

Insomnia Management

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Introduction

Insomnia is a subjective diagnosis defined as difficulty falling asleep, staying asleep, or experiencing non-restorative sleep with associated impairment of function or clinically significant distress. The need to evaluate and treat insomnia is determined by the frequency of sleep disruption and the degree to which it significantly affects the daily function of the patient. Insomnia may be classified as:

Transient insomnia: lasting one to three nights

Short-term insomnia: lasting three nights to one month

Chronic insomnia: lasting greater than one month

Key Points for Treatment of Insomnia

- The need to evaluate and treat insomnia is determined by the incidence of sleep disruption and the extent to which it significantly affects daily function.
- Initiation of therapy may be warranted with only an initial evaluation if the patient presents with an obvious acute stress inducer, such as grief.
- For severe or chronic insomnia, a thorough evaluation is necessary to determine coexisting medical, neurological, or psychiatric problems.
- Initial treatment should include nonpharmacologic therapy, emphasizing exercise and good sleep hygiene.
- Evidence supports the effectiveness of cognitive behavior therapy.
- Exercise has been shown to improve sleep as effectively as benzodiazepines.
- Short-term therapy with benzodiazepines is supported by clinical studies; however, the long-term use of this class of drugs may lead to dependence and tolerance.
- Newer non-benzodiazepines (zolpidem, zaleplon, eszopiclone, and ramelteon) have better safety profiles and are better first-line choices for long-term treatment of chronic insomnia.¹⁻³
- Hypnotics should only be used short-term, with frequency and duration of therapy customized to patients' individual circumstances.
- Patients should be advised against routinely using antihistamine-containing OTC medications.
- The use of alcohol as a sleep aid should be discouraged.

Prevalence^{4,5}

- At least one third of adults in the U.S. have experienced intermittent symptoms of insomnia, with at least 10% experiencing chronic insomnia.
- Between 5% and 15% of Americans experience impairment as a result of insomnia.
- A recent poll by the National Sleep Foundation (NSF) found that 65% of respondents experience at least one insomnia symptom at least one night per week and 44% had at least one symptom of insomnia almost every night.
- Of patients who initially reported insomnia symptoms, 59% of those with mild symptoms and 83% of those with severe symptoms at baseline still had symptoms of insomnia two years later.

Period Prevalence of Insomnia by Age Group in the Louisiana Medicaid Population (1/1/2006 - 12/31/2006)

Age Group (Years of Age)	Number of Distinct Recipients with an Insomnia Diagnosis and/or Insomnia Medication	Unadjusted Prevalence (%)
0 to 21	4,253	0.6
22 through 45	8,875	5.8
46 and above	7,283	12.8
Total	20,411	2.1

Table Notes:

1. Recipients with Medicare coverage during 2006 were excluded from this claims data analysis.
2. Period Prevalence for 2006 = $\frac{\text{\# of recipients with an insomnia diagnosis and/or insomnia drug}}{\text{Population within age group}}$
Recipients were counted only once if they had a diagnosis and an insomnia prescription(s).
3. For a list of diagnoses and/or medications used in this analysis, please email mmassey@ulm.edu.

Impact^{2,6}

In addition to the obvious physical and mental impact that a chronic sleep disorder can have on a patient, insomnia has a negative impact on the individual's quality of life. Patients with severe insomnia assess themselves as having a quality of life similar to patients that suffer with congestive heart failure or depression.

People with severe insomnia:

- | | |
|--|--|
| <ul style="list-style-type: none"> ■ Report more medical problems ■ Have more physician office visits ■ Are hospitalized twice as often | <ul style="list-style-type: none"> ■ Have higher absenteeism from work ■ Miss work twice as often as good sleepers ■ Have more work-related accidents |
|--|--|

The combined economic impact of insomnia including job absenteeism, decreased productivity, accidental property damage, and healthcare costs is estimated to be greater than \$100 billion annually.

Comorbid Conditions^{7,8}

For severe or chronic insomnia, a thorough evaluation is necessary to determine coexisting medical, neurological, or psychiatric problems. Chronic insomnia is more prevalent in patients with one or more medical or psychological disorders.

- There is a well-established link between insomnia and depression.
- Insomnia may be the first sign that a major depressive episode is approaching, and among the last symptoms to resolve after the patient's depression has been treated.
- Insomnia may precede an increased risk of subsequent depressive episodes and suicidal ideations.

Besides depression, other factors can cause or worsen insomnia, including:

- Anxiety
- Nicotine use
- Restless leg syndrome
- Substance abuse
- Obstructive sleep apnea
- Periodic limb movement

Other consequences associated with insomnia include higher than expected rates of:

- Hypertension
- Diabetes mellitus
- Recurrent cardiac events
- Chronic pain
- Obesity

Some Medications Associated With Secondary Insomnia⁹⁻¹²

Insomnia is a potential adverse effect of many medications. The sleep difficulties may arise due to direct physiological effects, disruption of sleep patterns, or withdrawal from certain medications. Response to a particular medication is highly individualized and varies depending on factors such as dosage level, time of administration, and age of the patient.

Some medications associated with secondary insomnia:

Albuterol	Lamotrigine	Oral contraceptives	Quinidine
Atenolol	Leuprolide acetate	Phenelzine	Reserpine
Benzphetamine	Levodopa	Phenytoin	Salmeterol
Bupropion	Lisdexamfetamine	Pindolol	Terbutaline
Clonidine	Medroxyprogesterone	Prednisolone	Theophylline
Cortisone	Methamphetamine	Prednisone	Thyroid preparations
Dextroamphetamine	Methyldopa	Progesterone	Tranlycypromine
Fluoxetine	Methylphenidate	Propranolol	Triamterene
Imipramine	Metoprolol	Protriptyline	Venlafaxine
Ipratropium bromide	Modafinil	Pseudoephedrine	

In addition to gathering patient history and examining the patient for coexisting medical or psychiatric illness, further examination may include:

- Obtaining a sleep history
- Interviewing, with permission, a partner or family member about the sleep habits of the patient, their daily function, history of substance use, and problems with snoring or apnea
- Evaluating neurological function in physical exams

Other methods of evaluating insomnia are:

Sleep Diary Evaluation: to get an accurate picture of the patient’s sleep habits, moods, and daytime function.

Polysomnography: for suspected apnea or periodic limb movement disorder; also used when behavioral or pharmacological therapies are not successful.

Actigraphy: for monitoring activity; useful in evaluation of sleep patterns.

Neuroimaging: for suspected lesions.

Non-Pharmacologic Treatments^{3,6,14}

- Treatment should start with nonpharmacologic therapy, emphasizing exercise and good sleep hygiene.
- Exercise, cognitive behavior therapy, and relaxation therapy are effective, nonpharmacologic treatments for chronic insomnia.

Nonpharmacologic treatments for chronic insomnia:

Exercise	Engage in moderate exercise but not immediately before bedtime.
Cognitive Behavior Therapy (CBT)	Helps the patient change inaccurate beliefs and attitudes about sleep and CBT through various techniques such as: goal setting, planning coping responses, attention shifting, and balancing automatic anxious thoughts.
Relaxation Therapy	Some forms of relaxation therapy include: tensing and relaxing various muscle groups, biofeedback, meditation, and hypnosis.
Paradoxical Intention Therapy	Bedtimes are set earlier or later in response to improvement (or worsening) of sleep quality and duration.
Sleep Restriction Therapy	Reassociating the bed with sleep by limiting the amount of time spent in bed to actual sleep time.
Stimulus Control Therapy	Good sleep hygiene should include: <ul style="list-style-type: none"> ■ Avoiding large meals, tobacco, caffeine, alcohol, television, bright lights, noises, and temperature extremes ■ Minimizing evening fluid intake ■ Leaving the bedroom if not asleep within 20 minutes ■ Using the bedroom for sleep or intimacy only
Temporal Control Measures	Set consistent wake times and limit daytime napping to a minimum.

Patients tend to self-medicate:

Nonprescription sleep aids are popular for self-treatment of insomnia. Recently published data from the NSF stated that choices for self-treatment for insomnia ranked as follows:

- | | |
|---|------------------------------|
| 1. Alcohol | 2. OTC non-herbal sleep aids |
| 3. Prescription medications intended for someone else's use | 4. Melatonin |

Characteristics of an ideal insomnia agent:

- | | |
|-------------------------------|------------------------------------|
| ■ Reduces time to sleep onset | ■ Avoids next-day residual effects |
| ■ Improves sleep maintenance | ■ Enhances next-day functioning |

FDA-approved insomnia medications:

Drug	Duration of Action	Insomnia Indication
Benzodiazepines		
Estazolam	Intermediate	Sleep Maintenance ^a
Flurazepam	Long	Sleep Maintenance ^a
Quazepam	Long	Sleep Maintenance ^a
Temazepam	Intermediate	Sleep Maintenance ^a
Triazolam	Short	Sleep Onset ^a
Nonbenzodiazepines		
Eszopiclone	Intermediate	Sleep Maintenance ^b
Zolpidem	Short	Sleep Onset and Sleep Maintenance ^{a,c}
Zaleplon	Ultrashort	Sleep Onset and Sleep Maintenance ^{a,d}
Melatonin-receptor agonist		
Ramelteon	Short	Sleep Onset

^a FDA approved for short-term (7-10 days) insomnia management.

^b FDA approved for treatment of chronic insomnia.

^c For sleep-maintenance insomnia, zolpidem extended-release formulation is recommended.

^d For sleep-maintenance insomnia, administered upon waking during the night.

Pharmacologic Treatments

Number of Louisiana Medicaid recipients who filled prescriptions used in the management of insomnia during 2006:

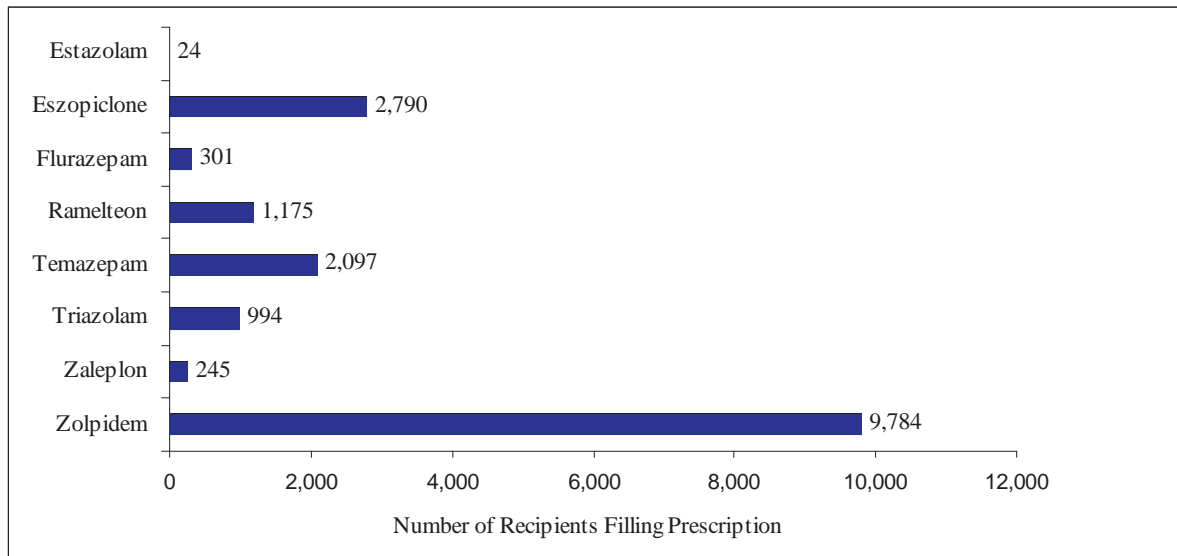


Figure Notes:

1. Recipients with Medicare coverage during 2006 were excluded from this claims-data analysis.
2. For recipients included in the analysis, no prescriptions were filled for quazepam in 2006.
3. For the 2006 calendar year, 58,207 prescriptions used in the management of insomnia were dispensed to 15,067 recipients. On average, for those recipients receiving an insomnia prescription, 3.86 prescriptions for insomnia were dispensed per recipient.
4. For the 2006 calendar year, 17,632 recipients received a prescription for diphenhydramine. Of these, only 3% (582 / 17,632) had a paid medical claim coded with an insomnia diagnosis. Because diphenhydramine has multiple indications, making it difficult to link its use to a specific indication, diphenhydramine was excluded from analysis.

Benzodiazepines (BZDs)²

- FDA-approved BZDs for insomnia include: estazolam, flurazepam, quazepam, temazepam, and triazolam. These medications, when used at clinically recommended doses for short-term insomnia are safe and effective in improving both sleep-onset and sleep-maintenance.
- The long-term use of this class of drugs may lead to tolerance and dependence.
- Evidence for long-term efficacy is lacking, as clinical trial durations have been short (< 6 weeks).
- Common undesirable effects include: residual daytime sedation, anterograde amnesia, cognitive impairment, motor impairment, rebound insomnia, and withdrawal symptoms upon discontinuation.
- Most adverse effects are dose dependent; therefore, the lowest effective dose should be used for the shortest period of time, as determined by clinical need.

Non-Benzodiazepines²

- Non-benzodiazepines that are FDA-approved for treatment of insomnia include: zolpidem, zaleplon, eszopiclone, and ramelteon. Due to their superior safety profile and lower risk for abuse and dependence, they are a more appropriate first-line choice for long-term treatment of chronic insomnia.
- Zolpidem has been shown to improve sleep latency and increase duration of sleep for treatment periods of up to 35 days.
- Zolpidem ER has been shown to improve both sleep latency and sleep maintenance.
- Zaleplon, due to its rapid absorption and ultra-short half-life, is approved for bedtime or later in the night dosing when difficulty with sleep onset exists.
- Eszopiclone has been shown to be effective for six months of therapy without apparent tolerance to the drug. Additionally, withdrawal symptoms were not observed after the eszopiclone was stopped.

Melatonin-Receptor Agonists²

- Ramelteon is currently the only melatonin-receptor agonist approved by the FDA for insomnia.
- The drug is indicated for insomnia due to difficulty with sleep onset. It has not been shown to improve symptoms of sleep maintenance.
- The advantage of this medication is that it has very low abuse and dependence potential.

Antihistamines^{2,3}

OTC antihistamines such as diphenhydramine and doxylamine should not be recommended routinely for insomnia because they:

- Are minimally effective for sleep induction,
- May reduce sleep quality, and
- May cause residual drowsiness.

Herbal and Dietary Supplements^{2,3}

- Melatonin has been determined to be safe and effective for the short-term use in circadian rhythm sleep disorders which arise from shift work or jet lag. It has been approved for orphan drug status for circadian rhythm sleep disorders in blind patients; however, preparations are unregulated and vary in quality.
- Valerian root has shown some benefit for short-term insomnia in clinical trials; however, it is currently not FDA-approved. Clinical trials have not fully evaluated tolerance, dependence, or withdrawal symptoms on discontinuation.

Other Sleep Aids³

- Alcohol should not be used to treat insomnia due to its potential for abuse. Alcohol reduces sleep onset latency but increases sleep disruptions after onset and suppresses REM sleep.
- Opiates may be helpful for certain patients with insomnia associated with pain, however, the quality of sleep produced is poor and fragmented.

Conclusion

Insomnia is a major public health concern that affects the lives of millions of people. Healthcare professionals should understand that a patient's insomnia may be related to a variety of causes or contributors, including physical or psychiatric problems. An accurate diagnosis is essential to guide an individualized treatment strategy, which may include a variety of behavioral and pharmacologic approaches.

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Complete Wellness: A Guide to Managing Your Health

* The following is an abbreviated version of the education material sent to selected Medicaid recipients.

Insomnia Management

By: Gregory W. Smith, PharmD, Michelle Massey, Publications Coordinator, and Larry Humble, PharmD, Office of Outcomes Research and Evaluation, The University of Louisiana at Monroe College of Pharmacy



Insomnia is common among adults. You may have insomnia if:

- ♦ You have a hard time falling asleep
- ♦ You wake up frequently during the night
- ♦ You have trouble waking up early

Sometimes insomnia only lasts a little while. This type of insomnia is easy to manage. But, if you have insomnia for a long time, it can affect your work, your relationship with family and friends, and your overall health.

How much sleep is enough?

Most healthy adults need 7 to 9 hours of sleep every night. Some people are okay with only 6 hours and other people may need up to 10 hours of sleep to feel completely rested.

Signs that you may not be getting enough sleep

Do you have trouble paying attention if something is boring?

Are you often irritable with coworkers, friends, or family for no reason at all?

Do you have a hard time concentrating or remembering things?

Why do I have insomnia?

There are many things that can cause insomnia, such as:



One way to find out what could be causing your insomnia is to keep a "sleep diary." A sleep diary makes it easy to keep up with how sleepy you are during the day and compare it to how good you sleep at night. It can also help you figure out if something is causing your insomnia. Finding and fixing "bad sleep habits," and learning "good sleep habits" can help you control your insomnia. If you are able to get enough sleep, you will feel better and have a better quality of life.

Ask your doctor about a sleep diary, or go to <http://www.sleepfoundation.org> to download and print one.

Ask your doctor, pharmacist, or nurse about the information contained in this brochure.

Treating Insomnia

If your doctor decides that you have insomnia, he may want to try other things before putting you on medication. Some things your doctor may want to try:

- ♦ Regular exercise
- ♦ Relaxation therapy
- ♦ Activities to help you change how you think about sleep and managing your thoughts or worries.

Sometimes there may be a medical reason causing your insomnia. Medications may be needed to help you sleep easier. Even if your doctor gives you medicine to help your insomnia, you should still use "good sleep habits" to get the best night's sleep.

Warning!

DO NOT try to treat your insomnia with alcohol.

DO NOT use over-the-counter sleeping pills too often.

NEVER use someone else's prescription medicine to help you sleep.

"Good Sleep Habits"

Create a sleep routine.

Go to bed and get up at the same time every day, even on weekends. Your body will get used to the routine and it will be easier to fall asleep.

The bedroom is for sleeping.

If you use your bedroom for watching TV, reading, working, or eating, your body will think you are supposed to be awake when you are in bed.

Don't go to bed unless you are sleepy.

You can't force yourself to go to sleep. If you get in bed and don't fall asleep within 20 minutes, get out of bed and do something relaxing until you feel sleepy.

Relax and put your worries away.

Clear your mind and do something relaxing within an hour before bedtime. Things like taking a warm bath, reading, or listening to music will help you calm down and get ready for sleep. Do not use this time to think about your worries.

Avoid caffeine, alcohol, & nicotine.

Try to avoid anything that contains caffeine, alcohol, or nicotine. Things like coffee, soft drinks, tea, and chocolate have caffeine in them and can keep you awake. Drinking alcohol may make you sleepy at first, but it often makes you wake up during the night and keeps you from resting well. Tobacco products can also keep you up at night.

Do not eat large meals late at night.

Going to bed right after eating a large meal can result in a long night of heartburn and restlessness.

Move the clock away from your bed.

Move your clock so you can't see it if you wake up during the night. Try to relax and go back to sleep without worrying about what time it is.

Make your bedroom comfortable.

Make your bedroom as cozy and comfortable as you can. Try to keep your bedroom at a comfortable temperature. It is important that your bedroom makes you feel relaxed.

Stay awake during the day.

If you don't sleep well at night, you may be tempted to take a nap the next day. Try not to nap during the day. Sleeping during the day tells your body that you should be awake when it is time to go to sleep at night.

Keep children in their own beds.

If you have young children who wake up during the night, feed or change them if needed, but put them back in their own beds to sleep. You may lose some rest trying to teach them to sleep alone, but it will be well worth it once you do.

Exercise, but not right before bed.

Exercise is very important, but it can keep you awake. If you have insomnia, do not exercise right before bedtime. Try to exercise around 5-6 hours before you go to bed. You may want to exercise in the morning or early afternoon.

Avoid things that keep you from falling asleep and staying asleep, such as:

- Loud noises
- Bright light
- Television
- Pets
- Outside traffic
- Other outside noises

Getting help for your insomnia

If you have tried the "good sleep habits" but still can't sleep, you should talk to your pharmacist or doctor. Make an appointment with your doctor if you have trouble sleeping for more than 10 days. If you have been keeping a sleep diary, take it with you to your doctor's appointment.



Try these websites to learn more about insomnia:

<http://www.cdc.gov/sleep>

<http://www.nlm.nih.gov/medlineplus/sleepdisorders.html>

<http://www.webmd.com/sleep-disorders/insomnia>

Remember, with the right help and habits you can put insomnia "to bed" and get a good night's sleep.



Educational material provided to Louisiana Medicaid recipients and providers by the Louisiana Medicaid Pharmacy Benefits Management Program (PBM) in the Department of Health and Hospitals and developed by the University of Louisiana at Monroe College of Pharmacy.

Complete Wellness: **A Guide to Disease Management**

The Department of Health and Hospitals, Bureau of Health Services Financing, and the University of Louisiana at Monroe, College of Pharmacy, continue to develop Disease Management programs to address the education component of the Louisiana Medicaid Pharmacy Benefits Management system.

Selected Medicaid recipients and their health care practitioners receive these educational brochures. We appreciate your taking time to review these and incorporating this information into your practice as you deem appropriate.

Thank you for your continued participation in the Medicaid program. Should you need additional information concerning the Disease Management program, please contact M.J. Terrebonne at (225)342-9768.

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