Louisiana Medicaid | Provider UPDATE

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FDA Drug Safety Communication Regarding Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, and Invokamet XR)

On May 16, 2017, the U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication regarding the diabetes medication canagliflozin (Invokana, Invokamet, Invokamet XR). Canagliflozin is a sodium-glucose cotransporter-2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Based on new data from two large clinical trials, the FDA concluded that canagliflozin causes an increased risk of leg and foot amputations. The FDA now requires a Boxed Warning on the canagliflozin drug labels to describe this risk.

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Final results from two clinical trials – the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus) – showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo. The CANVAS trial showed that over a year's time, the risk of amputation for patients in the trial were equivalent to:

- 5.9 out of every 1,000 patients treated with canagliflozin
- 2.8 out of every 1,000 patients treated with placebo

The CANVAS-R trial showed that over a year's time, the risk of amputation for patients in the trial were equivalent to:

- 7.5 out of every 1,000 patients treated with canagliflozin
- 4.2 out of every 1,000 patients treated with placebo

Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs.
Before initiating canagliflozin, healthcare professionals should consider factors that may predispose patients to the need for amputations. These factors include a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers. Patients receiving canagliflozin should be monitored for any new pain or tenderness, sores, ulcers, or infections in their legs or feet. Canagliflozin should be discontinued if these complications occur.
Healthcare professionals and patients should report side effects involving canagliflozin to the FDA MedWatch program available at www.fda.gov/safety/medwatch.

Reference: www.fda.gov/Drugs/DrugSafety/ucm557507.htm

Checklist for Prescribing Opioids for Chronic Pain

For primary care providers treating adults (18 years of age or older) with chronic pain lasting for 3 months or longer, excluding cancer, palliative, and end-of-life care.

CHECKLIST	REFERENCE
When CONSIDERING long-term opioid therapy: ☐ Set realistic goals for pain and function based on diagnosis (such as walk around the block). ☐ Check that non-opioid therapies tried and optimized. ☐ Discuss benefits and risks (such as addiction and overdose) with patient. ☐ Evaluate risk of harm or misuse. • Discuss risk factors with patient. • Check prescription monitoring program (PMP) data. • Check urine drug screen. ☐ Set criteria for stopping or continuing opioids. ☐ Assess baseline pain and function. (PEG scale is an example of a screening instrument used to do this.) ☐ Schedule initial reassessment within 1– 4 weeks. ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment. **If RENEWING without patient visit:** ☐ Check that return visit is scheduled ≤3 months from last visit. **When REASSESSING at return visit:** ***Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.*** ☐ Assess pain and function; compare results to baseline. ☐ Evaluate risk of harm or misuse: • Observe patient for signs of over-sedation or overdose risk. – If yes: Taper dose. • Check PMP. • Check for opioid use disorder if indicated (such as difficulty controlling use). – If yes: Refer for treatment. ☐ Check that non-opioid therapies optimized.	**EVIDENCE ABOUT OPIOID THERAPY** • *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.* • *Short-term benefits small to moderate for pain; inconsistent for function.* • *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.* **NON-OPIOID THERAPIES** Use alone or combined with opioids, as indicated: • *Non-opioid medications (such as NSAIDs, TCAs, SNRIs, anti-convulsants).* • *Physical treatments (such as exercise therapy, weight loss).* • *Behavioral treatment (such as CBT).* • *Procedures (such as intra-articular corticosteroids).* **EVALUATING RISK OF HARM OR MISUSE** Known risk factors include: • *Illegal drug use; prescription drug use for nonmedical reasons.* • *History of substance use disorder or overdose.* • *Mental health conditions (such as depression, anxiety).* • *Sleep-disordered breathing.* • *Concurrent benzodiazepine use.* **Urine drug testing**: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use. **Prescription monitoring program (PMP)**: Check for opioids or benzodiazepines from other sources. **ASSESSING PAIN & FUNCTION USING PEG SCALE** PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Checklist for Prescribing Opioids for Chronic Pain, continued

CHECKLIST	REFERENCE
☐ Determine whether to continue, adjust, taper, or stop opioids. ☐ Calculate opioid dosage morphine milligram equivalent (MME). • If ≥50 MME/day total (for example, ≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone. • Avoid ≥90 MME/day total (for example, ≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral. ☐ Schedule reassessment at regular intervals (≤3 months).	**Q1**: *What number from 0 –10 best describes your pain in the past week?* 0 = "no pain", 10 = "worst you can imagine" **Q2:** *What number from 0 –10 describes how, during the past week, pain has interfered with your enjoyment of life?* 0 = "not at all", 10 = "complete interference" **Q3:** *What number from 0 –10 describes how, during the past week, pain has interfered with your general activity?* 0 = "not at all", 10 = "complete interference"

For information regarding the CDC guideline for prescribing opioids for chronic pain, visit www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Reference: www.cdc.gov

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.

Online Medicaid Provider Manual Chapter Revisions as of November, 2017

Manual Chapter	Section(s)	Date of Revision(s)
Applied Behavior Analysis	Table of Contents 4.1 Covered Services 4.5 Reimbursement Appendix A Contact Information Appendix B Billing Codes	11/02/17 11/02/17 11/02/17 11/02/17 11/02/17 and 11/13/17

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

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Remittance Advice Corner

Attention Fee for Service (FFS) Louisiana Medicaid Providers:

Effective November 29, 2017 Fee (FFS) for Service pharmacy claims for buprenorphine implant kit (Probuphine®) will have edits at Point of Sale (POS). Please refer to http://www.lamedicaid.com for specifics.

Attention LTC and ICF-DD Facilities:

Beginning March 2018, monthly Optional State Supplement (OSS) payments will be generated by State of Louisiana Division of Administration.

To receive OSS payments for eligible residents of Long Term Care and ICF-DD Facilities after February 2018, the Facility **must** complete the following no later than **January 12, 2018:**

1. Register as a Vendor with Louisiana Division of Administration @ http://www.doa.la.gov/pages/osp/vendorcenter/vendorregn.aspx
2. Submit a completed IRS W-9 form for the Facility to DOA-OSRAP, via e-mail at DOA-OSRAP-LAGOV@LA.GOV or fax (225) 342-0960**.**

If you need help with LAGOV registration, contact Office of State Procurement via email VENDR_INQ@la.gov or phone 225-342-8010.

Providers must continue to review the OSS Payment Remittances through the OSS web application in order to verify and issue individual recipient payments.

Return Payments must be made through the OSS system. **Payments should not be returned to Louisiana Department of Health.**

Refer to the OSS Provider User Guide located on the "Forms/Files/Surveys/User Manuals" tab at LaMedicaid.com for additional information.

For questions related to this announcement, **email to OSS@la.gov; or contact LDH's OSS Program Manager, Lorie Young, by phone at (225) 342-0456.**

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