Louisiana Medicaid | Provider UPDATE

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Use of Codeine and Tramadol Products in Breastfeeding Women

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Table of Contents

The FDA issued a Drug Safety Communication regarding the strengthened warning to mothers (among other warnings) that breastfeeding is not recommended during treatment with codeine or tramadol due to the risk of serious adverse reactions in breastfed infants, such as excess sleepiness, difficulty breastfeeding, and serious breathing problems that may result in death.

- Both codeine and tramadol are metabolized in the liver to their active forms by an enzyme called cytochrome P450 isoenzyme 2D6 (CYP2D6). Codeine is metabolized to morphine and tramadol is metabolized to O-desmethyltramadol (known as M1). Some patients have a variation of this enzyme that changes these drugs to their metabolites faster and to a greater extent than in other patients. These individuals are called CYP2D6 ultra-rapid metabolizers. The number of CYP2D6 ultra-rapid metabolizers varies among different population groups. In breastfeeding mothers, the ultra-rapid conversion of codeine to morphine and tramadol to M1 can result in high and unsafe levels of morphine and M1 in breast milk.

- In the FDA review of the medical literature for data regarding codeine use during breastfeeding, there were numerous cases of excess sleepiness and serious breathing problems, including one death, in infants of breastfeeding mothers who were taking codeine. A review of the available medical literature for data regarding tramadol use during breastfeeding did not reveal any cases of adverse events. However, tramadol and its metabolite M1 are also present in breast milk. Therefore, tramadol has the same risk as codeine with regard to ultra-rapid metabolism and the potential for life-threatening respiratory depression in an infant breastfeeding from a mother who is an ultra-rapid metabolizer.

- Most patients do not know if they are ultra-rapid metabolizers, and early signs of opioid overdose in an infant may be difficult to notice. Therefore, breastfeeding is not recommended during treatment with codeine or tramadol due to the risk of serious adverse reactions in breastfed infants, which may result in death. It is important for healthcare professionals and breastfeeding women to discuss the use of pain medicines and to consider alternatives to codeine or tramadol.

- The FDA wants breastfeeding mothers or caregivers to watch closely for signs of problems in infants when the mothers are taking any opioid pain medicine, and especially when they are using codeine or tramadol for pain. Because most mothers will not know if they are ultra-rapid metabolizers, they will not know that using codeine or tramadol may place their babies at greater risk for an overdose.

- Symptoms of opioid overdose in infants include the following:
    - Increased sleepiness (breastfed babies usually eat every 2 to 3 hours and should not sleep more than 4 hours at a time)
    - Difficulty breastfeeding
    - Breathing difficulties
    - Limpness in the baby

- Healthcare professionals are encouraged to read the FDA Drug Safety Communications about codeine and tramadol.

- The FDA urges healthcare providers and breastfeeding mothers to report side effects that occur while using codeine or tramadol to the FDA's MedWatch Adverse Event Reporting program.

For more information, both patients and providers can visit the FDA Codeine Information website.

Reference: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/use-codeine-and-tramadol-products-breastfeeding-women-questions-and-answers

Providers should communicate the following to their breastfeeding mothers*:*

If a breastfed baby shows symptoms of opioid overdose, the baby's doctor must be called right away. An overdose of opioid pain medicine in a baby can cause death. If the doctor cannot be reached right away, the baby should be taken to an emergency room or help should be sought by calling 911 (or local emergency services).

LactMed®External: Up-to-Date Information on Medications and Lactation

The US National Library of Medicine (NLM) at the National Institutes of Health (NIH) maintains LactMed®External, a database containing information on drugs and other chemicals to which breastfeeding mothers may be exposed. LactMed®External includes information on the levels of such substances in breast milk and infant blood, and the possible adverse effects in the nursing infant. Suggested therapeutic alternatives to those drugs are provided, where appropriate. All data come from scientific literature and are fully referenced. A peer review panel reviews the data for scientific validity and currency.

Reference: https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/vaccinations-medications-drugs/prescription-medication-use.html

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

June 28, 2019

Hepatitis C Subscription Model

LDH is excited to announce the launch of the hepatitis C subscription model, a partnership with Asegua, a subsidiary of Gilead, to provide unlimited access to the authorized generic of Epclusa (sofosbuvir/velpatasvir) to Louisiana Medicaid recipients. On July 15, 2019, sofosbuvir/velpatasvir (AG) will be the sole preferred drug on the Medicaid Single Preferred Drug List (PDL) with no prior authorization. The managed care organizations (MCO) will follow the updated LDH criteria for the non-preferred direct-acting antiviral (DAA) agents.

Fee-for-Service (FFS) and the MCOs will continue to reimburse pharmacy claims for hepatitis C at the current reimbursement methodology (professional dispensing fee, ingredient cost and provider fee). Pharmacies may continue to utilize their current wholesaler for inventory purposes.

The subscription model is in conjunction with a multi-year campaign led by the Office of Public Health to bolster treatment capacity throughout the state. Planning for the implementation of public health strategies that will support the subscription model is ongoing and includes input from LDH, Medicaid, the Department of Corrections, the Office of Public Health, national experts, pharmacists, medical providers and other stakeholders. The following strategies will be implemented in parallel with the subscription model:

- Expanding provider capacity to treat hepatitis C. This will include optional training for primary care providers to diagnose and treat hepatitis C as well as guidance on referring individuals with advanced liver disease, cancer and substance use disorder to specialists as appropriate.
- Educating the public on the availability of a cure and mobilizing priority populations for screenings. The campaign will include public messaging around risk factors for contracting hepatitis C; education on the importance of treatment before symptoms appear; increased access to screening; and information about the state's new, unprecedented access to DAAs.
- Expanding HCV screening and expediting linkage to an HCV cure. Screening for hepatitis C is recommended for all individuals born between 1945 and 1965 and for those who are at increased risk of infection. Healthcare providers across the state will screen priority populations to ensure all individuals with hepatitis C are linked to care for treatment.
- Strengthening HCV surveillance to link persons previously diagnosed to treatment. LDH's existing hepatitis C surveillance system will be upgraded to support the timely identification of individuals with chronic hepatitis C infections.
- Implementing harm reduction and complementary treatment strategies. Strategies to prevent new or reinfections must also be employed, including expanded access to syringe service programs and behavioral and medication-assisted treatment for opioid use disorder.
- Extending elimination efforts to all populations within the state. Many Louisianans infected with hepatitis C are neither Medicaid beneficiaries nor incarcerated. To truly achieve statewide elimination, the state will work with new and existing partners, including commercial insurers, health systems and entities serving the uninsured through other appropriate mechanisms.

Single PDL

As an update to the Single PDL implementation, LDH was recently made aware that the FMOLHS providers (Our Lady of the Lake, Our Lady of the Lake Ascension, Our Lady of the Angels, Our Lady of the Lake Children's Health, Our Lady of Lourdes in Lafayette and St. Francis in Monroe) and the Baton Rouge Clinic providers have embedded the Medicaid Single PDL within their EPIC electronic health record. This will allow their providers access with a single click. LDH encourages other provider groups to incorporate the Single PDL in their electronic medical records as well.

Rebate Eligible Manufacturers

Pharmacy providers and other stakeholders can access Appendix C of the Medicaid Pharmacy Provider Manual to determine which manufacturers are participating in the federal rebate program. The first five digits of the National Drug Code (NDC) identify the manufacturer and those labeler numbers are included in Appendix C. Medicaid will receive federal funding on claims when the manufacturer signed the federal rebate agreement with the Centers for Medicare and Medicaid Services. Since we do not receive federal funding, Medicaid does not pay for claims when there is not agreement between CMS and the manufacturer.

Appendix C can be found at: https://www.lamedicaid.com/provweb1/forms/drug_appendices/APNDC.pdf

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 August 2019

Manual Chapter	Section(s)	Date of Revision(s)
Children's Choice Waiver	Appendix E-5 – Billing Codes	08/19/19
EPSDT - Health And IDEA Related Services	20.1 Covered Services	08/16/19
Personal Care Services	30.13 EPSDT – PCS Overview 30.14 EPSDT – PCS Covered Services 30.15 EPSDT – PCS Recipient Criteria 30.16 EPSDT – PCS Rights and Responsibilities 30.17 EPSDT – PCS Prior Authorization 30.18 EPSDT – PCS Provider Requirements 30.19 EPSDT – PCS Service Delivery 30.20 EPSDT – PCS Record Keeping Appendix C Billing Codes Appendix H EPSDT – PCS Contact Information Appendix I EPSDT – PCS Forms Appendix J Claims Related Information **Updated the following forms:** • EPSDT PCS Daily Schedule • Request For Medicaid EPSDT - Personal Care Services • Request for Prior Authorization • EPSDT Personal Care Services – Plan of Care • EPSDT Personal Care Services – Social Assessment Form	08/23/19
New Opportunities Waiver	Appendix E – Billing Codes	08/19/19
Pediatric Day Health Care	Appendix E - Forms and Links **Updated the following form:** Forms/Files/Surveys/User Manuals link, Web Forms or Files: • Updated PDHC Prior Authorization checklist	08/16/19
Professional Services	5.1 Covered Services Laboratory and Radiology	08/26/19
Supports Waiver	Appendix B - Service Procedure Codes/Rates	08/19/19

Archived Online Medicaid Provider Manual Chapter Archived as of August 2019

Manual Chapter	Section(s)	Date of Omission(s)
Children's Choice Waiver	Appendix E-5 – Billing Codes	08/19/19
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Remittance Advice Corner

Attention Louisiana Medicaid Providers

On August 5, 2019, Fee/or Service (FFS) Medicaid updated their 340B billing policy. Reminder: only providers registered as 340B entities and listed on the HRSA Medicaid Exclusion File (MEF) may bill drug stock purchased through 340B to Medicaid. Please refer to lamedicaid.com under pharmacy and prescribing providers to access the document.

Attention Louisiana Medicaid Providers

Fee for Service (FFS) Medicaid and Managed Care Organizations (MCOs) updated the criteria for select drugs and therapeutic classes on the Louisiana Medicaid Single Preferred Drug List (PDL). Therapeutic classes/drugs with updated criteria include acne treatment agents, Orilissa®, Corlanor®, ergotamines, Endari®, GI antibiotics, Hepatitis C Direct-Acting Antiviral agents, anti-infectives, anticoagulants, antipsychotics, Behavioral Health agents, anxiolytics, Hereditary Angioedema (HAE) agents, Spravato®, cytokine and CAM Antagonists, incretin mimetics, sodium glucose co-transporter 2 (SGLT2) inhibitors, Kalydeco®, Substance Use Disorder (SUD) agents, and Calcitonin Gene-Related Peptide (CGRP) Antagonists. Please refer to http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf to access the document.

Attention Louisiana Medicaid Providers

On August 1, 2019, Fee for Service (FFS) Medicaid and Managed Care Organizations (MCOs) implemented diagnosis code requirements at Point of Sale (POS) for progesterone (Crinone®) and tobramycin (Kitabis®). Please refer to http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf to access the Single Preferred Drug List (P DL), which contains a complete listing of drugs with diagnosis code requirements at POS.

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