 mg) doxepin. (*Weak for; Reviewed, New-added*)**

- Yeung et al. (2015) is comprised of six industry-sponsored RCTs of low quality evidence that compared the efficacy of low-dose (1 mg, 3 mg, and 6 mg) doxepin versus placebo in individuals with a diagnosis of insomnia disorder.[109] The SR did not combine findings from the different RCTs due to heterogeneity of study design. ISI was significantly improved at week four in two RCTs in older adults, favoring the 3 mg or 6 mg dose of doxepin over placebo; there were variable effects with the 1 mg dose. Subjective sleep latency, total sleep time, and sleep quality outcomes were significantly improved with low-dose doxepin with the 3 mg and 6 mg doses in older adults in one study. These were also significantly improved in younger adults with the 6 mg dose.
- None of the RCTs found significant differences in adverse event rates between low-dose doxepin and placebo, though the SR authors indicated that the incidence of adverse events appeared to increase with longer duration of treatment. Unlike the higher dose formulations, low-dose doxepin has no black box warning for suicide risk. However, the risk of suicidal ideation from the use of low-dose doxepin as a hypnotic agent is unknown and cannot be excluded. Moreover, doxepin’s anticholinergic effects may be additive with other anticholinergic medications.

Geriatric patients are sensitive to the anticholinergic side effects of tricyclic antidepressants. According to the 2019 Beers Criteria, doxepin is a potentially inappropriate medication in geriatric patients and should be avoided.

- The Work Group’s confidence in the quality of the evidence for this recommendation is low.[\[109\]](#) Low-dose doxepin has not been directly compared with other hypnotics for treating insomnia disorder and the optimal dose of doxepin for insomnia remains unclear. Data on low-dose doxepin (e.g., efficacy and safety long-term), use of 6 mg in the elderly after one month, and the use in patients with comorbid conditions are not available. Nevertheless, the Work Group determined the clinical benefits, including improved ISI, subjective sleep quality, subjective and objective total sleep time, objective sleep efficiency, sleep onset latency, and wake after sleep onset, outweighed the small potential harm. There may be some variation in provider and patient preferences. The patient focus group revealed that there may be a stigma associated with taking an antidepressant drug for insomnia. Moreover, providers may be hesitant to use a tricyclic antidepressant medication in patients with cardiac disease or those who might be susceptible to anticholinergic side effects.

**36. In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest the use of a non-benzodiazepine benzodiazepine receptor agonist. (Weak for; Reviewed, New-added)**

- An SR by Winkler et al. (2014) suggests that patients with primary insomnia benefited from a non-benzodiazepine benzodiazepine receptor agonist compared to placebo for many of the sleep outcomes of interest, including the critical outcome sleep efficiency and the important outcomes sleep onset latency, sleep quality, total sleep time, and wake after sleep onset.[\[110\]](#) The SR specifically included 17 RCTs studying the efficacy of different formulations, doses, and frequency of administration of four non-benzodiazepine benzodiazepine receptor agonists: zolpidem, zaleplon, eszopiclone, and zopiclone (not available in the U.S.). Wilt et al. (2016) reported adverse events and withdrawals of non-benzodiazepine benzodiazepine receptor agonists in 18 RCTs of at least four weeks duration published between 2004 and September 2015.[\[111\]](#)
- Potential harms associated with this class of agents should also be of concern. In April 2019, the FDA released a safety announcement on the risk of serious injuries caused by sleep behaviors (i.e., sleepwalking, sleep driving, and other activities while not fully awake) associated with the non-benzodiazepine benzodiazepine receptor agonists.[\[112\]](#) To minimize the incidence of adverse events, a non-benzodiazepine benzodiazepine receptor agonist, if prescribed, should be at the lowest effective dose and for the shortest duration possible. All patients offered non-benzodiazepine benzodiazepine receptor agonists should be counseled on the potential risks.
- The Work Group’s confidence in the quality of the evidence is very low.[\[110,111\]](#) Despite general consistency in the evidence supporting the benefits of non-benzodiazepine benzodiazepine receptor agonists, nearly all of the patient focus group participants expressed a preference for non-pharmacologic treatment to a pharmacologic one. Patient focus group participants emphasized the importance of daytime functioning as an outcome measure, and this was not addressed in any of the studies reviewed. As stated in [Recommendation 23](#), non-pharmacologic treatments should be considered first before beginning pharmacotherapy.

**37. There is insufficient evidence to recommend for or against the use of ramelteon for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- Kuriyama et al. (2014) evaluated the efficacy of ramelteon for treating insomnia.[\[113\]](#) Study participants were mostly female (62%) between 18 – 93 years old. The dose range of ramelteon was 4 – 32 mg/day and the duration of drug administration ranged from 6 – 180 days. Relative to placebo, ramelteon significantly improved sleep efficiency, sleep onset latency, total sleep time, and wake after sleep onset.
- The methodological quality of the studies included in the SR was rated as poor. The main concerns were lack of clarity around randomization, allocation concealment, blinding of patients and investigators, and outcome assessors. Furthermore, ITT analysis was not used or was unclear. Kuriyama et al. (2014) found somnolence as the only significant adverse event and found mixed results for sleep efficiency.[\[113\]](#)
- The Work Group’s confidence in the quality of evidence is very low.[\[113\]](#) Somnolence was the only significant adverse event, and there were positive findings for sleep quality, total sleep time, and sleep onset latency. The Work Group determined that there was some variation in patient and provider values and preferences. For instance, the drug might negatively impact daily functions including driving, and patients may experience stigma associated with taking sleep medication. The VA and DoD may have different criteria for use. Active duty Service Members may require limitations in duties. Similarly, some Veterans may have a commercial driving license or operate heavy machinery.

**38. There is insufficient evidence to recommend for or against the use of suvorexant for the treatment of chronic insomnia disorder. (Neither for nor against; Reviewed, New-added)**

- The limited evidence available for this recommendation is from one SR by Kuriyama and Tabata (2017) comprising four industry-sponsored RCTs (n=3,076) ranging from one month to one year in duration comparing the efficacy and safety of suvorexant (10 mg – 80 mg at bedtime) to placebo in patients with chronic insomnia disorder per DSM-IV-TR (Text Revision) criteria.[\[114\]](#) The RCTs were mostly dose finding trials evaluating several doses exceeding the currently approved dose range (5 mg – 20 mg) at bedtime. Comparing groups taking suvorexant doses of 40/30 mg (nonelderly/elderly) and 20/15 mg (nonelderly/elderly) to placebo, the patient-rated baseline ISI of 16 (0 – 28 scale) was significantly improved in both suvorexant groups versus placebo at both one and three months. Importantly, a clinically meaningful improvement, defined as ≥6-point improvement, was not achieved.
- Despite high quality evidence supporting the use of suvorexant and the possibility that it could be useful when other sedative-hypnotic agents have been ineffective, the occurrence of adverse effects may be substantial. The most common side effect reported is somnolence. Based on suvorexant’s long half-life (~12 hours), there is a concerning risk of impaired alertness and other complex behaviors (e.g., “sleep driving”) if it is taken with <7 hours of sleep before awakening. For patients taking higher than the recommended dose or a dose co-administered with other central nervous system (CNS) depressants or other drugs that increase the blood levels of suvorexant, there needs to be a patient-centric, SDM discussion before suvorexant is started.

The SDM discussion should also include the potential longer exposure of the drug in women and obese patients (>30 kg/m<sup>2</sup>).

- The Work Group’s confidence in the quality of the evidence is moderate.[\[114\]](#) The body of evidence had several limitations. For instance, the benefits and harms may have been overestimated by including studies that used a higher than recommended dose of suvorexant. Also, the evidence reviewed included exposure to suvorexant 10 mg dose in only 62 nonelderly patients for one month. Other limitations included the inconsistent reporting of similar outcomes, insufficient evidence to determine the clinical significance of a statistically significant finding, the small number of trials, the limited inclusion of older patients and patients with comorbid conditions, and variations in treatment duration.

**39. We suggest against the use of antipsychotic drugs for the treatment of chronic insomnia disorder. (Weak against; Reviewed, New-added)**

- The systematic evidence review conducted for this CPG did not identify any evidence that met inclusion criteria regarding the use of antipsychotics for treating chronic insomnia disorder. The Work Group acknowledged, however, that atypical antipsychotics used off-label, of which quetiapine is the most common, have been used to treat insomnia because of their sedating and drowsiness properties. This often occurs in patients with concomitant psychiatric disorders.
- Evidence on using low-dose quetiapine for the treatment of chronic insomnia disorder is limited to a few studies and case series with short duration, small sample sizes, and vague and incomplete details, thus making any determination regarding efficacy inconclusive. Although doses of quetiapine typically used for insomnia are lower than the FDA-recommended dosage of 150 – 800 mg/day for either the immediate-release or extended-release products, all antipsychotics, including low-dose quetiapine, are known for causing harms.[\[115\]](#) Quetiapine has a black box warning indicating a 1.6 to 1.7 fold increase in mortality in elderly populations with dementia-related psychosis and increased suicidal tendencies in children, adolescents, and young adults.[\[116\]](#) In addition, all second atypical antipsychotics carry a strong recommendation in the 2019 Beers Criteria to avoid their use in the elderly, except in patients with schizophrenia or bipolar disorders, due to an increased risk of cerebrovascular accident and a greater rate of cognitive decline and mortality in persons with dementia.[\[104\]](#)
- Because of the lack of clinical studies supporting the efficacy of antipsychotic drugs, and the potential safety concerns, the Work Group decided upon a “Weak against” recommendation.

**40. We suggest against the use of benzodiazepines for the treatment of chronic insomnia disorder. (Weak against; Reviewed, New-added)**

- The Work Group examined an evidence base of four SRs that compared various pharmacologic interventions to placebo in treating insomnia disorder.[\[110,113,117,118\]](#) The studies showed significantly improved sleep efficiency, sleep onset latency, sleep quality, total sleep time, and wake after sleep onset relative to placebo. The longest duration of follow-up was approximately seven months, but the majority of trials in the SRs had a duration of ≤12 weeks. The authors of one of the SRs commented that, although they had significant findings, it was not clear whether these findings were clinically relevant.[\[110\]](#) The methodological quality of the studies included



in the SRs was generally rated as fair by the authors of the reviews.<sup>[110,117,118]</sup> The main concerns were lack of clarity around randomization; allocation concealment; blinding of patients, investigators, and outcome assessors; and incomplete outcome reporting. The studies did not examine harms, doses of benzodiazepines, and the time course of changes in treatment outcomes and adverse events (ranging from 2 – 224 days; majority were <35 days of use).

- The Work Group concluded that harms/burden outweighed the benefits. This was in part because of the widely known harms/adverse events of benzodiazepines. Indeed, the Work Group acknowledged the VA/DoD Management of Opioid Therapy CPG's<sup>1</sup> recommendation against benzodiazepine use with opioids and the VA/DoD PTSD CPG's<sup>2</sup> recommendation against benzodiazepine use in the management of PTSD. Furthermore, benzodiazepines may have an adverse effect on sleep architecture (slow wave sleep suppression), be difficult to taper and discontinue, and have significant interactions with alcohol and with other drugs, notably other CNS depressants.
- The Work Group's confidence in the quality of evidence is moderate.<sup>[110,113,117,118]</sup> The Work Group found some variation in patient and provider values and preferences based on the negative impact of benzodiazepines on daytime function (e.g., driving) and the known adverse event profile of the drugs. The stigma associated with taking benzodiazepines for insomnia was considered. The Work Group also considered the risk of dependency and diversion as well as harms to older patients; patients with respiratory conditions (including sleep apnea and obesity hypoventilation), neuromuscular diseases, and cognitive disorders; and those at risk for falls. Furthermore, active duty Service Members may require limitations in duties and/or a temporary restricted profile (possibly for the duration of treatment), depending on job function. Similarly, some Veterans may have a commercial driving license or operate heavy machinery.

**41. We suggest against the use of trazodone for the treatment of chronic insomnia disorder. (*Weak against; Reviewed, New-added*)**

- One SR reported no statistically significant differences for sleep efficiency or the rate of discontinuation due to adverse events when comparing trazodone (dose range 50 – 150 mg/prior to bedtime) to placebo in treating patients diagnosed with chronic insomnia (primary or secondary insomnia).<sup>[117]</sup> There is moderate quality evidence that trazodone was more effective at improving sleep quality (a subjective finding) compared to placebo, while there were no differences noted in sleep onset latency, total sleep time, or wake after sleep onset.<sup>[117]</sup> The SR had limitations. The mean treatment length was 1.7 weeks with a follow-up of one to four weeks, which is shorter than the typical duration of sedative hypnotic use. Further, in some trials, patients were also taking another antidepressant or methadone, which may have altered the results.
- Despite the evidence that trazodone improves sleep quality, the evidence showing benefits in other key sleep outcomes is very low quality. Additionally, there were several factors making it difficult to evaluate the safety of using trazodone for the treatment of chronic insomnia

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<sup>1</sup> See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain (2017) (available at: <https://www.healthquality.va.gov/guidelines/Pain/cot/>).

<sup>2</sup> See the VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Reaction (2017) (available at: <https://www.healthquality.va.gov/guidelines/MH/ptsd/>).



disorder. The rates of adverse events were low overall in the trials where they were reported; most studies in the SR, though, did not present this data. Trazodone has an FDA black box warning for the possibility of increasing suicidal thoughts and behaviors in pediatric and young adult patients (up to age 24).[\[119\]](#) Further, trazodone is associated with numerous other adverse events (e.g., morning sedation) and drug-drug interactions, which outweigh any benefits for its use in treating chronic insomnia disorder. Thus, the limited evidence of benefits is outweighed by the potential safety concerns associated with trazodone use.

- The Work Group’s confidence in the quality of the evidence is very low.[\[117\]](#) The body of evidence had some limitations, including limited evidence on benefits versus harms, use in geriatric populations, limited duration in trials, and some variation in patient preferences. There are several other implications to consider with implementing this recommendation. Our recommendation is limited to patients with chronic insomnia disorder alone and does not pertain to use of trazodone for other clinical conditions.

## Provider Guide to Sleep Education for Insomnia Disorder

Primary care providers are encouraged to provide patient education that includes general information on insomnia disorder, treatment goal setting, and an accurate description of behaviorally-based treatments. To effectively communicate with patients about chronic insomnia disorder, providers are encouraged to become familiar with the 3 Ps Model of Insomnia [\[120\]](#) to understand the process by which insomnia disorder develops and why chronic insomnia disorder is driven less by what caused one’s insomnia symptoms, but rather by the strategies enacted to cope with insomnia symptoms. For patients who have already initiated CBT-I and BBT-I treatments, primary care providers are encouraged to inquire about their ability to adhere to the intervention components by identifying and helping patients problem-solve to overcome any barriers to continuing with their plan of care. Examples of these provider education and support conversations and activities are provided in the following sections.

### A. General Information on Insomnia Disorder

“I’m glad you let me know about the sleep problems you’ve been having. From all that you’ve told me, it sounds like you are suffering from insomnia disorder. Insomnia disorder can be a difficult experience. While it can impact how you feel during the day, your mood and concentration, your general health, and your enjoyment of activities, it doesn’t have to. There are treatments that are effective.”

“Insomnia symptoms are usually first brought on because of stressful life events, such as military training, deployment, trauma, emotional distress, or illness. During that stressful period, it is understandable that your habits may change to cope with not getting enough sleep. During this time, even thoughts and beliefs about sleep can change. But after the stressful period ends, your sleep difficulties can persist due to the coping strategies used that were actually unhelpful. Ironically, these unhelpful strategies turn into the cause of the ongoing insomnia. So, no matter what caused your insomnia, the solution must address the unhelpful coping strategies that cause your insomnia to persist.”

**If also treating a comorbid condition:** “I want to emphasize that insomnia is not merely a symptom of another condition. Just as we are treating your (*comorbid condition [e.g., pain, depression]*), we should treat the insomnia as well.”

**If insomnia symptoms have been of short duration:** “Although you have not experienced insomnia for a long time, the strategies you have adopted to cope with insomnia can promote a chronic problem if we don’t correct these unhelpful strategies. I’d like to get you started with a behavioral treatment to avoid that happening if possible.”

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## **B. Goals of Insomnia Treatment**

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“Not everyone will be able to achieve, or even needs, a solid eight hours of sleep every night. Everyone is different and sleep patterns change as people age. That said, you’ve told me that you are struggling with (*e.g., falling asleep, staying asleep, feeling rested when you wake*), and these issues are impacting you during the daytime. We can work together to help you sleep better and feel better during the day. What do you most hope to achieve with insomnia treatment? What would you like to change about your sleep?”

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## **C. Describing CBT-I and BBT-I to Patients**

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“CBT-I and BBT-I are primarily behavioral treatments for insomnia. There is good evidence that these are the treatments of choice for people with insomnia that has lasted a few months or longer. For example, they are more effective than if I just gave you some sleep strategies to help your sleep which we call ‘sleep hygiene.’ Also, the effects of CBT-I and BBT-I are longer lasting than if we treated the insomnia with sleep medication, and these behavioral treatments do not have the risk of medication interactions and side effects. I also want you to know that sleep inducing medications have NOT been found to be as effective for treatment of chronic insomnia, and, in fact, behavioral therapy is more likely to be effective than sleep medications in the long run.”

“In addition to including the sleep hygiene education I mentioned, CBT-I and BBT-I use multiple techniques to target factors that maintain insomnia, and they provide you with skills that will help you to regulate when you are asleep and awake. For example, a technique called ‘stimulus control’ will help make the bed and the bedroom stronger cues for your brain to know that it is time to be asleep. Another technique will help you figure out how much time you should spend in bed in order to sleep well. You may also learn skills to help you relax at bedtime and techniques to address thoughts and beliefs that interfere with your sleep. The provider will work with you to create an individualized plan to best suit your needs. What questions do you have about this? Could I set you up with an initial appointment (or provide a referral) to learn more about it?”

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## **D. Examples of Supporting Self-management Goals Related to the Stimulus Control and Sleep Restriction Components of CBT-I/BBT-I**

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**Associating bed with sleep:** “Many patients who have trouble sleeping spend a lot of time in bed hoping they fall asleep. Their minds and bodies end up associating the bed with a place to be awake rather than a place to be asleep. What sorts of things has (*name of CBT-I or BBT-I provider*) discussed with you to do that may improve this? How difficult has this been for you?” (*Note: Alert the CBT-I or BBT-I provider if the patient is unsure of how they are approaching this.*)

**Keeping a schedule:** “I saw that Dr. (*name of CBT-I or BBT-I provider*) has talked with you about an earlier bedtime and when to get out of bed each day. It is important to stick to that schedule. How has this been for you? Some patients tell me it is a challenge. (*Note: Alert the CBT-I or BBT-I provider if the patient is*

unable to stick to their prescribed sleep schedule so adjustments can be made.) Please complete a two week sleep diary, when recommended by your healthcare provider, to allow the provider to get a more accurate estimate of your sleep schedule.”

## Provider Guide to Sleep Education for Obstructive Sleep Apnea

Primary care providers are encouraged to provide patient education that includes general information on OSA, an accurate description of PAP and/or MAD therapy, and setting treatment goals. In addition, primary care providers are encouraged to support adherence to the patient’s OSA therapy of choice by either reviewing a PAP therapy download in patients using either auto-adjustable PAP or continuous (fixed pressure) PAP or, in the case of patients using MAD therapy, inquiring about their usage of the device. Primary care providers should assess for any treatment-related side effects, identify barriers to adherence, and determine if the patient’s presenting symptoms, to specifically include sleepiness, are adequately addressed. Examples are provided in the following sections.

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### A. General Information on Obstructive Sleep Apnea

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“Sleep apnea is a very common, serious sleep disorder, which affects many military personnel and Veterans. Snoring is one common symptom of sleep apnea but not all patients with sleep apnea snore. Other common sleep apnea symptoms include sleepiness, morning headaches, using the bathroom frequently at night, a dry sore mouth, and daytime fatigue. If you are experiencing any of these symptoms, you may have sleep apnea.”

“What defines sleep apnea are pauses in breathing – either a partial pause (hypopnea) or complete absence of breathing (apnea) – that occur while an individual is sleeping. During these periods of little to no breathing, oxygen levels can decrease (hypoxia) and carbon dioxide levels can increase (hypercapnia). Many of the serious medical consequences, such as hypertension, heart failure, cerebrovascular disease, and death, result from the frequent episodes of hypoxia. Frequent awakenings during the night also lead to excessive daytime sleepiness and increased risk for motor vehicle accidents. We will need to obtain a sleep study to confirm this diagnosis. There are effective treatments for sleep apnea.”

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### B. Diagnosing Sleep Apnea: Sleep Studies

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“There are two options for obtaining a diagnosis of sleep apnea: (1) a home sleep apnea test, which is only used to confirm a highly suspected diagnosis of sleep apnea, and (2) an in-lab sleep study, which provides more information. Both studies measure your oxygen levels and the number of times per hour you stop breathing, which is called the apnea-hypopnea index. If you have sleep apnea symptoms and your AHI is >5 events per hour, you have sleep apnea. If a home sleep apnea test does not confirm a diagnosis of sleep apnea, then additional testing is required.”

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### C. Describing Sleep Apnea Treatment to Patients

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“The primary and most efficacious treatment for sleep apnea is PAP therapy. PAP is delivered from a machine connected to a mask that you wear while sleeping. There are 2 types of PAP: (1) an auto-adjustable PAP, which determines how much pressure is required to keep your airway open, or (2) a fixed-pressure PAP (continuous PAP, or CPAP), which uses one pressure level only (i.e., it doesn’t vary over

time). You should use PAP whenever you sleep or take a nap and for the longest possible duration. Longer use of PAP is better for your sleep and overall health. For a variety of reasons, some patients may choose other treatments for sleep apnea.”

“MADs are another treatment for sleep apnea. Depending on your teeth and severity of sleep apnea, this may be a reasonable treatment. This device works by moving your jaw forward – to open your airways – and maintaining it in this position while you wear it during your sleep. In order to obtain a MAD, you will need to see a dentist who is experienced in making these devices.”

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#### **D. Other Areas that Can Make Sleep Apnea Better or Worse**

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“Overall, men have a higher prevalence of sleep apnea than women. Moreover, post-menopausal status in women also increases the risk of having sleep apnea. There are some areas of your lifestyle you can change to either improve or worsen sleep apnea. Having a regular sleep schedule and making sure you receive 7 – 8 hours of sleep on a regular, nightly basis can improve your sleep and sleep apnea. Not sleeping, or sleeping too little, can worsen your sleep apnea. Also, alcohol and certain medications (e.g., opioids/pain medications, sleeping medications) can make sleep apnea worse. Weight loss can improve sleep apnea while weight gain can make sleep apnea worse. Also, what position you sleep in can improve sleep apnea in some patients as sleeping on your back typically makes sleep apnea worse.”

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#### **E. Addressing Sleepiness**

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“Sleepiness is one of the primary symptoms of sleep apnea. Patients with untreated sleep apnea are at increased risk of motor vehicle crashes and mistakes on duty or at work. If you are sleepy, you should neither drive nor perform dangerous or critical tasks.”

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#### **F. Addressing Adherence to Positive Airway Pressure**

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“The following are interventions that can help with PAP adherence:

- Use of heated humidification for PAP therapy
- Ensuring the appropriate mask choice, noting nasal masks are associated with higher adherence
- Educational strategies to include an overview of OSA and their treatment modality
- Cognitive behavioral therapies addressing distorted views of sleep and sleep apnea, promoting positive associations with PAP, and enlisting social support
- Investigate and address issues of high leak
- Close follow-up (at least at 4-weeks, if not sooner) after initial PAP prescription to evaluate usage”

## ICSD-3 Diagnostic Criteria

### A. Chronic Insomnia Disorder [121]

ICD-9-CM code: 307.42

ICD-10-CM code: F51.01

#### a. Alternate Names

Chronic insomnia, primary insomnia, secondary insomnia, comorbid insomnia, disorder of initiating and maintaining sleep, behavioral insomnia of childhood, sleep-onset association disorder, limit-setting sleep disorder

#### b. Diagnostic Criteria

Criteria A-F must be met

- A. The patient reports, or the patient's parent or caregiver observes, one or more of the following:
  1. Difficulty initiating sleep
  2. Difficulty maintaining sleep
  3. Waking up earlier than desired
  4. Resistance to going to bed on appropriate schedule
  5. Difficulty sleeping without parent or caregiver intervention
- B. The patient reports, or the patient's parent or caregiver observes, one or more of the following related to the nighttime sleep difficulty:
  1. Fatigue/malaise
  2. Attention, concentration, or memory impairment
  3. Impaired social, family, occupational, or academic performance
  4. Mood disturbance/irritability
  5. Daytime sleepiness
  6. Behavioral problems (e.g., hyperactivity, impulsivity, aggression)
  7. Reduced motivation/energy/initiative
  8. Proneness for errors/accidents
  9. Concerns about or dissatisfaction with sleep
- C. The reported sleep/wake complaints cannot be explained purely by inadequate opportunity (i.e., enough time is allotted for sleep) or inadequate circumstances (i.e., the environment is safe, dark, quiet, and comfortable) for sleep
- D. The sleep disturbance and associated daytime symptoms occur at least three times per week

- E. The sleep disturbance and associated daytime symptoms have been present for at least three months
- F. The sleep/wake difficulty is not better explained by another sleep disorder

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## **B. Obstructive Sleep Apnea [121]**

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*ICD-9-CM code: 327.23*

*ICD-10-CM code: G47.33*

### ***a. Alternate Names***

OSA syndrome, sleep apnea, sleep apnea syndrome, obstructive apnea, sleep disordered breathing, obstructive sleep apnea hypopnea syndrome

### ***b. Diagnostic Criteria***

(A and B) or C satisfy the criteria

- A. The presence of one or more of the following:
  - 1. The patient complains of sleepiness, nonrestorative sleep, fatigue, or insomnia symptoms
  - 2. The patient wakes with breath holding, gasping, or choking
  - 3. The bed partner or other observer reports habitual snoring, breathing interruptions, or both during the patient's sleep
  - 4. The patient has been diagnosed with hypertension, a mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus
- B. PSG or HSAT demonstrates:
  - 1. Five or more predominantly obstructive respiratory events (obstructive and mixed apneas, hypopneas, or respiratory effort related arousals [RERAs]) per hour of sleep during a PSG or per hour of monitoring (HSAT)

OR

- C. PSG or HSAT demonstrates:
  - 1. Fifteen or more predominantly obstructive respiratory events (apneas, hypopneas, or RERAs) per hour of sleep during a PSG or per hour of monitoring (HSAT)

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*Access to the full guideline and additional resources are available  
at the following link:*

<https://www.healthquality.va.gov/guidelines/cd/insomnia/>

