

In the Clinic®

Insomnia

Insomnia—the unwelcome experience of difficulty sleeping—is common and can be acute, intermittent, or chronic. Insomnia can be the presenting symptom for several common sleep disorders, but it also often occurs comorbidly with mental and physical health conditions. Evaluating the symptom of insomnia requires assessing—largely by history—whether an underlying condition explains it. *Insomnia disorder* is the diagnostic term for the symptom of insomnia that merits specific attention. Cognitive behavioral therapy for insomnia is the preferred treatment approach because of its efficacy, safety, and durability of benefit, but pharmaceutical treatments are widely used for insomnia symptoms.

CME/MOC activity available at [Annals.org](https://annals.org).

Physician Writer
Eliza L. Sutton, MD
University of Washington,
Seattle, Washington

doi:10.7326/AITC202103160

This article was published at [Annals.org](https://annals.org) on 9 March 2021.

CME Objective: To review current evidence for screening, diagnosis, treatment, patient education, and practice improvement of insomnia.

Funding Source: American College of Physicians.

Acknowledgment: The author thanks Philip A. Masters, MD, author of the previous version of this In the Clinic.

Disclosures: Dr. Sutton, ACP Contributing Author, has nothing to disclose. The form can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M20-4269.

With the assistance of additional physician writers, the editors of *Annals of Internal Medicine* develop *In the Clinic* using **MKSAP** and other resources of the American College of Physicians. The patient information page was written by Monica Lizarraga from the Patient and Interprofessional Partnership Initiative at the American College of Physicians.

In the Clinic does not necessarily represent official ACP clinical policy. For ACP clinical guidelines, please go to https://www.acponline.org/clinical_information/guidelines/.

© 2021 American College of Physicians

Screening

Diagnosis

Treatment

Patient Education

Practice Improvement

1. Mukherjee S, Patel SR, Kales SN, et al; American Thoracic Society ad hoc Committee on Healthy Sleep. An official American Thoracic Society statement: the importance of healthy sleep. Recommendations and future priorities. *Am J Respir Crit Care Med*. 2015;191:1450-8. [PMID: 26075423] doi:10.1164/rccm.201504-0767ST
2. Walsh JK, Coulouvrat C, Hajak G, et al. Nighttime insomnia symptoms and perceived health in the America Insomnia Survey (AIS). *Sleep*. 2011;34:997-1011. [PMID: 21804662] doi:10.5665/SLEEP.1150
3. Maust DT, Solway E, Clark SJ, et al. Prescription and nonprescription sleep product use among older adults in the United States. *Am J Geriatr Psychiatry*. 2019; 27:32-41. [PMID: 30409547] doi:10.1016/j.jagp.2018.09.004
4. Abraham O, Pu J, Schleiden LJ, et al. Factors contributing to poor satisfaction with sleep and healthcare seeking behavior in older adults. *Sleep Health*. 2017;3:43-8. [PMID: 28346150] doi:10.1016/j.sleh.2016.11.004
5. Appleton SL, Gill TK, Lang CJ, et al. Prevalence and comorbidity of sleep conditions in Australian adults: 2016 Sleep Health Foundation national survey. *Sleep Health*. 2018;4:13-9. [PMID: 29332673] doi:10.1016/j.sleh.2017.10.006
6. Nesbitt AD. Delayed sleep-wake phase disorder. *J Thorac Dis*. 2018;10:S103-S111. [PMID: 29445534] doi:10.21037/jtd.2018.01.11
7. Zhu L, Zee PC. Circadian rhythm sleep disorders. *Neurol Clin*. 2012;30: 1167-91. [PMID: 23099133] doi:10.1016/j.ncl.2012.08.011
8. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 3rd ed. 2014.
9. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2020. [PMID: 33164742] doi:10.5664/jcsm.8986
10. Qaseem A, Kansagara D, Forcica MA, et al; Clinical Guidelines Committee of the American College of Physicians. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2016;165:125-33. doi:10.7326/M15-2175

Insomnia is the term used to describe the unwelcome experience of difficulty sleeping. People describe having insomnia when they want and have an opportunity to sleep but experience difficulty falling or staying asleep or getting back to sleep after awakening during the night, when they wake up earlier than intended, and/or when they feel that sleep is unrefreshing. Insomnia can occur acutely, intermittently, or chronically. Insomnia is the most common sleep problem in population surveys (1) and is associated with chronic mental and physical health conditions (2-4) and other sleep disorders, particularly obstructive sleep apnea (OSA) and restless legs syndrome (RLS) (2, 5). Delayed sleep-wake phase disorder (DSWPD), a circadian rhythm sleep disorder, is also common in population surveys and in studies of people with insomnia (6, 7). People with insomnia often try to address it by using over-the-counter (OTC) or

prescription medications (3, 4), including diphenhydramine and pain medications (3). Maladaptive habits, including alcohol consumption before bedtime and spending too much time in bed, can be perpetuating factors.

Many medical or psychiatric conditions can disrupt sleep (**Table 1**) and are sometimes reported by patients as insomnia, but further description may suggest nocturnal symptoms that warrant specific evaluation and treatment (see the **Box: Areas to Consider When Taking a History About Insomnia**). The diagnosis of insomnia disorder (8) requires that the sleep difficulty experienced as insomnia cause daytime symptoms (which can include fatigue, moodiness, and/or impaired function in social or work situations) and that it “not [be] better explained by another sleep disorder” (8) (**Table 2**). Insomnia disorder is commonly comorbid with chronic health conditions that themselves also affect

Table 1. Medical and Psychiatric Conditions That May Disrupt Sleep*

Organ System	Condition
Cardiac	Arrhythmias Congestive heart failure†
Pulmonary	Asthma Chronic obstructive lung disease Neuromuscular diseases of chest wall and/or diaphragm‡
Gastrointestinal	Gastroesophageal reflux disease‡ Hepatic encephalopathy
Musculoskeletal	Arthritis Fibromyalgia‡ Nocturnal leg cramps
Neurologic	Dementia Epilepsy†† Migraine and other headache disorders‡ Neurodegenerative diseases†
Psychiatric‡	Anxiety disorders Bipolar disorders (manic phase) Depressive disorders Posttraumatic stress disorder
Endocrine	Hyperthyroidism Menopause
Dermatologic	Pruritic skin conditions Medical conditions causing pruritus
Urologic	Benign prostatic hypertrophy Overactive bladder

* Treatment of these conditions or their symptoms may improve sleep.

† Evaluation with polysomnography may be warranted.

‡ Bidirectional relationship with insomnia or sleep disruption.

Areas to Consider When Taking a History About Insomnia

Is the problem new (acute), intermittent, or chronic?

Is the problem falling asleep; staying asleep or getting back to sleep after awakening during the night; disrupted, nonrefreshing sleep; and/or early morning awakening?

Are there symptoms or observations suggesting a specific cause?

Are there symptoms or observations suggesting another sleep disorder? (Table 2)

If the problem is falling asleep, does the patient describe restless legs or features of a circadian rhythm sleep-wake disorder (CRSWD)?

If the problem is waking early in the morning, does the patient describe features of a CRSWD or depression?

If the problem is disrupted or nonrefreshing sleep, does the patient describe features of obstructive sleep apnea, periodic limb movements, or narcolepsy?

If acute or intermittent and infrequent, focus on possible precipitating factors:

- Stressors
- Travel across time zones (jet lag) or changing work shifts
- New medication or change in dose or timing of activating medication (especially afternoon dosing), including bupropion, corticosteroids, fluoroquinolones, or stimulants
- New symptoms affecting sleep
- Change in medical or psychiatric conditions
- Change in substance use (caffeine, alcohol, nicotine, stimulants)
- Change in timing of sleep (time zone [jet lag], bedtime, or wake-up time)
- Change in sleep environment (bedroom noise or light, sleep position)

If chronic or intermittent but frequent, obtain a description of the problem:

- Activities before sleep (e.g., caffeine consumption, alcohol intake, exercise, screen use, relaxation)
- Over-the-counter or prescription medication use for sleep
- Bedtime, wake-up time, and estimated sleep duration (current, past, and patient's ideal)
- How does time in bed compare with estimated total sleep time achieved?
- Stability of timing of bedtime and wake-up time over a week
- Symptoms affecting sleep at bedtime (e.g., degree of sleepiness, restless legs, anxiety, pain)
- Symptoms affecting sleep during the night (e.g., snoring, choking, dyspnea, hot flashes, nocturia, anxiety, pain)
- Symptoms upon awakening in morning (e.g., dry mouth, headache)
- Habits after unwanted awakening (e.g., lying awake, checking clock, watching television)
- Daytime impairment from insomnia (e.g., drowsiness or fatigue, irritability)
- Daytime napping (when and for how long)

sleep, such as anxiety, depression, and pain (**Table 1**). Insomnia disorder is often shortened to “insomnia” in medical literature, but it will be referred to as “insomnia disorder” here to distinguish it from the symptom of insomnia. Although population surveys ask about the symptom of insomnia, sleep medicine trials and guidelines on insomnia treatment (9–12) focus on those who meet the criteria for insomnia disorder, and thus these guidelines do not apply to all people experiencing the symptom.

Insomnia disorder can be chronic (>3 months) or short-term (<3 months) (8). The previously used terms “primary” and “secondary” insomnia and different subsets of chronic insomnia, such as “psychophysiologic insomnia,” have been replaced by the broader term “insomnia disorder” but are sometimes still encountered in the medical literature. Insomnia disorder is common in people with comorbid mental or physical health conditions affecting sleep, but it may still be diagnosed as a

11. Riemann D, Baglioni C, Bassetti C, et al. European guideline for the diagnosis and treatment of insomnia. *J Sleep Res.* 2017;26:675-700. [PMID: 28875581] doi:10.1111/jsr.12594
12. Sateia MJ, Buysse DJ, Krystal AD, et al. 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;13:307-49. [PMID: 27998379] doi:10.5664/jcsm.6470
13. Morin CM, LeBlanc M, Daley M, et al. Epidemiology of insomnia: prevalence, self-help treatments, consultations, and determinants of help-seeking behaviors. *Sleep Med.* 2006;7:123-30. [PMID: 16459140]
14. Ryden AM, Martin JL, Matsuoka S, et al. Insomnia disorder among older veterans: results of a postal survey. *J Clin Sleep Med.* 2019;15:543-51. [PMID: 30952212] doi:10.5664/jcsm.7710
15. Koopman ADM, Beulens JW, Dijkstra T, et al. Prevalence of insomnia (symptoms) in T2D and association with metabolic parameters and glycemic control: meta-analysis. *J Clin Endocrinol Metab.* 2020;105. [PMID: 31603475] doi:10.1210/clinem/dg2065
16. Morin CM, Bélanger L, LeBlanc M, et al. The natural history of insomnia: a population-based 3-year longitudinal study. *Arch Intern Med.* 2009;169:447-53. [PMID: 19273774] doi:10.1001/archinternmed.2008.610
17. Horn MA, Hames JL, Bodell LP, et al. Investigating insomnia as a cross-sectional and longitudinal predictor of loneliness: findings from six samples. *Psychiatry Res.* 2017;253:116-28. [PMID: 28364589] doi:10.1016/j.psychres.2017.03.046
18. Suh S, Cho N, Zhang J. Sex differences in insomnia: from epidemiology and etiology to intervention. *Curr Psychiatry Rep.* 2018;20:69. [PMID: 30094679] doi:10.1007/s11920-018-0940-9
19. Sutton EL. Psychiatric disorders and sleep issues. *Med Clin North Am.* 2014;98:1123-43. [PMID: 25134876] doi:10.1016/j.mcna.2014.06.009

Table 2. Sleep Disorders That Cause or May Present as Difficulty Sleeping*

<i>Disorder or Issue</i>	<i>Common Features</i>
Isolated symptoms and normal variants	
Short sleeper (needs <6 h of sleep) Excessive time in bed	Sleep time is routinely short; feels rested during the day Spends time awake in bed trying to sleep; feels rested during the day
Insomnia disorder	
Chronic insomnia disorder Short-term insomnia disorder Other insomnia disorder	Difficulty initiating or maintaining sleep "despite adequate opportunity and circumstances for sleep" "Some form of daytime impairment" (i.e., fatigue, irritability) "Not better explained by another sleep disorder"
Sleep disorders	
Circadian rhythm sleep-wake disorders, including: Jet lag (acute) Delayed sleep-wake phase disorder (night owl) Advanced sleep-wake phase disorder (early bird or lark) Shift work disorder Non-24 sleep-wake disorder Irregular sleep-wake rhythm disorder	Mismatch between actual sleep time and socially acceptable or desired sleep times Difficulty falling or being asleep at desired times, but can sleep at other times; also excessive daytime sleepiness
Obstructive sleep apnea	Short sleep latency Unrefreshing sleep and/or repeated short awakenings Nocturia Loud or habitual snoring Gasping or choking during sleep Dry mouth and/or headache upon awakening Daytime sleepiness or fatigue
Movement disorders	
Restless legs syndrome	Urge to move the limbs (usually legs) Usually accompanied by or attributed to "uncomfortable and unpleasant sensations" in the limbs Occurs or is predominant in the evening or night Occurs or worsens with inactivity Improves with movement Not better explained by another diagnosis
Periodic limb movement disorder	Repetitive movement of limbs (usually legs) during sleep Not associated with another sleep disorder on polysomnography
Narcolepsy	Unrefreshing or disrupted sleep Excessive daytime sleepiness; unplanned sleep Cataplexy Hypnagogic and/or hypnopompic hallucinations Sleep paralysis

* The information in this table was adapted from reference 8. Some cases of difficulty sleeping may have a readily identifiable and reversible or treatable factor not listed here (new or worse medical symptom [Table 1] or activating medication). Insomnia disorder can coexist with medical and psychiatric conditions (Table 1) and with the other sleep disorders listed in this table.

specific problem when insomnia is bothersome enough to warrant treatment apart from or in addition to the underlying health condition.

To understand insomnia, it is useful to understand the basic underpinnings of sleep. Sleep and wakefulness are normal physiologic states of the brain. Two processes, sleep-wake homeostasis and circadian rhythm, govern the sleep-wake cycle, and when aligned, they consolidate sleep to

occur at night and wakefulness to occur during the day (6, 7). The homeostatic drive to sleep increases over time spent awake and decreases during time spent asleep. The circadian drive cycles over 24 to 25 hours, promoting sleepiness during the night and alertness during the day, except for a daily lull in alertness in the afternoon. The circadian drive has its greatest effect on sleep during the early morning hours, when the homeostatic drive for sleep has

20. Schutte-Rodin S, Broch L, Buysse D, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*. 2008;4:487-504. [PMID: 18853708]
21. Luik AI, Machado PF, Sriwardena N, et al. Screening for insomnia in primary care: using a two-item version of the Sleep Condition Indicator. *Br J Gen Pract*. 2019;69:79-80. [PMID: 30705006] doi:10.3399/bjgp19X701045

decreased, and conversely has its greatest effect on wakefulness during the late evening hours, when the homeostatic drive for sleep has increased (7). Factors affecting the sleep-wake cycle include light exposure, habits around sleep, and both endogenous and exogenous triggers of physiologic arousal.

Evaluation of the symptom of insomnia requires investigation through

history (**Box: Areas to Consider When Taking a History About Insomnia**) to assess for clues about underlying medical or psychiatric conditions (**Table 1**) or other sleep disorders (**Table 2**). Given the prevalence of insomnia, its substantial effect on quality of life, and the common quandary of whether and how to prescribe sleep medications, clinicians should be comfortable in evaluating and managing it.

What are the risk factors for insomnia?

Insomnia is common. In surveys, 19% to 50% of adults report experiencing insomnia (2, 4, 13–15), half of them chronically (16).

Insomnia is associated with advancing age; poorer health (2, 4, 5, 14, 15); and lack of social connection, including being single (4) and feeling lonely (17). It is 1.3 to 1.7 times more prevalent in women than men (18). Insomnia can occur or worsen with hormonal changes (before menses, during and after pregnancy, and after menopause) (18).

What are potential causes and associated health conditions?

Insomnia may be caused by acute stressors; activating medications; or mental and physical conditions (**Table 1**), including depression, anxiety, and pain. Insomnia has a bidirectional association with psychiatric disorders (19, 20) and gastroesophageal reflux (8). In some people, insomnia persists chronically after the original trigger has passed. Some may attempt to cope with insomnia by developing maladaptive habits, such as alcohol consumption before bed or an irregular sleep-wake schedule. Physiologic hyperarousal during wakefulness and sleep is

found in some studies of people with insomnia (8) and may commonly predispose to insomnia and/or perpetuate it.

Should clinicians screen for insomnia, and if so, how?

Although there are no standard recommendations to screen for insomnia and no evidence that screening improves outcomes, clinicians may wish to consider screening as part of routine patient care given the high prevalence of insomnia. Screening should ask about frequency and severity of poor sleep. A validated 2-question version (21) of the 8-item Sleep Condition Indicator (22) developed for insomnia screening asks, “Thinking about the past month, to what extent has poor sleep troubled you in general?” (not at all, a little, somewhat, much, or very much) and “Thinking about a typical night in the past month, how many nights do you have a problem with your sleep?” (0 to 1, 2, 3, 4, or 5 to 7). Responses are on a 5-point scale scored from 4 (best) to 0 (worst). A summed score of 0 to 2 for the 2 questions suggests a problem with sleep and may be followed by either the other 6 questions from the full instrument or a more detailed sleep history.

Screening

22. Espie CA, Kyle SD, Hames P, et al. The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. *BMJ Open*. 2014;4:e004183. [PMID: 24643168] doi:10.1136/bmjopen-2013-004183
23. National Sleep Foundation. Sleep Diary. Accessed at www.sleepfoundation.org/wp-content/uploads/2016/01/SleepDiaryv6.pdf on 12 January 2021.
24. University of Pittsburgh Center for Sleep and Circadian Science. Measures and Study Instruments. Accessed at www.sleep.pitt.edu/instruments on 12 January 2021.
25. Morin CM, Belleville G, Bélanger L, et al. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*. 2011;34:601-8. [PMID: 21532953]
26. Amra B, Pirpiran M, Soltaninejad F, et al. The prediction of obstructive sleep apnea severity based on anthropometric and Mallampati indices. *J Res Med Sci*. 2019;24:66. [PMID: 31523252] doi:10.4103/jrms.JRMS_653_18
27. Aurora RN, Kristo DA, Bista SR, et al; American Academy of Sleep Medicine. The treatment of restless legs syndrome and periodic limb movement disorder in adults—an update for 2012: practice parameters with an evidence-based systematic review and meta-analyses: an American Academy of Sleep Medicine Clinical Practice Guideline. *Sleep*. 2012;35:1039-62. [PMID: 22851801] doi:10.5665/sleep.1988
28. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13:479-504. [PMID: 28162150] doi:10.5664/jcsm.6506
29. Littner MR, Kushida C, Wise M, et al; Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep*. 2005;28:113-21. [PMID: 15700727]

30. Smith MT, McCrae CS, Cheung J, et al. Use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2018;14:1231-7. [PMID: 29991437] doi:10.5664/jcsm.7230
31. Haghayegh S, Khoshnevis S, Smolensky MH, et al. Accuracy of wristband Fitbit models in assessing sleep: systematic review and meta-analysis. *J Med Internet Res*. 2019;21:e16273. [PMID: 31778122] doi:10.2196/16273
32. Liu J, Wong WT, Zwetsloot IM, et al. Preliminary agreement on tracking sleep between a wrist-worn device Fitbit Alta and consensus sleep diary. *Telemed J E Health*. 2019;25:1189-97. [PMID: 30601109] doi:10.1089/tmj.2018.0202
33. Morgenthaler T, Kramer M, Alessi C, et al; American Academy of Sleep Medicine. Practice parameters for the psychological and behavioral treatment of insomnia: an update. *An American Academy of Sleep Medicine report*. *Sleep*. 2006;29:1415-9. [PMID: 17162987]
34. van Straten A, van der Zweerde T, Kleiboer A, et al. Cognitive and behavioral therapies in the treatment of insomnia: a meta-analysis. *Sleep Med Rev*. 2018;38:3-16. [PMID: 28392168] doi:10.1016/j.smrv.2017.02.001
35. Beaulieu-Bonneau S, Ivers H, Guay B, et al. Long-term maintenance of therapeutic gains associated with cognitive-behavioral therapy for insomnia delivered alone or combined with zolpidem. *Sleep*. 2017;40. [PMID: 28364426] doi:10.1093/sleep/zsx002
36. Chung KF, Lee CT, Yeung WF, et al. Sleep hygiene education as a treatment of insomnia: a systematic review and meta-analysis. *Fam Pract*. 2018;35:365-75. [PMID: 29194467] doi:10.1093/fampra/cmz122
37. Rezaie L, Fobian AD, McCall WV, et al. Paradoxical insomnia and subjective-objective sleep discrepancy: a review. *Sleep Med Rev*. 2018;40:196-202. [PMID: 29402512] doi:10.1016/j.smrv.2018.01.002

Screening... Insomnia is common and increases with age. It is often associated with mental and physical health conditions. There are no standard recommendations for routine screening, but a report of frequent or severe difficulty with sleep warrants further evaluation. Several common treatable sleep disorders can present with insomnia. Insomnia disorder is insomnia that is not better explained by another condition (including another sleep disorder) and is the focus of sleep medicine research and published guidelines on insomnia.

CLINICAL BOTTOM LINE

Diagnosis

What elements of the history should clinicians include in the evaluation?

History is key in the evaluation of insomnia and should focus on the timing and experiences around bed, sleep, and wakefulness (**Box: Areas to Consider When Taking a History About Insomnia**), including symptoms that suggest an underlying cause, a medical or psychiatric condition (**Table 1**), or a sleep disorder (**Table 2**). Diagnosis and treatment of an underlying medical or psychiatric condition may ameliorate insomnia symptoms. For acute or occasional insomnia, a cause or trigger may be clear, such as a stressor, a change in sleep environment or timing, a change in medication, or a medical condition (**Table 1**). In patients with chronic or frequent insomnia or an unclear cause of acute insomnia, eliciting patterns and experiences around sleep can point to an underlying sleep disorder (20). Describing insomnia by timing (difficulty falling asleep [sleep onset insomnia] vs. difficulty staying asleep or getting back to sleep after awakening [sleep maintenance insomnia] vs. disrupted or nonrefreshing sleep and/or early morning awakening) can be useful in diagnosis and distinguishing among sleep disorders (**Table 2**). Sleep history should include assessment for the

common sleep disorders RLS and DSWPD (for which history is diagnostic) and for possible OSA (**Table 2**).

In sleep medicine practices, patients are typically asked to complete a sleep diary plus a sleep-focused history that includes standard sleep-related questionnaires (**Table 3**) and information from any bed partners. For clinicians outside sleep medicine, history about a sleep problem is often simply taken in discussion with the patient. When evaluation can be planned ahead, ideally at a dedicated visit, the patient should be asked to keep a sleep diary for 1 to 2 weeks and bring it to the return visit. Sleep diary forms are available online (23, 24). Sleep questionnaires (**Table 3**)—some requiring permission or attribution for use—and history forms specific to insomnia can be useful. The Insomnia Severity Index (ISI) (25) can be particularly useful for initial assessment of insomnia severity and periodic assessment of treatment response.

What elements of the physical examination should clinicians include in the evaluation?

Physical examination is of limited use in the evaluation of insomnia. If history suggests an underlying medical condition that might

be disrupting sleep (**Table 1**), focused examination for that condition is indicated. Although risk for OSA increases with greater body mass index, neck circumference, waist circumference, and Mallampati score (26) and examination findings of macroglossia, micrognathia, or retrognathia, normal findings on physical examination do not exclude OSA.

What is the role of laboratory testing?

For patients who report RLS, ferritin level should be checked because a low or low-normal level suggests iron therapy may be indicated (27). If history suggests an underlying medical condition that might be disrupting sleep (**Table 1**), testing for that condition may be indicated. Toxicologic testing may be considered if undisclosed use of stimulants is suspected. Laboratory testing is otherwise not indicated for evaluation of insomnia.

What is the role of sleep studies?

Sleep studies are not indicated except when an underlying sleep disorder is suspected or, in some cases, when insomnia is severe or resistant to therapy or when history on sleep duration and timing is unreliable or cannot be obtained.

Polysomnography

Nocturnal polysomnography (PSG), a multichannel overnight

sleep study, is indicated when history suggests an underlying sleep disorder, such as OSA, or when sleep disruption is associated with unusual nocturnal activity or is significant but unexplained. A full PSG in a sleep laboratory is recommended instead of home sleep apnea testing because the latter will not detect sleep disorders other than OSA and has not been validated for evaluation of OSA in patients with severe insomnia (28).

Multiple sleep latency test

Multiple sleep latency testing quantifies daytime sleepiness and evaluates for rapid eye movement (REM) onset in naps. This test is indicated only for patients with significant hypersomnolence in whom narcolepsy is suspected (29).

Actigraphy

Actigraphy detects motion through a monitoring device worn around the nondominant wrist. Periods of inactivity suggest sleep. Actigraphy is not used routinely to evaluate insomnia but may be useful for home-based evaluation of sleep timing and duration in patients who have difficulty reporting or recalling their sleep pattern and may have a CRSWD or those with insomnia who do not seem to be responding to treatment (30). Some patients may have access to similar

38. Herbert V, Kyle SD, Pratt D. Does cognitive behavioural therapy for insomnia improve cognitive performance? A systematic review and narrative synthesis. *Sleep Med Rev.* 2018;39:37-51. [PMID: 28918315] doi:10.1016/j.smrv.2017.07.001
39. Brasure M, Fuchs E, MacDonald R, et al. Psychological and behavioral interventions for managing insomnia disorder: an evidence report for a clinical practice guideline by the American College of Physicians. *Ann Intern Med.* 2016;165:113-24. doi:10.7326/M15-1782
40. Soh HL, Ho RC, Ho CS, et al. Efficacy of digital cognitive behavioural therapy for insomnia: a meta-analysis of randomised controlled trials. *Sleep Med.* 2020;75:315-25. [PMID: 32950013] doi:10.1016/j.sleep.2020.08.020
41. Gunn HE, Tutek J, Buysse DJ. Brief behavioural treatment of insomnia. *Sleep Med Clin.* 2019;14:235-43. [PMID: 31029189] doi:10.1016/j.jsmc.2019.02.003
42. Glass J, Lanctôt KL, Herrmann N, et al. Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. *BMJ.* 2005;331:1169. [PMID: 16284208]
43. U.S. Food and Drug Administration. Sleep Disorder (Sedative-Hypnotic) Drug Information. 2019. Accessed at www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/sleep-disorder-sedative-hypnotic-drug-information on 12 January 2021.

Table 3. Useful Tools in Clinical Evaluation of Chronic Insomnia*

Tool	Use	Reference
Sleep diaries		
National Sleep Foundation Sleep Diary	Logs sleep-wake patterns and habits for 1-2 wk	23
Consensus Sleep Diary	Logs sleep-wake patterns and habits for 1-2 wk	24
Insomnia-related instruments		
Glasgow Sleep Effort Scale	Evaluates effort made to sleep; screens for insomnia	52
Insomnia Severity Index	Screens for insomnia; follows response to treatment	25
Morningness-Eveningness Questionnaire	Assesses circadian type	53
STOP and STOP-Bang Questionnaires	Assesses likelihood of obstructive sleep apnea	54

* These tools are available online; some require permission for use.

44. Drugs for chronic insomnia. *Med Lett Drugs Ther.* 2018;60:201-5. [PMID: 30625122]
45. Kishi T, Nomura I, Matsuda Y, et al. Lemborexant vs suvorexant for insomnia: a systematic review and network meta-analysis. *J Psychiatr Res.* 2020;128:68-74. [PMID: 32531478] doi:10.1016/j.jpsychires.2020.05.025
46. Kolla BP, Mansukhani MP, Bostwick JM. The influence of antidepressants on restless legs syndrome and periodic limb movements: a systematic review. *Sleep Med Rev.* 2018;38:131-40. [PMID: 28822709] doi:10.1016/j.smrv.2017.06.002
47. Rios P, Cardoso R, Morra D, et al. Comparative effectiveness and safety of pharmacological and non-pharmacological interventions for insomnia: an overview of reviews. *Syst Rev.* 2019;8:281. [PMID: 31730011] doi:10.1186/s13643-019-1163-9
48. Schroeck JL, Ford J, Conway EL, et al. Review of safety and efficacy of sleep medicines in older adults. *Clin Ther.* 2016;38:2340-72. [PMID: 27751669] doi:10.1016/j.clinthera.2016.09.010
49. Stewart NH, Arora VM. Sleep in hospitalized older adults. *Sleep Med Clin.* 2018;13:127-35. [PMID: 29412979] doi:10.1016/j.jsmc.2017.09.012
50. Erland LA, Saxena PK. Melatonin natural health products and supplements: presence of serotonin and significant variability of melatonin content. *J Clin Sleep Med.* 2017;13:275-81. [PMID: 27855744] doi:10.5664/jcs.m.6462
51. Capezuti E, Sagha Zadeh R, Pain K, et al. A systematic review of non-pharmacological interventions to improve nighttime sleep among residents of long-term care settings. *BMC Geriatr.* 2018;18:143. [PMID: 29914382] doi:10.1186/s12877-018-0794-3
52. Broomfield NM, Espie CA. Towards a valid, reliable measure of sleep effort. *J Sleep Res.* 2005;14:401-7. [PMID: 16364141]
53. Horne JA, Ostberg O. A self-assessment questionnaire to determine morningness-eveningness in human circadian rhythms. *Int J Chronobiol.* 1976;4:97-110. [PMID: 1027738]
54. Chung F, Elsaid H. Screening for obstructive sleep apnea before surgery: why is it important. *Curr Opin Anaesthesiol.* 2009;22:405-11. [PMID: 19412094] doi:10.1097/ACO.0b013e32832a96e2

information through a personal activity tracker (31, 32).

When should clinicians consider consulting a specialist for diagnosis?

Most patients with insomnia do not need sleep medicine consultation or sleep testing. Exceptions include when an underlying sleep disorder outside the clinician's scope of practice is suspected, when a patient reports severe insomnia that is resistant to behavioral measures or safe pharmacologic therapy, or when there is evidence of potentially injurious behavior during sleep (20).

Consultation with an appropriate specialist is recommended when a patient has or may have an underlying mental or physical health disorder disrupting sleep for which evaluation or treatment is outside the clinician's scope of practice. For a patient with nightmares, appropriate referral may be warranted because nightmares can be caused by posttraumatic stress disorder, panic disorder and other anxiety disorders, narcolepsy, sleep paralysis, REM behavior disorder, and nocturnal seizures (8).

Diagnosis... History is crucial in the evaluation of insomnia and is often aimed at identifying another mental or physical health condition that may explain the insomnia and be responsive to treatment, with insomnia disorder as the diagnosis of exclusion. Evaluation of insomnia includes consideration of other sleep disorders: RLS is diagnosed by history; OSA, narcolepsy, and periodic limb movement disorder (PLMD) may be suggested by history; and CRSWDs are diagnosed by history and sleep diaries or actigraphy. Physical examination may suggest OSA but has limited benefit otherwise. Sleep studies are not useful except when OSA, PLMD, or narcolepsy is suspected or rarely (ideally as part of a consultation with a sleep medicine specialist) to evaluate patients with atypical or refractory symptoms.

CLINICAL BOTTOM LINE

Treatment

What is the overall approach to treatment?

The goal of insomnia treatment is to improve the patient's experience of sleep and quality of life without introducing unnecessary harm. When an underlying medical or psychiatric condition (**Table 1**) is clearly disrupting sleep or another sleep disorder is suspected (**Table 2**), that condition should be identified and appropriately treated. Treatment approaches for insomnia are appropriate in insomnia disorder that is comorbid with medical, psychiatric, or sleep disorders but are not a substitute for

appropriate treatment of another symptomatic condition.

The approach to treatment of insomnia can be nonpharmacologic, pharmacologic, or both. Treatment cannot guarantee perfect sleep every night, and this should not be the goal. The preferred treatment should introduce minimal risk at acceptable cost, be accessible and acceptable to the patient, and reduce symptoms to the patient's satisfaction. Both cognitive behavioral therapy for insomnia (CBTI) and pharmacologic therapy have only modest effects on quantitative measures

of sleep. Guidelines for treatment all recommend CBTI as the preferred long-term approach for chronic insomnia disorder (10, 11, 20, 33) with or without psychiatric, medical, and/or social comorbidities—including for patients already using long-term hypnotics (33, 34)—due to CBTI's efficacy (34), durability (35), and cost. However, CBTI is harder to access than pharmacologic treatments. For patients with chronic insomnia disorder, physicians should preferentially consider CBTI, should consider pharmacologic therapy when CBTI is not effective enough or not available (11), and should engage in shared decision making with patients when considering pharmacologic therapy (10).

Sleep hygiene

Sleep hygiene is the term used for a set of behavioral and environmental recommendations to optimize sleep. Sleep hygiene advice varies but typically recommends avoiding naps, exercising (but not late in the day), avoiding caffeine late in the day, avoiding alcohol before bedtime, setting a stable sleep schedule, and using the bedroom only for sleep and sex. Education on sleep hygiene is a popular first-line approach, but sleep hygiene education alone has limited benefit, is less effective than CBTI (36), and is not recommended as single-component therapy for chronic insomnia (9, 33).

CBTI

The first-line treatment for insomnia, CBTI, is a multicomponent treatment that includes sleep education, cognitive therapy to address maladaptive beliefs and expectations about sleep, and 3 behavioral therapies: sleep restriction, stimulus control, and relaxation techniques (**Table 4**).

Sleep education

Although not effective as a standalone intervention, sleep education includes sleep hygiene advice and education about normal sleep and is a basic component of CBTI. It addresses expectations about sleep and includes explaining the 2-process model so that patients with insomnia know about their sleep drive (which increases after a night of sleep loss) and their circadian sleep-wake cycle (including the importance of light exposure during the day).

Cognitive therapy

Cognitive education helps the patient with insomnia identify, expose, and address dysfunctional beliefs and attitudes about sleep and reframe negative beliefs and attitudes to neutral or even positive ones.

Sleep restriction

Sleep restriction is a counterintuitive behavioral intervention that increases the drive to sleep by limiting the time allowed for it. Sleep restriction purposefully induces sleep debt in order to improve sleep efficiency (the proportion of time in bed spent asleep). The patient is asked to keep a sleep diary for 1 to 2 weeks, then meets with a clinician to set a stable daily wake-up time for getting out of bed every morning and a total time in bed. The assigned time in bed is calculated as the usual total sleep time (TST), as estimated by the patient in sleep diary entries, plus 30 minutes (but not less than 6 hours). The patient then starts a new schedule of deferring bedtime until the time of night that will allow only the assigned time in bed and getting up at the assigned wake-up time even if sleeping or sleepy then. On follow-up, the time allowed in bed is increased by 15 minutes if the patient has been awake in bed for

less than 30 minutes on most nights or is reduced by 15 minutes if the patient has been awake in bed for more than 30 minutes on most nights. Alternatively, 15 to 30 minutes is added when sleep efficiency exceeds 85% or is removed if sleep efficiency is below 85%. The patient then maintains the bedtime and wake-up time determined through this process.

Sleep restriction is inappropriate for patients who cannot tolerate a period of sleep deprivation, including those with bipolar disorder, seizure disorder, or untreated sleep disorder with excessive daytime sleepiness (for example, OSA). Sleep restriction also warrants 2 additional considerations. First, patients should be warned that inducing sleep deprivation may worsen daytime function initially, including alertness while driving. Second, some people with insomnia have the sensation of lying awake in bed while they are objectively asleep. This “subjective-objective mismatch in sleep” or “sleep state misperception” is challenging to treat and may be particularly common in people with OSA and insomnia, in which case it may respond to continuous positive airway pressure. In other patients, it can improve with CBTI that includes education about the phenomenon. In a few reported cases, olanzapine has been effective (37).

Stimulus control

Stimulus control aims to associate the bed with sleep and to reduce stimuli that contribute to hyperarousal. Patients are advised to use the bedroom only for sleep and sex, to avoid screen time, and to turn or cover any bedside clock so it is not visible during the night. Patients are advised that if they are awake in bed for more than an estimated 15 to 20 minutes, they should get out of bed and do a

Table 4. Cognitive Behavioral Therapy for Insomnia*

<i>Component</i>	<i>Purpose</i>	<i>Description</i>
Education		
Sleep education	Improve understanding of normal sleep and behaviors that affect sleep	Educate on normal sleep (e.g., sleep drive, which increases after a night of sleep loss; sleep-wake cycle and the importance of a regular schedule; that waking briefly during the night is normal; that attempting to force sleep backfires) Advise patient on sleep hygiene, including avoiding naps (except short naps in elderly adults); avoiding late exercise, caffeine intake, and alcohol intake before bedtime; and setting a stable sleep schedule Sleep hygiene alone is not sufficient
Cognitive		
Cognitive therapy	Change dysfunctional beliefs about sleep to reduce fear, anxiety, and effort around sleep	Elucidate, question, and help the patient change dysfunctional beliefs and attitudes about sleep (incorrect assumptions and fears); for example, reframing difficulty sleeping to accept some degree of insomnia and to use unplanned time awake to good effect Paradoxical intention, an advanced technique, involves the patient lying quietly awake in bed in a dark room, trying (without use of external stimuli) to stay awake
Behavioral		
Sleep restriction†	Improve sleep efficiency by reducing time spent awake in bed, and set a stable schedule	Review patient's sleep diary, explain sleep restriction, determine a stable daily wake-up time, and assign duration for time in bed with the patient, then follow up using sleep diary information The patient's assigned time in bed is limited to their average total sleep time plus 30 min (but not <6 h in case of sleep-state misperception) Advise patient to get up every day at the assigned stable wake-up time, even if sleepy Advise patient that the restricted time in bed increases sleep drive and initially can be expected to increase daytime sleepiness and impairment Adjust the assigned time in bed periodically: increase by 15 min if time awake in bed is <30 min on most nights, or reduce by 15 min if time awake in bed is >30 min on most nights Advise maintaining the schedule and wake-up time that result in good sleep efficiency
Stimulus control†	Reduce stimuli that increase wakefulness before and during sleep time	Advise the patient to do the following: Use bedroom only for sleep and sex Avoid lighted screens before bed; do not read or watch television in bed Cover or turn bedside clock so it is not visible during the night Leave the bedroom if awake for 15–20 min in bed during the night, go do a quiet activity elsewhere but do not fall asleep, and return to bed when sleepy; repeat this as often as necessary
Relaxation	Reduce mental activity and physical tension before bed	Structured approach to relaxation, including: Progressive muscle relaxation Abdominal breathing Meditation

* Cognitive behavioral therapy for insomnia is most effective when it includes all 5 components, but sleep restriction, stimulus control, and relaxation therapy may be used as single-component therapy if appropriate (9, 33). Sleep hygiene alone is not recommended (9, 33).

† Brief behavioral therapy for insomnia includes education about sleep, focuses on sleep restriction and stimulus control, and can be offered by practitioners without behavioral training (41) if appropriate to the patient and clinician (9).

quiet activity in another room but should not fall asleep there; when sleepy, they should return to bed and lie down. This process should be repeated as necessary.

Relaxation techniques

Structured approaches for relaxation can reduce cognitive arousal and physical tension, assisting with the ability to fall asleep. Progressive muscle relaxation, abdominal breathing, and meditation are among the approaches studied that may offer modest benefit for insomnia at low risk (9).

In randomized clinical trials of CBTI compared with no treatment or with sleep hygiene advice, CBTI was superior in improving nocturnal measures of sleep in adults without and with psychiatric and/or medical comorbidities and with or without concomitant use of sleep medication (34). CBTI also alleviates anxiety and depression (and insomnia) in people with chronic insomnia disorder, but its effects on daytime measures of cognition and performance have been less well studied (34, 38). CBTI improves subjective more than objective measures of sleep, with less improvement in TST than in other aspects.

A meta-analysis found that the number needed to treat (NNT) with CBTI or its components for improvement in the Insomnia Severity Index (ISI) is 1.95, whereas the NNT for improvement in TST is 11.11 (34).

A randomized trial found that 6 weeks of CBTI produced a durable benefit lasting at least 24 months. CBTI was not better than sleep medication in the short term, but medication use during CBTI did not impair its benefit. In fact, CBTI with zolpidem use, tapered and stopped after 6 weeks, led to better long-term improvement than CBTI without zolpidem or with

long-term as-needed zolpidem (35).

CBTI was initially developed and studied as a 6- to 8-week face-to-face intervention delivered by trained psychologists to patients individually or in a group setting. The Society of Behavioral Sleep Medicine maintains an online directory of practitioners, but there are too few trained therapists to meet the need for face-to-face CBTI. Because of this, alternate approaches have been studied. CBTI is also effective when delivered by telephone (39), as self-help via a book or the internet (39) in 2 or 4 sessions, and in primary care practices; evidence is insufficient to recommend one of these approaches over others (9). CBTI provided on digital platforms over 5 to 6 weeks is noninferior to face-to-face CBTI, and digital approaches have the potential to make CBTI widely accessible (40).

Brief behavioral treatment of insomnia (BBTI) by practitioners who do not specialize in behavioral sleep medicine is effective for at least 6 months after the intervention, and session-by-session instructions have been published. This approach focuses on sleep restriction and stimulus control provided in a total of 4 sessions (2 in-person visits and 2 follow-up discussions by telephone) (41).

When and how should clinicians consider pharmacologic treatment?

Hypnotic medications improve sleep only modestly, with the placebo effect explaining up to 60% of the response to medication both subjectively and objectively (11). Hypnotic medications pose risk even with short-term use, and the risks of long-term use have not been well studied.

A meta-analysis of medication use for 5 days or more for insomnia in

people aged 60 years or older included studies on the non-benzodiazepine receptor agonist drugs (zaleplon, zolpidem, and eszopiclone), benzodiazepines, and diphenhydramine and found an NNT of 13 and a number needed to harm of 6 (42).

However, pharmacologic therapy is widely used and may be preferred, more accessible, or more effective than CBTI for some patients. Patients who have used pharmacologic treatment for sleep in the long term may prefer not to change. The decision to treat should include consideration of risks, comorbidities, and patient preference. Shared decision making is recommended (10).

Risks

All medications used to treat insomnia are sedating and thus increase risk for falls and confusion. Benzodiazepines can cause respiratory depression, and long-term use can result in tolerance, dependence, and withdrawal. Long-acting benzodiazepines are not recommended for treatment of insomnia, and benzodiazepines in general are not recommended for insomnia in elderly adults. Triazolam can cause anterograde amnesia. Complex sleep-related behaviors (activity typical for wakefulness but occurring during sleep, such as eating, walking, or driving) can occur in patients taking hypnotic medications, particularly the non-benzodiazepine receptor agonist ("Z drug") medications (43) but also benzodiazepines (particularly triazolam), ramelteon, and suvorexant (44). Complex sleep-related behaviors may be more likely to occur in people with a history of sleepwalking, those who take the medication in high doses or with other sedatives, or those who take it well before bedtime (44). The orexin receptor antagonists suvorexant and lemborexant can rarely

Table 5. Selected FDA-Approved Pharmacologic Treatments for Insomnia*

Medications, by Class†	Usual Dose	Onset‡/Duration§	Use	Comments on Dosing
Benzodiazepines				
Triazolam	0.125, 0.25 mg	Rapid/short	SO	-
Temazepam	7.5, 15, 22.5, 30 mg	Slow/intermediate	SO, SM	-
Non-benzodiazepine receptor agonists				
Zaleplon	5, 10 mg	Rapid/ultra-short	SO	-
Zolpidem immediate-release sublingual tablet	1.75, 3.5 mg	Rapid/ultra-short	Nighttime awakening	For all zolpidem formulations, women should use the lower dose to reduce next-day effects
Zolpidem oral tablet	5, 10 mg	Rapid/short	SO, SM	
Zolpidem sublingual tablet	5, 10 mg	Rapid/short	SO, SM	
Zolpidem controlled-release tablet	6.25, 12.5 mg	Rapid/short	SO, SM	
Eszopiclone	1, 2, 3 mg	Rapid/intermediate	SO, SM	Initial dose, 1 mg for men and women
Melatonin receptor agonist				
Ramelteon	8 mg	Rapid/short	SO	-
Orexin receptor antagonist				
Lemborexant	5, 10 mg	Slow/long	SM¶	Food delays absorption Initial dose, 5 mg
Suvorexant	5, 10, 20 mg	Slow/long	SM¶	Initial dose, 10 mg
Tricyclic antidepressant				
Doxepin	3, 6 mg	Slow/long	SM	-

FDA = U.S. Food and Drug Administration; SM = sleep maintenance insomnia; SO = sleep onset insomnia.

* The medications listed in this table (except lemborexant, which was approved in 2019) are those recommended in the American Academy of Sleep Medicine (AASM) Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults (12) when pharmacologic treatment is indicated. Each is graded at a weak level of evidence for use. Information on formulations and doses is added here. Data are from references 20, 44, and 48.

† All classes are Schedule C-IV by the U.S. Drug Enforcement Administration except doxepin and ramelteon, which are not scheduled.

‡ Onset: rapid, 15–30 min; slow, 30–60 min.

§ Duration (elimination half-life): ultra-short, <2 h; short, 2–5 h; intermediate, 6–10 h; long, >10 h.

|| Product label does not limit duration of use.

¶ Lemborexant and suvorexant are FDA-approved for difficulties with SO and/or SM but can cause daytime somnolence. Suvorexant is recommended only for SM in the AASM clinical practice guideline.

cause sleep paralysis, cataplexy, and suicidal ideation.

Medication choice

No particular sleep medication approved by the U.S. Food and Drug Administration (FDA) is recommended over others for insomnia. The American Academy of Sleep Medicine (AASM) Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults (12) presents a list of hypnotic medications (Table 5) for which evidence, though limited, suggests that benefits likely outweigh harms when pharmacologic treatment is

warranted. The guideline was published before lemborexant was available; its profile is similar to that of suvorexant (45).

The pattern of sleep difficulty provides a basis to match a medication based on timing of onset and duration of effect. When the difficulty is with sleep onset, the rapid-onset short-acting medications (ramelteon, zaleplon, or [with caution] triazolam) may be useful. When the difficulty is both falling asleep and staying asleep, zolpidem (regular or controlled release) or eszopiclone is more likely to be effective. When the

difficulty is with sleep maintenance but not sleep onset, the AASM guideline suggests suvorexant or doxepin (3 or 6 mg) given the lack of benefit for sleep onset (12). The orexin antagonists suvorexant and lemborexant are FDA-approved for both sleep onset and sleep maintenance insomnia, but they can cause next-day somnolence (45). Zaleplon and low-dose sublingual zolpidem can each be taken as needed for middle-of-the-night awakenings as long as there is adequate time (4 hours) for the medication to clear before the planned morning awakening time.

Dosing

Medications should be initiated at the lower end of the FDA-recommended dose range and should not exceed it. These medications can cause morning grogginess and affect daytime function, and because of this concern, the FDA reduced the recommended dose for eszopiclone to 1 mg and recommended that zolpidem be limited to the lower end of the dosing range, especially for women (43).

Other considerations for prescribing

Sedating medications should not be mixed with each other or used with alcohol. Medication costs and availability on a local or insurance formulary are considerations; generic zolpidem (oral tablet forms) and temazepam are usually the lowest-cost options among the hypnotic medications listed in **Table 5**. Clinicians or patients who wish to avoid a controlled substance may prefer ramelteon or doxepin. Those 2 medications as well as eszopiclone, suvorexant, and lemborexant are FDA-approved without specification that duration be limited. Eszopiclone has a notably bitter taste.

Off-label prescribing and OTC use

Antipsychotic medications and antidepressants, including trazodone, are not recommended for off-label use for treatment of insomnia because of limited or poor evidence for efficacy and safety, with harms likely outweighing benefits (12). These medications should only be prescribed if there is another indication for their use and if their sedating effect could be tolerable or beneficial; doxepin at 3- and 6-mg doses is FDA-approved for insomnia and is the exception. Mirtazapine and amitriptyline can cause or exacerbate RLS and PLMD (46). Diphenhydramine is commonly used over the counter for insomnia, but

evidence for benefit is lacking (12).

What is the appropriate duration of prescription drug therapy?

The appropriate duration of pharmacologic therapy for chronic insomnia is not known. Long-term drug therapy raises concerns based on risks and possible lack of long-term efficacy. Most studies have been limited to less than 16 weeks and have included little information about harms (47). The American College of Physicians (ACP) clinical practice guideline on the management of chronic insomnia disorder in adults recommends that medication use be limited to 4 to 5 weeks, with CBTI for longer-term management (10). On the other hand, insomnia disorder is frequently chronic, the AASM Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults does not include limits on duration of therapy (12), and several hypnotic medications are FDA-approved for long-term use (doxepin at 3 and 6 mg, eszopiclone, ramelteon, lemborexant, and suvorexant).

How should clinicians advise patients on the use of alternative therapies?

Although the AASM clinical practice guideline (12) suggests that melatonin not be used for insomnia because of a lack of evidence for benefit or harm, others suggest melatonin as first-line pharmacotherapy for sleep-onset insomnia in older adults (44, 48), including those who are hospitalized (49) or in long-term care (7), when medication is warranted. Melatonin can cause daytime sleepiness (48). As an OTC supplement, the product quality (amount of melatonin per dose and presence of contaminants, notably serotonin) can vary substantially (50). Melatonin dosing 1 hour (48) or 2 hours (44) before

bedtime may be best for insomnia, whereas for DSWPD, melatonin should be dosed approximately 6 hours before the usual time sleep is achieved (6, 7). Lower doses (0.5 to 1 mg) of melatonin are as effective as higher doses. Other alternative approaches (including valerian, tryptophan, acupuncture, tai chi, and yoga) are not recommended because of insufficient evidence for benefit (10, 11).

When should clinicians consider consulting a specialist for treatment?

Clinicians should refer patients suspected of having an underlying sleep disorder if the evaluation or treatment of it is outside the clinician's scope of practice or when insomnia symptoms are particularly severe or resistant to treatment. Referral to a sleep specialist offers an opportunity for reassessment of the insomnia problem and, in some practices, for implementation of multicomponent CBTI. Referral to a psychiatrist for medication management may be useful when a concurrent psychiatric disorder or medication may be contributing to insomnia (19).

How should clinicians manage insomnia in hospitalized and institutionalized patients?

Sleep disruption is common among patients in hospital (49) and long-term care (51) settings because of environmental factors, including noise and light; patient care processes, such as nighttime interruptions and daytime activity level; and patient factors, such as underlying health conditions, anxiety, and pain. Older patients with dementia or delirium are particularly susceptible to sleep disruption but may not report insomnia. Interventions, ideally implemented across a unit or facility along with training for staff, include adjustments to the environment and to patient care processes to improve the sleep-wake

cycle and reduce nighttime disruptions. During the day, patients should ideally be exposed to bright light, engage in activities appropriate to their health, and avoid napping. During the night, exposure to light and noise should be minimized, as should unnecessary awakening for routine care. Clinicians should strive to avoid or change pharmacologic treatments that may be inadvertently activating and to control physical symptoms, such as pain, that may be disrupting sleep. Low-dose melatonin is suggested for older adults when medication is believed to be warranted because there is evidence of efficacy and safety and circadian

sleep-wake cycle disruption is common in advanced age and in institutional settings (49, 51). Other pharmacologic treatments for insomnia should be avoided in elderly adults.

What type of follow-up care should clinicians provide?

Chronic or intermittent insomnia warrants periodic follow-up. Clinicians interested in a measure of patients' insomnia experience may choose to administer the ISI to assess response to therapy. Patients prescribed sleep medication should be periodically reevaluated for efficacy and adverse effects. Lack of response (by patient report or on the ISI) or new

symptoms suggest the need to reevaluate for a coexisting sleep disorder or health condition causing insomnia. In case of insufficient response to medication, clinicians should also consider nonpharmacologic therapies, including BBTI, and should consider increasing the dose within the usual range for that medication if it is safe for the patient or switching to a different medication. If a patient reports complex sleep-related behaviors while using a hypnotic medication or is misusing a medication (including dose escalation), that medication should be stopped and referral to a sleep medicine specialist for evaluation should be considered.

Treatment... Nonpharmacologic therapy for chronic insomnia disorder should not be limited to sleep hygiene advice but should include one or more of the behavioral components of CBTI given the evidence of its efficacy, safety, and durability of benefit. Behavioral sleep medicine practitioners are in short supply in many areas, but CBTI approaches are available in other formats, including via the internet. BBTI consisting of CBTI principles is an alternative. Pharmacologic therapy may be useful when behavioral therapy is started or when behavioral therapy is not an option or is not effective. Medications for insomnia warrant risk assessment and shared decision making. They should be used for the short term or intermittently and at the lowest effective dose if possible. Medications that are FDA-approved for insomnia are preferred over sedating medications used off-label.

CLINICAL BOTTOM LINE

Patient Education

How should clinicians educate patients?

Even though sleep hygiene advice is not effective alone for treatment of insomnia, it includes sound

information that promotes sleep, including taking time to relax and unwind before bed, maintaining a regular sleep-wake schedule, getting regular exercise, avoiding

caffeine in the evening and lighted screens before bedtime, and getting out of bed if unable to sleep.

Practice Improvement

What do organizations recommend regarding diagnosis and management of insomnia?

Guidelines on evaluation and management of insomnia from the AASM (20) and the European Sleep Research Society (ESRS) (11) address the clinical assessment of insomnia as discussed

here, but with more emphasis on the use of sleep diaries and questionnaires. The ACP guideline on management of chronic insomnia disorder (10) mentions considering treatable underlying causes of insomnia, including OSA and RLS, in patients taking medication for insomnia. Recent AASM clinical practice guidelines on treatments

for insomnia (9, 12) use the 2014 ICSD-3 (International Classification of Sleep Disorders - Third Edition) diagnosis "insomnia disorder" (8) and briefly mention the importance of history in evaluation (12) but are primarily addressed to the sleep medicine community, for whom differentiation between chronic insomnia

disorder and other sleep disorders is a routine part of clinical practice.

Guidelines on the management of insomnia all emphasize CBTI as first-line therapy, some specifying that 1 or more specific components rather than the full package may be useful for some patients and that sleep hygiene advice alone is not useful (9, 20, 33). They differ in their recommendations on the threshold for pharmacologic therapy, from allowing

medication to be used alone or with 1 or more components of CBTI (20) to suggesting that medication may be an option if CBTI is not accessible or not effective (11) to stating that medication should be reserved for patients in whom CBTI alone is not effective (10).

Guidelines addressing pharmacologic treatment of chronic insomnia agree on the profiles and risks of the FDA-approved and off-label medications used for insomnia, but their weighting of benefits

and risks differs slightly, and medication options and data have changed over time, resulting in variation in suggested options for short-term therapy. Only the AASM's clinical practice guideline (12) makes recommendations about long-term pharmacotherapy (**Table 5**). Only the ESRS guideline makes a weak endorsement for alternative approaches (light therapy and exercise) as adjunct treatments (11).

In the Clinic Tool Kit

Insomnia

Patient Information

<https://medlineplus.gov/insomnia.html>

<https://medlineplus.gov/languages/insomnia.html>

Information and handouts in English and other languages from the National Institutes of Health's MedlinePlus.

www.nhlbi.nih.gov/health-topics/insomnia

www.nhlbi.nih.gov/health-topics/espanol/insomnio

Information in English and Spanish from the National Heart, Lung, and Blood Institute.

<http://sleepeducation.org/essentials-in-sleep/insomnia>

Information from the American Academy of Sleep Medicine.

Information for Health Professionals

<https://jasm.aasm.org/doi/10.5664/jasm.8986>

American Academy of Sleep Medicine 2020 clinical practice guideline on behavioral and psychological treatments for chronic insomnia disorder in adults.

<https://onlinelibrary.wiley.com/doi/full/10.1111/jsr.12594>

European Sleep Research Society 2017 guideline for diagnosis and treatment of insomnia.

www.acpjournals.org/doi/10.7326/M15-2175

American College of Physicians 2016 clinical practice guideline on management of chronic insomnia disorder in adults.

In the Clinic

WHAT YOU SHOULD KNOW ABOUT INSOMNIA

In the Clinic
Annals of Internal Medicine

What Is Insomnia?

Insomnia involves trouble falling asleep, staying asleep, or both. It can come and go or be long-lasting.

Insomnia disorder is when poor sleep causes tiredness, moodiness, or trouble functioning during the day and is not caused by another sleep disorder.

What Causes It?

Insomnia can happen to anyone but is more common in women and older adults. Common causes include:

- Stress
- Depression or anxiety
- Drinking alcohol or caffeine
- Loud or distracting sleep environment
- Changes in schedule
- Taking certain medicines
- Underlying sleep disorders
- Symptoms from underlying health conditions

What Are the Symptoms?

- Trouble falling asleep or staying asleep
- Difficulty falling asleep after waking at night
- Waking up too early
- Not feeling rested after sleep
- Feeling sleepy during the day
- Trouble concentrating or paying attention

How Is It Diagnosed?

Your doctor will ask about your sleep and medical history, including your sleep environment, sleep quality and timing, stressors, medicine or substance use, and habits that affect sleep. Input from a sleep partner may be helpful.

You may be asked to keep a sleep diary for 1 to 2 weeks to keep track of your sleep and factors that could be causing insomnia. You may also be asked to complete sleep surveys.

Blood tests or sleep studies are usually not required. If your doctor suspects an underlying sleep disorder or another medical condition is causing your insomnia, you may need other tests.

How Is It Treated?

The main goal is to improve your sleep and quality of life as safely as possible. Nondrug treatment is preferred because it is more effective and safer.

Try to create a bedtime routine that helps you relax, such as taking a bath or reading a book, and keep a stable sleep schedule. Exercise, ideally early in the day, can improve your sleep. Some habits make insomnia worse, such as drinking alcohol or caffeine before bedtime or looking at electronic screens in bed or before bedtime.



Cognitive behavioral therapy for insomnia (CBTI) can teach you how to improve your sleep habits and can help you cope with stress or anxiety, which can affect sleep. CBTI can be done in one-on-one sessions; in a group setting; or via telephone, the internet, apps, or books. The duration ranges from 4 to 8 weeks, and it can be used with medicines. CBTI is preferred because it works best, lasts longest, and is safe.

Medicines for insomnia are available but are not always effective. They also have risks (especially in older people), which may include falls, confusion, daytime sleepiness, and dependence. They should not be mixed with one another or with alcohol. Talk with your doctor about whether medicines are right for you and how to use them safely.

Melatonin is an over-the-counter therapy that can help older adults, “night owls,” and residents of long-term care facilities. It should generally be taken 1 to 2 hours before bedtime. Product quality may vary substantially. Other over-the-counter medications have not been shown to help and carry risks, such as falling.

Your doctor should ensure that underlying sleep and medical disorders that contribute to insomnia are treated.

Questions for My Doctor

- What treatment is best for my insomnia?
- Is an underlying medical condition or medication making my insomnia worse?
- How can I create a positive sleep environment?
- What is the best way for me to access CBTI?
- What if CBTI doesn't work for me?
- How can I safely use medicines for sleep?
- Will melatonin or other over-the-counter medicine help?
- Should I see a sleep specialist? Do I need a sleep study?

For More Information



American College of Physicians
Leading Internal Medicine, Improving Lives

National Heart, Lung, and Blood Institute

www.nhlbi.nih.gov/health-topics/insomnia

MedlinePlus

<https://medlineplus.gov/insomnia.html>