Louisiana Medicaid | Provider UPDATE

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FDA Drug Safety Communication: Addition of Boxed Warning to Tofacitinib (Xeljanz®, Xeljanz XR®) Regarding Increased Risk of Blood Clots and Death with Higher Dose

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On July 26, 2019, the U.S. Food and Drug Administration (FDA) approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of tofacitinib (Xeljanz®, Xeljanz XR®), which is used in patients with ulcerative colitis.
In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. The FDA approved these changes, including the addition of a *Boxed Warning,* after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine.

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The 10 mg twice daily dose of tofacitinib is not approved for RA or psoriatic arthritis (PsA). This dose is only approved for ulcerative colitis for initial treatment and for long-term use in limited situations. While the increased risks of blood clots and of death were seen in patients taking this dose for RA, these risks may also apply to those taking tofacitinib for ulcerative colitis.

Tofacitinib works by decreasing the activity of the immune system; an overactive immune system contributes to RA, PsA, and ulcerative colitis. Tofacitinib was first approved in 2012 to treat adult patients with RA who did not respond well to methotrexate. In 2017, the FDA approved tofacitinib to treat patients with PsA, who did not respond well to methotrexate or other similar medicines. In 2018, the FDA approved tofacitinib to treat ulcerative colitis.

Healthcare professionals should talk to their patients about whether or not they have a history of blood clots or heart problems and discuss any questions or concerns they may have. Patients should be instructed to stop taking tofacitinib and seek emergency medical attention right away if they experience any unusual symptoms, including those that may signal a blood clot such as:

- Sudden shortness of breath
- Chest pain that worsens with breathing
- Swelling of a leg or arm
- Leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm

Patients should be advised to not stop taking tofacitinib without first talking to their healthcare professional, as doing so can worsen their condition.

When FDA first approved tofacitinib in 2012, the FDA required a postmarketing clinical trial in patients with RA on background methotrexate, to evaluate the risk of heart-related events, cancer, and infections. An interim analysis of the trial's results found an increased occurrence of blood clots and of death in patients treated with tofacitinib 10 mg twice

daily compared to patients treated with tofacitinib 5 mg twice daily or a TNF blocker. Based on these results, the 10 mg twice daily treatment was stopped and patients were allowed to continue treatment on 5 mg twice daily.

The interim results of the trial, as of January 2019, have identified the following:

- 19 cases of blood clots in the lung out of 3,884 patient-years of follow-up in patients who received tofacitinib 10 mg twice daily, compared to 3 cases out of 3,982 patient-years in patients who received TNF blockers
- 45 cases of death from all causes out of 3,884 patient-years of follow-up in patients who received tofacitinib 10 mg twice daily, compared to 25 cases out of 3,982 patient-years in patients who received TNF blockers

Healthcare professionals should discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Patients should be counseled about the risks and advised to seek medical attention immediately if they experience any unusual symptoms, including those of thrombosis listed above. Tofacitinib should be reserved to treat ulcerative colitis for patients who have failed or do not tolerate tumor necrosis factor (TNF) blockers. Tofacitinib should be avoided in patients who may have a higher risk of thrombosis. When treating ulcerative colitis, tofacitinib should be taken at the lowest effective dose and the use should be limited to the 10 mg twice daily dosage with the shortest duration needed.

FDA Drug Safety Communication: Addition of Boxed Warning for Increased Risk of Death with Gout Medicine Uloric® (febuxostat)

In February of this year, the FDA concluded that there is an increased risk of death with Uloric® (febuxostat) compared to another gout medicine, allopurinol. This conclusion is based on the FDA's in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric®. As a result, the FDA updated the Uloric® prescribing information requiring a *Boxed Warning*, the most prominent FDA warning, and a new patient Medication Guide. The FDA also limited the approved use of Uloric® to certain patients who are not treated effectively or experience severe side effects with allopurinol.

Uloric® was FDA-approved in 2009 to treat gout in adults. Gout, a chronic disease that affects approximately 8.3 million adults in the U.S., occurs when uric acid builds up and causes sudden attacks of redness, swelling, and pain in one or more joints. Uloric® works by lowering uric acid levels in the blood.

Healthcare providers should ask patients if they have a history of heart problems or stroke and discuss the benefits and risks of using Uloric® to treat gout. Patients should be instructed to seek emergency medical attention right away if they experience the following symptoms while taking Uloric®:

- Chest pain
- Shortness of breath
- Rapid or irregular heartbeat
- Numbness or weakness on one side of the body
- Dizziness
- Trouble talking
- Sudden severe headache

Patients should also be instructed to not stop taking Uloric® without first talking to their healthcare professional, as doing so can worsen their gout.

When the FDA approved Uloric® in 2009, a *Warning and Precaution* was included in the prescribing information regarding possible cardiovascular events in patients treated with Uloric®. In addition, the FDA required the drug manufacturer, Takeda Pharmaceuticals, to conduct a large postmarket safety clinical trial. The trial was conducted in more than 6,000 patients with gout treated with either Uloric® or allopurinol. The primary outcome was a combination of heart-related death, non-deadly heart attack, non-deadly stroke, and a condition of inadequate blood supply to the heart requiring intervention, called unstable angina.

The results showed that overall, Uloric® did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, Uloric® showed an increased risk of heart-related deaths and death from all causes. In patients treated with Uloric®, 15 deaths from heart-related causes were observed for every 1,000 patients treated for a year compared to 11 deaths from heart-related causes per 1,000 patients treated with allopurinol for a year. In addition, there were 26 deaths from any cause per 1,000 patients treated for a year with Uloric® compared to 22 deaths per 1,000 patients treated for a year with allopurinol.

Healthcare professionals should reserve Uloric® for use only in patients who have failed or do not tolerate allopurinol. Patients should be counseled about the cardiovascular risk with Uloric® and advised to seek medical attention immediately if they experience the symptoms listed above.

To help the FDA track safety issues with medicines, patients and healthcare professionals are urged to report side effects involving any medication to the FDA MedWatch program. This program can be accessed at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

References

www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and

https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-death-gout-medicine-uloric-febuxostat

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

November 15, 2019

Voltaren® Gel

LDH recently became aware that brand name Voltaren® Gel has been discontinued by the manufacturer. This was a brand preferred product over the generic on the Single PDL. The generic product has been moved to a preferred status and does not require prior authorization for all Medicaid plans (MCOs and FFS) to assist in recipient care.

Not sure what Medicaid MCO plan a member is in?

Process a pharmacy claim to legacy Medicaid (DXC, formerly Molina) with the member's 16-digit Medicaid CCN number (starts with 777). The response message will provide billing information including the BIN, PCN and pharmacy help desk number.

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.

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.

http://www.ldh.la.gov/index.cfm/page/3616

Remittance Advice Corner

Attention Louisiana Medicaid Providers

On November 1, 2019, Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Managed Care Organizations (MCOs) will implement quantity limits for opioid liquids, collagenase topical (Santyl®), and galcanezumab injection (Emgality ®). Please refer to lamedicaid.com under pharmacy and prescribing providers to access the document.

Attention Louisiana Medicaid Providers

On November 1, 2019, Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Managed Care Organizations (MCOs) will implement diagnosis code requirements for antiretroviral agents, agalsidase beta (Fabrazyme®), alglucosidase (Lumizyme®), amikacin (Arikayce®), and eculizumab (Soliris®). Please refer to lamedicaid.com under pharmacy and prescribing providers to access the document.

Attention Louisiana Medicaid Providers

On November 1, 2019, Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Managed Care Organizations (MCOs) will implement revised duration of therapy edits for Proton Pump Inhibitors (PPIs) and Histamine (H_2) Antagonists. Please refer to lamedicaid.com under pharmacy and prescribing providers to access the document.

Recycle of Denied Claims for CPT Code 82962

Louisiana Medicaid has recently updated the fee-for-service (FFS) Clinical Laboratory Improvement Amendments (CLIA) claims processing logic to no longer require modifier QW when submitting Current Procedural Terminology (CPT) code 82962 (Glucose, blood by glucose monitoring device(s)…).

Fee-for-service claims submitted with date of service January 1, 2018 and after with procedure code 82962 that were denied due to requiring modifier QW will be recycled without any action required by providers.

Please contact DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040 if there are questions related to this matter concerning FFS claims.

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Applied Behavior Analysis		11/13/19
Adult Day Health Care	9.2 Recipient Requirements	11/13/19
Community Choices Waiver	7.3 Recipient Requirements	11/13/19
Federally Qualified Health Centers	22.1 Covered Services 22.4 Reimbursement	11/21/19
Rural Health Clinics	40.1 Covered Services 40.4 Reimbursement	11/21/19

Archived Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Applied Behavior Analysis	4.1 Covered Services 4.6 Coordination of Care	11/18/19
Adult Day Health Care	9.2 Recipient Requirements	11/09/19
Community Choices Waiver	7.3 Recipient Requirements	11/09/19
Federally Qualified Health Centers	22.1 Covered Services 22.4 Reimbursement	11/21/19
Rural Health Clinics	40.1 Covered Services 40.4 Reimbursement	11/21/19

For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370
Prior Authorization:	
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
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