

FDA Drug Safety Communications

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Nonpharmacological Therapy Approaches for Insomnia

Cognitive behavioral therapy for insomnia (CBT-I) is considered the mainstay of nonpharmacologic therapy for insomnia and has been endorsed as first-line therapy by multiple societies and guideline panels for the treatment for chronic insomnia in adults.^{1,2,3} CBT-I and other behavioral therapy approaches to chronic insomnia such as sleep hygiene education, stimulus control, relaxation, and sleep restriction therapy are outlined below.⁴

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CBT-I	<p>This approach involves elements of sleep restriction, stimulus control, sleep hygiene education, and cognitive therapy and may include relaxation techniques. Theoretically, insomnia develops in some individuals as a result of:</p> <ul style="list-style-type: none"> • Predisposing factors (genetic risks, early life experiences, some chronic comorbidities). • Precipitating factors (life events that lead to sleep disruptions). • Perpetuating factors (behavioral and cognitive factors that sustain poor sleep). <p>Multicomponent CBT-I directly addresses perpetuating factors, which are believed to be the source of ongoing, chronic sleep-related problems.⁴ American College of Physicians recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder.³ An Agency for Healthcare Research and Quality (AHRQ) systematic review reported that the strongest evidence for the efficacy were from the use of CBT-I.²</p>
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Sleep Hygiene	<p>Sleep hygiene alone is not considered an effective treatment for insomnia disorder, although this approach is typically incorporated into CBT-I.⁴</p> <p>These actions tend to improve and maintain good sleep:⁴</p> <ul style="list-style-type: none"> • Maintain a regular sleep schedule. • Avoid caffeinated beverages after the noon meal. • Avoid alcohol in late afternoon/evening. • Avoid nicotine intake during the evening. • Decrease lighting and sound stimuli in the bedroom environment. • Avoid excessive use of light-emitting screens before bedtime. • Exercise regularly, but no more than 4 to 6 hours before bedtime. • Avoid daytime naps longer than 1 hour, especially late in the day. • Avoid checking the time to prevent cognitive arousal.
Stimulus Control Therapy	<p>Patients may associate their sleeping environment with the fear of not sleeping, rather than the anticipation of good sleep. To help disrupt this association, patients should:⁴</p> <ul style="list-style-type: none"> • Go to bed only when drowsy. • Only use the bedroom for sleeping and intimacy. • Leave the bed if unable to sleep after 20 minutes and return to bed when sleepy. • Avoid stimulating activities, such as eating or watching television, upon waking during the night. • Set an alarm to wake at the same time every day, including weekends.
Relaxation	<p>There are two common techniques implemented before each sleep period:⁴</p> <ul style="list-style-type: none"> • Progressive muscle relaxation – Learning to relax one muscle at a time until the whole body is relaxed. • Diaphragmatic breathing – Elicits relaxation by balancing oxygen and carbon dioxide levels.
Sleep Restriction Therapy	<p>Limiting extended time in bed (including naps and other sleep outside of bed) helps to consolidate sleep and improves sleep efficiency. This therapy approach is conducted over multiple sessions and a sleep diary is recommended.⁴</p>

Insomnia Resources for Providers

[American Academy of Sleep Medicine | Provider Fact Sheet Insomnia](#)

Insomnia is a multifaceted medical problem that affects patients in different ways and can even present with other comorbid conditions, such as pain or psychiatric disorders. Insomnia is affected by the 3 P’s which are predisposing, precipitating, and perpetuating factors.

[American Sleep Association | ASMR Defined – Sounds, Whispers and Triggers for Sleep](#)

Autonomous Sensory Meridian Response (ASMR) is known to cause a relaxing effect to help those who have trouble sleeping. Certain sounds cause chemicals such as endorphins to be released in the brain to help reduce stress and induce sleep.

[Annals of Internal Medicine | Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline from the American College of Physicians](#)

Based on a systematic review of randomized, controlled trials published in English from 2004 through September 2015, this guideline was developed to present the evidence and provide clinical recommendations on the management of chronic insomnia in adults.

[Centers for Disease Control and Prevention \(CDC\) | Sleep and Sleep Disorders: For Clinicians](#)

Resources for clinicians, such as practice guidelines, recommendations and policy statements, are available from the CDC.

[Journal of Clinical Sleep Medicine | Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline](#)

This guideline establishes clinical practice recommendations for the pharmacologic treatment of chronic insomnia in adults, when such treatment is clinically indicated.

Insomnia Resources for Patients

[Healthy Sleep: Division of Sleep Medicine at Harvard Medical School | Twelve Simple Tips to Improve Your Sleep](#)

Quality sleep improves every aspect of daily life, and achieving a consistent schedule of exercise, diet, and bedtime routines are most beneficial to allowing deep, restful sleep.

[John Hopkins Medicine | Better Sleep: 3 Simple Diet Tweaks](#)

Diet can have a huge impact on quality of sleep by triggering the release of certain hormones and causing metabolic changes in the body. Caffeine and high protein foods cause metabolic issues that can upset the sleep cycle. However, two dietary options that help regulate the sleep cycle include foods high in carbs that trigger the release of serotonin and tart cherries that are a natural source of melatonin.

[John Hopkins Medicine | Exercising for Better Sleep](#)

Regular exercise can improve physical health, but also helps maintain a better sleep schedule. It helps stabilize mood and decompress the mind. It also raises core body temperature which then starts to fall, facilitating sleepiness. Be cautious of the timing of exercise; too close to bedtime can interrupt sleep.

[National Heart, Lung and Blood Institute | Insomnia Patient Information](#)

Learn more about chronic insomnia and how it can affect your brain, heart, and other areas of your body.

[Sleep Foundation | Alcohol and Sleep](#)

Alcohol has sedative properties which can cause sleepiness and relaxation; however, the metabolization process can disrupt a phase in sleep known as REM sleep. Alcohol may make it easier to fall asleep, but sleep disruptions are common due to its effects on REM sleep which causes unwanted awakening.

[U.S. National Library of Medicine - MedlinePlus | Insomnia Patient Information](#)

This reputable resource provides information on the various aspects of insomnia, including who is at risk, diagnosis, and treatments.

References

1. Qaseem A, Kansagara D, Forcica M, Cooke M, Denberg T. Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians. *Annals Of Internal Medicine*. July 19, 2016;165(2):125-133.
2. Brasure M, MacDonald R, Fuchs E, et al. Management of Insomnia Disorder. Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Dec. (Comparative Effectiveness Reviews, No. 159.) Executive Summary. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK343495/>
3. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349.
4. Martin JL. Cognitive behavioral therapy for insomnia in adults. In: UpToDate, Benca R(Ed), UpToDate, Waltham, MA. Accessed October 12, 2020.

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 DXC will need to complete a [temporary emergency application](#) with Medicaid's fiscal intermediary, DXC, 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 Department of Health to provide COVID-19 testing for these patients. If Medicaid identifies other third party coverage is available (e.g., Medicare, private insurance), Medicaid will not cover the services.

For additional guidance, visit [Medicaid's provider web page for COVID-19 testing coverage for uninsured individuals](#). The site contains billing information, a [detailed provider guide](#), frequently asked questions for providers, and the [simplified application](#) patients can fill out to determine if they are eligible for coverage.

Open Enrollment

Open Enrollment for Louisiana Medicaid enrollees is approaching. Between October 15, 2020 and November 30, 2020, enrollees can change their health plan without a qualifying reason, outside of their initial enrollment period. Please download the [Open Enrollment Informational Flyer](#) and display it in your office.

There are five health plans to choose from: Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections and United Healthcare. In addition, for the first time, enrollees will have a choice between two dental plans. Previously, all Medicaid enrollees received dental coverage through one dental plan. There are two dental plans to choose from: DentaQuest and MCNA. Letters with information and instructions for choosing plans will be mailed in September to all enrollees that are included in this Open Enrollment period.

As a provider, it is important to let your patients know which plans you are accepting. **There are limitations on what you can tell an enrollee.** In general, you can inform enrollees which plans you accept, and the benefits, services and specialty care offered. However, you cannot:

- recommend one plan over another or incentivize a patient to select one plan over the other; or
- change an enrollee's plan for him/her, or request a disenrollment on an enrollee's behalf. These prohibitions against patient steering apply to participation in all Medicaid programs.

More details on Open Enrollment can be found on the [Informational Bulletins page](#).



PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

October 2, 2020

Catapres-TTS Patch

Boehringer Ingelheim has updated the federal rebate term dates on National Drug Codes (NDC) for Catapres-TTS brand patch products through 2022. If you have trouble with claims, please contact the appropriate help desk for Medicaid Fee-For-Service (FFS) or a Managed Care Organization (MCO).

Health Care Provider	Pharmacy Help Desk	Pharmacy Help Desk Phone Number
Aetna	CVS Health	(855) 364-2977
Amerihealth Caritas	PerformRx	(800) 684-5502
Fee-For-Service	DXC Technology	(800) 648-0790
Healthy Blue	CVS	(833) 236-6194
Louisiana Healthcare Connections	CVS Caremark	(800) 311-0543
UnitedHealthcare	Optum Rx	(866) 328-3108

Adult Immunizations

Just a reminder that FFS and MCOs started covering adult vaccines on July 1, 2020 and started covering flu shots on September 15, 2020. Please contact us if you have any problems processing claims.

Change in National Provider Identifier (NPI)

Local pharmacies are to be reimbursed for at least the FFS rate on pharmacy claims. Providers who have a change in the NPI should be sure to alert the LDH Pharmacy program of this change. The pharmacy provider should then use the new NPI when billing all Medicaid MCOs/PBMs and FFS. Monthly, LDH provides MCOs with a list of pharmacies that qualify as local pharmacies. To assure timeliness of appropriate dispensing fee reimbursement, please contact the Pharmacy program at the Help Desk number (800) 648-0790 or Jennie Stelly at (225) 342-4665 to assure continuity in reimbursement status.

Remittance Advice Corner

CHANGES TO DME, HOME HEALTH, PEDIATRIC DAY HEALTH CARE, REHABILITATION AND PERSONAL CARE SERVICES DUE TO HURRICANE DELTA - OCTOBER 2020

On October 6, 2020, Governor John Bel Edwards declared a state of emergency ahead of Hurricane Delta as significant impact to the state of Louisiana is expected. This policy change is effective October 8, 2020 and shall only be applicable for beneficiaries residing in parishes that have instituted mandatory evacuations.

Medicaid beneficiaries who live in one of the parishes under mandatory evacuation, and who are in need of replacement equipment or supplies previously approved by Medicaid, may contact a Medicaid-enrolled durable medical equipment (DME) provider of their choice. Medicaid-enrolled providers must make a request to Gainwell Technologies' Prior Authorization Unit; however, a new prescription and medical documentation are not required. The provider shall submit the required Prior Authorization Form (PA-01) along with a signed letter from the recipient, giving a current place of residence and stating that the original equipment or supplies were lost due to Hurricane Delta.

Beneficiaries who were approved to receive medical equipment, supplies, home health services, rehabilitation, pediatric day health care or personal care services from a provider in a parish with a mandatory evacuation that is no longer in business or unable to provide the approved equipment, supplies or services may obtain the approved items or services from a new provider of their choice. The provider must be enrolled in Medicaid. Gainwell Technologies shall provide any guidance to the provider on the cancellation of the original authorization and issuance of a new authorization, if applicable.

All other prior authorization requests shall continue to be subject to the applicable requirements to establish medical necessity.

Questions concerning Healthy Louisiana managed care organization processes are to be directed to the appropriate MCO. Those questions related to Medicaid fee-for-service claims should be directed to Gainwell Technologies Provider Relations at (800) 473-2783 or (225) 924-5040.

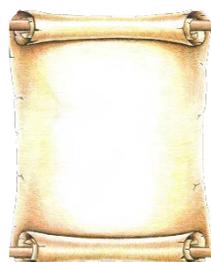
Medicaid Public Notice and Comment Procedure

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)
Behavioral Health Behavioral Health Services Manual Chapter	Table of Contents Section 2.4 – Addiction Services – Opioid Treatment Programs (OTPs)	10/07/20

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: Home Health/EPSTD – PCS	1-800-807-1320	MMIS Claims Processing	(225) 342-3855
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
Hospital Pre-Certification	1-800-877-0666		MMIS Claims Reimbursement
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 Pharmacy Hotline	1-877-544-9544 1-800-437-9101 Medicaid Pharmacy Benefits
		Medicaid Fraud Hotline	1-800-488-2917 Report Medicaid Fraud