Louisiana Medicaid | Provider UPDATE

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FDA Drug Safety Communications

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Overview of Insomnia and Sedative-Hypnotic Agents

The impaired ability to fall asleep and maintain sleep without excessive waking is influenced by multiple factors. Management of insomnia begins with attempts to eliminate or minimize factors and comorbid conditions that contribute to insomnia. Successful behavioral and pharmacologic approaches to insomnia can be initiated once all contributing factors are recognized and addressed.

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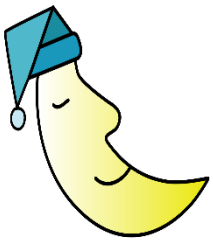
Evaluation and Diagnosis

- Insomnia symptoms lasting less than three months are considered short-term insomnia.
- Chronic insomnia diagnosis requires symptoms at least three times a week for at least three months despite adequate opportunity and circumstances for sleep.
- The FDA recommends further evaluation for the presence of a psychiatric and/or medical illness if treatment of insomnia fails after 7 to 10 days.
- All patients should receive sleep hygiene education to identify targets for intervention.
- The diagnosis of insomnia disorder requires the distinction between insufficient sleep, in terms of ability to sleep, opportunity for sleep, and sleep duration; diagnosis further requires that sleep difficulties be accompanied by compromised daytime function.
- Insomnia should be distinguished clinically from several other common sleep complaints and conditions that might suggest alternative diagnosis or contributing comorbidities.
- Drug-induced insomnia is a potential adverse effect of many substances, such as alcohol, OTC medications, illicit drugs, and various drug classes, including central nervous system stimulants, bronchodilators, antidepressants, beta agonists, and glucocorticoids.
- All patients should be evaluated for any coexisting medical or psychiatric illnesses, substance abuse, or other sleep disorders for focused treatment of insomnia symptoms.
- In patients with comorbid depression, assess for suicidal ideation before prescribing sedative-hypnotics.



Therapy and Safe Prescribing Considerations

- Cognitive behavioral therapy for insomnia (CBT-I) is considered the mainstay of nonpharmacologic therapy for chronic insomnia and has been endorsed as first-line therapy by multiple societies and guideline panels.
- When CBT-I is not sufficiently effective, clinical practice guidelines support adjunctive pharmacotherapy with a plan for monitoring potential adverse effects.
- The lowest possible effective dosage should be initiated; refills should be restricted until continued need and tolerability are established.
- Maximum recommended dosage should not be exceeded.
- Patients should be instructed on the proper timing of taking medication based on desired sleep onset and duration of effect to reduce the risk of next-day impaired alertness, memory, coordination and driving; patients should avoid dosing if there is insufficient time for medication elimination between planned bedtime and rise time.
- The risk of complex sleep-related behaviors such as sleepwalking, eating, and driving should be discussed with the patient.
- Patients should be warned to avoid combining insomnia medications with alcohol or other sedatives.
- Older adults have a higher risk of adverse effects from sedative-hypnotic drugs, including excessive sedation, cognitive impairment, delirium, balance difficulties, and impaired daily activity performance; an increased risk of falls with severe consequences (e.g. hip fracture, traumatic brain injury) are associated with benzodiazepines (BZDs) and non-BZDs among the elderly.
- BZDs and non-BZDs should be initiated using the lowest dose shown for those with low body weight, debilitated patients, and those receiving treatment with opioid analgesics or other central nervous system or cardiorespiratory depressants.
- Alcohol as a sleep aid should be discouraged due to the potential for abuse, and the increased risk of sleep disturbances, upper airway instability, and sleep apnea.
- Insomnia may persist despite successful treatment of the coexisting condition; therefore, therapy directed at both the insomnia and the comorbidity may be necessary.
- Given that insomnia can precipitate, worsen, or prolong comorbid conditions, treatment of insomnia may improve comorbidities.
- Regular follow-up should be scheduled to review efficacy, side effects, nonpharmacologic options, and assess ongoing need for pharmacotherapy.
- If the decision is made to discontinue sedative-hypnotic use, literature supports the role of CBT-I in combination with hypnotic drug tapering to help ensure a successful discontinuation.
- See *Chronic Pharmacotherapy Considerations for Insomnia* and drug class sections below for agent-specific details.

Choice of Agent

- Older benzodiazepine hypnotics should not be considered first-line pharmacotherapy due to longer half-lives, higher risk of dependence, and the availability of safer options.
- Selection of a medication should be individualized based on the predominant sleep complaint (sleep-onset or sleep-maintenance insomnia), past treatment response, medication availability and cost, side effects, contraindications, comorbidities, and patient preference.
- For sleep-onset, consider a nonbenzodiazepine (all except middle-of-the-night and extended-release zolpidem), a dual orexin receptor antagonist (DORA), or ramelteon.
- For sleep-maintenance consider medications with an appropriately long duration of action, such as a nonbenzodiazepine (all except zaleplon), a DORA, or low-dose doxepin.
- Refer to the American Academy of Sleep Medicine's *Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults* for specific agent guidance.

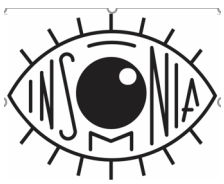
Selected FDA-Approved Insomnia Medications

Drug	Duration of Action	Insomnia Indication	
Benzodiazepines		Sleep Onset	Sleep Maintenance
Estazolam	Intermediate	X	X
Flurazepam	Long	X	X
Quazepam	Long	X	X
Temazepam	Intermediate	X	X
Triazolam	Short	X	X
Nonbenzodiazepines			
Eszopiclone	Intermediate	X	X
Zaleplon	Short	X	-
Zolpidem -Extended Release	Intermediate	X	X
Zolpidem -Immediate Release -Sublingual (Edluar®) -Oral Spray	Short	X	-
Zolpidem -Sublingual (Intermezzo®)[a]	Short	-	X
Melatonin-receptor agonists			
Ramelteon	Short	X	-
Dual Orexin receptor antagonists			
Lemborexant	Long	X	X
Suvorexant	Intermediate	X	X
Antidepressants			
Doxepin -3 or 6 mg tablets (Silenor®)	Long	-	X

[a] As-needed treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep and the patient has ≥4 hours of sleep time remaining

Benzodiazepines (BZDs)

- BZDs commonly cause undesirable adverse drug events (ADEs), such as drowsiness, dizziness, lightheadedness, residual daytime sedation, anterograde amnesia, cognitive impairment, motor impairment, and rebound insomnia and withdrawal symptoms upon discontinuation.
- Due to respiratory suppression, BZDs can potentially worsen obstructive sleep apnea or chronic pulmonary insufficiency, therefore are generally contraindicated.
- Dose dependence occurs with most ADEs, so the lowest effective dose should be used for the shortest amount of time, as determined by clinical need.
- Avoid long-acting BZDs in older adults due to increased risk of adverse effects; there is an increased risk of falls with severe consequences such as traumatic brain injury and hip fracture with BZD use in older patients.
- Treatment should be initiated with lowest dose indicated for individuals with low body weight, debilitated patients, and those receiving treatment with opioid analgesics or other central nervous system or cardiorespiratory depressants.
- In September 2020, the FDA released a Drug Safety Communication requiring manufacturers of benzodiazepines to update Boxed Warnings to further address the serious risks of abuse, addiction, physical dependence, and withdrawal reactions.



Non-Benzodiazepines (non-BZDs)

- Common ADEs of non-BZDs include residual daytime sedation, drowsiness, dizziness, lightheadedness, cognitive impairment, motor incoordination, and dependence.
- Due to respiratory suppression, non-BZDs can potentially worsen obstructive sleep apnea.
- In older patients there is an increased risk of falls with severe consequences such as traumatic brain injury and hip fracture with non-BZD use, particularly with zolpidem.
- In 2013, the FDA issued a series of safety announcements requiring the manufacturer to lower the zolpidem dose in women from 12.5 mg to 6.25 mg for extended-release, and from 10 mg to 5 mg for immediate-release products, due to next day mental impairment. The FDA further recommended this lower dose for men, and required product labeling revision to include warnings about the risks of next day impairment for activities requiring complete mental alertness the day after taking zolpidem.
- In April 2019, the FDA advised of rare but potentially fatal injuries associated with certain insomnia medicines because of complex sleep behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These behaviors have appeared to be more common with eszopiclone, zaleplon, and zolpidem products.

Melatonin-Receptor Agonists

- Ramelteon is the only melatonin-receptor agonist with FDA approval for sleep-onset insomnia and has very low abuse and dependence potential.
- Ramelteon should be avoided in patients with severe hepatic insufficiency.
- Adverse reactions are generally milder than the BZD and non-BZD medications.

Dual Orexin Receptor Antagonists (DORAs)

- Lemborexant and suvorexant have FDA approval for sleep onset and sleep maintenance.
- Consider the increased risk of adverse effects in obese women before increasing the dose of suvorexant.
- Common adverse effects include daytime somnolence, headache, and possible next day driving impairment.
- DORAs should be used with caution in patients with COPD or obstructive sleep apnea.
- DORAs are contraindicated in patients with narcolepsy.

Antidepressants

- Low dose doxepin (Silenor®) is the only antidepressant approved for the treatment of insomnia.
- Common adverse effects include daytime somnolence and next day driving impairment.

Chronic Pharmacotherapy Considerations for Insomnia

Deleterious health effects may result from chronic insomnia disorder, and the pharmacotherapeutic benefits of improving sleep deprivation is not fully understood. Evidence is insufficient to assess the balance of the benefits and risks of long-term use of pharmacologic treatments in chronic insomnia. Ideally, pharmacologic therapy should only be used short-term (4 to 5 weeks). Regular follow-up should be scheduled to review efficacy, side effects, nonpharmacologic options, and assess ongoing need for pharmacotherapy. Benzodiazepines are effective for treating chronic insomnia but carry the risk of significant adverse effects and dependency. Nonbenzodiazepines are effective treatments for chronic insomnia and appear to have fewer adverse effects than benzodiazepines based on indirect comparisons; however, are not without risks.

Chronic Use of Sedative-Hypnotic Agents

Drug	Duration of Continuous Therapy Reported by Manufacturer Labeling
Benzodiazepines	
Estazolam	There is evidence to support the ability of estazolam to enhance the duration and quality of sleep for intervals up to 12 weeks.
Flurazepam	Studies determined efficacy for at least 28 consecutive nights of drug administration.

Drug	Duration of Continuous Therapy Reported by Manufacturer Labeling
Quazepam	Clinical studies demonstrated efficacy for 5 nights duration in acute and chronic insomnia; a sleep lab study demonstrated sustained effectiveness for chronic insomnia in a study of 28 nights duration.
Temazepam	Clinical trials of 2 weeks in duration support efficacy. However, indication is for the short-term treatment of insomnia (generally 7 to 10 days).
Triazolam	Indication is for short-term treatment of insomnia (generally 7 to 10 days) and quantities exceeding a 1-month supply should not be prescribed.
Nonbenzodiazepines	
Eszopiclone	Clinical trials support efficacy for up to 6 months in duration.
Zaleplon	Clinical trials support efficacy for up to 5 weeks in duration.
Zolpidem Immediate-Release	Clinical trials support efficacy for 4 to 5 weeks duration.
Zolpidem Extended-Release	Evidence supports efficacy up to 3 weeks (using polysomnography for 2 weeks in both adult and elderly patients).
Melatonin-receptor agonists	
Ramelteon	Clinical trials support efficacy for up to 6 months in duration.
Orexin receptor antagonists	
Lemborexant	Clinical trial conducted for 6 months demonstrated efficacy.
Suvorexant	Clinical trial conducted for 3 months demonstrated efficacy.
Antidepressants	
Doxepin (Silenor® only)	Clinical trials support efficacy for up to 3 months in duration.

Conclusion

Insomnia is a major public health concern that affects the lives of millions of people. Healthcare professionals should understand that a patient's insomnia may be related to a variety of causes or contributors including physical or psychiatric problems. An accurate diagnosis is essential to guide an individualized treatment strategy, which may include a variety of behavioral and pharmacologic approaches. Little evidence is available on the efficacy and safety of long-term pharmacotherapy for insomnia. The risk of side effects must be assessed both before, and regularly during the course of management of insomnia.

References
Available upon request.

New Medicaid Eligibility Group Covers COVID-19 Testing for Uninsured Patients

Per the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act, Louisiana Medicaid has expanded coverage to include COVID-19 testing for uninsured individuals for the duration of the federally declared public health emergency. Coverage is limited to COVID-19 testing and related office visits for uninsured Louisiana residents. No treatment costs are covered under this program.

The new benefit is provided through Medicaid fee-for-service and not Healthy Louisiana through a managed care organization. Providers must be a Medicaid enrolled provider and must be enrolled before services are provided. Providers not enrolled as a Medicaid provider with Gainwell will need to complete a temporary emergency application with Medicaid's fiscal intermediary, Gainwell, to be paid for testing and testing related services for the uninsured. Providers will be required to self-attest on the uninsured individual's application to Medicaid that they are not also billing the Department of Health and Human Services (HHS) or the Health Resources and Services Administration (HRSA) for the same services. You also may not bill on any contract with the Louisiana

PHARMACY FACTS

Program Updates from Louisiana Medicaid

Pharmacy Facts can also be found online at: http://ldh.la.gov/index.cfm/page/3036.

November 20, 2020

Louisiana Medicaid Annual Recertification
Due to the COVID-19 pandemic, Louisiana Medicaid is currently drafting an editable PDF for providers to update and electronically sign with correct information and return by email with supporting documentation. Louisiana Medicaid will allow three months from the date the editable PDF is sent for providers to submit the requested recertification documents. Providers should expect to receive an email from Louisiana Medicaid around the first week of December. To confirm that Louisiana Medicaid has your correct email address on file, please send a message to mailto:roderick.anderson@la.gov, providing the email address where your recertification information should be sent. If you have additional questions or concerns, you may also contact the Pharmacy Help Desk at (800) 648- 0790.

Brand Over Generic List
The Louisiana Department of Health (LDH) scheduled a Pharmaceutical & Therapeutics (P&T) Committee meeting for October 2020. Although there was a quorum for the virtual meeting, legislation changed the meeting requirements during special session, therefore not allowing for a virtual meeting. LDH polled the P&T Committee members to see if we could meet the quorum for a face to face meeting. We were unable to meet the quorum as stated in the bylaws.

In the absence of a P&T meeting, LDH pharmacy staff, the Medicaid Medical Director and the Deputy Director for Program Operations and Compliance reviewed the potential financial and clinical impacts provided by Magellan to determine which recommendations are in the best interest of the Medicaid program. Each P&T committee member was asked to review the recommendations and provide responses to proposed recommendations. In addition, the Pharmacy Advisory Council (PAC) members reviewed the brand over generic list and provided feedback as well. There are times when brand products are preferred over generics because the net price to the state is less expensive after rebate. After considering the financial and clinical impacts as well as the feedback on the proposed recommendations, the Brand over Generic List will be as follows effective January 1, 2021:

Brand over Generic List for Fall 2020 – Effective January 1, 2021

	Proposed Brand Over Generic/Fall 2020	P&T Cycle
1	SYMBICORT (INHALATION)	Fall-new
2	CIPRODEX (OTIC)	Fall-keep
3	FOCALIN XR (ORAL)	Fall-keep
4	SABRIL TABLET (ORAL)	Fall-new class
5	TRILEPTAL SUSPENSION (ORAL)	Fall-new class
6	AFINITOR (ORAL)	Fall-new
7	ADVAIR DISKUS (INHALATION)	Fall-new

	Proposed Brand Over Generic/Fall 2020	P&T Cycle
8	TEGRETOL XR (ORAL)	Fall-new class
9	TRAVATAN Z 2.5 ML (OPHTHALMIC)	Fall-keep
10	TOBRADEX SUSPENSION (OPHTHALMIC)	Fall-keep
11	DEPATKOTE SPRINKLE (ORAL)	Fall-new class
12	CARBATROL (ORAL)	Fall-new class
13	ALPHAGAN P 0.15% (OPHTHALMIC)	Fall-keep
14	ELIDEL (TOPICAL)	Fall-new
15	CATAPRES-TTS (TRANSDERM)	Fall-keep
16	FELBATOL TABLET (ORAL)	Fall-new class

	Current Spring Brand over Generic	P&T Cycle
1	REVATIO SUSPENSION (ORAL)	Spring
2	COPAXONE 20 MG/ML (SUBCUTANE.)	Spring
3	NATROBA (TOPICAL)	Spring
4	TRANSDERM-SCOP (TRANSDERM)	Spring
5	HUMALOG VIAL/PEN (SUBCUTANE.)	Spring
6	NOVOLOG MIX VIAL/PEN (SUBCUTANE.)	Spring
7	NOVOLOG PEN/VIAL/CART (SUBCUTANE.)	Spring
8	TRACLEER TABLET (ORAL)	Spring
9	SUBOXONE FILM (SUBLINGUAL)	Spring

	Brand Over Generic Product Removed - Fall 2020
1	PROCENTRA (ORAL)

Remittance Advice Corner

Attention Professional Service Providers
Tobacco Cessation Counseling for Pregnant Women

Effective for dates of service on or after December 1, 2020, Louisiana Medicaid will cover tobacco cessation counseling during pregnancy through 60 days postpartum.

Additional information on this policy can be found on the home page of www.lamedicaid.com. Updates to the *Professional Services* manual and fee schedule are forthcoming and will be found under the appropriate links on www.lamedicaid.com.

Questions regarding this message and fee for service claims may be directed to Gainwell Technologies provider relations at (800) 473-2783 or (225) 924-5040. Questions regarding managed care claims may be directed to the appropriate managed care organization.

Medicaid Public Notice and Comment Procedure

As of Aug. 1, 2019, a public notice and comment period is required before certain policies and procedures are adopted. Drafts will be published on LDH's website to allow for public comment, as per HB 434 of the 2019 Regular Legislative Session. This requirement applies to managed care policies and procedures, systems guidance impacting edits and payment, and Medicaid provider manuals.

In compliance with R.S. 46:460.51(15), 460.53, and 460.54, this procedure provides for a defined term, a public notice requirement, implementation of a policy for the adoption of policies and procedures, and for related matters. Public Comments for the following policies and procedures can be left at the link below.

- Louisiana Medicaid (Title XIX) State Plan and Amendments;
- Louisiana Medicaid Administrative Rulemaking Activity;
- Medicaid Provider Manuals;
- Contract Amendments;
- Managed Care Policies & Procedures; and
- Demonstrations and Waivers.

http://www.ldh.la.gov/index.cfm/page/3616

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
EPSDT HEALTH AND- IDEA, Part C – EarlySteps EPSDT Health and Idea, Part C – Early Steps Manual Chapter	Title Page Table of Contents Section 47.0 - Overview Section 47.1 - Covered Services Section 47.2 - Eligibility Requirements Section 47.3 - Provider Requirements Section 47.4 - Program Requirements Section 47.5.1 - Procedure Codes and Rates Section 47.5.2 - Definitions and Acronyms Section 47.5.3 - Contact Referral Information	11/30/20

Manual Chapter Revision Log (continued)

Manual Chapter	Section(s)	Date of Revision(s)
Professional Services Professional Services Manual Chapter	Table of Contents Table of Contents 5.1 – Covered Services – Diabetes Self-Management Training 5.1 – Covered Services – Newborn Care and Discharge 5.1 – Covered Services – Oral and Maxillofacial Surgery 5.1 – Covered Services – Outpatient Chemotherapy	11/06/20

For Information or Assistance, Call Us!

Provider Relations	1-800-473-2783 (225) 294-5040 Medicaid Provider Website	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization:		MMIS Claims Processing	(225) 342-3855
Home Health/EPSDT – PCS	1-800-807-1320		
Dental	1-855-702-6262 MCNA Provider Portal	Resolution Unit MMIS Claims Reimbursement	
DME & All Other	1-800-488-6334 (225) 928-5263	MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905 MMIS Claims Reimbursement
Hospital Pre-Certification	1-800-877-0666		
REVS Line	1-800-776-6323 (225) 216-(REVS)7387 REVS Website	Medicare Savings	1-888-544-7996 Medicare Provider Website
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	For Hearing Impaired	1-877-544-9544
		Pharmacy Hotline	1-800-437-9101 Medicaid Pharmacy Benefits
		Medicaid Fraud Hotline	1-800-488-2917 Report Medicaid Fraud