



# Management Guidelines for Pediatric Insomnia

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## 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. 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 a behavioral health specialist.

The most effective treatment strategy for insomnia in children includes consistent implementation of healthy sleep habits, which may need to be combined with other behavioral interventions. Medications are not FDA approved, nor proven effective as a long-term treatment for childhood insomnia.

Additional resources can be found at the Behavioral Health Treatment Insights and Provider Support (BH-TIPS) line. The BH-TIPS line allows community providers to consult with a Nationwide Children's psychiatrist via a virtual appointment. Further details as well as appointment scheduling can be found at the link below:

[NationwideChildrens.org/BHTIPS](https://NationwideChildrens.org/BHTIPS)

[BHOfficeHours@NationwideChildrens.org](mailto:BHOfficeHours@NationwideChildrens.org)



## 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 regimens 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.”
  - [Behavioral Health Resources - Partners For Kids](#)
    - Select the relevant guideline.

## Evaluation for Insomnia

- **Underlying conditions**
  - Insomnia may manifest as a result of untreated or undiagnosed anxiety and depression, ADHD, acid reflux, poorly controlled asthma or other conditions.
  - Behavioral modifications to improve sleep may still be implemented, provided the other underlying behavioral health disorder is being addressed.
  - For patients with ADHD being treated with a stimulant, ensure it is taken early in the day and at the lowest effective dose. Psychostimulants administered at a consist time every morning can help to maintain a regular and more consistent sleep-wake cycle.
  - Partners For Kids maintains both Anxiety & Depression and ADHD guidelines to facilitate screening and diagnosis of these two disorders.
  - These guidelines can be accessed at the link below.
    - [Behavioral Health Resources - Partners For Kids](#)
- **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:
    - **B**edtime problems
    - **E**xcessive daytime sleepiness
    - **A**wakenings during the night
    - **R**egularity and duration of sleep
    - **S**leep-disordered breathing
  - The full BEARS Sleep Screening tool can be found using the link below:
    - [BEARS screening tool - UpToDate](#)
- **Key Evaluation Points**
  - A diagnosis of chronic insomnia includes the following:
    - Sleeping difficulty that is not solely explained by an underlying medical condition, mental health disorder, medication or substance use
    - Lack of sleep produces daytime dysfunction
    - Lack of sleep occurs despite an adequate opportunity for sleep
    - Adequate time for sleep
    - Appropriate environment for sleep
    - Occurs at least 3 times a week for at least 3 months

- Use the responses to these evaluation questions to fine tune the more general recommendations that are provided below to determine if a referral is most appropriate.
  - 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
    - How do the parents respond to the child's nighttime awakenings?
    - 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 or before falling asleep
    - 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

## Behavioral Modifications and Sleep Hygiene

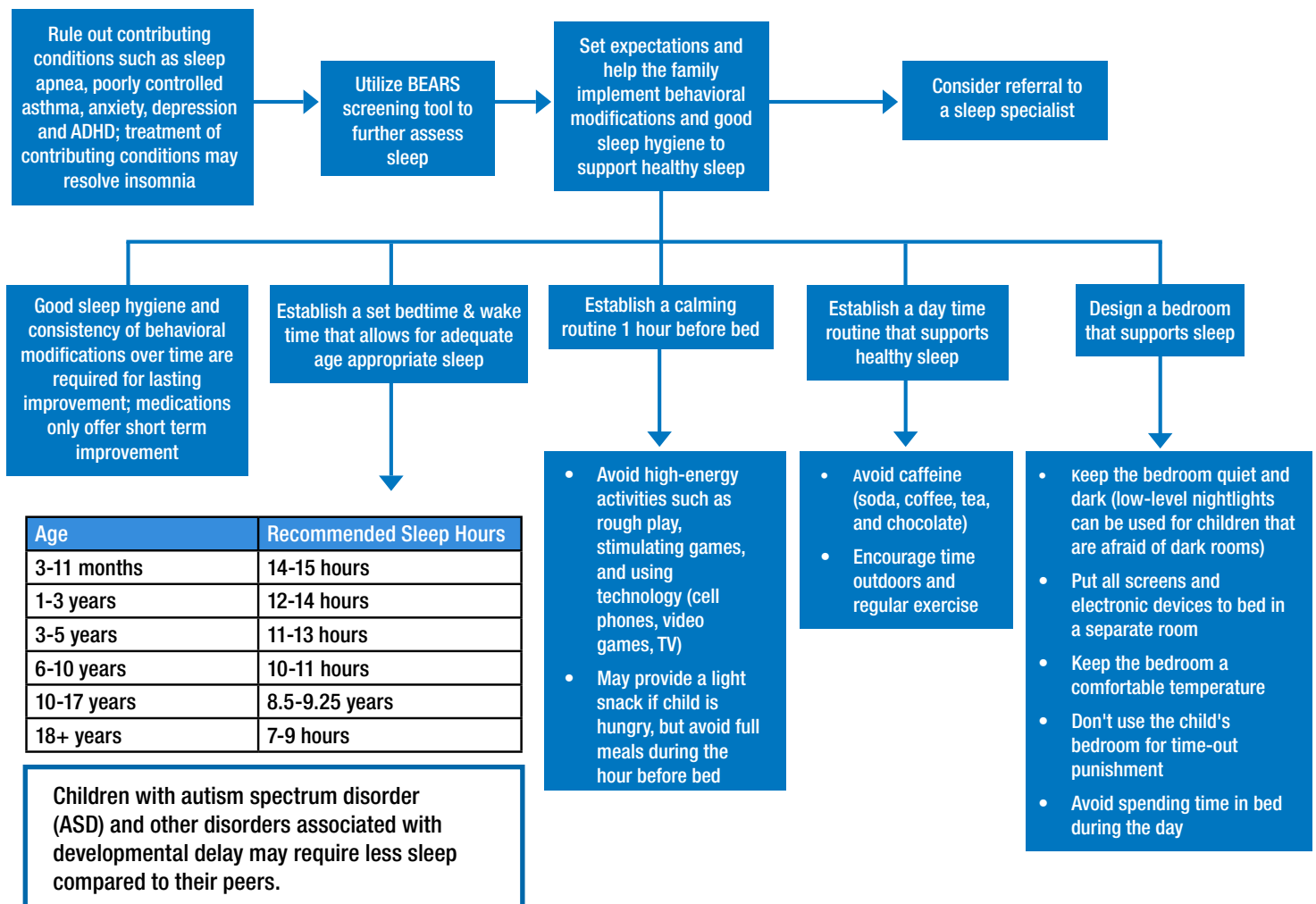
### • General Recommendations

- Ensure adequate time each night is dedicated to sleep using the table below
  - Focus on quality of sleep over length of sleep

**NOTE:** Children with autism spectrum disorder (ASD) and other disorders associated with developmental delay may require less sleep compared to their peers.

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.
- Eliminate naps if age appropriate. By one year old, most children only need one nap per day. By three years old, about 50% of children no longer need a nap at all. School age children and teenagers should eliminate naps completely.
- Delayed production of melatonin in teenagers leads to a later onset of sleep. When combined with early wake-up time for school, may not allow for adequate sleep time. Elimination of naps and consistent wake-up times are important to improve sleep.
- 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, etc.), 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 cool temperature.
- Don't use your child's bedroom for time-out or punishment.





## Medications for the Treatment of Pediatric Insomnia

- Behavioral modifications and optimizing sleep hygiene are the main and the most important treatment for chronic insomnia in children. Medications should NOT be considered before optimizing sleep hygiene and implementing behavioral modifications for insomnia. It is strongly recommended that a thorough evaluation by a sleep specialist should take place prior to starting any sleep aids since this can ensure a higher success rate of the treatment strategy. Behavioral modifications have been proven to be more effective in generating a long-lasting benefit, while sleep improvements related to medications typically fade over time. Furthermore, a well-designed treatment strategy that might combine medications with behavioral interventions can significantly improve the treatment outcomes.
- In the rare occasions medications are used by the sleep specialist, medications will be started at a low dose and evaluated for effect and next day sedation before changing the dose. The medications are not prescribed with refills, rather it will be prescribed as a short-term therapy started at the same time the behavioral interventions are implemented.
- All medications used in pediatric insomnia are NOT approved by the FDA to treat insomnia in pediatric patients.
- If there are any concerns related to medication selection, or other diagnoses, please utilize the BH-TIPS line.  
[NationwideChildrens.org/BHTIPS](https://www.nationwidechildrens.org/BHTIPS)



## Medication Table:

Drug	Initial Daily Dose <sup>1</sup>	Titration Recommendation	Max Daily Dose	Strengths	Taper Recommendation	Clinical Pearls
<b>Melatonin (3-5 years)**</b>	1mg	Increase daily dose by 1-2 mg every 2 weeks	5 mg	1,3,5,10, 20 mg	NA	There is no current evidence doses higher than 4mg provide greater efficacy
<b>Melatonin (6+ years)**</b>	1-3 mg	Increase daily dose by 1-2 mg every 2 weeks	5 mg	1,3,5,10, 20 mg	NA	There is no current evidence doses higher than 4mg provide greater efficacy
<b>Clonidine (age ≥4 years and weight &lt;27 kg)</b>	25-50 mcg at bedtime	Increase daily dose by 25 mcg every 1-2 weeks as needed and tolerated	10 mcg/kg/ day	0.1, 0.2, 0.3 mg	Decrease daily dose by 20 to 30% every 2 to 3 days	Should not be used in the absence of ADHD or developmental delays
<b>Clonidine (age ≥4 years and weight 27-40.5 kg)</b>	25-50 mcg at bedtime	Increase daily dose by 25 mcg every 1-2 weeks as needed and tolerated	0.2 mg	0.1, 0.2, 0.3 mg	Decrease daily dose by 20 to 30% every 2 to 3 days	Should be used nightly for insomnia, not intermittently
<b>Clonidine (age ≥4 years and weight &gt;40.5- 45 kg)</b>	25-50 mcg at bedtime	Increase daily dose by 25 mcg every 1-2 weeks as needed and tolerated	0.3 mg	0.1, 0.2, 0.3 mg	Decrease daily dose by 20 to 30% every 2 to 3 days	May cause a decrease in blood pressure, do not discontinue suddenly as severe rebound hypertension may occur
<b>Clonidine (age ≥4 years and weight &gt;45 kg)</b>	25-50 mcg at bedtime	Increase daily dose by 25 mcg every 1-2 weeks as needed and tolerated	0.4 mg	0.1, 0.2, 0.3 mg	Decrease daily dose by 20 to 30% every 2 to 3 days	Taper slowly over 1-2 weeks by decreasing dose every 2-3 days
<b>Trazodone (18 months to &lt;3 years)</b>	1-2 mg/kg/dose at bedtime. Max initial dose 25mg	Increase daily dose by 12.5-25 mg every 2 weeks	3 mg/kg/dose OR 100mg, whichever is lower***	50,100, 150, 300 mg	Decrease daily dose by 50 mg every 5 days	May be beneficial for patients with comorbid depression, but SSRIs remain first line treatment for depression and treating depression may alleviate insomnia
<b>Trazodone (3 years to 5 years)</b>	1-2 mg/kg/dose at bedtime. Max initial dose 50mg	Increase daily dose by 12.5-25 mg every 2 weeks	3 mg/kg/dose OR 150mg, whichever is lower***	50,100, 150, 300 mg	Decrease daily dose by 50 mg every 5 days	Has serotonergic activity at higher doses
<b>Trazodone (6 years and older)</b>	0.75-1 mg/kg/dose at bedtime OR 25-50 mg. Max initial dose is 50 mg.	Increase daily dose by 12.5-25 mg every 2 weeks	200 mg***	50,100, 150, 300 mg	Decrease daily dose by 50 mg every 5 days	Tolerance to sleep effects develop over time
<b>Mirtazapine</b>	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 Tolerance to sleep effects develop over time

<sup>1</sup>All medications are dosed in the evening before bed.

\*\*Melatonin is an over-the-counter preparation. Medicaid coverage of this product will depend upon specific manufacturer of each product.

Melatonin products are not FDA regulated and have been shown to contain varying amounts of active ingredient, especially gummy products.

\*\*\*Doses over 50mg are rarely beneficial, higher doses don't necessarily provide greater benefit.

## Medication Highlights:

### • Melatonin

- Melatonin is not a hypnotic agent and 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.
- Melatonin products are not regulated by the FDA and have been shown to contain varying amounts of active ingredients, including gummy products. Also, products may be contaminated with other 'sleep promoting' agents not on the label, like serotonin.
- Supplements that have obtained the following certifications undergo annual product testing to confirm ingredients and quantities match the product label and to look for the presence of contaminants (heavy metals, pesticides, microbes, etc).
  - United States Pharmacopoeia (USP) Verification
  - NSF Contents Certified
  - ConsumerLab Quality Certified
- Melatonin use may cause delayed onset of puberty. Discontinuation of melatonin after long term use may lead to precocious puberty.

### • 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 at low doses 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 peak effect of clonidine is approximately 3 hours and may lead to middle of the night waking in some patients. There is no evidence that extended release clonidine is any more effective than regular clonidine.
- Tolerance to clonidine can develop, which may necessitate increasing the dose.
- Patients on greater than the minimum dose should be tapered slowly off medications in this class.
- 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 doxepin 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.
- Antihistamines may cause paradoxical excitation in children, instead of the desired effect.
- **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.
- **Not recommended for treatment of insomnia in primary care.**

- **The following medications and classes are NOT recommended for the treatment of insomnia in children and adolescents.**

- Benzodiazepines
- Z-drugs such as eszopiclone (Lunesta®) and zolpidem (Ambien®)
- Quetiapine and other antipsychotics

### **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.
- If the sleeping difficulties do not improve after optimizing sleep hygiene and/or sleep aids are being considered as a treatment option.

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**Referrals and Consultations**

Online: [NationwideChildrens.org](https://NationwideChildrens.org)

Phone: (614) 722-6200 or (877) 722-6220

Fax: (614) 722-4000

Physician Direct Connect Line for 24-hour  
urgent physician consultations:

(614) 355-0221 or (877) 355-0221

Pharmacy Consultations/Assistance:

[PFKPharmacy@NationwideChildrens.org](mailto:PFKPharmacy@NationwideChildrens.org)



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