Louisiana Medicaid | Provider UPDATE

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FDA Drug Safety Communication: Risk of Serious Injuries Caused by Sleepwalking with Certain Prescription Insomnia Medications

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Table of Contents

On April 30, 2019, the U.S. Food and Drug Administration (FDA) issued a drug safety communication regarding the risk of serious injuries caused by sleepwalking with certain prescription insomnia medications. The FDA is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone, zaleplon, and zolpidem than other prescription medicines used for sleep.

As a result, the FDA is now requiring a *Boxed Warning*, the most prominent FDA warning, to be added to the prescribing information and the patient *Medication Guide* for these medicines. A contraindication, the strongest FDA warning, is also being required by the FDA stating that patients who have previously experienced an episode with complex sleep behavior with eszopiclone, zaleplon, and zolpidem should avoid use.

Serious injuries and death from complex sleep behaviors have occurred in patients with and without a history of such behaviors, even at the lowest recommended doses, and the behaviors can occur after just one dose. These behaviors can occur after taking these medicines with or without alcohol or other central nervous system depressants that may be sedating such as tranquilizers, opioids, and anti-anxiety medicines.

Healthcare professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. When initiating treatment with eszopiclone, zaleplon, or zolpidem, prescribers should follow the dosing recommendations in the prescribing information and start with the lowest possible dose. Patients should be encouraged to read the *Medication Guide* every time they fill their eszopiclone, zaleplon, or zolpidem prescriptions, and reminded not to combine them with other insomnia medicines, alcohol, or CNS depressants. Patients should be advised that although rare, the behaviors caused by these medicines have led to serious injuries and death. In addition, patients should be informed that they should discontinue taking these medicines and contact their healthcare provider immediately if they experience a complex sleep behavior where they engage in activities while they are not fully awake or if they do not remember activities that occurred while taking the medicine.

The FDA identified 66 cases of complex sleep behaviors occurring with these medicines over the past 26 years that resulted in serious injuries, including death (see FAERS Data Summary). This number includes only reports submitted to FDA or those found in the medical literature so there may be additional cases about which the FDA is unaware. These cases included accidental overdoses, falls, burns, near drowning, exposure to extreme cold temperatures leading to loss of limb, carbon monoxide poisoning, drowning, hypothermia, motor vehicle collisions with the patient driving, and self-injuries such as gunshot wounds and apparent suicide attempts. Patients usually did not remember these events. The

underlying mechanisms by which these insomnia medicines cause complex sleep behaviors are not completely understood.

The FDA is also reminding the public that all medicines taken for insomnia can impair driving and activities that require alertness the morning after use. Drowsiness is already listed as a common side effect in the drug labels of all insomnia medicines, along with warnings that patients may still feel drowsy the day after taking these products. Patients who take insomnia medicines can experience decreased mental alertness the morning after use even if they feel fully awake. The FDA is continuing to monitor the safety of insomnia medicines and will update the public as new information becomes available.

FDA Adverse Event Reporting System (FAERS): Data Summary of Complex Sleep Behaviors Resulting in Serious Injuries or Death after TakingCertain Insomnia Medicines

The FDA Adverse Event Reporting System (FAERS) is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. FDA receives voluntary reports directly from healthcare professionals and consumers.

FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product. The reports in FAERS are evaluated by clinical reviewers to monitor the safety of products after they are approved by FDA. If a potential safety concern is identified in FAERS, further evaluation is performed. Based on this evaluation, the FDA may take regulatory action(s) to improve product safety and protect the public health, such as updating a product's labeling information, restricting the use of the drug, communicating new safety information to the public, or, in rare cases, removing a product from the market.

FDA identified 62 cases of complex sleep behaviors that resulted in serious injuries or death after taking insomnia medicines eszopiclone, zaleplon, or zolpidem reported in the FAERS database between December 16, 1992 and February 27, 2018, and four additional cases reported in the medical literature between December 16, 1992 and March 13, 2018. Of the 66 cases, 20 cases were reported as resulting in fatal outcomes. Forty-six cases reported serious non-fatal injuries; these patients usually did not remember experiencing these complex sleep behaviors. The underlying mechanisms by which these insomnia medicines cause complex sleep behaviors are not completely understood.

The cases reported one or more episodes of the sleep behaviors and reported one or more adverse events. The adverse events included falls (n=22) with serious injuries such as intracranial hemorrhages, vertebral fractures, and hip fractures. Other events included self-injuries (n=7), fatal falls (n=6), accidental overdoses (n=5), hypothermia (n=5), suicide attempts (n=5), apparent completed suicides (n=4), fatal motor vehicle collisions (n=4), gunshot wounds (n=3), carbon monoxide poisoning (2), drowning or near drowning (n=2), burns (n=2), and homicide (n=1).
Most of these patients reported using zolpidem (n=61) when they experienced a complex sleep behavior. The remaining patients took eszopiclone (n=3) or zaleplon (n=2). These data are consistent with the higher number of zolpidem prescriptions dispensed compared to eszopiclone and zaleplon.

To help FDA better track safety issues with medicines, healthcare professionals and patients are encouraged to report side effects involving eszopiclone, zaleplon, and zolpidem or other medicines to the FDA at www.fda.gov/safety/medwatch.

References:
www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia
www.fda.gov/safety/medwatch

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

May 9, 2019

On May 1, 2019, Medicaid Pharmacy implemented several initiatives:

- All providers: A Single Preferred Drug List (PDL) is now used across managed care organizations (MCO) and Fee-for-Service Medicaid (FFS).
- FFS and MCO-enrolled local pharmacy providers:
  - Ingredient cost reimbursement changed to National Average Drug Acquisition Cost (NADAC).
  - The professional dispensing fee increased to $10.99.
- All pharmacy providers:
  - AmeriHealth Caritas (ACLA) has a new claims processor [new RXBIN: 019595].
  - Healthy Blue (HB) changed its pharmacy benefit manager to IngenioRx [new RXBIN: 020107, RXPCN: FG, RXGRP: WKLA].

Single PDL

Overall, the implementation of the Single PDL went smoothly thanks to multiple productive conversations with diverse stakeholders; provider and member advance notices sent by MCOs; and efforts by MCO pharmacy staff, LDH pharmacy staff, and University of Louisiana at Monroe (ULM) pharmacy staff.

The Single PDL is posted at http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf. Please review to determine the status of a drug (preferred vs. non-preferred).

A cover page has been added to the PDL that includes useful information in response to inquiries that have been received.

For specific drugs and/or National Drug Code and processing issues, the provider should contact the recipient's plan.

Legacy Medicaid or Fee-for-Service FFS Processing Questions	Pharmacy Recipient Help Desk: 1-800-437-9101 Pharmacy Provider Help Desk: 1-800-648-0790
Aetna Better Health Claims/Billing Issues	CVS Health Pharmacy Help Desk: 1-855-364-2977
AmeriHealth Caritas Claims/Billing Issues	PerformRx: 1-800-684-5502
Healthy Blue Claims/Billing Issues	Pharmacy Help Desk: 1-833-236-6194
Louisiana Healthcare Connections Claims/Billing Issues	CVS Caremark Pharmacy Help Desk: 1-800-311-0543
United Healthcare Community Plan Claims/Billing Issues	OptumRx: 1-866-328-3108

Diabetic supplies are not included on the Single PDL; therefore, each MCO may have different preferred products.

NADAC and professional dispensing fee
Although the professional dispensing fee and NADAC changes are only applicable to FFS Medicaid, MCOs are mandated through legislation to reimburse local pharmacies at the FFS rate. The provider fee requirement remains unchanged.

Since NADAC is a national pricing rate, the state does not have input on the rates or rate development. There is a NADAC Help Desk rate review form. This form, along with other helpful information, is available at https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html.

Provider Outreach
As we continue our efforts to notify providers (pharmacy and prescribers) of Medicaid pharmacy changes on a timely basis, we want to make sure we are reaching as many providers as possible. Please send pharmacy fax numbers and/or email addresses of colleagues to Roderick.Anderson@la.gov to ensure our outreach is effective. Chain pharmacies are welcome to send each store's contact information.

Copay
Copayment changes were implemented on April 1, 2019. For details, please refer to the provider notice at: https://www.lamedicaid.com/provweb1/Pharmacy/FFS_and_MCO_Assessment_of_Updated_Pharmacy_Copayments_3-28-19.pdf

If a recipient has questions or thinks they have reached the maximum copayment threshold, the recipient may call the FFS help desk at 1-800-437-9101.

Medicaid recipients urged to respond to eligibility letters
To prevent potential loss of Medicaid healthcare coverage, including pharmacy benefits, LDH is urging all Medicaid recipients to respond to any mailing they receive from the Department about their coverage. Because Medicaid coverage requires an annual renewal, approximately 125,000 people receive letters each month. The renewal letters direct Medicaid members to renew either online or by phone.

Eligibility and Enrollment System Provider Bulletins

Louisiana Medicaid is publishing bi-weekly provider bulletins to address provider questions and concerns around the new eligibility and enrollment system. The information in these bulletins covers a wide range of provider issues and provider types. This and other news can be found on the web site dedicated to the new system, found here: http://ldh.la.gov/index.cfm/page/3497.

If there are topics you feel need to be covered in these public communications, please let us know by sending an email to Healthy@la.gov.

Online Medicaid Provider Manual Chapter Revisions as of May 2019

Manual Chapter	Section(s)	Date of Revision(s)
Adult Day Health Care	Table of Contents Appendix E Claims Related Information	05/22/19
Applied Behavior Analysis	Table of Contents 4.4 Provider Requirements	05/23/19
Community Choices Waiver	Table of Contents Appendix D Claims Related Information	05/22/19
Federally Qualified Health Centers	Table of Contents 22.0 Overview 22.1 Covered Services 22.4 Reimbursement Appendix A Contact Information Appendix B Forms and Links Appendix C Glossary Appendix D Claims Related Information	06/01/19
Hospice	Table of Contents 24.3 Covered Services 24.4 Reserved 24.5 Provider Requirements 24.13 Reserved	05/30/19
Personal Care Services	Table of Contents 30.1 LT-PCS - Overview 30.2 LT-PCS - Covered Services 30.3 LT-PCS – Recipient Requirements 30.4 LT-PCS Rights and Responsibilities 30.5 Service Access and Authorization Process 30.6 Provider Requirements 30.7 Service Delivery 30.8 Record Keeping 30.9 LT-PCS Incidents, Accidents, and Complaints 30.10 Reimbursement 30.11 Fraud and Abuse 30.12 Program Oversight and Review Appendix A LT-PCS Forms and Links Appendix B LT-PCS Contact Information Appendix C Billing Codes Appendix D Reserved Appendix F Reserved Appendix G Glossary Appendix J Claims Related Information	05/16/19
Pharmacy Benefits Management Services	Appendix O - Louisiana Medicaid Single Preferred Drug List (PDL) – Fee-For-Service and Managed Care Organizations	05/01/19 05/03/19
Professional Services	Appendix E - Claims Related Information	05/16/19
Rural Health Clinics	Table of Contents 40.1 Covered Services 40.4 Reimbursement Appendix D Claims Related Information	06/01/19

Archived Online Medicaid Provider Manual Chapter Archived as of May 2019

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Remittance Advice Corner

Attention Louisiana Medicaid Providers

On May 1, 2019, Louisiana Medicaid updated the pharmacy reimbursement policy for Fee for Service (FFS) and Managed Care Organizations (MCOs) local pharmacies. The ingredient cost reimbursement is based on the National Average Drug Acquisition Cost (NADAC). The maximum allowable professional dispensing fee for all pharmacies in FFS and local pharmacies in MCOs changed from $10.41 to $10.99.

Attention Louisiana Medicaid Providers

On May 1, 2019, Fee for Service (FFS) Medicaid and Managed Care Organizations (MCOs) implemented the Louisiana Medicaid Single Preferred Drug List (PDL). Please refer to http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf to access the document.

Attention Hospice and Transportation Providers

This notice is to clarify and reinforce the following policy related to Hospice beneficiaries and transportation provision.

Hospice providers are responsible for payments for any services rendered to the recipient on the day of hospice election and after, when related to the recipient's terminal illness. This includes inpatient facility services and transportation if the services are/were rendered on the same day a recipient elects/elected hospice.

The time of day is not factored in when recipient information is processed and claims are submitted for payment. Hospice providers bill Medicaid for the whole day and not a partial day.

Compliance with this policy will be monitored by the department and the Prior Authorization Unit (PAU) at DXC Technology. Any non-compliance may be subject to administrative sanctions and/or monetary penalties.

Providers should refer to the *Hospice* provider manual chapter at www.lamedicaid.com, under the Provider Manuals link, which affirms this policy.

Questions regarding this message and fee-for-service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040.

Questions related to managed care claims should be directed to the appropriate managed care organization (MCO).

Attention Louisiana Medicaid Providers

On May 1, 2019, Fee for Service (FFS) Medicaid implemented Point of Sale (POS) Clinical Pre-Authorization for methadone and updated the maximum daily dose for buprenorphine agents to 24mg/day for FFS and Managed Care Organization (MCO) enrollees. Please refer to www.lamedicaid.com for more information.

Attention Obstetricians and Gynecologists

The Office of Population Affairs (OPA) has updated and published a new Sterilization Consent form (HHS 687), with an expiration date of 4/30/2022. This new form is effective immediately. Any previous forms must have had a valid expiration date at the time of signature in order to be accepted by DXC Technology.

Providers can access the most current Sterilization Consent form at www.lamedicaid.com, under the *Forms/Files/Surveys/User Manuals* tab, or by visiting the U.S. Department of Health and Human Services (HHS) website directly at https://www.hhs.gov/opa/sites/default/files/consent-for-sterilization-english-updated.pdf.

Questions regarding this message and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040. Questions regarding managed care claims should be directed to the appropriate managed care organization.

Attention Durable Medical Equipment (DME) Providers

Effective with date of service June 1, 2019, Medicaid guidelines for oxygen probes for use with an oximeter device are being updated. DME providers will submit the appropriate HCPCS code from the DMEPOS fee schedule to bill for these supplies. The rate on file for the HCPCS code includes reimbursement for the tape. The U5 modifier (oxygen probe for use with oximeter device, disposable) must be included on the prior authorization and claim for disposable oxygen probes. If the DME provider bills for a replacement oxygen probe, a modifier would not be used.

Medicaid will publish the new oxygen probe policy in the DMEPOS provider manual on www.lamedicaid.com.

Questions regarding this message and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040. Questions regarding managed care claims should be directed to the appropriate managed care organization.

For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization:		MMIS Claims Processing Resolution Unit	(225) 342-3855
Home Health/EPSDT – PCS	1-800-807-1320		
Dental	1-866-263-6534 1-504-941-8206		
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		
Provider Relations	1-800-473-2783 (225) 924-5040	Medicare Savings Program and Medicaid Purchase Hotline	1-888-544-7996
REVS Line	1-800-776-6323 (225) 216-(REVS)7387		
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 Fraud Hotline	1-800-488-2917