VA/DOD Clinical Practice Guidelines

THE MANAGEMENT OF CHRONIC INSOMNIA DISORDER AND OBSTRUCTIVE SLEEP APNEA





VA/DoD Evidence-Based Practice

Provider Summary

Version 2.0 | 2025





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 (VA) and the Department of Defense (DOD) guidelines are based on the best information available at the time of publication. The guidelines 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 (CPG) 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 providers consider the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Therefore, every health care professional using these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation with a patient-centered approach.

These guidelines are not intended to represent VA or DOD policies. Further, inclusion of recommendations for specific testing, therapeutic interventions, or both within these guidelines does not guarantee coverage of civilian sector care.

Version 2.0 - 2025

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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.(<u>1</u>) 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.

	Sub-				
Topic	topic	#	Recommendation	Strength ^a	Category ^b
Screening		1.	For screening of patients with sleep complaints, we suggest using validated screening instruments for both insomnia (e.g., Insomnia Severity Index or Athens Insomnia Scale) and obstructive sleep apnea (e.g., STOP) to identify patients who need further evaluation.	Weak for	Not reviewed, Amended
4 <i>pnea</i>		2.	For diagnosis of clinically suspected obstructive sleep apnea, we recommend diagnosis with polysomnography or home sleep apnea testing.	Strong for	Reviewed, New-added
Obstructive Sleep Apnea Diagnosis		3.	For diagnosis of obstructive sleep apnea in appropriate patients*, we suggest home sleep apnea testing as an alternative to in-laboratory polysomnography.	Weak for	Reviewed, New- replaced
Obstruc I		4.	For diagnosis of patients with a non-diagnostic home sleep apnea test, we recommend further sleep testing for obstructive sleep apnea with in-lab polysomnography or HSAT.	Strong for	Reviewed, New- replaced
	Behavioral and Psychological Treatments	5.	For treatment of chronic insomnia disorder, we recommend treatment with CBT-I.	Strong for	Not reviewed, Amended
der		6.	For treatment of chronic insomnia disorder, we suggest treatment with BBT-I.	Weak for	Not reviewed, Amended
Insomnia Disorder		7.	For treatment of chronic insomnia disorder, we suggest against sleep hygiene education as a stand-alone treatment.	Weak against	Not reviewed, Not changed
	nia	8.	For treatment of chronic insomnia disorder, we suggest CBT-I over pharmacotherapy as first-line treatment.	Weak for	Reviewed, Amended
Treatment of Chronic	Pharmacotherapy-Insomnia	9.	For treatment of chronic insomnia disorder in patients who are offered a course of pharmacotherapy, we suggest the use of one of the following agents: Daridorexant Doxepin Eszopiclone Lemborexant Suvorexant Zaleplon Zolpidem	Weak for	Reviewed, New- replaced

Tonio	Sub-	ш	Decommondation	Ctron oth a	Cotomorub
Topic topic #		#	Recommendation	Strength ^a	Category ^b
	Pharmacotherapy-Insomnia (cont.)	10.	 For treatment of chronic insomnia disorder in patients who are offered a course of pharmacotherapy, we suggest against the use of: Antipsychotic drugs Benzodiazepines Diphenhydramine Trazodone 	Weak against	Reviewed, New- replaced
	Pharmac	11.	For treatment of chronic insomnia disorder in patients who are offered a course of pharmacotherapy, there is insufficient evidence to recommend for or against the use of ramelteon.	Neither for nor against	Reviewed, Amended
	Complementary and Integrative	12.	For treatment of chronic insomnia disorder, we recommend against the use of kava.	Strong against	Not reviewed, Amended
		13.	For treatment of chronic insomnia disorder, we suggest against the use of cannabis and/or its derivatives.	Weak against	Reviewed, New-added
		14.	For treatment of chronic insomnia disorder, we suggest against the use of: • Chamomile • Melatonin • Passionflower • Saffron • Valerian	Weak against	Reviewed, Amended
		15.	For treatment of chronic insomnia disorder, there is insufficient evidence to recommend for or against the use of magnesium.	Neither for nor against	Reviewed, New-added
		τώς 16.	For treatment of chronic insomnia disorder, there is insufficient evidence to recommend for or against: Aerobic exercise Mindfulness meditation Qigong Resistive exercise Tai chi Yoga	Neither for nor against	Not reviewed, Amended
DescriptionFor treatment of obstructive sleep apnea, we recommend one or more of the following evidence- based therapies, depending on patient values and characteristics:17.For treatment of obstructive sleep apnea, we recommend one or more of the following evidence- based therapies, depending on patient values and characteristics:17.Mandibular advancement devices • Positive airway pressure (PAP) • Referral for surgical evaluation		Strong for	Reviewed, New-added		

	Sub-				
Topic	topic	#	Recommendation	Strength ^a	Category ^b
		18.	For treatment of mild to moderate obstructive sleep apnea (Event Index <30 per hour), we suggest either mandibular advancement devices or positive airway pressure as first line therapy options.	Weak for	Reviewed, Amended
		19.	For treatment of newly diagnosed obstructive sleep apnea, we suggest initiating auto-titrating over fixed continuous positive airway pressure to facilitate usage.	Weak for	Reviewed, New- replaced
		20.	For treatment of obstructive sleep apnea in patients with overweight or obesity, we suggest evidence- based weight management in combination with other treatments for obstructive sleep apnea. (See VA/DOD CPG on Management of Overweight and Obesity)	Weak for	Reviewed, New-added
		21.	For treatment of positional obstructive sleep apnea, we suggest positional therapy.	Weak for	Reviewed, New-added
		22.	For treatment of obstructive sleep apnea in appropriate* patients (including with an apnea hypopnea index of 15 or greater per hour) who have not been successful with positive airway pressure therapy, we suggest referral for evaluation for hypoglossal nerve stimulation therapy. *Note FDA criteria for appropriate patients in the narrative.	Weak for	Reviewed, Amended
		23.	For treatment of obstructive sleep apnea in patients who cannot tolerate other recommended therapies, we suggest against oxygen therapy as a standalone treatment.	Weak against	Not reviewed, Amended
		24.	For treatment of obstructive sleep apnea, we suggest against atomoxetine or a combination of atomoxetine and oxybutynin.	Weak against	Reviewed, New-added
		25.	 For treatment of obstructive sleep apnea there is insufficient evidence to suggest for or against these interventions: Expiratory positive airway pressure (EPAP) Inspiratory muscle therapy Intra-oral negative airway pressure Myofunctional exercise Neuromuscular electrical stimulation Transcutaneous electrical nerve stimulation (TENS) 	Neither for nor against	Reviewed, New- replaced
		26.	For treatment of obstructive sleep apnea in patients who are prescribed positive airway pressure therapy, we suggest the use of in-person or telehealth	Weak for	Reviewed, New- replaced

Торіс	Sub- topic	#	Recommendation	Strength ^a	Category ^b
			educational, behavioral, and supportive interventions to improve PAP usage.		
27. For treatment of obstructive sleep apnea in appropriate patients, we suggest up to a two-week course of eszopiclone to improve positive airway pressure usage.		appropriate patients, we suggest up to a two-week course of eszopiclone to improve positive airway	Weak for	Reviewed, New-added	
		28.	For treatment of obstructive sleep apnea in patients with anatomical nasal obstruction as a barrier to positive airway pressure use, we suggest evaluation for nasal surgery.		Reviewed, Not changed
		29.	For treatment of obstructive sleep apnea-related residual excessive daytime sleepiness in patients who are optimally treated with sufficient therapy use, we suggest adding: Armodafinil Modafinil Solriamfetol.	Weak for	Reviewed, New-added

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

^b 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

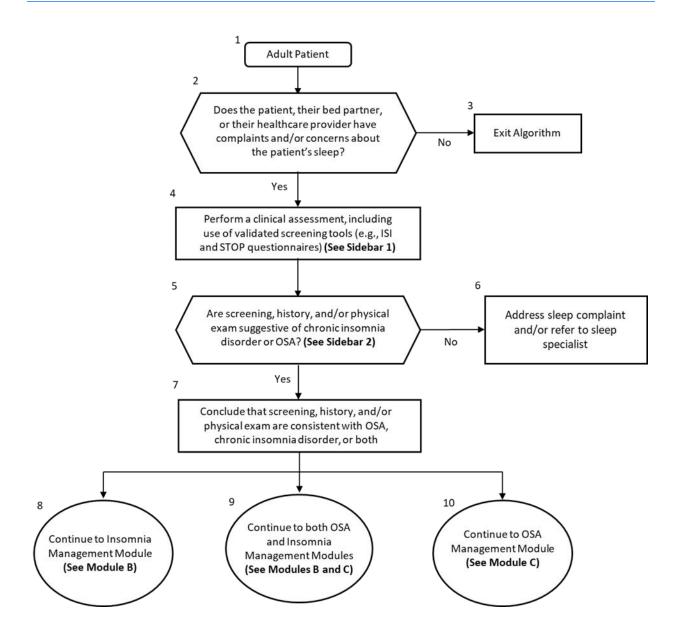
This algorithm is designed to inform providers of the recommended interventions and appropriate timing of each of the interventions for patients with chronic insomnia disorder and/or OSA. The interventions included in the algorithm are paired with the corresponding recommendation in the VA/DOD CPG for the Management of Chronic Insomnia Disorder and OSA. The use of the algorithm format 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-bystep 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. (2)Sidebars 1-9 provide more detailed information to assist in defining and interpreting elements in the boxes.

Shape	Description
	Rounded rectangles represent a clinical state or condition
\bigcirc	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
\bigcirc	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 (See Appendix F in the full CPG for detailed ICSD-3-TR Diagnostic Criteria):

- Sleepiness
- Loud, bothersome snoring
- Witnessed apneas
- Nightly gasping/choking
- Obesity (BMI > 30 kg/ m²)
- Treatment resistant hypertension

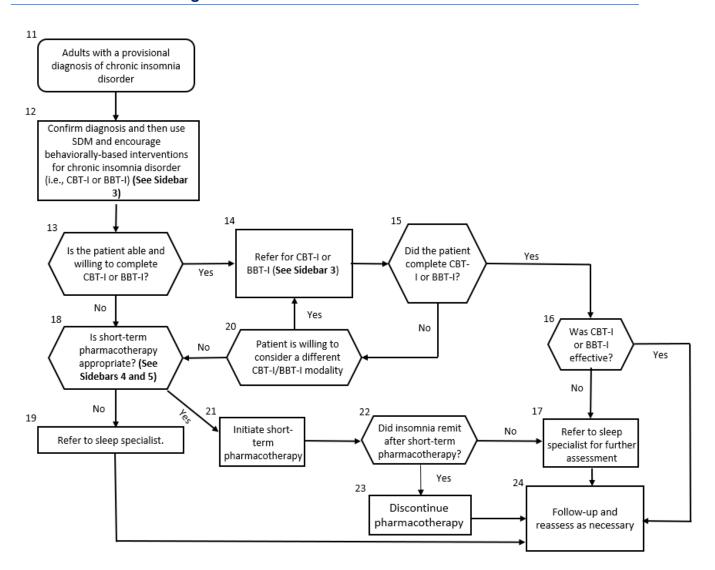
Chronic Insomnia Disorder (See Appendix F in the full CPG for detailed ICSD-3 TR Diagnostic Criteria):

- 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

Sidebar 2. Other Sleep Disorders

- Insufficient Sleep Syndrome
- Restless Legs Syndrome/ (Also known as Willis-Ekbom Disease)
- Narcolepsy/Idiopathic CNS-Hypersomnia
- Nightmare Disorder
- REM Sleep Behavior Disorder
- Circadian Rhythm Sleep-Wake Disorders
- NREM Parasomnias-Sleepwalking/Sleep Eating
- Central Sleep Apnea
- Other forms of sleep disordered breathing

Module B: Management of Chronic Insomnia Disorder



- ^a In cases where the patient requires immediate intervention, providers may exercise clinical judgment to determine if pharmacotherapy may be safely initiated.
- ^b 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 Shared Decision Making (SDM):

- General information on chronic insomnia disorder
- Education about available behavioral and psychological treatment options and available modalities
- Discussion of risks, benefits, preferences and alternatives to treatment options

Components of behavioral and psychological treatment (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
- Arousal reduction techniques: introduction of calming bedtime routine, relaxation techniques to reduce physiological arousal such as diaphragmatic breathing, body scan, or grounding exercises
- Sleep Hygiene Education (optional): Planned changes in target behaviors and environmental factors that negatively impact sleep including light/noise exposure, eating/drinking near bedtime and at night, caffeine/nicotine/alcohol use (See Recommendation 7 in the full CPG)
- Cognitive Restructuring (CBT-I only): Addresses cognitive arousal (busy or racing mind) and inaccurate sleep-related thoughts by challenging unhelpful thoughts and beliefs about sleep

Conditions requiring adaptations or delay of CBT-I/BBT-I:

- Medically unstable (delay)
- Active alcohol or drug use disorder (delay)
- Excessive daytime sleepiness (adapt/delay)
- Nighttime fall risk or inability to transfer in/out of bed (adapt)
- Engaged in exposure-based PTSD treatment (delay)
- Uncontrolled seizure disorder (delay)
- Bipolar disorder (adapt)
- Current acute mental health symptoms (delay)
- Pregnancy and postpartum insomnia

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, reproductive status, 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 agents and discuss deprescribing plan:

- Low-dose doxepin; or
- Dual orexin receptor antagonists; 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) (See Recommendation 9 in the full CPG)

The use of antipsychotic agents, benzodiazepines, diphenhydramine, and trazodone are NOT suggested for treatment of chronic insomnia disorder (See Recommendation 10 in the full CPG).

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: Interventions Not Advised for Use in Chronic Insomnia Disorder

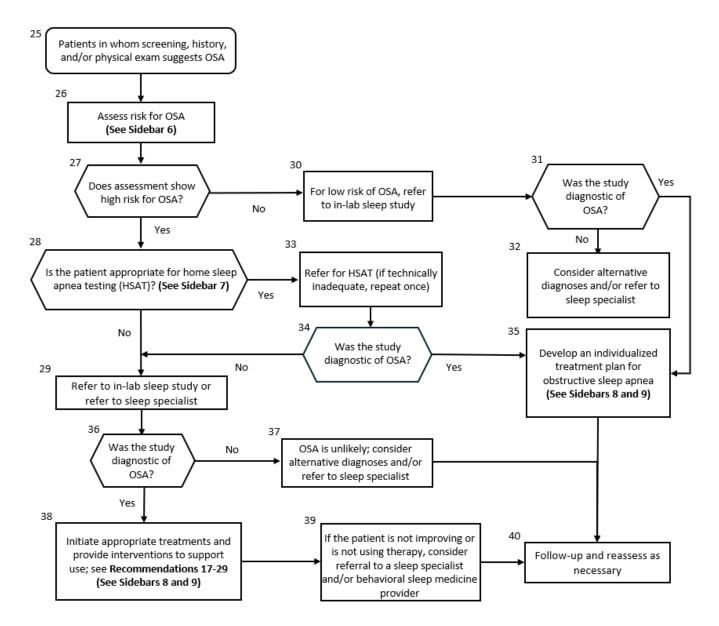
Treatments **NOT** suggested for chronic insomnia disorder:

- Alpha stim
- Cannabis or its derivatives
- Chamomile
- Cranial electrical stimulation
- Melatonin
- Passionflower
- Saffron
- Valerian (See Recommendations 13 and 14 in the full CPG)

Treatments **NOT** recommended for chronic insomnia disorder:

Kava (See Recommendation 12 in the full CPG)

Module C: Management of Obstructive Sleep Apnea



Abbreviations: AHI: apnea-hypopnea index; HSAT: home sleep apnea testing; OSA: obstructive sleep apnea

Sidebar 6: Risk of Obstructive Sleep Apnea (OSA)

Consider using STOP questionnaire for risk stratification:

- 1. Snoring loudly
- 2. Tired, fatigue, sleepy in daytime
- 3. Observed to stop breathing
- 4. Hypertension

High risk of OSA: greater than ≥2 items are answered "yes"

Low risk of OSA: less than <2 items are answered "yes"

STOP questionnaire should not replace clinical judgment; clinical assessment should include BMI >30 kg/m2, age >50, menopausal status, neck circumference, family history, and crowded oropharynx

Abbreviations: BMI: body mass index; kg/m²: kilograms per meter squared; OSA: obstructive sleep apnea; STOP: Snoring, Tiredness, Observed apnea, and high blood Pressure

Sidebar 7: Appropriateness for HSAT

In-laboratory polysomnography is preferred over HSAT in the following groups:

1. Significant comorbid conditions

- Advanced heart failure
 - Established or suspected hypoventilation/hypoxic conditions
 - Neuromuscular dysfunction
 - Advanced primary neurological conditions
 - Medication related (opioid, sedative and hypnotics)
 - Advanced respiratory comorbidities.
- Stroke
- 2. Patients with significant sleep disruption (e.g. due to chronic insomnia disorder)
- 3. Physical, sensory and cognitive impairment
- 4. Chain of custody concerns
- 5. Low pretest probability for obstructive sleep apnea

Abbreviations: HSAT: home sleep apnea testing

Sidebar 8: AHI 5 to <15 on HSAT

- 1. Treatment for OSA is recommended for symptomatic patients
- with an AHI or REI of 5 to <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 to <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. Prescribe PAP as first line therapy for patient with severe OSA (i.e., AHI >30 events per hour)
- 2. Prescribe PAP or MAD for other OSA severity (i.e., AHI 5 to <30 events per hour), based on clinical evaluation, comorbidities, and patient preference.
- 3. Offer educational, behavioral therapy, and supportive interventions to improve PAP adoption and use
 - Consider a two-week course of eszopiclone to improve PAP adoption
 - Consider referral to behavioral sleep medicine provider to enhance PAP adoption and use
- 4. Encourage weight loss and a comprehensive lifestyle intervention program in patients with OSA who are overweight or obese.
- 5. Refer patients for follow up to a sleep medicine specialist:
 - Who do not adopt/use PAP and/or MAD therapy
 - With persistent symptoms despite adequate therapy

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 consider 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, ethnicity, and other differences. The information that patients are provided about treatment, and care should be culturally appropriate and 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 intended for use by VA, DOD, community providers, and others involved in the health care team evaluating and managing adults with chronic insomnia disorder and/or obstructive sleep apnea. The patient population of interest for this CPG is adult patients with chronic insomnia disorder and/or obstructive sleep apnea who may receive care in the VA or DOD health care delivery systems, or VA and DOD adult beneficiaries who receive care from community-based providers. Recommendations in this CPG are applicable for any adult patients of VA or DOD, inclusive of all care locations (VA, DOD, or community-based care).

Methods

The methodology used in developing the 2025 CPG follows the *Guideline for Guidelines*, an internal document of the VA and DOD EBPWG that was updated in July 2019 that outlines procedures for developing and submitting VA/DOD CPGs. (<u>3</u>) The *Guideline for Guidelines* can be downloaded from <u>http://www.healthquality.va.gov/policy/index.asp</u>. This CPG also aligns with the National Academy of Medicine's (NAM) principles of trustworthy CPGs (e.g., explanation of evidence quality and strength, the management of potential conflicts of interest (COI)(<u>4</u>), interdisciplinary stakeholder involvement, use of SR and external review)(<u>5</u>) This CPG also aligns with the National Academy of Medicine's (NAM) principles of trustworthy CPGs (e.g., explanation of evidence quality and strength, the management of potential conflicts of interest (COI)(<u>4</u>), interdisciplinary stakeholder involvement, use of SR and external review)(<u>5</u>) This CPG also aligns with the National Academy of Medicine's (NAM) principles of trustworthy CPGs (e.g., explanation of evidence quality and strength, the management of potential conflicts of interest(<u>4</u>), interdisciplinary stakeholder involvement, use of SR and external review)(<u>5</u>) Appendix A of the full CPG provides a detailed description of the CPG development methodology.

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 Evidence Based Practice, Office of Quality and Patient Safety, in collaboration with the Clinical Quality Improvement Program, DHA, identified the following four providers to serve as Champions (i.e., leaders) of this CPG's Work Group: Amir Sharafkhaneh, MD, and Christi Ulmer, PhD, CBSM, DBSM, from VA; and Matthew Brock, MD, FAASM, and Vincent Capaldi, ScM, MD, DFAPA, FACP, FAASM, from DOD.

The Sigma Team, including Sigma Health Consulting and Duty First Consulting 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 December 2023, 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: internal medicine, sleep medicine, neurology, psychiatry, pulmonology, dental, psychology, mental/behavioral health counseling, and otolaryngology.

The guideline development process for the 2025 CPG consisted of the following steps:

- 1. Determining the scope of the CPG;
- 2. Crafting clinically relevant KQs to guide the systematic evidence review;
- 3. Identifying discussion topics for the Patient Focus Group and considering the patient perspective;
- 4. Providing direction on inclusion and exclusion criteria for the systematic evidence review and the assessment of the level and quality of evidence;
- 5. Developing evidence-based clinical practice recommendations, including determining the strength and category of each recommendation; and
- 6. Drafting and submitting a final CPG on the management of chronic insomnia disorder and/or OSA to the VA/DOD EBPWG

Grading Recommendations

The Work Group used the GRADE approach to craft each recommendation and determine its strength. Per the GRADE approach, recommendations must be evidence based and cannot be made based on expert opinion alone. The GRADE approach uses the following four domains to inform the strength of each recommendation ($\underline{6}$)

- Confidence in the quality of the evidence
- Balance of desirable and undesirable outcomes
- Patient or provider values and preferences
- Other implications, as appropriate, e.g.,
 - o Resource use

- o Equity
- o Acceptability
- Feasibility
- Subgroup consideration

Using these four domains, the Work Group determined the relative strength of each recommendation (Strong or Weak). The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework above, which incorporates the four domains.(7) A Strong recommendation generally indicates High or Moderate confidence in the quality of the available evidence, a clear difference in magnitude between the benefits and harms of an intervention, similar patient values and preferences, and understood influence of other implications (e.g., resource use, feasibility).

In some instances, insufficient evidence exists on which to base a recommendation for or against a particular therapy, preventive measure, or other intervention. For example, the systematic evidence review might have found little or no relevant evidence, inconclusive evidence, or conflicting evidence for the intervention. The way this finding is expressed in the CPG might vary. In such instances, the Work Group might include among its set of recommendations a statement of insufficient evidence for an intervention that might be in common practice although it is unsupported by clinical evidence and particularly if other risks of continuing its use might exist (e.g., high opportunity cost, misallocation of resources). In other cases, the Work Group might decide to exclude this type of statement about intervention. For example, the Work Group might remain silent where an absence of evidence occurs for a rarely used intervention. In other cases, an intervention might have a favorable balance of benefits and harms but might be a standard of care for which no recent evidence has been generated.

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 2025 CPG can be found in the section on <u>Recommendations</u>. Additional information regarding the use of the GRADE system can be found in Appendix A in the full Chronic Insomnia Disorder and OSA CPG.

Calacinic Work Croup					
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	Aaron Thomas, MD				
	Constance Fung, MD, MS, FAASM, FACP				
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Guideline Work Group

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		Jake Fausnacht, BS		

*Additional contributor contact information is available in Appendix I in the full text Chronic Insomnia Disorder and OSA CPG.

Patient-Centered Care

Intended to consider patient needs and preferences, guideline recommendations represent a whole/holistic health approach to care that is patient-centered, culturally appropriate, and available to people with limited literacy skills and physical, sensory, or learning disabilities. VA/DOD CPGs encourage providers to use a patient-centered, whole/holistic health approach (i.e., individualized treatment based on patient needs, characteristics, and preferences). This approach aims to treat the condition while also optimizing the individual's overall health and wellbeing.

Regardless of the care setting, all patients should have access to individualized evidence-based care. Patient-centered care can decrease patient anxiety, increase trust in providers, and improve treatment adherence.(8,9) A whole/holistic health approach (<u>https://www.va.gov/wholehealth/</u>) empowers and equips individuals to meet their personal health and wellbeing goals. Good communication is essential and should be supported by evidence-based information tailored to each patient's needs. An empathetic and non-judgmental approach facilitates discussions sensitive to gender, culture, ethnicity, and other differences.

Shared Decision Making

This CPG encourages providers to practice shared decision making, a process in which providers, patients, and patient care partners (e.g., family, friends, caregivers) consider clinical evidence of benefits and risks as well as patient values and preferences to make decisions regarding the patient's treatment.(10) Shared decision making is emphasized in Crossing the Quality Chasm, an Institute of Medicine (IOM), now NAM, report in 2001 (11) and is inherent within the whole/holistic health approach. Providers must be adept at presenting information to their patients regarding individual treatments, expected risks, expected outcomes, and levels or settings of care or both, especially where patient heterogeneity in weighing risks and benefits might exist. The VHA and DHA have embraced shared decision-making. Providers are encouraged to use shared decision making to individualize treatment goals and plans based on patient capabilities, needs, and preferences.

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 (12) 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 provide 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 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."

B. Goals of Insomnia Treatment

"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 you're concerned about how 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?"

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

"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 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, in the short run, sleep-inducing medications are less effective than behavioral therapies for chronic insomnia. In the long run, sleep medications seem to be even less effective than behavioral therapies, suggesting that behavioral therapies may address the underlying cause of chronic insomnia."

"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 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?"

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

Associating bed with sleep: "Many patients who have trouble sleeping spend a lot of time in bed hoping they fall asleep. Over time, their minds and bodies end up associating the bed with wakefulness rather than asleep. What sorts of things has (name of CBT-I or BBT-I provider) discussed with you to help you to strengthen the association between your bed and sleep? Has this been difficult 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 be sure to complete your sleep diary as recommended by your healthcare provider, to allow them 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 reviewing a PAP therapy download in patients using either auto-adjusting 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, specifically including sleepiness, are adequately addressed. Examples are provided in the following sections.

A. General Information on Obstructive Sleep Apnea

"Obstructive sleep apnea is a very common and 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, sleep fragmentation, 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."

B. Diagnosing Sleep Apnea: Sleep Studies

"There are two options for diagnosing obstructive sleep apnea: (1) a home sleep apnea test, which is only used to confirm a highly suspected case of obstructive sleep apnea, and (2) an in-lab sleep study (polysomnography), which provides more comprehensive information. Both studies measure your oxygen levels and the number of times per hour your breathing decreases or stops, which is called the apnea-hypopnea index (AHI). 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 may be required."

C. Describing Sleep Apnea Treatment to Patients

"The primary and most efficacious treatment for obstructive sleep apnea is positive airway pressure (PAP) therapy. PAP is gentle air pressure that is delivered by a small bedside machine connected to a mask that you wear while sleeping. There are 2 types of PAP: (1) an auto-adjusting PAP (APAP), which automatically adjusts how much pressure is delivered to keep your airway open, or (2) a continuous PAP (CPAP), which delivers one set pressure (i.e., it does not vary over time). You should use PAP whenever you sleep, including naps, 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 obstructive sleep apnea. One alternative is a mandibular advancement device (MAD). Depending on your teeth and severity of sleep apnea, this may be a reasonable treatment. This device works by moving your lower jaw forward to open your airway and maintaining it in this position while you wear it during sleep. In order to obtain a MAD, you will need to see a dentist who is experienced in making these devices."

"There are other less common medical devices and surgeries that can be considered for treatment of your sleep apnea. However, you will need to speak with a sleep specialist to determine the appropriateness of these therapies."

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

"Overall, men have a higher prevalence of sleep apnea than women. In women, postmenopausal status increases their risk of having sleep apnea. Weight loss can improve sleep apnea while weight gain can make sleep apnea worse. Avoiding sleep on your back can improve sleep apnea in some patients as sleeping on your back typically makes sleep apnea worse. Using certain substances and medications (i.e., alcohol, opioids/pain medications, sleeping medications) can make sleep apnea worse."

E. Addressing Sleepiness

"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."

F. Addressing Adherence to Positive Airway Pressure

The following are interventions that can help with PAP adherence:

- Provide education that includes an overview of OSA and the patient's treatment modality
- Use heated humidification to help with nasal dryness and congestion with PAP usage
- Ensure the appropriate mask choice, noting nasal masks are associated with higher adherence
- Investigate and address issues of high mask leak
- Refer to cognitive behavioral therapies that address distorted views of sleep and sleep apnea, promote positive associations with PAP, and enlist social support
- Arrange close follow-up (at least at 4-weeks, if not sooner) after PAP initiation to evaluate usage

ICSD-3-TR Diagnostic Criteria

A. Chronic Insomnia Disorder (<u>13</u>)

ICD-9-CM code:

307.42 ICD-10-CM

code: F51.01

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

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 disturbance and associated daytime symptoms are not solely due to another current sleep disorder, medical disorder, mental disorder, or medication/substance use.

B. Obstructive Sleep Apnea (13)

ICD-9-CM code:

327.23 ICD-10-CM

code: G47.33

Alternate Names

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

Diagnostic Criteria

((A and B) or C) +D satisfy the criteria

- A. The presence of one or more of the following:
 - 1. The patient complains of sleepiness, fatigue, insomnia, or other symptoms leading to impaired sleep-related quality of life
 - 2. The patient complains of sleepiness, fatigue, insomnia, or other symptoms leading to impaired sleep related quality of life.
 - 3. The patient wakes with breath holding, gasping, or choking
 - 4. The bed partner or other observer reports habitual snoring or breathing interruption during the patient's sleep
- 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)
- C. PSG or HSAT demonstrates:
 - 1. Fifteen 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)
- D. The symptoms are not better explained by another current sleep disorder, medical disorder, medications, or substance use.

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Access to the full guideline and additional resources are available at the following link: <u>https://www.healthquality.va.gov/guidelines/cd/insomnia/</u>

