



Prescribing Guidelines for Pediatric Insomnia

PARTNERS
FOR **KIDS**[®]



Prescribing for Pediatric Insomnia

This document was developed by Nationwide Children's Hospital in conjunction with Partners For Kids using evidence-informed clinical guidelines and expert opinion where evidence is lacking, and are generally reflective of FDA approved indications and recommendations. It is designed to help primary care practitioners provide timely and effective treatment for children with difficulty falling asleep or staying asleep. This document should not be considered a substitute for sound clinical judgment and clinicians are encouraged to seek additional information if questions arise. If therapeutic response is inadequate, refer to or consult with specialty behavioral health.

Additional information and resources are available through the Dayton Children's psychiatry team. To speak with one of the psychiatrists, call (937) 641-4385 or visit www.ChildrensDayton.org/Patients-Visitors/Services/Behavioral-Health-3/Programs-and-Services/Psychiatry.



Overview of Insomnia in the Pediatric Population

- Insomnia is a common presenting problem in children and adolescents.
- The prevalence of insomnia is approximately 36% in preschool children, 20% in school-age children and 24% in adolescents.
- Clinicians should utilize clinical judgment to create behavioral and, if needed, pharmacologic therapies for their patients with insomnia.
- Insomnia may be the result of another untreated behavioral health concern. If another diagnosis is suspected, please review the Partners For Kids guidelines for “Anxiety & Depression” and/or “ADHD.”
 - partnersforkids.org/resources
 - Navigate to prescribing resources and select the relevant guideline.

Evaluation for Insomnia

• Underlying conditions

- Insomnia may manifest as a complication of untreated or undiagnosed anxiety and depression, ADHD or other disorder.
- Anxiety and Depression should be ruled out first or properly treated before using pharmacologic therapy targeted for sleep.
- Behavioral modifications to improve sleep may still be implemented, provided the other underlying behavioral health disorder is being addressed.
- Partners For Kids maintains both Anxiety & Depression and ADHD guidelines to facilitate screening and diagnosis of these two disorders.
- Partners For Kids resources may be found at the link below:
 - partnersforkids.org/resources
 - Navigate to prescribing resources and select the relevant guideline.

• BEARS sleep screening tool

- The BEARS Sleep Screening tool is an acronym for an easy-to-administer screening tool that can be used to find the possibility of sleep related problems.
- The tool asks patients, or their parents a question related to each of the following:
 - Bedtime problems
 - Excessive daytime sleepiness
 - Awakenings during the night
 - Regularity and duration of sleep
 - Sleep-disordered breathing
- The full BEARS Sleep Screening tool can be found using the link below:
 - [BEARS screening tool - UpToDate](#)

• Key Evaluation Points

- Description of sleeping problems:
 - Type of problem, bedtime resistance, difficulty initiating sleep and nighttime awakenings
 - What age did sleep difficulties first occur, and how often do they occur
 - The child’s usual sleep schedule, both weekdays and weekends
 - Sleeping environment

- Bedtime routine: pre-sleep activities, such as exercise, video games or stimulating activities
- What has already been tried that works? What hasn't worked?
- Patient's preferred sleep schedule
- Psychosocial factors:
 - Potential triggers: assess major life events
 - Developmental history
 - Screen time and time screens are used
 - Anxiety about falling or staying asleep
- Biologic/Medication factors:
 - Assess for primary contributors to sleep disorders
 - Sleep apnea: snoring, loud snoring, pauses in breathing during sleep
 - Restless Leg Syndrome: urge to move legs, especially at rest
 - Child's medical history, particularly, allergies, dermatitis, seizure disorders, generalized anxiety disorder and depression
 - Medications or caffeine use (including energy drinks)
 - Family history of insomnia
- Additional factors:
 - Activities in bed other than sleep: such as use of phones, TV, or other electronics in bed, especially if active while sleeping (such as a phone vibrating in the middle of the night)
 - Daytime napping: when and how long
 - Daytime sleepiness: dozing off at school, while doing homework, on a car ride



- **General Recommendations**

- Ensure adequate time each night is dedicated to sleep using the table below

Age	Recommended Sleep Hours
3-11 months	14-15 hours
1-3 years	12-14 hours
3-5 years	11-13 hours
6-10 years	10-11 hours
10-17 years	8.5-9.25 years
18+ years	7-9 hours

- Set a bedtime, a wake time and a bedtime routine, and enforce all three.
- Bedtime and wake-up time should be approximately the same time on weeknights and weekends. There should not be more than an hour difference in sleep and wake times on different days of the week.
- An hour before bed there should be a calming routine. Avoid high-energy activities such as rough play, stimulating games and using technology (social media, cell phones, video games, TV).
- Parents may provide a light snack before bed if the patient is hungry, but full meals should be spread out from bed by at least an hour or more.
- Avoid caffeine (soda, coffee, tea, chocolate, energy drinks, etc.), especially after noon.
- Make sure your child spends time outside whenever possible and is involved in regular exercise.
- Keep your child's bedroom quiet and dark. Low-level nightlights can be used for children that are frightened of dark rooms.
- Put all screens and electronic devices "to bed" in a room that your child is not using for sleep.
- Keep the bedroom at a comfortable temperature, generally, cooler is better.
- Don't use your child's bedroom for time-out or punishment.

Medications for the Treatment of Pediatric Insomnia

- Behavioral modifications are recommended as first-line treatment before utilizing pharmacologic therapy. Behavioral modifications may generate long-lasting benefits, while sleep improvements related to medications typically fade if the medication is removed.
- Many medications used in pediatric insomnia do not carry an FDA approval for insomnia in pediatric patients.
- Medications for pediatric insomnia should be started at a low dose and evaluated for effect before elevating the dose.
- Below the table are highlights of each medication or class of medications, as well as some medications or classes not included in the table.
- If there are any concerns related to medication selection, or other diagnoses, contact the Dayton Children's psychiatry team at (937) 641-4385.

Medication Table:

Drug*	Initial Daily Dose ¹	Titration Recommendation	Max Daily Dose	Strengths	Taper Recommendation	Clinical Pearls
Melatonin**	1-3 mg	Increase daily dose by 1-2 mg each week	5 mg	1, 3, 5, 10, 20 mg	NA	There is no current evidence that doses higher than 4mg provide greater efficiency
Clonidine	0.1 mg	Increase daily dose by 0.1mg each week	0.4 mg	0.1, 0.2, 0.3 mg	Decrease daily dose 0.1 mg each week	May cause a decrease in blood pressure
Gabapentin	5 mg/kg	If necessary, titrate to max effect over 3 days	15 mg/kg [†]	100, 300, 400, 600, 800 mg	Decrease daily dose by 100 mg every 5 days	May cause disinhibition in younger children
Trazodone	50 mg	Increase daily dose by 25 mg every 2 weeks	150 mg	50, 100, 150 mg	Decrease daily dose by 50 mg every 5 days	Has serotonergic activity at higher doses
Mirtazapine	7.5 mg	Dose may be increased every 2 weeks	30 mg	7.5, 15, 30 mg	Decrease daily dose 7.5 mg every 5 days	Lower doses are typically more sedating

* All medications are dosed in the evening before bed.

** Melatonin is an over-the-counter preparation. Medicaid Managed Care Plans may differ in coverage of this product.

† Max adult dosage is 1,200 mg in a single dose. 800mg is the largest available single tablet.

Medication and Medication Class Highlights:

• Melatonin

- Melatonin does not cause sedation. It is a naturally occurring hormone produced by the pineal gland that triggers sleep onset. Light inhibits melatonin release from the pineal gland and the absence of light triggers melatonin secretion in the brain.
- There is no evidence that higher doses of melatonin or slow-release melatonin are any more effective than three to five milligrams of immediate release melatonin.
- Melatonin may be helpful in the management of sleep-onset insomnia in children, based primarily on data from patients with ADHD and autism.

• Alpha Agonists

- Alpha agonists, such as clonidine, may cause sedation. There are no controlled studies for their use in pediatric insomnia, but they are generally well-tolerated in children with ADHD and initial insomnia.
- This medication class is also used to reduce blood pressure and as such, patients may benefit from close blood pressure monitoring, even at low doses. Counseling should also be provided to parents about the risks of low blood pressure.
- The half-life of clonidine is approximately three hours and may lead to middle of the night waking in some patients.
- Tolerance to clonidine can develop, which may necessitate increasing the dose.
- It is essential to warn parents about the danger of using more than one dose of these agents during the night. Dosing multiple times in a single night can lead to dangerous decreases in blood pressure and worsen tolerance to the medication.

• Sedating antidepressants

- There is no controlled data about the use of these agents in pediatrics.
- Antidepressants like Trazodone or Mirtazapine have antihistaminic properties at low doses that lead to sedation while higher doses can cause next-day sedation.
- Over time, the sedating effects of these medications wear off.

- **Antihistamines**

- Antihistamines, such as diphenhydramine (Benadryl®), are widely used in pediatrics despite the lack of evidence for their efficacy.
- The majority of over-the-counter sleeping medications on the market include diphenhydramine as the active sedating agent.
- Antihistamines are generally well tolerated in the short term but tolerance can develop with nightly use and daytime sedation can occur with their use.
- These agents are best left for occasional use in younger children and adolescents.

- **Gabapentin**

- In a small review of 23 pediatric patients, gabapentin was found to be effective in a majority of the patients treated and was well tolerated. For many of the patients studied, melatonin was trialed first, with melatonin providing benefits in time to fall asleep, but did not benefit sleep maintenance. When these patients used gabapentin most experienced improvement.
- There were complaints of paradoxical reactions (feeling “wired”) by five of the patients in the trial referenced above. Upon discontinuation of gabapentin the side effect resolved.

- **Benzodiazepines**

- There are a variety of benzodiazepines that are sometimes used for sleep in adults.
- Due to their mechanism of action, they can cause significant dependence if used consistently, as well as considerable side effects. Most notably, there can be next-day sedation with their use, or a “hangover” effect.
- They are considered to have very limited use as hypnotics in children, but due to their long duration of action, they may have use in some patients. Benzodiazepines should be used as a last resort and **only by sleep specialists**.
- **Their use is not routinely recommended in children and adolescents.**

- **Z-Drugs**

- The non-benzodiazepine receptor agonists, such as eszopiclone (Lunesta®) and zolpidem (Ambien®) have not shown efficacy for insomnia in children and adolescents.
- There are concerns about behavioral changes the next day following the use of these agents.
- **Their use is not recommended in children and adolescents.**

- **Quetiapine and other antipsychotics**

- Quetiapine is an antipsychotic medication that can have considerable side effects, most notably metabolic and movement disorders.
- While the antipsychotic medications can be sedating, there have been no controlled trials showing safety or efficacy when used for insomnia in children and they are not FDA approved for this use.
- For quetiapine specifically, lower doses impact histaminergic and alpha adrenergic receptors causing sedation, whereas escalated doses are usually required for more D2 receptor activity and antipsychotic effect.
- Due to the potential for metabolic and movement disorder adverse effects, **quetiapine and antipsychotics are not recommended for sleep disorders in children and adolescents.**

When to consider a referral

- The child snores three or more nights/week and is tired or irritable during the day.
- The child has ADHD and complains of restless legs symptoms, e.g. leg discomfort, urge to move, or pain when not moving.
- Insomnia associated with neurodevelopmental comorbidities.
- Failure of behavioral modifications and medication therapies.

References

1. Owens J, Mindell J. Pediatric insomnia. *Pediatr Clin North Am*. 2011 Jun;58(3):555-69. doi: 10.1016/j.pcl.2011.03.011. PMID: 21600342
2. Mindell J, Owens J. Sleep Hygiene: Healthy Sleep Habits for Children and Adolescents. In: *A Clinical Guide to Pediatric Sleep*, 2nd ed, Lippincott Williams & Wilkins, Philadelphia 2009.
3. Janjua I, Goldman RD. Sleep-related melatonin use in healthy children. *Can Fam Physician*. 2016;62(4):315-317.
4. Felt BT, Chervin RD. Medications for sleep disturbances in children. *Neurol Clin Pract*. 2014;4(1):82-87. doi:10.1212/01.CPJ.0000442521.30233.ef
5. Kelly M. Brown, Beth A. Malow Pediatric Insomnia, *Chest*, Volume 149, Issue 5, 2016. Pages 1332-1339, ISSN 0012-3692, <https://doi.org/10.1378/chest.15-0605>
6. A.A. Robinson, B.A. Malow. Gabapentin shows promise in treating refractory insomnia in children. *J Child Neurol*, 28 (12) (2013), pp. 1618-1621
7. Owens J, Chervin R, Eichler A. Pharmacotherapy for insomnia in children and adolescents: A rational approach. UpToDate. Waltham, MA: UpToDate.
8. Sangal RB, Blumer JL, Lankford DA, Grinnell TA, Huang H. Eszopiclone for insomnia associated with attention-deficit/hyperactivity disorder. *Pediatrics*. 2014;134(4):e1095-1103
9. Relia S, Ekambaram V. Pharmacological Approach to Sleep Disturbances in Autism Spectrum Disorders with Psychiatric Comorbidities: A Literature Review. *Med Sci (Basel)*. 2018;6(4):95.

Partners For Kids is the oldest and largest pediatric accountable care organization in the United States. It was founded 25 years ago by Nationwide Children's Hospital and has improved the health of millions of children in south central and southeastern Ohio.

PartnersForKids.org

PARTNERS
FOR KIDS®

