

FDA Drug Safety Communications

Compiled by:

Office of Outcomes Research and Evaluation
College of Pharmacy
The University of Louisiana at Monroe

FDA Drug Safety Communication: Update to Boxed Warning of Benzodiazepine Drug Class To Improve Safe Use

On September 23, 2020, the U.S. Food and Drug Administration (FDA) issued a drug safety communication requiring updates to the *Boxed Warning* for all benzodiazepine medicines. The current prescribing information for benzodiazepines does not provide adequate warnings about the serious risks and harms associated with these medicines. The FDA is requiring an update to the *Boxed Warning*, with the addition of other information to the prescribing for all benzodiazepine medicines. This information will describe the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions consistently across all the medicines in the class. In addition, the FDA is requiring updates to the existing patient *Medication Guides* to help educate patients and caregivers about these risks. Other changes are also being required to several sections of the prescribing information, including to the *Warnings and Precautions*, *Drug Abuse and Dependence*, and *Patient Counseling Information* sections.

Benzodiazepines can be an important treatment option for treating disorders for which these drugs are indicated. However, even when taken at recommended dosages, their use can lead to misuse, abuse, and addiction. When deciding whether the benefits of prescribing a benzodiazepine outweigh the risks, healthcare professionals should consider the patient's condition and the other medicines being taken, and assess the risk of abuse, misuse, and addiction. Abuse and misuse can result in overdose or death, especially when benzodiazepines are combined with other medicines, such as opioid pain relievers, alcohol, or illicit drugs. Particular caution should be taken when prescribing benzodiazepines with opioids and other medicines that depress the central nervous system (CNS), which has resulted in serious side effects, including severe respiratory depression and death. Patients should be advised to seek immediate medical attention if they experience symptoms, such as difficulty breathing. In addition, precautions should be taken when benzodiazepines are used in combination with opioid addiction medications; careful medication management by healthcare professionals can reduce the increased risk of serious side effects.

When prescribing benzodiazepines, alone or in combination with other medicines, healthcare providers should limit the dosage and duration of each medicine to the minimum needed to achieve the desired clinical effect. Throughout therapy, the patient should be monitored for signs and symptoms of abuse, misuse, or addiction. If a substance use disorder is suspected, the patient should be evaluated and referred to substance abuse treatment, if appropriate.

To reduce the risk of acute withdrawal reactions, a gradual taper should be utilized to reduce the dosage or to discontinue benzodiazepines. No standard benzodiazepine tapering schedule is suitable for all patients; therefore, a patient-specific plan should be created to gradually reduce the dosage, and the healthcare provider should provide ongoing monitoring and support as needed to avoid serious withdrawal symptoms or worsening of the

Table of Contents

FDA Drug Safety Communications	1
New Medicaid Eligibility Group Covers COVID-19 Testing for Uninsured Patients	2
Pharmacy Facts	3
Remittance Advice Corner	4
Medicaid Public Notice and Comment Procedure	4
Manual Chapter Revision Log	5
For Information or Assistance	5

patient's medical condition. For more information regarding how to taper benzodiazepine prescriptions, refer to the U.S. Department of Veterans Affairs brochure, [Helping Patients Taper Benzodiazepines](#).

It is important to encourage patients to read the *Medication Guide* they receive with their benzodiazepine prescriptions because there may be new or important additional information about the medicine. Also, patients and caregivers should be warned about the risks of abuse, misuse, addiction, dependence, and withdrawal with benzodiazepines and the associated signs and symptoms. The healthcare provider should also alert them of the serious risks of taking benzodiazepines with alcohol or other substances, including opioids.

Reference: [FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class | FDA](#)

FDA Drug Safety Communication: Avoiding the Use of NSAIDs in Pregnancy at 20 Weeks or Later

On October 15, 2020, the U.S. Food and Drug Administration (FDA) issued a drug safety communication warning that the use of nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks gestation or later in pregnancy may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby and possible complications. Therefore, labeling changes to the prescribing information of prescription NSAIDs will be required by the FDA. It is now recommended that NSAIDs be avoided in pregnant women at 20 weeks or later in pregnancy rather than the 30 weeks currently described in NSAID prescribing information. At around 30 weeks, NSAIDs can cause a problem that may result in heart issues in the unborn baby. If deemed necessary by a healthcare professional, use of NSAIDs between 20 and 30 weeks of pregnancy should be limited to the lowest effective dose for the shortest duration. The changes to the prescribing information also indicate that healthcare professionals should consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours.

One exception to the above recommendations is the use of the low 81 mg dose of the NSAID aspirin for certain pregnancy-related conditions at any point in pregnancy under the direction of a healthcare professional.

Reference: [FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid](#)

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.

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

December 18, 2020

Vaccine

Medicaid is working to make both the Pfizer and Moderna COVID vaccines payable; more information is forthcoming. The Pfizer vaccine was granted Emergency Use Authorization (EUA) on Friday, December 11, 2020. Click here to read about the vaccine and be prepared when the time comes to vaccinate recipients. Medicaid will reimburse the Medicare rates for administration (1st dose = \$15.92 and 2nd dose = \$26.68).

Louisiana Medicaid Annual Recertification

Annual recertification forms are going out this month. Louisiana Medicaid will allow three months to complete the paper form or the editable PDF version that was sent by email. The deadline to submit the requested recertification documents is March 31, 2021. If you have additional questions or concerns, you may contact Roderick Anderson at roderick.anderson@la.gov or call the Pharmacy Help Desk at (800) 648-0790. Preferred Drug List (PDL) Updates (<http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf>) The new PDL will go into effect on January 1, 2021. There are 12 new therapeutic classes added to the PDL. Those classes include:

- Anthelmintics
- Anti-Allergens, Oral
- Anticonvulsants
- Botulinum Toxins
- Enzyme Replacements
- Idiopathic Pulmonary Fibrosis
- Immune Globulins
- Immunomodulators, Asthma
- Methotrexate
- Movement Disorders
- Sickle Cell Anemia Treatments
- Thrombopoiesis Stimulating Proteins

New Diabetic Supply Quantity Link (PDL, page 1)

DIABETIC SUPPLY LIST LINKS BY PLAN	Prior Authorization Information Phone Numbers for MCOs and FFS
AETNA	Aetna Better Health of Louisiana 1-855-242-0802
AMERIHEALTH CARITAS LA	AmeriHealth Caritas Louisiana 1-800-684-5502
HEALTHY BLUE	Healthy Blue 1-844-521-6942
LOUISIANA HEALTHCARE CONNECTIONS	Louisiana Healthcare Connections 1-888-929-3790
UNITEDHEALTHCARE	UnitedHealthcare 1-800-310-6826
	Fee-for-Service (FFS) Louisiana Legacy Medicaid 1-866-730-4357
Click this Link to View Quantity Limits for Diabetic Test Strips and Lancets for FFS and All MCOs	

New Medically Necessary Criteria Link (First Page of PDL)

- For the request of clinical overrides for the use of medications outside of the established Point-of-Sale edits, such as diagnosis and quantity limits, please refer to the following criteria: [Medically Necessary](#)

Drugs highlighted in yellow indicate a new addition or a change in status.

Cetirizine Solution RX (1 mg/mL) (Generic)	Cetirizine Capsule OTC (Generic)
Cetirizine Tablet OTC (Generic)	Cetirizine Chewable Tablet OTC (Generic)
Levocetirizine Tablet OTC (Generic)	Cetirizine 5 mg/5 mL Solution OTC (Generic)
Levocetirizine Tablet (Generic)	Desloratadine Tablet (Generic; Clarinex®)



Remittance Advice Corner

**ESRD Facilities and Independent Laboratory:
 Non-Routine Laboratory Services**

Effective with date of service October 20, 2020, covered medically necessary non-routine laboratory services performed by approved Medicaid laboratories can be billed separately by either the contracted laboratory or by the dialysis facility. The ESRD facility and their contracted laboratory must coordinate billing to ensure duplicate payments do not occur.

Routine lab work continues to be an integral part of outpatient hemodialysis services and reimbursement for routine lab services is included in the dialysis reimbursement rate.

Information regarding this policy is forthcoming and will be found on www.lamedicaid.com under the Provider Manuals link, within the *End Stage Renal Disease Services* manual.

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.

- 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.

Public Comments for the listed policies and procedures can be left at the link below.

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

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Professional Services Professional Services Manual Chapter	5.1 Covered Services – Bariatric Surgery 5.1 Covered Services – Breast Surgery 5.1 Covered Services – Concurrent Care – Inpatient 5.1 Covered Services – Obstetrics	01/01/21

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/EPSDT – PCS Dental	1-800-807-1320 1-855-702-6262 MCNA Provider Portal	MMIS Claims Processing Resolution Unit MMIS Claims Reimbursement	(225) 342-3855
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