

OBJECTIVE

Clinicians in Alberta will know how to assess and diagnose insomnia; when insomnia can be effectively treated and/or managed in primary care using the tools and resources provided, and when referral to a [sleep physician](#) is required.

TARGET POPULATION

Adults

EXCLUSIONS

Children under the age of 18 years
Overnight/rotating shift workers

RECOMMENDATIONS

TYPES OF INSOMNIA

Note: Although definitions in this CPG are based on The Diagnostic and Statistical Manual of Mental Disorders (5th ed.; DSM-5; American Psychiatric Association, 2013),¹ there is no longer a definition of acute insomnia. For purposes of patients presenting with what was previously defined as acute insomnia, the following evidence-based definition will be used.

ACUTE INSOMNIA

Acute insomnia or adjustment insomnia is characterized as a sudden onset and a short course of insomnia, generally lasting less than three months. Patients present with difficulty initiating sleep, maintaining sleep, short duration of sleep, and/or poor sleep quality.

CHRONIC INSOMNIA

Chronic insomnia is characterized by difficulty initiating or maintaining sleep despite adequate opportunity for sleep, with associated distress or impairment of daytime functioning lasting three months or longer for at least three nights each week. Profiles of typical patients presenting with chronic insomnia include:

- Insomnia (without comorbidity)
- Insomnia with comorbidity:
 - Medical disorders
 - Psychiatric disorders
- Insomnia with another primary sleep disorder

ASSESSMENT/DIAGNOSIS (See algorithm in [Appendix A](#))

Note: There is currently no validated questionnaire to assist diagnosis of sleep disorders available in the public domain and for use by primary care physicians.

- ✓ Use the Sleep Disorders Assessment Questionnaire* (see [Appendix B](#)).
 - *Created for this clinical practice guideline (CPG) and based on expert opinion and other validated sleep disorders questionnaires used in clinical and research settings.
- ✓ Use the [Insomnia Severity Index \(ISI\)](#) to determine severity of the sleep disorder and to monitor the effect of treatment interventions (see sample in [Appendix C](#)).
- ✓ ALWAYS screen for sleep apnea.
 - Use Stop Bang Screening Questionnaire: <http://www.stopbang.ca/osa/screening.php>
<http://www.stopbang.ca/screen.php>.
- ✓ ALWAYS screen for depression/anxiety disorder (GAD-7/PHQ-9) available for free at: <http://www.phqscreeners.com/overview.aspx>.
- ✓ CONSIDER screening for other mental health conditions if relevant (Bipolar/ADHD).
- ✓ CONSIDER screening for other medical issues such as pain syndromes, and disease states in all other systems that can disrupt sleep.
- ✓ Ask the patient to keep a sleep diary (see [Appendix D](#)).
- ✓ Develop a treatment/management plan in collaboration with the patient once the type of sleeping disorder is diagnosed and the severity established.

TREATMENT/MANAGEMENT

PRACTICE POINT

It is important to provide the patient with the tools to manage their insomnia and to prevent or minimize the disturbance associated with future episodes.

ACUTE INSOMNIA

- ✓ Treat acute insomnia only if there is a substantial negative impact on daytime performance.
- ✓ Intervene early and suggest behavioral therapy such as cognitive behavioural therapy - insomnia (CBT-I).
- ✓ Consider using short term (e.g., two weeks) pharmacotherapy with close follow-up based on the severity and urgency of the presentation.
- ✓ Start medication at same time as CBT-I.
- ✓ Follow-up to monitor progress in two to four weeks. This timeframe is suggested and realistic for acute insomnia follow-up.

CHRONIC INSOMNIA

NON-PHARMACOLOGIC TREATMENT

- ✓ Manage chronic insomnia with CBT-I.
- ✓ Explore options for CBT-I programs within your primary care network (PCN) or in the community. If no CBT-I program is available, use CBT-I strategies.
- ✓ Use CBT-I or CBT-I strategies and emphasize the synergistic effect of combining CBT-I and medication for those patients who are using sedative/hypnotic medication.

PRACTICE POINT

CBT-I is the cornerstone of treatment for insomnia. When CBT-I is combined with medication it may produce faster improvements in sleep than CBT-I alone. If combining CBT-I and medication, after the initial phase, it is best to continue CBT-I while tapering/discontinuing medication.

PHARMACOLOGIC TREATMENT

- ✓ Start treatment with a short term prescription and arrange follow-up with the patient preferably for one to two weeks (but no longer than two to four weeks) to assess whether or not there is a need for continued treatment.
- ✓ Select an agent according to the type of insomnia and the presence of comorbidities:
 - Consider first line pharmacotherapy (those with strongest evidence for effectiveness, efficacy) – see [Table 2](#).
 - If considering second line pharmacotherapy (those with moderate/variable evidence for effectiveness) – see [Table 3](#).
- ✓ Consider off-label medications in specific clinical scenarios – see [Appendix F](#).
- X NEVER exceed the recommended dose.
- X DO NOT suggest over-the-counter (OTC) sleep aids or OTC medication with drowsiness as a side effect.
- ✓ Always provide quantity-limited prescriptions and no refills – this will motivate the patient to return for follow-up.
- ✓ Arrange follow-up to assess for adverse effects, dependence and tolerance to sedative/hypnotic medication.

PATIENT FOLLOW-UP

TYPICAL SEDATIVE USE

- ✓ Review if any emerging and other comorbidities exist (i.e., patient may be more amenable to admitting mental health issues on subsequent visits).

- ✓ Always reassess behavioural issues and reinforce the need to focus on behaviours not increase the medication dose.
- ✓ Use gradual tapering of the sedative/hypnotic to allow for an easier transition, less rebound insomnia and long term success.
 - A tapering regimen can vary depending on provider assessment, type of medication, and patient anxiety about discontinuation, but typically should last about two to six weeks. In some cases tapering may take several months but should be less than a year.
- ✓ Consider asking the patient’s pharmacist to design a tapering regimen.

LONGER TERM SEDATIVE USE

- ✓ If/when a long term sedative/hypnotic therapy is required:
 - Establish a rationale and chart it.
 - Maintain a stable dose.
- ✓ Schedule follow-up with the patient for refills ideally every three to four months to reassess the patient. (Note: if time frame is unrealistic in practice, follow-up can be extended but should not be longer than six months.)
- ✓ Monitor for:
 - Adverse effects
 - Comorbid conditions
- ✓ Reinforce the importance of behavioral therapy and practice.

PRACTICE POINT

The goal of follow-up should be to monitor acute insomnia for the development of chronic insomnia. Monitoring is necessary for all types of insomnia to detect sedative/hypnotic dependence and complicating factors such as other medical disorders, pain syndromes, etc.

REFERRAL

- ✓ Consider referral to a sleep physician or medical sleep centre for a more detailed assessment and possible sleep investigations for primary sleep disorder.
 - A listing of medical sleep centres is available for Alberta on the Canadian Sleep Society website link: <http://css-scs.ca/sleepclinics>.
- ✓ Consider referring to a sleep physician if the patient does not improve with CBT-I strategies ideally within six weeks (according to the literature) but realistically no longer than 12 weeks.
- ✓ Consider contacting a sleep physician remotely for advice in situations where sleep physicians are not locally available.

- ✓ Refer patients to local respiratory home care company for suspected obstructive sleep apnea (OSA) where a medical sleep centre/sleep physician is not available in local communities or wait times are long (i.e., ≥ 6 months).
- ✓ Select a respiratory company for patients with obstructive sleep apnea. The company should meet your standard of care and be aligned with your clinical judgement. For more guidance on selecting OSA in-home testing companies see: http://css-scs.ca/images/12835_blac.pdf.

SPECIAL POPULATIONS

OLDER ADULTS

- ✓ Non-pharmacological interventions are the preferred treatment option.
- ✓ Consider CBT-I before prescribing medication for both the short and long term management of insomnia.
- ✓ Take special care when prescribing sleep medications for older adults.
- ✓ If a medication is required, low dose doxepin (Silenor®) is considered safe for use in the elderly.
- ✓ Other options to consider are melatonin or a short acting GABA-A agonist (e.g., Sublinox®).
- ✓ Controlled hypnotic dosing for the long term (with appropriate monitoring and regular follow-up) may be a better option than a sudden discontinuation of a long term medication.
- X DO NOT use over-the-counter (OTC) medications (e.g., antihistamines) and patients should be advised against purchasing them.

PREGNANCY AND POST-PARTUM

- ✓ Use CBT-I for those patients with physical or mental health issues.

BENZODIAZEPINES (BZDs)

- ? Use of BZDs during pregnancy remains controversial at this time.
- ✓ If a BZD must be prescribed, lorazepam is preferred during pregnancy and lactation.

OTHER MEDICATIONS

- ✓ Limit use of non-benzodiazapine hypnotics (zopiclone, zaleplon, and zolpidem) or use with caution.

ANTIDEPRESSANTS

- ✓ If an antidepressant is required, nortriptyline is considered safe for use in pregnancy.
- ✓ Consider trazodone for reducing sleep-onset latency.

ADDITIONAL RESOURCES

- ✓ Find high quality current information regarding the use of medications during pregnancy and lactation at the following websites:
 - <http://toxnet.nlm.nih.gov>
 - www.reprotox.org
 - www.motherisk.org

BACKGROUND

Insomnia can be successfully managed in primary care with the appropriate tools to manage most common insomnia-related sleep complaints and advice on a strategy for referral. Referral to a sleep physician or medical sleep centre with a sleep laboratory is subject to availability and in some cases wait times are lengthy.

Insomnia is a significant health issue and common complaint among the general population. A survey of adult Canadians revealed that 19.8% were dissatisfied with their sleep, 13% had consulted a healthcare provider for sleep difficulties at least once in their lifetime, and family physicians were identified as the professional most frequently consulted (74%).² Daytime fatigue, physical discomfort and psychological distress were the most common reasons to seek help for sleep.³

Patients with insomnia describe difficulty falling asleep at bedtime, waking up during the night several times or for a long time, and/or waking too early. During the day, they frequently experience fatigue, irritability and poor concentration. These nighttime and daytime symptoms lead to distress and functional impairment.

Chronic insomnia increases the risk of subsequent mental health problems, including major depression, anxiety and substance use disorders.⁴⁻⁶ Chronic insomnia increases demand on health care resources including more visits to the family physician⁷ and can result in work disability.⁸ The indirect costs of insomnia in terms of lost productivity and absenteeism have been estimated to be 10 times greater than the direct costs of treating insomnia.⁹ It is therefore important to identify and treat insomnia in order to restore the patient's quality of life and to reduce the mental, physical and health-care burden.

EPIDEMIOLOGY

Insomnia is the most common sleep disorder. Estimates of prevalence will depend on the definition of insomnia used in epidemiological research. Recent estimates suggest that approximately 13% of adults in Canada experience chronic insomnia.² The prevalence among primary care patients is even higher than those with other co morbid conditions.¹⁰ Of patients attending family medicine clinics, 38-69% are likely to have insomnia.^{7, 11,12} Sleep complaints tend to persist, even if treated with hypnotic medication, illustrating how difficult insomnia can be to cure.¹³

RISK FACTORS

Age, female sex, and comorbid medical or psychiatric conditions are the most common risk factors for insomnia.^{2,14-16}

Insomnia prevalence increases with age. Middle-aged adults (aged 30-59) are nearly twice as likely to have insomnia than young adults (aged 18 to 29 years).² Older adults have high rates of insomnia for a variety of reasons, including medical problems that disrupt sleep as well as normal age-related changes in sleep.¹⁷ In a study of Australian general practices, 63% of patients age 60 and older reported sleep complaints.¹⁸

Females are 1.2 to 1.5 times more likely than males to report insomnia.² Insomnia incidence is higher among those with a first-degree relative (especially a mother) who has insomnia.¹⁹

In addition, social and environmental factors such as unemployment, low level of education, separation and divorce are associated with increased risk of insomnia.^{2, 20}

COMORBIDITIES – MEDICAL DISORDERS

PSYCHIATRIC

The comorbid, bidirectional relationship between insomnia and psychiatric conditions especially major depression, anxiety disorders and substance abuse is well established.^{4-6,20}

Insomnia should always be considered a comorbidity in these psychiatric conditions and addressed independently. This will improve the overall outcome for the patient.²²

PAIN

Studies suggest that pain perception can be altered by sleep quality. Pain threshold is lower following disrupted sleep. Sleep disruption leads to higher pain and stiffness ratings in arthritis patients the following day.²² For any type of chronic pain, flare-ups are likely to be followed by sleep disruption, which then leads to pain exacerbation in a vicious cycle.²⁴⁻²⁶

OTHER

There is a consistent, significant relationship between poor sleep and poor health.²⁷⁻³⁴ Heart disease, breathing problems, hypertension, neurologic disease, gastrointestinal problems, urinary problems, prostate problems, cancer, diabetes and chronic pain are all associated with poor sleep.^{27,28,32,33}

Physical disturbances such as chronic cough, shortness of breath, gastroesophageal reflux, chest pain and other common symptoms will be triggers for sleep fragmentation. Metabolic factors such as nocturnal glucose control, physical discomfort due to obesity, and hypercortisolemia will cause sleep disturbance. Pain associated with rheumatologic conditions, connective tissue disease and chronic inflammatory states will cause a state of hyper-arousal impeding normal sleep-initiating and maintenance factors. Nausea, pain and chemotherapy in cancer patients can contribute to sleep disturbance. Sleep is important for patients' quality of life and therefore if addressed can be highly beneficial to the patient.³⁵

ASSESSMENT

The essential elements of an insomnia diagnosis (as described in the DSM-5 [definition](#) below) are a complaint of difficulty initiating or maintaining sleep despite adequate opportunity for sleep, and associated distress or impairment of daytime functioning. For patients whose sleep complaint is consistent with this definition, an evaluation of sleep using a sleep diary is recommended. It is important to rule out other sleep disorders. Specific tools are discussed below (see [Useful Clinical Tools for Practice](#)).

DIAGNOSTIC CRITERIA

Note: for the purposes of clarity and simplicity, acute insomnia is differentiated from chronic insomnia in this CPG. Acute insomnia is common in practice but no longer defined as such in the DSM-5.

Insomnia disorder is the new DSM-5 terminology. The DSM-5 definition of an insomnia disorder is:

Dissatisfaction with sleep quality or quantity along with a complaint of difficulty initiating sleep (initial insomnia), maintaining sleep (middle insomnia) and/or waking up too early in the morning (late insomnia)

The DSM-5 criteria are:

The sleep disturbance causes clinically significant distress or impairment in functioning;

- It occurs at least three nights per week.
- It is present for at least three months.
- It occurs despite adequate opportunity for sleep.
- It is not better explained by another sleep-wake disorder.
- It is not attributable to the physiological effects of a substance.

Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia.

FOR THIS CPG THE FOLLOWING DEFINITIONS APPLY:

ACUTE INSOMNIA

Acute insomnia has also been known as short term or adjustment insomnia and is an abrupt onset of difficulty initiating and maintaining sleep that is associated with an identifiable trigger. It is **less than** three months in duration. Acute insomnia is most commonly the result of stressful event(s), environmental disturbances (such as noise, extreme temperatures or caring for a newborn), or a disruption of the sleep/wake cycle due to jet lag.

CHRONIC INSOMNIA

Chronic insomnia is defined as insomnia that has persisted for **at least** three months. Unlike acute insomnia, chronic insomnia is likely to be sustained by factors that are distinct from the initial triggers for the sleep difficulty. Although stressful life events are usually present when insomnia

begins, it is behavioural and cognitive factors that are believed to maintain the pattern of hyper-arousal and sleep difficulty. It is these factors that are the focus of effective interventions to reverse chronic insomnia.

COMORBID INSOMNIA

Insomnia often occurs with other sleep disorders, medical conditions, or psychological disorders. The relationship between the insomnia and the other condition is frequently bi-directional in that they both serve to re-enforce and worsen the other. Because of this interconnection, the term “secondary insomnia” that was formerly used to denote insomnia that occurred as a consequence of a medical or psychiatric condition, has been replaced by the term “comorbid insomnia.”²² If the insomnia is associated with another sleep disorder (e.g., obstructive sleep apnea), sleep physician assistance is required to address the other sleep disorder as a priority.

USEFUL CLINICAL TOOLS FOR PRACTICES

Currently there is no validated sleep disorders questionnaire for use in primary care and available in the public domain. The Sleep Assessment Questionnaire ([Appendix B](#)) may be useful to help distinguish insomnia from other common sleep disorders with similar symptoms. This tool was created specifically for this CPG based on expert opinion and other similar questionnaires used and validated in research settings.³⁶ It is currently not validated but will be undergoing validation in the near future. Until that time, it should be used to assist but not used exclusively to diagnose specific sleep disorders. Clinical judgement should be used to determine diagnosis.

Once a diagnosis of insomnia is made, the [Insomnia Severity Index \(ISI\)](#)³⁷⁻⁴⁰ (also in [Appendix C](#)) is a valid and reliable self-report measure of perceived insomnia severity. The ISI has been validated in a primary care setting and can be used to monitor the patient’s progress with treatment and help the primary care provider to make decisions regarding ongoing care and the need for referral.

The assessment of insomnia is summarized in the [algorithm](#) ([Appendix A](#))

A sleep diary such as the Consensus Sleep Diary⁴¹ in ([Appendix D](#)) is an expert consensus sleep diary and is the one suggested for use in order to reduce variability in sleep diaries. Sleep diaries are the standard clinical measure of insomnia and it is standard practice to have the patient complete a baseline sleep diary for one or two weeks.

The sleep diary is completed by the patient each morning to provide useful information about the patient’s sleep routine. The sleep diary is examined to determine variation in bedtimes and rise times so advice can be tailored appropriately. Subsequent sleep diaries can be compared to the baseline one. This diary estimates the range of bedtime and rise time, sleep onset latency, time awake after sleep onset, and time spent awake in bed.

DIFFERENTIAL DIAGNOSIS

Ensure that the sleep difficulty is, in fact, insomnia and not another condition presenting as insomnia. Similar sleep complaints can occur with a) other sleep disorders b) some medical conditions, and c) certain substances and medications.

Insomnia is usually accompanied by fatigue, not sleepiness. Patients who are sleepy are more likely to have another sleep disorder or comorbidity other than insomnia.

TREATMENT

Whether acute or chronic insomnia, the following non-pharmacologic and pharmacologic treatments may apply depending on the individual patient and circumstances.

[Sleep hygiene](#)-related education generally includes practices and environmental factors that may positively or negatively affect sleep (see [Appendix E](#) for patient resources). Although these strategies can be useful and effective for those with acute insomnia, they are ineffective as a monotherapy for chronic insomnia.

NON-PHARMACOLOGIC TREATMENT

COGNITIVE BEHAVIOURAL THERAPY FOR INSOMNIA (CBT-I)

Cognitive behavioural therapy for insomnia (CBT-I) is the treatment of choice especially for chronic insomnia^{13,41} and can also be used for acute insomnia depending on individual circumstances. The efficacy of this treatment is well established for adults with insomnia, including older adults and patients with comorbid conditions (such as chronic pain, depression, cancer).^{43,44}

CBT-I is a multi-component intervention that includes sleep restriction therapy (reducing time in bed in order to build up the homeostatic sleep drive), stimulus control therapy (strengthening the association between the bed and sleep), cognitive therapy (addressing key concerns about insomnia thereby reducing distress and arousal), and relaxation techniques (reducing physiological arousal).

CBT-I IN PRIMARY CARE

A comprehensive CBT-I program is considered the best approach. It is typically offered to patients as sessions once a week for four to eight weeks and conducted by a clinician trained in behavioural sleep medicine and is effective in the primary care setting when provided by a psychologist or a trained nurse.^{45,46} Many PCNs in Alberta now offer doctoral level psychologist services and/or CBT programs. It is important for primary care providers to inquire about the availability of CBT-I within their own PCN.

An abbreviated, two-session version of CBT-I can be effective for primary care patients⁴⁷ if a comprehensive CBT-I program is not available. There is preliminary evidence that an intervention consisting of sleep restriction alone, provided directly by the primary care physician in two sessions, may be helpful.⁴⁸

For most primary care providers in general practice, the time requirement to learn and offer CBT-I themselves is likely not feasible.

Until brief physician-administered methods have been adequately tested, or there are more behavioural sleep professionals on the primary care team, a reasonable compromise based on expert opinion is to offer some behavioural advice to patients based on the principles of CBT-I. See [Table 1](#).

CBT-I Strategy	Rationale
<ul style="list-style-type: none"> • Don't go to bed too early. Go to bed when you are sleepy. • Maintain a regular sleep schedule. • Minimize bright light before going to bed, including all technology. 	<ul style="list-style-type: none"> • Helps build up the homeostatic sleep drive, and counters the unproductive strategy of going to bed early in an attempt to gain more sleep
<ul style="list-style-type: none"> • Keep a constant rise time seven days a week, regardless of how little sleep you have had. • Wake up (and get out of bed) at the same time every day, including weekends. • Expose yourself to bright light in the morning to help wake up. 	<ul style="list-style-type: none"> • Strengthens the circadian rhythm of sleep regulation
<ul style="list-style-type: none"> • Your bed is for sleep. • Get out of bed when not sleeping. Go to another room. Return when sleepy. • Remove electronic devices from the bedroom. • Take time to unwind and relax before bed. 	<ul style="list-style-type: none"> • Strengthens the association of the bed and bedroom with sleep and sleepiness
<ul style="list-style-type: none"> • Relax the body using deep breathing, relaxation techniques or visualization. • Calm racing thoughts by: <ul style="list-style-type: none"> ○ Writing down worrisome issues and find temporary solutions for them so that you have dealt with them for the night ○ Using meditation (e.g., mindfulness) to calm the mind • Identify any sleep-related worries and make sure your thoughts are realistic and not catastrophic. • Do not check or watch the clock. 	<ul style="list-style-type: none"> • Relaxation exercises should be done in the early evening, not in bed. • Reduces hyper-arousal and makes it easier for sleep to arrive • Visual imagery can be used in bed to take the mind away from worry or racing thoughts.

Table 1: Strategies from CBT-I and the Rationale for Use

Note: Based on expert opinion

Treatment decisions should always be based on the clinician's assessment and clinically appropriate care plan. The clinician should also be aware that a combination of sleep medication and CBT-I can be beneficial, but the combination is not superior to CBT-I alone⁴⁹ and the reliance on sleep medication may be counterproductive to the principles of CBT-I. (Note: Further advice regarding tapering of sedatives when combined with CBT-I is found in the [pharmacology section](#).)

Both comorbid insomnia and insomnia without comorbidities require early intervention. Although treating/managing the comorbid condition is important, there is no reason to postpone insomnia treatment until the other condition has resolved. Treatment of comorbid insomnia may even improve the comorbid condition itself. For example, CBT-I can lead to a reduction in depression severity.^{50,51}

IN-PRINT CBT-I RESOURCES

Additional hard copy resources for the physician and patient can be found in [Appendix E](#).

ON-LINE CBT-I PROGRAMS

Several online CBT programs have been developed for insomnia that can be effective for patients in lieu of in-person CBT-I programs/counselling in the primary care setting.

There are some disadvantages including costs associated with accessing these programs, determining whether or not they are evidence-based and/or have the necessary components required for effective treatment.

The following programs are evidence-based (randomized control trials), effective and recommended for use with patients:

- <https://app.shuti.me/modules/8>
- <http://www.sleepio.com>

A leaflet ([CBT for Insomnia](#)) prepared for physicians by Dr. David Gardner is available at: <http://medicationinfoshare.com>. It includes online CBT-I programs recommended for use with patients and also a comprehensive review of several online insomnia resources and services as of the publication date (2014).

PHARMACOLOGIC TREATMENT

Pharmacotherapy should be considered an adjunctive therapy to cognitive and behavioural therapies in the comprehensive management of insomnia for both acute and chronic insomnia. In cases of short duration, mild to moderate insomnia where the clinician feels the patient is highly motivated, CBT-I should be the preferred method of treatment.

In the case of combined therapy (CBT-I and medication) the goals are to prevent dependence on medication and successfully use CBT-I. A small study indicated that the best sequence is to introduce CBT-I before, or concurrent with medication.⁵² A recent study suggests that CBT-I combined with medication may produce faster improvements in sleep than CBT-I alone.⁵³ If combining CBT-I and medication, after the initial phase, it is best to continue CBT-I while discontinuing medication.⁵⁴

When insomnia is acute and/or when sleep restriction is not well tolerated, or if the patient is not sufficiently motivated or psychologically minded, medication may play a more central role to improve the effectiveness of the treatment program. However, the clinician should be aware that even short term and low dose medication requires close follow-up to minimize dependence (psychological and physical), prevent tolerance and improve the efficacy of the medication taper.

Comorbid insomnia may also require more frequent use of adjunctive medication. The presence of comorbidities associated with insomnia may require different, sometimes off label, sedative medication. This will be necessary to treat the comorbidity or the comorbidity plus the insomnia, while CBT-I can address the insomnia complaint. This does not imply that medication in co-morbid insomnia is a replacement for CBT-I. The efficacy of CBT-I has been demonstrated in co-morbid populations as a recent meta-analysis suggests.⁵⁵

In the context of chronic insomnia, nightly administration has been shown to be safe and effective (without dose escalation) for certain agents (i.e., zolpidem⁵⁶ for periods of up to one year. Intermittent dosing (three to five doses per week) is thought to be ideal for long term administration of certain agents, but there are no data to suggest that this approach reduces the possibility of tolerance or reduces the incidence of side effects.⁵⁷

PRINCIPLES OF TREATMENT

Pharmacotherapy should be initiated at the lowest effective dose and for short-term duration-ideally for one to two weeks based on most studies. However, in reality this short duration may not be acceptable to patients or effective. Therefore it is reasonable to provide medication for up to, but no longer than one month's duration otherwise there is a risk of patient dependency on the drug.

Although long-term use of hypnotic agents is discouraged due to the potential for tolerance and dependence with many agents, there are specific situations and circumstances with resistant and comorbid insomnia (severe or refractory insomnia resistant to CBT-I, high burden of medical or psychiatric comorbidities) under which long term use of hypnotics may be appropriate.

In these cases, follow-up and re-assessment are needed on a regular basis to ensure that comorbidities do not emerge and that tolerance and dependence is not occurring. Principles of behavioural management should always be the focus, even if the patient is on medication. Tapering and discontinuing medications should be attempted when the comorbidity is successfully treated.

Tolerance and dependence may have physical dimensions (i.e., benzodiazepines), but psychological dependence can occur as well, even with agents with no or limited evidence for physical dependence.

THERAPEUTIC OPTIONS

The evidence supporting therapeutic medication options is limited, and of the available evidence, the methodology is questionable and/or study cohort numbers are small. There are no strong randomized control trials (RCTs) or systematic reviews that allow for definitive recommendations. However, the following information is provided based on expert opinion/consensus, other guidelines and/or drug monograph information for clinicians to use when making clinical judgements.

Clinicians prescribing medications for insomnia need to take into account the known efficacy, safety, duration of action of the drug, and adverse effects, as well as patient history of substance abuse or dependence. The principles of CBT-I should always be stressed in some form, even if patient is on medication.

See [Table 2](#)

Medication/Drug Classification	Suggested Dosing	Considerations
zopiclone (Imovane®) <i>Non-BZD</i> <i>Specific GABA_A agonist</i>	3.75 – 7.5mg (Max 5.0 mg for elderly; pt with kidney/liver disease or taking other medications)	<ul style="list-style-type: none"> • Should allow at least eight hours in bed • Metallic after-taste most common adverse reaction • Complex sleep related behaviors can be induced • Risk of physical tolerance and dependence
zolpidem (Sublinox®) <i>Non-BZD</i> <i>Specific GABA_A agonist</i>	5 - 10 mg	<ul style="list-style-type: none"> • Less chance of morning hang-over effect • Rapid onset of action • Should allow at least eight hours in bed • Complex sleep related behaviors can be induced • Risk of physical tolerance and dependence
doxepin (Silenor®) tricyclic (H1 antagonist)	3 - 6 mg	<ul style="list-style-type: none"> • Indicated only for sleep maintenance • No fall risk or cognitive side effects seen • Minimal risk of physical tolerance/ dependence • Higher doses doxepin appear to have traditional TCA side effect profile^{58,59}
temazepam (Restoril®) BZD Non-Specific GABA _A agonist	15 - 30 mg	<ul style="list-style-type: none"> • Risk of physical tolerance and dependence • Intermediate half-life carries a low-moderate risk of morning hang-over
Note: flurazepam, oxazepam, triazolam are indicated for, but not recommended for primary insomnia		
trazodone (Desyrel®) phenylpiperazine 5-HT ₂ /H ₁ antagonist	25 - 100 mg	<ul style="list-style-type: none"> • Short half-life provides lower risk of morning hang-over effect • Minimal risk of tolerance/dependence • Risk of orthostatic hypotension • Rare risk of priapism and cardiac conduction issues • Multiple mechanisms of promoting sleep
Additional information to aid decision making regarding Z-drugs can be found at Alberta College of Family Physicians Tools for Practice: https://www.acfp.ca/tools-for-practice/articles/details/?id=126&title=Z-drugs+for+sleep%3A+Should+we+%E2%80%9CCatch+Some+Z%E2%80%99s%E2%80%9D%3F		

Table 2: Commonly Used Medications

Agent	Suggested Dose	Considerations
Melatonin*	0.3-5mg	<p>Some evidence of:</p> <ul style="list-style-type: none"> Increased effectiveness in older patients but higher risk of adverse effects such as daytime sleepiness in amounts >4mg⁶⁰ shift workers, jet lag, delayed sleep phase. Modest effect overall. <p>Need to determine use of melatonin, i.e., shift circadian rhythm? If yes take lower dose four to five hours before bed. If used as a hypnotic take 30-90 min before bed.</p> <p>No apparent physical tolerance and dependence</p> <p>Purity of source is often questionable.</p> <p>Only mild adverse effects for general population, such as dizziness, headache, nausea and sleepiness have been reported in studies to date.⁶⁰</p>
L-Tryptophan	500mg to 2g	Conflicting evidence of benefit
Valerian	400-900 mg	<p>Some evidence suggesting effect in insomnia, especially in menopause and for medical illness.⁶¹</p> <p>Purity of source is often questionable</p>
<p>*Additional information to aid decision making regarding Melatonin can be found at Alberta College of Family Physicians Tools for Practice https://www.acfp.ca/tools-for-practice/articles/details/?id=120&title=Melatonin+for+sleep%3A+Exhausted+by+other+options%3F</p>		

Table 3: Non-prescription “Natural” Agents

OVER-THE-COUNTER (OCT) AGENTS

Diphenhydramines (Benadryl®, Sleep Eze®, Simply Sleep®, Nytol®, Unisom®), dimenhydrinate (Gravol®) and doxylamine (Unisom 2®) should not be prescribed to patients because of the potential harms that may outweigh benefits. All have potentially serious side effects arising from anticholinergic properties, especially in elderly. Rapid tolerance and cognitive impairment may occur.

OFF LABEL AGENTS

Numerous medications have sedating side effects such as sedating antidepressants, antihistamines, anticonvulsants, anti-psychotics, other benzodiazepines and muscle relaxants. These drugs should not be used as sleep agents for insomnia alone because of lack of evidence, as well as harms that could outweigh the benefit. These agents may be helpful if the patient has insomnia in addition to another significant comorbid condition for which the medication is being prescribed. See [Appendix F](#) for additional information.

SPECIAL POPULATIONS

OLDER ADULTS

Elderly patients present particular challenges with insomnia. The aging process reduces the robustness of the sleep state and this combined with an increased likelihood of medical and mental health comorbidities, polypharmacy, drug interaction with sedative/hypnotic medication and the

potential for cognitive impairment due to sedating medication all require special attention when treating the elderly who present with insomnia.

CBT-I has been shown to be superior to medication in the short and long term management of insomnia in older adults⁸ as in other populations. It has been shown to be as successful in older adults as it is in younger adults.⁶²⁻⁶⁴

Special care must be taken when prescribing sleep medications for older adults due to the potential for increased falls, drug interactions, and increased potency.⁶⁵ For these reasons, non-pharmacological interventions are the preferred treatment option. If a medication is to be used, the safest and best studied sleep medication for use in the elderly is Silenor.^{61,66,67} Other medications that can be considered are melatonin or a short acting GABA-A agonist such as Sublinox.⁴²

PREGNANT AND LACTATING WOMEN

TREATMENT OF INSOMNIA DURING PREGNANCY AND POSTPARTUM

It is important to screen for a physiological sleep disorder, a medical condition or a psychiatric illness that may be affecting sleep during pregnancy or postpartum. The patient's sleep may be affected by their use of caffeine, alcohol and nicotine. Child care without adequate spouse/ family support can also result in sleep deprivation.

NON-PHARMACOLOGIC TREATMENT

There are no studies examining the efficacy of CBT-I during pregnancy and the postpartum period but based on expert opinion and experience, CBT-I principles can be effective and if available used as a first approach to managing insomnia based on the patient's individual situation. CBT-I can be used, even in those patients for whom physical or mental health factors play a role.

Women often believe their insomnia is negatively impacting their baby's growth and development. This can be addressed using CBT-I and there is no evidence that, in the absence of other medical or psychiatric factors, insomnia results in fetal damage. Primary care providers should normalize the sleep disturbance and minimize the anxiety for these women.

PHARMACOLOGIC TREATMENT IN PREGNANCY AND POSTPARTUM

Most women resist using sleep medication while pregnant or breastfeeding. However, when insomnia is having a severe impact, the use of a sleep aid may be warranted.

Benzodiazepines (BZDs) are frequently used to treat insomnia in the general population but their use in pregnancy remains controversial until more conclusive data regarding adverse effects is available. Studies to date suggest that use of BZDs and the hypnotic benzodiazepine receptor agonists (HBRAs) (Zopiclone, Zaleplon and Zolpidem) may cause adverse pregnancy outcomes such as low birth weight infants, preterm deliveries, SGA infants, and cesarean delivery, albeit of marginal significance and confounding factors not accounted for in these studies.⁶⁸ However, these drugs no longer appear to have the strong teratogenic potential as once thought.⁶⁹⁻⁷¹

If a BZD must be prescribed, lorazepam is preferred during pregnancy since it lacks active metabolites and is less likely to be associated with a withdrawal syndrome in the neonate. Regarding breastfeeding, lorazepam has low levels in breast milk and does not appear to cause any adverse

effects in breastfed infants with usual maternal dosages. Of sixty-four mothers who reported taking lorazepam while breastfeeding, none reported sedation in the infant.⁷²

The tricyclic antidepressant nortriptyline has considerable sedating properties but does not appear to have major teratogenic effects and is considered safe for use in pregnancy.⁷³ As with other antidepressants, there is a risk of neonatal (withdrawal) adaptation syndrome, a transient syndrome in most cases, and not associated with long term neurodevelopmental delays in the neonate/child.⁷⁴ When used during lactation, infants exposed through breast milk have low or undetectable concentrations of nortriptyline and its metabolites.⁷⁵

The antidepressant trazodone may be beneficial for reducing sleep-onset latency.⁷⁶ No difference in pregnancy outcome (including rate of major malformations and gestational age at birth) has been reported among patients taking trazodone during the first trimester when compared with women taking other non-teratogenic antidepressants or other non-teratogenic drugs (e.g., sumatriptan, dextromethorphan), matched for age, smoking, and alcohol use.⁷⁶ Although both antidepressant groups had a trend toward a higher rate of spontaneous abortion, the difference was not statistically significant.

According to a review published in 2015, there is a paucity of human studies supporting either clinical benefit or risk of adverse events with use of exogenous melatonin in pregnancy. The authors suggest avoiding use of melatonin until more data is forthcoming.⁶⁰

Excellent quality and current information regarding the use of medications during pregnancy and lactation is available at the following websites.

- <http://toxnet.nlm.nih.gov>
- www.reprotox.org
- www.motherisk.org

There is also an excellent review paper by Okun et al,⁷⁷ addressing sleep-promoting medications during pregnancy for more detailed information.

PATIENT FOLLOW-UP

OVERVIEW

Providing structured follow-up is critical for successful management of insomnia. This includes:

- Primary care provider support is available to enhance the effectiveness of behavioural therapy (CBT-I) especially if the patient is using a self-help format.
- Medication is monitored to identify adverse effects, possible dependence, tolerance, progress and improved outcome.
- Sedative/hypnotics are tapered appropriately (if prescribing).
- Emerging comorbidities are detected (e.g., psychiatric, substance abuse, pain, medical disorders) that may affect the sleep issue and undermine the therapeutic process.

Once a diagnosis of insomnia has been made, the treatment plan must be structured in the context of ongoing follow-up. Follow-up is critical to the efficacy of the treatment interventions and the long term success of the treatment plan. This must also be explained to the patient as an expectation from the outset.

While the efficacy and effectiveness of follow-up has not been specifically studied for insomnia management, follow-up has been established as necessary for successful behavioural treatment programs for many chronic conditions similar to insomnia. For example, managing mental health conditions requires structured follow-up to monitor symptoms and side effects, and for education and therapeutic support.⁷⁸ Most physicians would agree that regular follow-up allows for better assessment of the patient's motivation to pursue and/or monitor success with behavioural treatment for their insomnia; minimize dependence on medication or having professional support to improve their insomnia if the patient is not taking medication. Regular follow-up also allows the primary care provider to assess if the current medication or pharmacotherapy itself is a suitable treatment option.

In the case of combined therapy for insomnia (CBT-I and medication) it is very important to follow-up and not to prescribe medication for more than two weeks in the case of acute insomnia and four to six weeks in the case of chronic insomnia so that appropriate follow-up and reassessment takes place with the prescribing physician. This allows for better monitoring of medication use, identifying side effects and adverse effects, and efficacy of the treatments. This is the only approach that can minimize long term dependence on medication. Although follow-up has not been specifically studied as a predictor of outcome, adherence has been studied as a predictor of outcome albeit the data is limited.⁷⁹

FREQUENCY OF FOLLOW-UP AND DURATION OF FOLLOW-UP VISITS

There is no evidence on the number or frequency of follow-up visits, or time spent with patients during a follow-up visits. The frequency of follow-up and time spent with patients is determined by the capacity of the primary care practice. The suggestions provided in this CPG are based on expert opinion and experience.

An in-office follow-up visit of 10 to 15 minutes of time (using the monitoring tools suggested) is considered adequate and believed to make the process more efficient and effective.

Although follow-up every two weeks is preferred, scheduling the patient once within one month in the first six to eight weeks of treatment is acceptable and likely more realistic given the availability and demand on primary care providers. Once the insomnia is stabilized, follow-up can be extended and scheduled once within six months for a year or longer if required. This will establish a pattern of stability or pattern of recurrence of symptoms that will help the **primary care provider** better manage the insomnia over the long term.

Physicians can follow their patients in creative ways that do not necessitate an in-person office visit. Some physicians use technology (i.e., email, phone) and/or other allied health professionals available in their practices to provide successful follow-up under the direction and support of the physician (i.e., as in many PCNs in Alberta). As with mental health follow-up, these resources should be maximized in the treatment of insomnia.

Finally, the **PRIMARY CARE PROVIDER** should never prescribe sleep medication without follow-up as it is critical to assess that the medication is resolving the problem and/or determine if there is a risk of dependence developing.

REFERRAL

Referral should be considered when there is a sleep disorder that cannot be diagnosed or treated in the primary care setting, or a patient presents with a complex sleep-related problem requiring a more detailed assessment. Referral should also be considered after a reasonable length of time receiving treatment with little to no change or the condition is getting worse. Based on expert opinion and experience, about a six to twelve week trial of treatment is reasonable before considering referral. These decisions are also based on access to expert assessment with a sleep physician.

In Alberta, referral also requires a decision about whether or not sleep studies are necessary. In cases where it is clear that the patient has a high pretest probability of obstructive sleep apnea arranging a home-based sleep apnea study through the local respiratory company is quite reasonable and may result in a simple solution.

REFERRAL SOURCES AVAILABLE IN ALBERTA

SLEEP PHYSICIAN

In Alberta there are two types of sleep physicians; those who are trained in a fellowship sleep medicine program and have passed board exams in sleep medicine and those who have extra training in sleep medicine and have met the criteria designated by the College of Physicians and Surgeons of Alberta as physicians with a “special interest in sleep medicine.” Sleep physicians in Alberta may or may not be affiliated with a sleep centre that has a sleep laboratory and can do in-lab sleep investigations. The primary care provider should be aware of the resources available in their community.

Primary care providers referring patients to a sleep physician should expect the following:

- Assess, examine and treat/manage complex, resistant and specific sleep disorders
- Work collaboratively with the patient to manage and/or resolve sleep issues.
- Use appropriate technology for testing/diagnosing and treating sleep disorders.
- Ensure the referring physician is informed and consulted in each step of the process.

IN-LAB VS IN-HOME SLEEP STUDIES OFFERED IN ALBERTA

In Alberta referral to a sleep physician will include an assessment as to whether or not an in-lab or in-home sleep study is necessary for the patient. These sleep studies are defined as:

In-lab sleep studies: overnight testing in a medical sleep centre with an accredited health care professional (sleep technologist) in attendance under the direction of a medical director who is a sleep physician. These are community based diagnostic facilities that are accredited by the college of physicians and surgeons of Alberta or they are hospital based facilities. Level I sleep studies are comprehensive neurophysiological studies that are designed to objectively evaluate the patient’s

sleep state (sleep stages/parameters), respiratory/cardiovascular and neuromuscular parameters in sleep.

In-home sleep studies: conducted at the patient's home and are unattended sleep studies. In-home sleep studies are specifically designed to diagnose only obstructive sleep apnea in those patients with a moderate to high pretest probability of having sleep-disordered breathing. Guidelines for in-home tests can be found in the Canadian Thoracic Society (CTS) 2011 Guideline Update: Diagnosis and treatment of sleep disordered breathing:

http://www.respiratoryguidelines.ca/sites/all/files/cts_sleep_guideline_update_2011.pdf

MEDICAL SLEEP CENTRES IN ALBERTA

Referral to a medical sleep centre for a comprehensive sleep assessment with a sleep physician is at the discretion of the primary care provider and should be based on the following criteria:

- Another primary sleep disorder is suspected such as: obstructive sleep apnea, a movement disorder in sleep, a parasomnia or complex comorbid insomnia.
- The primary care provider has attempted a reasonable time frame, e.g., at least a six to twelve week trial of treatment with limited to no success.
- The primary care provider has specific concerns that require additional expertise to evaluate the patient's problem.
- The primary care provider should ensure that the sleep centre has the expertise to manage the patient's sleep disorder.

AHS-operated in-lab medical sleep centres with sleep physicians are available in the following AHS hospitals: Lethbridge Regional, Foothills Medical Centre, the Edmonton General Hospital and Wetaskiwin Hospital and Care Centre. Sleep investigations in AHS facilities are provided under the AHS global budget therefore patients do not pay for sleep studies but are required to pay for CPAP or any other equipment required for treatment. The wait time for consultation and sleep studies varies among AHS facilities. A non-urgent referral to one of their urban sleep centres ranges from several weeks to more than one year. (For Foothills Medical Centre referral form and approximate wait times see <http://www.albertahealthservices.ca/info/Page5046.aspx>.)

Community-based non-AHS operated in-lab medical sleep centres are available in Calgary and Edmonton. These facilities are accredited by the College of Physicians and Surgeons of Alberta. Although the cost of consultation is covered, sleep studies are not covered under the Alberta Health Fee Schedule therefore the cost, in these facilities, is passed on to the patient. Third party insurance plans may or may not cover the costs of the sleep studies and equipment required for treatment. The wait time for consultation and sleep studies in community-based medical sleep centres is four to six weeks.

Accredited medical sleep centres located in Alberta (AHS-operated and medical sleep centres in the community) are listed on the Canadian Sleep Society website link: <http://css-scs.ca/sleepclinics>

RESPIRATORY HOME CARE COMPANIES (CPAP)

It is important to distinguish between a medical sleep centre and services offered by respiratory CPAP companies.

Most respiratory companies and respiratory therapists assess obstructive sleep apnea and use in-home sleep studies.

According to the Canadian Thoracic Society recommendations⁷⁸ patients who are considered unsuitable for assessment with in-home sleep studies are those with:

- A potential for central sleep apnea (i.e., chronic heart failure, opiate medication or strokes)
- Significant issues with cardiovascular and pulmonary systems
- Significant comorbid medical, psychiatric sleep disorders
- Chronic or resistant insomnia⁸⁰

The primary care provider is encouraged to explore resources available in their area and assess the quality of the patient care to get the best possible outcome for their patients.

IMPLEMENTATION CONSIDERATIONS

In order to improve uptake of this CPG following dissemination and over time, the following suggestions are offered to primary care providers:

- Consider flagging patients with sleep disorders in your EMR or the patient's medical record and attach a link to this guideline and/or the tools and resources that can assist in diagnosing, treating and managing these patients.
- For those PCPs who have clinic teams, consider familiarizing them with the CPG useful clinical tools so they can assist you. For example, clinic staff can print the sleep questionnaire, have the patient complete it and tally the results; clinic staff can print and disseminate patient educational information that can be found on the TOP CPG Insomnia [web page](#).
- The experts who developed the CPG content will explore opportunities to present the CPG to PCPs at relevant medical events over time to reinforce the key messages and promote the information and educational resources included in the CPG.

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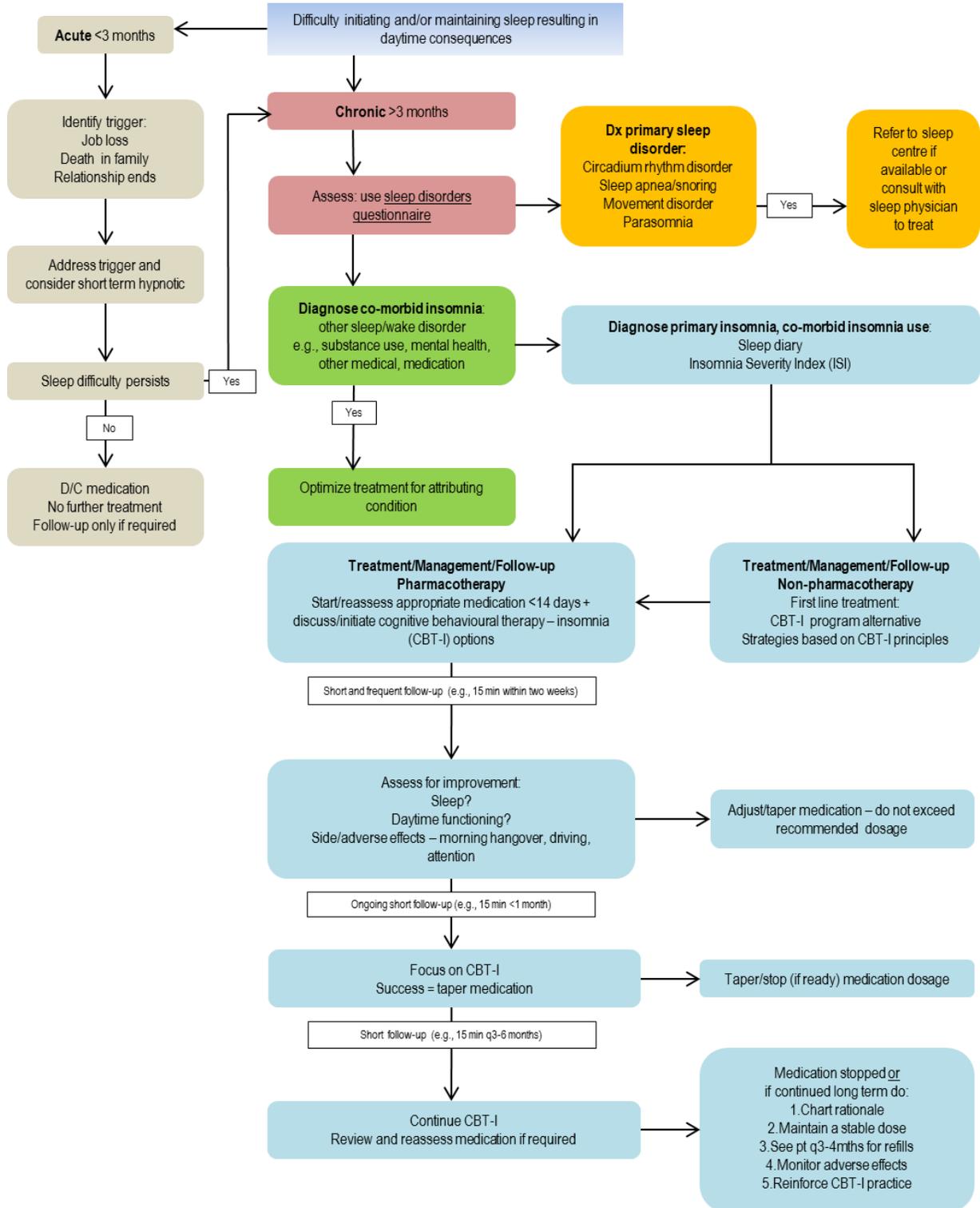
GUIDELINE COMMITTEE

The committee consisted of representatives of family medicine (with sleep interest/specialty), psychiatry, psychology and health policy research.

December 2015

APPENDIX A

Algorithm: Assessment to Management of Adult Insomnia



APPENDIX B

SLEEP DISORDERS QUESTIONNAIRE

This questionnaire is a screening tool for physicians to assist their clinical evaluation of insomnia. It can be used to screen for a sleep disorder. (For a printable version visit

<http://www.topalbertadoctors.org/cpgs/8640793>.)

The physician should perform a more detailed clinical evaluation and/or refer to specialist when appropriate.

Sleep Questionnaire		Grading Scale				
Circle one of the following for each question:		Never	Rarely	Occasionally	Most Nights/Days	Always
1	Do you have trouble falling asleep?	1	2	3	4	5
2	Do you have trouble staying asleep?	1	2	3	4	5
3	Do you take anything to help you sleep?	1	2	3	4	5
4	Do you use alcohol to help you sleep?	1	2	3	4	5
5	Do you have any medical conditions that disrupt your sleep?	1	2	3	4	5
6	Have you lost interest in hobbies or activities?	1	2	3	4	5
7	Do you feel sad, irritable, or hopeless?	1	2	3	4	5
8	Do you feel nervous or worried?	1	2	3	4	5
9	Do you think something is wrong with your body?	1	2	3	4	5
10	Are you a shift worker or is your sleep schedule irregular?	1	2	3	4	5
11	Are your legs restless and/or uncomfortable before bed?	1	2	3	4	5
12	Have you been told that you are restless or that you kick your legs in your sleep?	1	2	3	4	5
13	Do you have any unusual behaviours or movements during sleep?	1	2	3	4	5
14	Do you snore?	1	2	3	4	5
15	Has anyone said that you stop breathing, gasp, snort, or choke in your sleep?	1	2	3	4	5
16	Do you have difficulty staying awake during the day?	1	2	3	4	5

See next page for guide to interpreting the questionnaire.

GUIDE TO INTERPRETING THE INSOMNIA SCREENING QUESTIONNAIRE

DIAGNOSTIC DOMAINS:

- 1) Insomnia: Q1-5
- 2) Psychiatric disorders: Q6-9
- 3) Circadian rhythm disorder: Q10
- 4) Movement disorders: Q11-12
- 5) Parasomnias Q13

GENERAL GUIDELINES FOR INTERPRETING THE GRADING SCALE

- 1) Grading 3, 4 or 5 on any question – the patient likely suffers from insomnia. If they answer 3, 4 or 5 for two or more items and have significant daytime impairment the insomnia requires further evaluation and management.
- 2) Grading 4 or 5 on questions 6-9 require further screening for psychiatric disorders. Question 9 refers to somatization and may reflect an underlying somatoform disorder which requires specific treatment.
- 3) Grading 4 or 5 on question 10 may be a circadian rhythm disorder. Further questioning about shift work or a preference for a delayed sleep phase should be done.
- 4) Grading 4 or 5 on question 11 or 12 is significant and likely contributing to the patient's symptoms of insomnia or non-restorative sleep. Question 11 refers to restless legs syndrome and question 12 refers to periodic limb movement disorder.
- 5) Grading 2-5 on question 14 should raise concern especially if the event or movement is violent or potentially injurious to the patient or bed partner.
- 6) Grading 4 or 5 on question 14 or 15 alone require further clinical evaluation for sleep apnea. Grading above 3 on questions 14 and 15 or 14 and 16 is also suspicious for sleep apnea and further evaluation should be done.

APPENDIX C

INSOMNIA SEVERITY INDEX

http://www.deploymentpsych.org/system/files/member_resource/Insomnia%20Severity%20Index%20-ISI.pdf

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the ‘Guidelines for Scoring/Interpretation’ below to see where your sleep difficulty fits.

For each question, please CIRCLE the number that best describes your answer. Please rate the CURRENT (i.e., LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4
4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?	Very Satisfied	Satisfied	Moderately Satisfied	Dissatisfied	Very Dissatisfied
	0	1	2	3	4
5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life? Not at all	Noticeable	A little	Somewhat	Much	Very Much Noticeable
	0	1	2	3	4
6. How WORRIED/DISTRESSED are you about your current sleep problem? Not at all	Worried	A Little	Somewhat	Much	Very Much Worried
	0	1	2	3	4
7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g., daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?	Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
	0	1	2	3	4

GUIDELINES FOR SCORING/INTERPRETATION:

Add the scores for all seven items (questions 1+2+3+4+5+6+7) = ___ your total score

TOTAL SCORE CATEGORIES:

- 0-7 = No clinically significant insomnia
- 8-14 = Sub-threshold insomnia
- 15-21 = Clinical insomnia (moderate severity)
- 22-28 = Clinical insomnia (severe)

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APPENDIX D

SLEEP DIARY

Printable Sleep Diary (visit: <http://www.topalbertadoctors.org/cpgs/8640793>)

GENERAL INSTRUCTIONS FOR PATIENT

What is a Sleep Diary? A sleep diary will gather information about your daily sleep pattern.

How often and when do I fill out the sleep diary? Complete your sleep diary every day and it is best to complete it within one hour of getting out of bed in the morning.

What should I do if I miss a day? If you forget or are unable to finish recording each section, leave the diary blank for that day.

What if something unusual affects my sleep or how I feel in the daytime? If your sleep or daytime functioning is affected by some unusual event (such as an illness, or an emergency) make a note in the “comments” section of your diary.

What do the words “bed” and “day” mean on the diary? This diary is for people who are awake or asleep at unusual times. The word “day” means the time of day when you choose or must wake up. The term “bed” means the place where you usually sleep.

Will answering these questions about my sleep keep me awake? This is not usually a problem. Do not worry about exact times and do not watch the clock. Just provide your best estimate.

ITEM INSTRUCTIONS

Use the guide below to help you fill in each item of the Sleep Diary.

Date: Write the date of the morning you are filling out the diary.

What time did you get into bed? Write the time that you got into bed. This may not be the time that you began “trying” to fall asleep

What time did you try to go to sleep? Record the time that you began “trying” to fall asleep

How long did it take you to fall asleep? Beginning at the time you wrote in question 2, how long did it take you to fall asleep.

How many times did you wake up, not counting your final awakening? How many times did you wake up between the time you first fell asleep and your final awakening?

In total, how long did these awakenings last? What was the total time you were awake between the time you first fell asleep and your final awakening. For example, if you woke 3 times for 20 minutes, 35 minutes, and 15 minutes, add them all up (20+35+15= 70 min or 1 hour and 10 min).

What time was your final awakening? Record the last time you woke up in the morning.

What time did you get out of bed for the day? What time did you get out of bed with no further attempt at sleeping? This may be different from your final awakening time (e.g., you may have woken up at 6:35 a.m. but did not get out of bed to start your day until 7:20 a.m.)

How would you rate the quality of your sleep? “Sleep Quality” is your sense of whether your sleep was good or poor.

Comments: If you have anything that you would like to say that is relevant to your sleep, write it here

SAMPLE

ID/Name: John Doe

Today's date	Mon Nov 5 2014				
1. What time did you get into bed?	10:15 p.m.				
2. What time did you try to go to sleep?	1 :30 p.m.				
3. How long did it take you to fall asleep?	55 min				
4. How many times did you wake up, not counting your final awakening?	3 times				
5. In total, how long did these awakenings last?	1 hour 10 min				
6. What time was your final awakening?	6:35 a.m.				
7. What time did you get out of bed for the day?	7:20 a.m.				
8. How would you rate the quality of your sleep?	<input type="checkbox"/> Very poor <input checked="" type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good
9. Comments (if applicable)	I have a cold				

Permission to use the Consensus Sleep Diary is restricted to clinical use only. Research use requires permission from first author. Carney CE et al. Sleep 2012;35(2):287-302.

APPENDIX E

PHYSICIAN RESOURCES

Insomnia: A Clinical Guide to Assessment and Treatment – Charles M. Morin and Colin a. Espie

Overcoming Insomnia: A Cognitive-Behavioural therapy Approach Therapist Guide – Edinger & Carney
<http://www.amazon.ca/Insomnia-clinical-guide-Assessment-Treatment/dp/0306477505>

PATIENT RESOURCES

Quiet Your Mind and Get to Sleep: Solutions to Insomnia for Those with Depression, Anxiety or Chronic Pain – Colleen Carney Rachel Manber and Richard Bootzin <http://www.amazon.ca/Quiet-Your-Mind-Get-Sleep/dp/1572246278>

Overcoming Insomnia A Cognitive-Behavioural Therapy Approach - Edinger & Carney
<http://www.amazon.ca/Overcoming-Insomnia-Cognitive-Behavioral-Approach-Workbook/dp/0195365909>

Sink into Sleep: A Step-by-Step Workbook for Reversing Insomnia – Judith R. Davidson
<http://www.amazon.ca/Sink-into-Sleep-Step-Step/dp/1936303388>

The Insomnia Workbook: A Comprehensive Guide to Getting the Sleep You Need Paperback – Stephanie Silberman <http://www.amazon.ca/The-Insomnia-Workbook-Comprehensive-Getting/dp/1572246359>

APPENDIX F

AGENTS THAT HAVE SEDATING SIDE EFFECTS

Agent	Indications	Considerations
Sedating antidepressants: mirtazapine, tricyclics, doxepin in dosages >10 mg	TCAs can be used in comorbid migraine and other central sensitivity pain syndromes. Mirtazapine may be useful if appetite is low or there is depressed mood.	Weight gain, next day sedation and motor restlessness can be an issue with all of these drugs. Negative anticholinergic properties may also occur with tricyclic antidepressants (TCAs).
Antihistamines: chlorpheniramine	Insomnia associated with histamine-mediated sleep disturbance in allergies, atopic dermatitis etc.	Excessive risk of daytime sedation, psychomotor/cognitive impairment and anticholinergic toxicity. Similar to OTC antihistamines
Anticonvulsants: gabapentin, pregabalin	Fibromyalgia, neuropathic pain syndromes, restless leg syndrome (RLS)	Weight gain and next day sedation are often seen.
1st generation antipsychotics: chlorpromazine, methotrimeprazine, loxapine	Resistant bipolar disorder or schizophrenia	Possible harms do not outweigh the benefits used for insomnia alone. Unacceptable risk of anticholinergic and neurological toxicity.
Antipsychotics (atypical or 2nd generation): risperidone, olanzapine, quetiapine, asenapine, lurasidone	Bipolar disorder, schizophrenia, resistant depression and anxiety (quetiapine)	May be useful if significant mood, anxiety or psychotic disorder comorbid to insomnia. Metabolic issues and weight gain must be monitored.
Benzodiazepines (intermediate and long-acting): diazepam, clonazepam, lorazepam, nitrazepam, alprazolam	Anxiety disorders (2 nd line treatment) Insomnia associated with restless legs syndrome (RLS) insomnia associated with anxiety or hyperarousal	Intermediate to medium acting agents (clonazepam, lorazepam, nitrazepam) can be considered with significant comorbid anxiety or restless legs syndrome.