Louisiana Medicaid | Provider UPDATE

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FDA Restricts the Use of Prescription Codeine and Tramadol in Children and Recommends Against Use in Breastfeeding Women

On April 20, 2017, the Food and Drug Administration (FDA) issued a drug safety communication regarding new restrictions for the use of codeine and tramadol medications in children and nursing mothers.

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FDA Safety Announcement

The FDA is restricting the use of codeine and tramadol in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These opioid medications carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medications should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. The FDA is also recommending against the use of codeine and tramadol medications in breastfeeding mothers due to possible harm to their infants.

As a result, the FDA is requiring several changes to the labels of all prescription medications containing these drugs. These new actions further limit the use of these medications beyond the FDA's 2013 Drug Safety Communication regarding the restriction of codeine use in children younger than 18 years to treat pain after surgery to remove tonsils and/or adenoids. Additions to the 2013 restrictions include:

- FDA's strongest warning, called a Contraindication, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new Contraindication to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove tonsils and/or adenoids.
- A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medications due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death. Healthcare providers should instruct their patients to always read the label on prescription bottles to find out if a medication contains codeine or tramadol. Parents should watch closely for signs of breathing problems in a child of any age who is taking these medications or in infants exposed to codeine or tramadol through breastmilk. These signs include slow or shallow breathing, difficulty or noisy breathing, confusion, more than usual sleepiness, trouble breastfeeding, or limpness. If any of these signs are noticed, the medication should be discontinued and the patient should seek medical attention immediately by going to an emergency room or calling 911.

Healthcare professionals should be aware that tramadol and single-ingredient codeine medications are FDA-approved only for use in adults. Prescribers should consider recommending over-the-counter (OTC) or other FDA-approved prescription medications for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection and usually will get better on its own without treatment.

In early 2013, FDA added a Boxed Warning to the drug label of codeine-containing products cautioning about the risks of prescribing codeine to children to treat pain after surgery to remove tonsils and/or adenoids. The FDA also issued Drug Safety Communications in July 2015 and September 2015 warning about the risk of serious breathing problems in some children who metabolized codeine and tramadol to their active opioid forms much faster than usual (called ultra-rapid metabolism), causing potentially dangerously high levels in their bodies too quickly. At that time, the FDA stated that it would continue to evaluate this safety issue. As part of that safety review, the codeine-related safety issues were discussed at an FDA Advisory Committee meeting in December 2015.

The FDA reviewed adverse event report submitted to the agency spanning from January 1969 to May 2015, and found 64 cases of serious breathing problems, including 24 deaths, associated with codeine-containing medications in children younger than 18 years old. From January 1969 to March 2016, nine cases, including 3 deaths, were identified with the use of tramadol in children younger than 18 years of age. A review of medical literature for data regarding the use of codeine in nursing mothers found several cases of excess sleepiness and serious breathing problems in breastfed infants, including 1 reported death. No cases of adverse events were reported in a review of tramadol use in nursing mothers. However, tramadol and its active form are also present in breast milk, and tramadol has the same risks associated with ultra-rapid metabolism as codeine. The majority of serious side effects with both codeine and tramadol occurred in children younger than 12 years, and some cases occurred after a single dose of the medication.

The FDA urges patients and healthcare professionals to report side effects involving codeine-and tramadol-containing medications to the FDA MedWatch program, which can be found at https://www.fda.gov/safety/medwatch/default.htm.

Reference: FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women [news release]. FDA's website. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm. Accessed April 24, 2017.

ATTENTION PROVIDERS: PAYMENT ERROR RATE MEASUREMENT (PERM) FFY17 Currently Underway

Louisiana Medicaid is mandated to participate in the Centers for Medicare and Medicaid (CMS) **Payment Error Rate Measurement (PERM)** program which will assess our payment accuracy rate for the Medicaid and CHIP programs. If chosen in a random sample, your organization will soon receive a *Medical Records Request* from the CMS review contractor, CNI Advantage.

Please be advised that sampled providers who fail to cooperate with the CMS contractor by established deadlines may be subject to sanctioning by Louisiana Medicaid Program Integrity through the imposition of a payment recovery by means of a withholding of payment until the overpayment is satisfied, and/or a fine.

Please be reminded that providers who are no longer doing business with Louisiana Medicaid are obligated to retain recipient records for 5 years, under the terms of the Provider Enrollment Agreement.

For more information about PERM and your role as a provider, please visit the Provider link on the CMS PERM website: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/PERM/Providers.html

If you have any questions, please call Catherine Altazan at 225-342-2612.

Remittance Advice Corner

Attention Fee for Service (FFS) Louisiana Medicaid Providers:

Effective July 10, 2017, Fee-for-Service (FFS) pharmacy claims for opioid prescription products exceeding 120 MME (Morphine Milligram Equivalent) will deny at Point of Sale (POS). Prescribers can apply for an override of the denial by faxing an Opioid Analgesic Treatment Worksheet to l-866-797-2329. Also, short-acting opiate prescription claims will be subject to a 7 day quantity limit for opioid naive recipients. Please refer to www.lamedicaid.com for more information.

Attention Fee for Service (FFS) Louisiana Medicaid Providers:

Effective June 27, 2017, Fee-for-Service (FFS) Medicaid pharmacy claims will have the following clinical edits at Point of Sale (POS). Prescriptions for triptans will require an lCD-10-CM diagnosis code submitted in NCPDP field 424-DO (Diagnosis Code) for recipients less than 18 years old. Prescriptions for olmesartan / amlodipine / hydrochlorothiazide (Tribenzor®) and amlodipine / valsartan/ hydrochlorothiazide (Exforge HCT®) will require prior drug use of two select antihypertensive drug therapies. Please refer to www.lamedicaid.com for more information.

2017 Assistant Surgeon and Assistant at Surgery Covered Procedures – Revised May 2017

Louisiana Medicaid has republished the 2017 fee-for-service list of allowed procedures for assistant surgeons and assistant at surgery providers. Changes were made to better align with national coding standards and fee-for-service coverage of surgical procedures.

The updated 2017 list has been reposted to the LA Medicaid website (www.lamedicaid.com) under the 'ClaimCheck' icon titled, "2017 Assistant Surgeon and Assistant at Surgery List of Covered Procedure Codes – Revised May 2017." Some procedure codes have been marked out (ex. ~~22842~~), as they do not require the services of an assistant surgeon.

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.

Please contact the appropriate Managed Care Organization with any questions concerning their updates. For questions related to this information as it pertains to fee-for-service Medicaid claims processing, please contact Molina Medicaid Solutions Provider Services at (800) 473-2783 or (225) 924-5040.

Online Medicaid Provider Manual Chapter Revisions as of June, 2017

Manual Chapter	Section(s)	Date of Revision(s)
Behavioral Health Services	Table of Contents 2.0 Overview 2.1 Provider Requirements 2.1 Reserved 2.2 Outpatient Services – Behavioral Health in a Federally Qualified Health Center (FQHC) and Rural Health Center (RHC) 2.2 Outpatient Services – Outpatient Therapy by Licensed Practitioners 2.2 Outpatient Services – Rehabilitation Services 2.3 Reserved 2.4 Record Keeping Appendix A Forms and Links Appendix B Glossary and Acronyms Appendix C Medical Necessity and EPSDT Exceptions Policy Appendix D Approved Curriculum and Equivalency Standards Appendix E-1 Evidence Based Practices – (Assertive Community Treatment) Appendix E-2 Evidence Based Practices (Functional Family Therapy (FFT)/Functional Family Therapy-Child Welfare (FFT-CW) Appendix E-3 Evidence Based Practices (Homebuilders®) Appendix E-4 Evidence Based Practices (Multi-Systemic Therapy - MST)	06/09/17
Dental Services	Title Page 16.1 Provider Requirements 16.5 EPSDT – Covered Services 16.7 EPSDT – Prior Authorization 16.8 Adult Denture Program – Recipient Eligibility Requirements 16.9 Adult Denture Program – Covered Services 16.11 Adult Denture Program – Prior Authorization Appendix G Prior Authorization Checklist Appendix I Forms Appendix J Frequent Contact Information	06/09/17

Online Medicaid Provider Manual Chapter Revisions as of June, 2017 (cont.)

Manual Chapter	Section(s)	Date of Revision(s)
Federally Qualified Health Centers	Title Page 22.1 Covered Services 22.4 Reimbursement	06/22/17 06/21/17 06/01/17
Rural Health Clinics	40.1 Covered Services 40.4 Reimbursement	06/14/17

Archived Online Medicaid Provider Manual Chapter Revisions as of June, 2017

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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