General

Guideline Title

Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline.

Bibliographic Source(s)

Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017 Feb 15;13(2):307-49. [175 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- August 31, 2016: Opioid pain and cough medicines combined with benzodiazepines : A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.

Recommendations

Major Recommendations

The quality of evidence (High-Very Low), direction (for or against) and strengths of recommendations (Weak, Strong) are defined at the end of the "Major Recommendations" field.

Orexin Receptor Antagonists

Suvorexant for the Treatment of Chronic Insomnia

Recommendation 1: The task force suggests that clinicians use suvorexant as a treatment for sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 10, 15/20, and 20 mg doses of suvorexant.

Benzodiazepines (BZD) Receptor Agonists

Eszopiclone for the Treatment of Chronic Insomnia

Recommendation 2: The task force suggests that clinicians use eszopiclone as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 2 mg and 3 mg doses of eszopiclone.

Zaleplon for the Treatment of Chronic Insomnia

Recommendation 3: The task force suggests that clinicians use zaleplon as a treatment for sleep onset insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 10 mg doses of zaleplon.

Zolpidem for the Treatment of Chronic Insomnia

Recommendation 4: The task force suggests that clinicians use zolpidem as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 10 mg doses of zolpidem.

N.B. Although 10 mg was the recommended starting dosage for adults at the time of initial approval, the U.S. Food and Drug Administration (FDA) has subsequently lowered the recommended starting dosage of immediate-release zolpidem products to 5 mg. Further, the FDA has recommended a reduction of starting dosage for extended-release forms of zolpidem from 12.5 mg to 6.25 mg.

Benzodiazepines

Triazolam for the Treatment of Chronic Insomnia

Recommendation 5: The task force suggests that clinicians use triazolam as a treatment for sleep onset insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 0.25 mg doses of triazolam.

Temazepam for the Treatment of Chronic Insomnia

Recommendation 6: The task force suggests that clinicians use temazepam as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 15 mg doses of temazepam.

Melatonin Agonists

Ramelteon for the Treatment of Chronic Insomnia

Recommendation 7: The task force suggests that clinicians use ramelteon as a treatment for sleep onset insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 8 mg doses of ramelteon.

Heterocyclics

Doxepin for the Treatment of Chronic Insomnia

Recommendation 8: The task force suggests that clinicians use doxepin as a treatment for sleep maintenance insomnia (versus no treatment) in

adults. [WEAK]

Remarks: This recommendation is based on trials of 3 mg and 6 mg doses of doxepin.

Trazodone for the Treatment of Chronic Insomnia

Recommendation 9: The task force suggests that clinicians not use trazodone as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on one trial of a 50 mg dose of trazodone.

Anticonvulsants

Tiagabine for the Treatment of Primary Insomnia

Recommendation 10: The task force suggests that clinicians not use tiagabine as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 4 mg doses of tiagabine.

Over-the-Counter Preparations

Diphenhydramine for the Treatment of Primary Insomnia

Recommendation 11: The task force suggests that clinicians not use diphenhydramine as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 50 mg doses of diphenhydramine.

Melatonin for the Treatment of Primary Insomnia

Recommendation 12: The task force suggests that clinicians not use melatonin as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 2 mg doses of melatonin.

L-tryptophan for the Treatment of Primary Insomnia

Recommendation 13: The task force suggests that clinicians not use tryptophan as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of 250 mg doses of tryptophan.

Valerian for the Treatment of Primary Insomnia

Recommendation 14: The task force suggests that clinicians not use valerian as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. [WEAK]

Remarks: This recommendation is based on trials of variable dosages of valerian and valerian-hops combination.

Definitions

Quality of a Body of Evidence

High: Corresponds to a high level of certainty that the estimate of the effect lies close to that of the true effect.

Moderate: Corresponds to a moderate level of certainty in the effect estimate; the estimate of the effect is likely to be close to the true effect, but there is a possibility that it is substantially different.

Low: Corresponds to a low level of certainty in the effect estimate; the estimate of the effect may be substantially different from the true effect.

Very low: Corresponds to very little certainty in the effect estimate; the estimate of the effect is likely to be substantially different from the true effect.

Definitions of American Academy of Sleep Medicine (AASM) Strengths of Recommendations

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
FOR	STRONG	• There is a high degree of clinical certainty that the balance between benefits vs. harms (i.e., net benefits) favors benefit for this patient-care strategy. • The vast majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	WEAK	• There is a lower degree of clinical certainty that the balance between benefits vs. harms (i.e., net benefits) favors benefit for this patient-care strategy. • The majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
AGAINST	WEAK	• There is a lower degree of clinical certainty in the balance between benefits vs. harms (i.e., net harms) of this patient-care strategy. • The majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	STRONG	• There is a high degree of clinical certainty in the balance between benefits vs, harms (i.e., net harms) of this patient-care strategy. • The vast majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Chronic insomnia

Guideline Category

Treatment

Clinical Specialty

Family Practice

Geriatrics

Sleep Medicine

Intended Users

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To determine the efficacy of individual prescription and non-prescription medications for treatment of insomnia
- To assess the efficacy of individual medications for specific sleep complaints (i.e., difficulty initiating sleep/difficulty maintaining sleep)
- To evaluate the potential for adverse effects of these drugs
- To consider the evidence concerning efficacy and adverse effects in delineating evidence-based guidelines for the use of pharmacotherapy in the management of chronic insomnia
- To offer recommendations for optimizing quality and uniformity of future investigations

Target Population

Adult patients diagnosed with chronic insomnia

Interventions and Practices Considered

1. Orexin receptor antagonists (suvorexant)
2. Benzodiazepine receptor agonists
    - Eszopiclone
    - Zaleplon
    - Zolpidem
3. Benzodiazepines
    - Triazolam
    - Temazepam
4. Melatonin agonists (ramelteon)
5. Heterocyclics
    - Doxepin
    - Trazodone
6. Anticonvulsants (tiagabine)
7. Over-the-counter preparations (not recommended)
    - Diphenhydramine
    - Melatonin
    - L-tryptophan
    - Valerian

Major Outcomes Considered

- Sleep latency (SL)
- Total sleep time (TST)
- Wake after sleep onset (WASO)
- Quality of sleep (QOS)
- Sleep efficiency (SE)
- Number of awakenings (NOA)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Searches and Evidence Review

Multiple literature searches were performed by the American Academy of Sleep Medicine (AASM) research staff using the PubMed database throughout the guideline development process.

Keywords and Medical Subject Headings (MeSH) terms were:

- Insomnia OR sleep initiation and maintenance disorder NOT transient AND
- Clinical trial OR randomized controlled trial
- NOT editorial, letter, comment, case reports, biography, review

The full literature search string can be found in the supplemental material in the original guideline document. Searches were performed on April 26, 2011 (search 1), May 12, 2014 (search 2), October 15, 2014 (search 3), and January 25, 2016 (search 4). Based on their expertise and familiarity with the insomnia literature, task force members submitted additional relevant literature and screened reference lists to identify articles of potential interest. This served as a "spot check" for the literature searches to ensure that important articles were not missed.

Abstracts from all retrieved articles were individually assessed by two task force members to determine whether the publication should be included or excluded from further consideration in the project. Exclusion criteria can be found in Figure 1 (see the original guideline document). A total of 129 publications were approved for inclusion.

Number of Source Documents

A total of 129 studies were included in the evidence base for recommendations. Forty-six studies were included for meta-analysis (see Figure 1 in the original guideline document for the evidence base flow diagram).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of a Body of Evidence

High: Corresponds to a high level of certainty that the estimate of the effect lies close to that of the true effect.

Moderate: Corresponds to a moderate level of certainty in the effect estimate; the estimate of the effect is likely to be close to the true effect, but there is a possibility that it is substantially different.

Low: Corresponds to a low level of certainty in the effect estimate; the estimate of the effect may be substantially different from the true effect.

Very low: Corresponds to very little certainty in the effect estimate; the estimate of the effect is likely to be substantially different from the true effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Full texts of accepted articles were reviewed and data pertaining to Grading of Recommendations Assessment, Development and Evaluation (GRADE) for the outcomes of interest were extracted into spreadsheets by American Academy of Sleep Medicine (AASM) staff. All data pertaining to adverse events were extracted into separate spreadsheets. Articles that met inclusion criteria but did not report outcomes of interest were rejected from the final evidence base. If outcome data were not presented in the format necessary for statistical analysis (i.e., mean, standard deviation, and sample size), the authors were contacted in an attempt to obtain the necessary data. Finally, clinicaltrials.gov was used as a final resource for attempting to obtain data necessary for completing statistical analyses. If the necessary data were not available from the publication, the author, or clinicaltrials.gov, the paper was included in the evidence base as supporting evidence, but was not used for statistical analysis or for determining quality of evidence.

For some drugs, none of the accepted publications provided data that could be used for statistical analysis. In these cases, the task force did not make a recommendation, but provided a literature review of these accepted papers instead. These publications are not included the evidence base flow diagram (Figure 1 of the original guideline document).

Statistical and Meta-Analysis

For outcomes of interest, data from baseline and last-treatment time points were used for all statistical and meta-analyses. Data from crossover trials were treated as parallel groups. Change-from-baseline values were also used for statistical and meta-analyses, when the change-from-baseline standard deviation was provided or could be calculated from the provided statistic. Standardized mean difference (SMD) was used for meta-analyses of quality of sleep (QOS) when data were reported using variable scales. Analyses were limited to U.S. Food and Drug Administration (FDA)-approved doses. For adverse events, all data presented in the accepted papers were used for statistical and meta-analysis. All calculations and meta-analyses were performed using Review Manager 5.3 software. Whenever possible, meta-analyses were performed by pooling data across studies for each outcome and adverse event. The evidence was grouped for analysis based on the drug, dosage, clinical outcome of interest, and methodology used to obtain the data (e.g., data obtained by polysomnography [PSG] were analyzed separately from data obtained by sleep diary).

All meta-analyses were performed as per-treatment analyses using the random effects model. For most interventions, absolute effects of drug treatments are represented by the mean difference (MD) ± standard deviation (SD) of post-treatment drug versus post-treatment placebo. Meta-analyses for adverse events are presented as risk difference. The result of each meta-analysis is displayed as a forest plot. Pooled results are expressed as the total number of patients, MD and 95% confidence interval (CI) between the experimental treatment and placebo.

Interpretation of clinical significance for outcomes of interest was conducted by comparing the absolute effects of drug treatment to the clinical significance threshold previously determined by the task force for each outcome of interest. Interpretation of adverse events was based upon the risk difference and clinical expertise of the task force.

Quality of Evidence

The GRADE approach was used for the assessment of quality of evidence (see the "Rating Scheme for the Strength of the Evidence" field). For details on how the AASM uses GRADE to develop its clinical practice guidelines, refer to the AASM report by Morgenthaler et al. (see the "Availability of Companion Documents" field).

For the determination of the quality of evidence for an intervention, the task force used objective data whenever possible (e.g., PSG). When only subjective data were available (e.g., sleep diaries), this evidence was used to determine the overall quality of evidence. The decision to use objective data as the primary determinant of quality of evidence was based on the preference for an objective measure of physiologic changes for determining clinically significant efficacy, the standardization of sleep parameter measurements and reporting, and the current requirements of PSG data for FDA approval of hypnotic medications. The results of this assessment are presented as summary of findings tables for each intervention (see Tables S1–S24 in the supplemental material in the original guideline document).

Quality of evidence grades for randomized clinical trials begin at HIGH and are downgraded progressively for heterogeneity, imprecision, and/or potential publication bias. Since the vast majority of studies in this field are industry sponsored, the quality of evidence for nearly all of these studies is, therefore, reduced from HIGH to MODERATE. This is to be expected for clinical trials for many drugs (i.e. not only hypnotics), since the vast majority are industry-sponsored FDA registration studies. The extent to which this downgrading of evidence is warranted due to actual publication bias is unknown, but under the GRADE system the task force has chosen to adopt the conservative approach and assume risk of publication bias. When heterogeneity and imprecision are accounted for, the quality of evidence for many treatments considered is LOW or VERY LOW. These latter two factors are not uncommon, as there is substantial variability in sleep outcome variables across studies and confidence intervals frequently overlap the clinical thresholds for significance.

See also "Understanding the Methodology" section in the original guideline document for more information on the quality of evidence.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

Expert Task Force

In order to develop this clinical practice guideline, the American Academy of Sleep Medicine (AASM) commissioned a task force composed of content experts in the field of insomnia, an AASM Board of Directors liaison, and AASM Science and Research Department staff members.

PICO Questions

A PICO (Patient [Population or Problem], Intervention, Comparison, and Outcomes) question template was developed to be the focus of this guideline: "In adult patients diagnosed with primary chronic insomnia, how does [intervention] improve [outcomes], compared to placebo?"

The PICO question template was approved by the AASM Board of Directors. The task force identified the pharmacological interventions of interest, based on U.S. Food and Drug Administration (FDA) approval status and common off-label usage. Based on their expertise, the task force developed a list of patient-oriented clinically relevant outcomes that are indicative of whether a treatment should be recommended for clinical practice. The task force then rated their relative importance and selected the top six outcomes. The following outcomes were determined to be "critical" or "important" for clinical decision making across all interventions: sleep latency, wake after sleep onset, total sleep time, quality of sleep, number of awakenings, and sleep efficiency (see Table 1 in the original guideline document). The task force then determined which outcomes were "critical" for clinical decision making for each individual intervention (see Table 2 in the original guideline document). Lastly, clinical significance thresholds, used to determine if a change in an outcome was clinically significant, were defined for each outcome by task force clinical judgement, prior to statistical analysis (see Table 3 in the original guideline document). These decisions were made by nominal consensus of the task force, based on their expertise and familiarity with the literature and clinical practice.

Strength of Recommendations

The task force developed recommendation statements consistent with Grades of Recommendations Assessment, Development and Evaluation (GRADE) methodology based on the balance of the following factors:

1. Quality of evidence. Quality of evidence was based exclusively on the studies that could be included in meta-analyses. The task force determined their overall confidence that the estimated effect found in the literature was representative of the true treatment effect that patients would see, based on the following criteria: overall risk of bias (randomization, blinding, allocation concealment, selective reporting, and author disclosures); imprecision (when 95% confidence interval [CI] cross the clinical significance thresholds); inconsistency (I^2 cutoff of 75%); indirectness (study population); and risk of publication bias (funding sources). The task force also considered the consistency of the supporting evidence (i.e., data the met inclusion criteria, but could not be included in the meta-analyses). However such evidence did not impact judgments regarding the quality of evidence or final recommendations.
2. Benefits versus harms. The task force determined if the beneficial outcomes of the intervention outweighed any harmful side effects based on the following criteria: meta-analysis (if applicable); analysis of any harms/side effects reported within the accepted literature; and the clinical expertise of the task force.
3. Patient values and preferences. The task force determined if patient values and preferences would be generally consistent, and if patients would use the intervention based on the body of evidence reviewed. These judgments were based on the clinical expertise of the task force members and any data published on the topic relevant to patient preferences.

Taking these major factors into consideration, and adhering to GRADE recommendations, the task force assigned a direction (for or against) and strength (Strong or Weak) for each recommendation statement (see the "Rating Scheme for the Strength of the Recommendations" field).

Additional information is provided in the form of "Remarks" immediately following the recommendation statements, when deemed necessary by the task force (see the "Major Recommendations" field). Remarks are based on the evidence evaluated during the systematic review, and are intended to provide context for the recommendations.

See also "Understanding the Methodology" section in the original guideline document for more information on the strength of recommendations.

Rating Scheme for the Strength of the Recommendations

Definitions of American Academy of Sleep Medicine (AASM) Strengths of Recommendations

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
FOR	STRONG	• There is a high degree of clinical certainty that the balance between benefits vs. harms (i.e., net benefits) favors benefit for this patient-care strategy. • The vast majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	WEAK	• There is a lower degree of clinical certainty that the balance between benefits vs. harms (i.e., net benefits) favors benefit for this patient-care strategy. • The majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
AGAINST	WEAK	• There is a lower degree of clinical certainty in the balance between benefits vs. harms (i.e., net harms) of this patient-care strategy. • The majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	STRONG	• There is a high degree of clinical certainty in the balance between benefits vs, harms (i.e., net harms) of this patient-care strategy. • The vast majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.

Cost Analysis

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

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Approval of Recommendations

A draft of the guideline was made available for public comment for a two-week period on the American Academy of Sleep Medicine (AASM) Web site. The task force took into consideration all the comments received and made revisions when appropriate. Based on recommendations from public comments, the task force decided to include data from clinicaltrials.gov, which allowed the development of a recommendation for the use of suvorexant. The final guideline was submitted to the AASM Board of Directors who approved these recommendations.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

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

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Numerous investigations have demonstrated that hypnotic medications are comparably efficacious to cognitive behavioral therapies for insomnia (CBT-I) during acute treatment. However, these studies also make clear that the gains associated with CBT-I are durable following completion of treatment, whereas those associated with medication tend to dissipate following discontinuation of the drug. The vast majority of investigations which are included in the current analysis address relatively short-term use (e.g., one day to five weeks). Some studies have shown that long-term treatment with at least newer generation benzodiazepine receptor agonistic modulator (BzRA) hypnotics can be safe and effective under properly controlled conditions.

See the original guideline document for detailed discussions of the balance of benefits versus harms for each drug considered for treatment of chronic insomnia.

Potential Harms

The data on adverse effects derived from clinical trials, in general, do not suggest a high frequency of serious side effects. However, the data are scant and inconsistent, suggesting that caution should be applied in the assessment of relative risks associated with use of hypnotic medications. Other reported adverse effects include—but are not limited to—dependency/withdrawal, cognitive impairment, falls/fractures, parasomnias, and driving impairment and motor vehicle accidents. Epidemiological studies have also suggested a possible link between hypnotic use and infection, depression and overall mortality risk. These complications are observed most frequently in older populations, who are among the most frequent users of these drugs. Risks of dependency and serious withdrawal complications are of greatest concern with true benzodiazepine agents, particularly in the setting of escalating, long-term usage and insufficient monitoring. However, although much concern has understandably been raised about potential tolerance and addiction to these drugs, there is limited information regarding the true incidence of these complications. The risks associated with use of these agents are clearly increased not only in the elderly but also when they are used in dosages in excess of those recommended, or when combined with other psychoactive agents. Given the known sedative effects of these agents, particularly those with longer half-lives, clinicians must be diligent in cautioning patients regarding potential complications related to sedation. Such complications are most likely to occur with longer-acting agents and during morning hours following bedtime administration. Use of shorter-acting agents and the lowest effective dosage may help to reduce sedation-related complications. Appropriate patient counseling and careful monitoring will also serve to minimize risk. Complete avoidance of these medications should also be considered in those who may be particularly susceptible to adverse outcomes.

See the original guideline document for detailed discussions of the balance of benefits versus harms for each drug considered for treatment of chronic insomnia.

Contraindications

Contraindications

- The American Geriatric Society Beers criteria recommend that benzodiazepines be avoided for treatment of insomnia in older patients, due to risk of cognitive impairment, falls, and motor vehicle accidents.
- Complete avoidance of hypnotic medications should also be considered in those who may be particularly susceptible to adverse outcomes.

Qualifying Statements

Qualifying Statements

- This clinical practice guideline is intended to serve as one component in an ongoing assessment of the individual patient with insomnia. As discussed elsewhere, a comprehensive initial evaluation should include a detailed history of sleep complaints, medical and psychiatric history, and medication/substance use. These factors, together with patient preferences and treatment availability, should be used to select specific treatments for specific patients. This clinical practice guideline is not intended to help clinicians determine which patient is appropriate for

pharmacotherapy. Rather, it is intended to provide recommendations regarding specific insomnia drugs once the decision has been made to use pharmacotherapy. This guideline is also not intended to recommend one drug over another. Very few comparative efficacy studies have been conducted among these agents. Rather, the guideline provides a recommendation and evidence base for each individual drug. The selection of a particular drug should rest on the evidence summarized in the original guideline document, as well as additional patient-level factors, such as the optimal pharmacokinetic profile, assessments of benefits versus harms, and past treatment history.

- This guideline should be used in conjunction with other American Academy of Sleep Medicine (AASM) guidelines on the evaluation and treatment of chronic insomnia. These guidelines indicate that cognitive behavioral therapies for insomnia (CBT-I) is a standard of treatment and that such treatment carries a significantly favorable benefit:risk ratio. Therefore, based on these guidelines, all patients with chronic insomnia should receive CBT-I as a primary intervention. Medications for chronic insomnia disorder should be considered mainly in patients who are unable to participate in CBT-I, who still have symptoms despite participation in such treatments, or, in select cases, as a temporary adjunct to CBT-I.
- The recommendations in this guideline define principles of practice that should meet the needs of most adult patients, when pharmacologic treatment of chronic insomnia is indicated. This guideline should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably used to obtain the same results. The ultimate judgment regarding propriety of any specific care must be made by the clinician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options and resources, as well as safety considerations.
- The AASM expects this guideline to have an impact on professional behavior, patient outcomes, and, possibly, health care costs. This clinical practice guideline reflects the state of knowledge at the time of publication and will be reviewed and updated as new information becomes available.
- The existing data regarding sleep-promoting medications imposes limits on the degree of confidence as a result of several factors. These include: (1) a high degree of variability in the statistical information presented; (2) a significant degree of variability in sleep outcomes within and across studies; (3) industry sponsorship; (4) a paucity of systematic data collection and analysis of treatment-emergent adverse events; and (5) absence of outcome data (such as functional status or prevention of complications of chronic insomnia) that would inform judgments regarding the impact of therapy.
- See "Discussion and Future Directions," "Defining Efficacy" and "Understanding the Methodology" in the original guideline document for additional qualifying statements regarding the recommendations in this guideline.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017 Feb 15;13(2):307-49. [175 references] PubMed

Adaptation

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

Date Released

2017 Feb 15

Guideline Developer(s)

American Academy of Sleep Medicine - Professional Association

Source(s) of Funding

The development of this clinical practice guideline was funded by the American Academy of Sleep Medicine.

Guideline Committee

Expert Task Force

Composition of Group That Authored the Guideline

Expert Task Force Members: Michael J. Sateia, MD, Geisel School of Medicine at Dartmouth, Hanover, NH; Daniel J. Buysse, MD, University of Pittsburgh School of Medicine, Pittsburgh, PA; Andrew D. Krystal, MD, MS, University of California, San Francisco, San Francisco, CA; David N. Neubauer, MD, Johns Hopkins University School of Medicine, Baltimore, MD; Jonathan L. Heald, MA, American Academy of Sleep Medicine, Darien, IL

Financial Disclosures/Conflicts of Interest

Prior to appointment, the content experts were required to disclose all potential conflicts of interest according to the American Academy of Sleep Medicine (AASM)'s policy. In accordance with the AASM's conflicts of interest policy, task force members with a Level 1 conflict were not allowed to participate. Task force members with a Level 2 conflict were required to recuse themselves from any related discussion or writing responsibilities.

Disclosure Statement

Dr. Neubauer is a member of the Board of Directors for the National Sleep Foundation; and he has been a consultant for Purdue Pharma. Dr. Krystal serves on a scientific advisory board for Merck, and therefore did not participate in the development of the suvorexant recommendation; he has received research support from the NIH, TEVA and Sunovion; and he has been a consultant for Flamel, Atentiv, Ostuka, Neurocrine, Lundbeck, Pernix, Janssen, Jazz and Merck. Dr. Buysse has been a consultant for Cereve, Inc, Emmi Solutions, Philips Respironics, BeHealth; he has received research support from the NIH; and he owns intellectual property rights in the Pittsburgh Sleep Quality Index (PSQI). Mr. Heald is

employed by the American Academy of Sleep Medicine. The other authors have indicated no financial conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Academy of Sleep Medicine (AASM) Web site .

Availability of Companion Documents

The following is available:

- Morgenthaler TI, Deriy L, Heald JL, Thomas SM. The evolution of the AASM clinical practice guidelines: another step forward. J Clin Sleep Med. 2016;12(1):129–35.Available from the American Academy of Sleep Medicine Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 11, 2017. The information was verified by the guideline developer on April 20, 2017.

Copyright Statement

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