Louisiana Medicaid | Provider UPDATE

Volume 31, Issue 3 | October 2016

Overview of Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain

Greg W. Smith, Pharm.D. , Director of Drug Information Services – ULM School of Pharmacy
Ryan Byrd and Tiffany Mayer, Pharm.D. Candidates

Table of Contents

Due to the challenges of managing chronic pain, the limited evidence of long-term efficacy of opioids and the serious risks associated with opioid use for chronic pain, the Centers for Disease Control and Prevention (CDC) developed the following recommendations for primary care clinicians who are treating patients for chronic pain [pain lasting longer than three months or past the time of normal tissue healing] in outpatient settings. This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of active cancer treatment, palliative and end-of-life care. The CDC created the guideline through a systematic review of scientific evidence and through the use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. (See **Table 1**) For more information, refer to the complete guideline at www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Purpose of the Guideline:

- Improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain;
- Improve the safety and effectiveness of pain treatment; AND
- Reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

Summary of Recommendations

The twelve recommendations are grouped into three areas for consideration:

Determining When to Initiate or Continue Opioids for Chronic Pain (Recommendations 1-3)

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate. (Recommendation category: A, evidence type: 3)

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. (Recommendation category: A, evidence type: 4)

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy. (Recommendation category: A, evidence type: 3)

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation (Recommendations 4-7)

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation category: A, evidence type: 4)

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. (Recommendation category: A, evidence type: 3)

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation category: A, evidence type: 4)

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation category: A; evidence type: 4)

Assessing Risk and Addressing Harms of Opioid Use (Recommendations 8-12)

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present. (Recommendation category: A, evidence type: 4) See **Table 2** for some common risk factors that increase the risk of opioid-related harm.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation category: A; evidence type: 4) See **Table 3** for more information regarding the Louisiana Prescription Drug Monitoring Program.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. (Recommendation category: B, evidence type: 4)

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible. (Recommendation category: A; evidence type: 3)

12. Clinicians should offer or arrange evidence-based treatments (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder. (Recommendation category: A; evidence type: 2)

Guideline Resources

These recommendations focus on clinical practice and help providers implement best practices for responsible prescribing of opioids. The CDC offers numerous easy-to-use resources that provide guidance on opioid prescribing. See **Table 4** for some of these resources.

Table 1. Interpretation of Recommendation Categories and Evidence

Recommendation Categories: Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).	
Category A	Applies to all persons; most patients should receive the recommended course of action.
Category B	Individual decision-making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.
Evidence type: Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.	
Type 1	Randomized clinical trials or overwhelming evidence from observational studies.
Type 2	Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.
Type 3	Observational studies or randomized clinical trials with notable limitations.
Type 4	Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

Table 2. Some Common Risk Factors that May Increase Risk of Opioid-Related Harm

Sleep-disordered breathing, including sleep apnea	o Careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. o Opioid use should be avoided in patients with moderate or severe sleep-disordered breathing.
Pregnancy	o Opioid use in pregnancy may be associated with additional risks to both mother and fetus, and in some cases, may result in neonatal opioid withdrawal syndrome. o Clinicians should carefully weigh risks and benefits when deciding whether or not to initiate opioid therapy for chronic pain in pregnancy. o For pregnant women who are already receiving opioids, if tapering is considered, the clinician should consider the risk to the pregnant patient and to the fetus if the patient goes into withdrawal.

Renal or Hepatic Insufficiency	o Clinicians should use additional caution and increased monitoring to minimize risks of opioid-related effects in patients with renal or hepatic insufficiency.
Patients ≥ 65 years of age	o Due to reduced renal function and medication clearance, patients 65 years of age and older may be even more susceptible to accumulation of opioids, which increases the risk of respiratory depression and overdose. o Clinicians should use additional caution and increase monitoring for patients 65 and older on opioids.
Mental Health Conditions	o Use additional caution and increased monitoring in patients who have mental health conditions due to increased risks for opioid use disorder and overdose. o Clinicians should ensure that treatment used for depression and other mental health conditions is optimized and that behavioral health specialists are consulted when needed. o Patients with anxiety and other mental health conditions should be monitored closely if taking benzodiazepines with opioids due to increased risk of opioid-induced respiratory depression and increased risk for overdose.
Substance Use Disorder	o Patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. o Clinicians should ask the patient about alcohol and drug use, which can be done through the use of single screening questions or through the use of validated tools such as the Drug Abuse Screening Test (DAST). o If clinicians consider opioid therapy for chronic pain for patients with drug or alcohol use disorders, the clinician should discuss increased risks for opioid use disorder and overdose with the patient. Strategies should be incorporated into the treatment plan to mitigate the associated risks, such as considering offering naloxone and increasing frequency of monitoring when opioids are prescribed.
Prior Nonfatal Overdose	o Experts believe that prior nonfatal overdose will substantially increase the risk for future nonfatal or fatal opioid overdose. o If a patient experiences nonfatal opioid overdose, clinicians should work with the patient to reduce opioid dosage and discontinue when possible.

Table 3. Louisiana Prescription Drug Monitoring Program (PDMP)*

- The Louisiana PDMP is a web-based system that collects prescribing and dispensing data for controlled substances and other drugs of concern; the information is collected regardless of the payer (Medicaid, third-party payer, or cash transaction).

- Louisiana dispensers are required to report prescribing and dispensing data to the PDMP for controlled substances and other drugs of concern dispensed in the state or dispensed to an address within the state. Authorized users may access the program in the process of caring for their patients. These data may also be used by authorized state agencies to improve the state's ability to identify and inhibit the diversion of controlled substances and other drugs of concern.

- Effective August 1, 2014, prescribers licensed in the state of Louisiana are required to access the PDMP prior to initially prescribing any Schedule II controlled dangerous substance to a patient for the treatment of non-cancer-related chronic or intractable pain.

- For more information regarding creating a PDMP account, prescribers, pharmacists and/or their delegates may visit http://www.labp.com/index.cfm?md=pagebuilder&tmp=home&pid=5&pnid=0&nid=7.

* Reference: Louisiana Board of Pharmacy (www.labp.com)

Table 4. Guideline Resources

Assessing Benefits and Harms of Opioid Therapy
http://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf
Calculating Total Daily Dose of Opioids for Safer Dosage
http://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
Checklist for Prescribing Opioids for Chronic Pain
http://www.cdc.gov/drugoverdose/pdf/pdo_checklist-a.pdf
Guidelines for Prescribing Opioids for Chronic Pain
http://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf
Non-opioid Treatment for Chronic Pain
http://www.cdc.gov/drugoverdose/pdf/alternative_treatments-a.pdf
Pocket Guide: Tapering Opioids for Chronic Pain
http://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf
Prescription Drug Monitoring Programs (PDMPs)
http://www.cdc.gov/drugoverdose/pdf/pdmp_factsheet-a.pdf
Turn the Tide Pocket Guide: Prescribing Opioids for Chronic Pain
http://www.cdc.gov/drugoverdose/pdf/turnthetide_pocketguide-a.pdf
Why Guidelines for Primary Care Providers?
http://www.cdc.gov/drugoverdose/pdf/guideline_infographic-a.pdf

Reference:

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

New Genetic Testing for Breast and Ovarian Cancer

Effective for dates of service on or after July 1, 2016, Louisiana Medicaid will now cover genetic testing for BRCA 1 and BRCA 2 mutations in cancer-affected individuals and cancer-unaffected individuals. Louisiana Medicaid considers it to be medically necessary if the recipient meets the published criteria.

Information regarding this policy and criteria can be found on www.lamedicaid.com under the Provider Manuals link within the Professional Services Manual. The fee schedule can be found within the Professional Services Fee schedule under the Laboratory and Radiology section.

The managed care organizations (MCOs) will cover services listed on the Louisiana Medicaid Professional Services and related fee schedules. The fee schedules are updated to reflect the additional services. Updates to MCO changes are plan-specific and are the responsibility of each health plan to make appropriate changes to their fee schedule, coverage criteria and prior authorization process.

For more information, see “Genetic Testing for Breast and Ovarian Cancer with Instructions for Prior Authorization” in the Remittance Advice Corner, below.

Breast Reconstruction Post Mastectomy

Effective for dates of service on or after October 1, 2016, Louisiana Medicaid will now cover breast reconstruction post mastectomy of the contralateral unaffected breast for recipients diagnosed with breast cancer. Previously, Louisiana Medicaid only covered breast reconstruction post mastectomy on the affected/diseased breast. Breast reconstruction post mastectomy must be prior approved by the fiscal intermediary's Prior Authorization Unit (PAU). Information regarding this policy can be found on www.lamedicaid.com under the Provider Manuals link within the Professional Services Manual.

The Managed Care Organizations (MCOs) will be responsible for coverage of the above services for dates of service on or after February 1, 2017.

Please contact the appropriate MCO if there are any questions concerning their policies and prior authorization processes. In addition, questions regarding legacy Medicaid should be directed to Molina Provider Relations at (800) 473-2783 or (225) 924-5040.

Remittance Advice Corner

Update to 'ClaimCheck' Product Editing

McKesson's 'ClaimCheck' product is routinely updated by the McKesson Corporation based on changes made to resources used, such as Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) coding guidelines, the Centers for Medicare & Medicaid Services (CMS) Physician Fee Schedule database, National Correct Coding Initiative (NCCI) edits, and/or provider specialty society updates. The 'ClaimCheck' product's procedure code edits are guided by these widely accepted industry standards.

This update will affect claims with remittance advice of September 13, 2016 forward. Providers may notice some differences in claims editing. Providers should expect that some claims will continue to deny for the same error, but in some cases claims may now pay or deny for a different reason.

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.

Attention Eligible Providers

If you don't begin participation in the Medicaid Electronic Health Records Incentive Program by December 31, 2016, you'll miss out on $63,750 in incentive payments. Please visit the website at http://new.dhh.louisiana.gov/index.cfm/page/1159 for information. A new redesigned web portal will be ready for attestations starting September 19, 2016 at http://LAConnect.ThinkHTS.com. If you need additional information, please contact Kelli Douglas at 225-342-7742 or Gary Dillon at 225-342- 4810.

Attention Fee for Service (FFS) Louisiana Medicaid Providers

Effective September 15, 2016, Fee-for Service (FFS) Medicaid Pharmacy Program will reimburse enrolled pharmacies for influenza vaccines and the administration of the vaccines by a pharmacist per program policy. For more information, please refer to http://www.lamedicaid.com/provweb1/Pharmacy/Influenza.htm.

Genetic Testing for Breast and Ovarian Cancer with Instructions for Prior Authorization

Effective with date of service July 1, 2016, Louisiana Medicaid will now cover genetic testing for BRCA 1 and BRCA 2 mutations in cancer-affected individuals and cancer-unaffected individuals. The recipient is required to meet the following published criteria. Prior authorization is required through the fiscal intermediary' Prior Authorization (PA) Unit.

Eligibility Criteria

Patients with Cancer Diagnosis

Genetic testing for BRCA1 and BRCA2 mutations in cancer-affected individuals may be medically necessary under any of the following circumstances:

1. Individual from a family with a known BRCA1/BRCA2 mutation

2. Personal history of breast cancer and ≥1 of the following:

    - Diagnosed age ≤45 years
    - 2 primary breast cancers when 1st breast cancer diagnosis occurred age ≤50 years
    - Diagnosed age ≤50 years AND: ≥1 1st-, 2nd-, or 3rd-degree relative with breast cancer at any age, or
    - Unknown or limited family history
    - Diagnosed age ≤60 years with a triple negative (ER–, PR–, HER2–) breast cancer
    - Diagnosed any age AND ≥1 1st-, 2nd-, or 3rd-degree relative with breast cancer diagnosed ≤ 50 years
    - Diagnosed any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with breast cancer at any age.
    - Diagnosed any age AND ≥1 1st-, 2nd-, or 3rd-degree relative with epithelial ovarian/fallopian tube/primary peritoneal cancer.
    - Diagnosed any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with Pancreatic cancer or prostate cancer at any age
    - 1st-, 2nd-, or 3rd-degree male relative with breast cancer
    - Ethnicity associated with deleterious founder mutations, eg, Ashkenazi Jewish

3. Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer
4. Personal history of male breast cancer
5. Personal history of pancreatic cancer or prostate cancer at any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with any of the following at any age. For pancreatic cancer, if Ashkenazi Jewish ancestry, only 1 additional affected relative is needed.

    - Breast cancer
    - Ovarian/fallopian tube/primary peritoneal cancer
    - Pancreatic or prostate cancer

Genetic testing for BRCA1 and BRCA2 mutations of cancer-unaffected individuals may be considered medically necessary under any of the following circumstances:

Patients without cancer (Testing unaffected individuals)

1. Individual from a family with a known BRCA1/BRCA2 mutation
2. 1st- or 2nd-degree blood relative meeting any criterion listed above for Patients with Cancer.
3. 3rd-degree blood relative with breast cancer and/or ovarian/fallopian tube/primary peritoneal cancer AND ≥2 1st-, 2nd-, or 3rd-degree relatives with breast cancer

For the purpose of familial assessment, 1st-, 2nd-, and 3rd-degree relatives are blood relatives on the same side of the family (maternal or paternal).

- 1st-degree relatives are parents, siblings, and children.
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings.
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, grandchildren and first cousins

For the purpose of familial assessment, prostate cancer is defined as Gleason score ≥7.

Testing for Ashkenazi Jewish or other founder mutation(s) should be performed first (see guidelines: High risk ethic groups).

**Note: "Generally, genetic testing for a particular disease should be performed once per lifetime; however, there are rare instances in which testing may be performed more than once in a lifetime (eg, previous testing methodology is inaccurate or a new discovery has added significant relevant mutations for a disease)."

When Genetic Testing for Breast and Ovarian Cancer is not covered

Unless they meet the criteria above, genetic testing either for those affected by breast, ovarian, fallopian tube, or primary peritoneal cancer or for unaffected individuals, including those with a family history of pancreatic cancer, is considered **investigational.**

Genetic testing in minors for BRCA1 and BRCA2 mutations is considered **investigational.**

High-risk ethnic groups: Testing in eligible individuals who belong to ethnic populations in which there are well-characterized founder mutations should begin with tests specifically for these mutations. For example, founder mutations account for approximately three quarters of the BRCA mutations found in Ashkenazi Jewish populations. When the testing for founder mutations is negative, comprehensive mutation analysis should then be performed.

Testing unaffected individuals. In unaffected family members of potential BRCA mutation families, most test results will be negative and uninformative. Therefore, it is strongly recommended that an affected family member be tested first whenever possible to adequately interpret the test. Should a BRCA mutation be found in an affected family member(s), DNA from the unaffected family member can be tested specifically for the same mutation of the affected family member without having to sequence the entire gene. Interpreting the test results for an unaffected family member without knowing the genetic status of the family may be possible in the case of a positive result for an established disease-associated mutation, but leads to difficulties in interpreting negative test results (uninformative negative) or mutations of uncertain significance because the possibility of a causative BRCA mutation is not ruled out.

Prostate cancer. Patients with BRCA mutations have an increased risk of prostate cancer, and patients with known BRCA mutations may therefore consider more aggressive screening approaches for prostate cancer. However, the presence of prostate cancer in an individual, or in a family, is not itself felt to be sufficient justification for BRCA testing.

Prior Authorization

BRAC 1 and BRCA 2 testing must be prior approved by the fiscal intermediary's Prior Authorization Unit (PAU) or the managed care organization (MCO). Prior authorization (PA) requests should include the following:

- PA request form;
- Documentation of medical necessity;
- Other pertinent clinical information that may be requested.

Clinical information must be submitted by the provider involved in the recipient's care.

The documentation required for PA requests to the MCO shall be determined by the MCO. Managed care organizations will utilize the criteria they deem appropriate for BRCA 1 and BRCA 2 testing based upon the clinical information submitted by the provider involved in the recipient's care.

Online Medicaid Provider Manual Chapter Revisions

Manual Chapter	Section(s)	Date of Revision
Pediatric Day Health Care	Title Page 45.1 Covered Services 45.2 Recipient Criteria 45.3 Provider Requirements 45.4 Staffing Requirements 45.5 Record Keeping 45.6 Reimbursement 45.7 Plan of Care 45.8 Quality Assurance Appendix A Definitions Appendix B Procedure Codes Appendix C Fee Schedule Appendix D Contact/Referral Information	09/01/16 09/14/16
Personal Care Services	Title Page 30.2 Covered Services 30.6 Provider Requirements 30.7 Service Delivery 30.8 Record Keeping Appendix D Forms	09/09/16 09/16/16 09/22/16
Professional Services	5.1 Covered Services- Genetic Testing for Breast and Ovarian Cancer 5.1 Covered Services – Breast Reconstruction Post Mastectomy	09/01/16 09/13/16

Archived Online Medicaid Provider Manual Chapter Revisions As of September 1, 2016

Archived Manual Chapter	Section(s)	Date of Omission
Pediatric Day Health Care	Title Page 45.1 Covered Services 45.2 Recipient Criteria 45.3 Provider Requirements 45.4 Staffing Requirements 45.5 Record Keeping 45.6 Reimbursement 45.7 Plan of Care 45.8 Quality Assurance Appendix A Definitions Appendix B Procedure Codes Appendix C Fee Schedule Appendix D Contact/Referral Information	09/01/16
Personal Care Services	Title Page 30.2 Covered Services 30.6 Provider Requirements 30.7 Service Delivery 30.8 Record Keeping Appendix D Forms	09/09/16 09/16/16 09/22/16
Professional Services	5.1 Covered Services- Genetic Testing for Breast and Ovarian Cancer 5.1 Covered Services – Breast Reconstruction Post Mastectomy	09/01/16 09/13/16

For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370
Prior Authorization:	
Home Health/EPSDT – PCS	1-800-807-132
Dental	1-866-263-6534 1-504-941-8206
DME & All Other	1-800-488-6334 (225) 928-5263
Hospital Pre-Certification	1-800-877-0666
Provider Relations	1-800-473-2783 (225) 924-5040
REVS Line	1-800-776-6323 (225) 216-(REVS)7387
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381

General Medicaid Eligibility Hotline	1-888-342-6207
MMIS Claims Processing Resolution Unit	(225) 342-3855
MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Medicare Savings Program and Medicaid Purchase Hotline	1-888-544-7996
For Hearing Impaired	1-877-544-9544
Pharmacy Hotline	1-800-437-9101
Medicaid Fraud Hotline	1-800-488-2917