

FDA Drug Safety Communication: Montelukast (Singulair®) Boxed Warning about Serious Mental Health Side Effects

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On March 4, 2020, the U.S. Food and Drug Administration (FDA) issued a drug safety communication requiring a *Boxed Warning* for montelukast (Singulair® and generics). This action was taken after a review of available information prompted the FDA to reevaluate the benefits and risks of montelukast use. Montelukast prescribing information already included warnings about mental health side effects, including suicidal thoughts or actions; however, many healthcare professionals and patients/caregivers were not aware of the risk. The FDA decided a stronger warning was needed after conducting an extensive review of available information and convening a panel of outside experts. As a result of this review, the FDA determined that a *Boxed Warning* was appropriate.

Table of Contents

FDA Drug Safety Communication: Montelukast (Singulair®) Boxed Warning about Serious Mental Health Side Effects	1
New Medicaid Eligibility Group Covers COVID-19 Testing for Uninsured Patients	2
Louisiana Medicaid Provider Enrollment Portal Launches in June	3
Pharmacy Facts	3
Remittance Advice Corner	4
Medicaid Public Notice and Comment Procedure	4
Manual Chapter Revision Log	5
For Information or Assistance	6

Montelukast (Singulair® and generics) is a leukotriene receptor antagonist indicated for:

- Prophylaxis and chronic treatment of asthma in patients aged 12 months and older;
- Acute prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older; and
- Relief of symptoms of allergic rhinitis (AR). This includes seasonal allergic rhinitis (SAR) in patients 2 years of age and older and perennial allergic rhinitis (PAR) in patients 6 months of age and older. For allergic rhinitis, use should be reserved for patients who have an inadequate response or intolerance to alternative therapies.

Montelukast is available as tablets, chewable tablets, and oral granules. Common side effects of montelukast include upper respiratory infection, fever, headache, sore throat, cough, stomach pain, diarrhea, earache or ear infection, flu, runny nose, and sinus infection. In 2018, approximately 9.3 million patients of any age received a dispensed prescription for montelukast from U.S. outpatient retail pharmacies. Of these, approximately 2.3 million were children younger than 17 years of age.

Healthcare professionals should consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine. Because of the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines. For allergic rhinitis, also known as hay fever, the FDA determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicines. Prescribers should counsel all patients receiving montelukast about mental health side effects and should monitor all patients treated with montelukast for neuropsychiatric symptoms. Patients should also be advised to discontinue montelukast and contact a healthcare professional immediately if they develop any symptoms included but not limited to the following:

- agitation, including aggressive behavior or hostility
- attention problems
- bad or vivid dreams
- depression
- disorientation or confusion
- feeling anxious
- hallucinations
- irritability
- obsessive-compulsive symptoms
- restlessness
- sleepwalking
- stuttering
- suicidal thoughts and actions
- tremor or shakiness
- trouble sleeping
- uncontrolled muscle movements
- memory problems

Patients should also be encouraged to read the *Medication Guide* they receive with their montelukast prescriptions, which explains the safety risks and provides other important information. Patients should also be reminded to report adverse events involving montelukast or other medicines to the [FDA MedWatch](#) program.

Reference: [FDA Drug Safety Communication Regarding Montelukast Boxed Warning](#)

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 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.

Louisiana Medicaid Provider Enrollment Portal Launches in June

Louisiana Medicaid is launching a new provider enrollment portal in **June 2021**. The enrollment portal is being designed to meet a Centers for Medicare and Medicaid Services (CMS) requirement and must be used by all Medicaid providers. This includes current managed care organization (MCO) providers, Dental Benefits Program Manager (DBPM) providers, Coordinated System of Care (CSoc) providers and fee-for-service providers.

The state's fiscal intermediary and current provider enrollment vendor, Gainwell Technologies, will send providers an invitation to the mailing address on file when it is time for them to visit the portal and complete the enrollment process. Not all invitations will be mailed at the same time. Due to the large volume of enrollments, LDH plans to stagger invitations to avoid overwhelming the system. Providers should wait until they receive their invitation to access the portal.

[Informational Bulletin 21-5](#) has additional details about the portal and important information about what providers can do to prepare before the launch.

Information about the portal, including frequently asked questions, can also be found on [the Medicaid Provider Enrollment Portal webpage](#). The webpage includes a form for providers and stakeholders to submit questions and feedback.

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

April 5, 2021

Preferred Drug List (PDL) Update

Trulicity® will become a preferred medication on the PDL effective Thursday, April 1, 2021. This change is due to the discontinuation of the preferred Bydureon® product. There may be delays of up to seven days for programming implementation.

We get a lot of questions about why Medicaid has preferred brand products and the less expensive generic version is non-preferred. For Medicaid to make a drug payable, the drug manufacturer is required by CMS to supply a rebate to Medicaid states. The rebate amount varies depending on the drug designation (brand or generic) and is adjusted due to the rate of price increase (CPI-U). Sometimes the result is that the brand drug's net cost to the state is less than the generic version. LDH limits how many brand drugs are preferred over generics. The rebate program was designed to ensure Medicaid the best price, therefore saving taxpayer dollars.

Naloxone

Opioid abuse is a problem in Louisiana where almost all indicators—addiction to opioid medications, overdose deaths, emergency room admissions and over-prescribing—are evidence of the problem. Naloxone reverses the respiratory depression or unresponsiveness due to an opioid overdose. Prescribing and pharmacy providers are encouraged to prescribe and dispense naloxone to any Medicaid recipient who may be at risk for opioid overdose. The naloxone standing order serves as a prescription and is found here:

<https://ldh.la.gov/assets/HealthyLa/Pharmacy/NaloxoneStandingOrder.pdf>



Remittance Advice Corner

2021 Assistant Surgeon and Assistant at Surgery Services

Louisiana Medicaid has published the 2021 fee-for-service (FFS) list of allowed procedures for assistant surgeon and assistant at surgery providers. The list has been posted to the LA Medicaid website (www.lamedicaid.com) under the ClaimCheck icon.

The list is based on updates made by Change Healthcare to their 'ClaimCheck' product. Change Healthcare uses the American College of Surgeons as its primary source for determining assistant surgery designations.

This list does not ensure payment but provides a comprehensive list of codes that may be allowed when billed by an assistant surgeon or by an assistant at surgery.

For questions related to this information as it pertains to FFS Medicaid claims processing, please contact Gainwell Technologies Provider Services at (800) 473-2783 or (225) 924-5040.

Please contact the appropriate managed care organization with any questions concerning their 2021 HCPCS updates.

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 listed 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)
Hospice Hospice	24.14 – Acronyms/Definitions/Terms Appendix D – Contact Referral Information	04/23/21
EPSDT Health and IDEA - Related Services EPSDT Health and IDEA Related Services	Table of Contents 20.1 – Covered Services Appendix D – Claims Filing	04/22/21
Pharmacy Benefits Management Pharmacy	37.1 Covered Services	04/26/21
Professional Services Professional Services	5.1 - Covered Services – Prohibited and Non-Covered Services 5.1 - Covered Services – “Incident to Services” 5.1 - Covered Services – Physician Assistant 5.1 - Covered Services – Preventive Medicine 5.1 - Covered Services – Prior Authorization 5.1 - Covered Services – Professional Fee Schedule	04/08/21
Residential Options Waiver (ROW) ROW	Appendix E – Billing Codes	04/20/21



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	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 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 Pharmacy Hotline Medicaid Fraud Hotline	1-877-544-9544 1-800-437-9101 Medicaid Pharmacy Benefits 1-800-488-2917 Report Medicaid Fraud

