Louisiana Medicaid | Provider UPDATE

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Clarification of Clonidine Edits for Fee-for-Service (FFS) Louisiana Medicaid Pharmacy Program

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- For recipients 0 through 20 years of age:
    - On October 28, 2014, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana FFS Medicaid Drug Utilization Review (DUR) Board implemented diagnosis code requirements for all medications which may be used to treat Attention-Deficit Hyperactivity Disorder (ADHD) for recipients less than 21 years of age.
    - Covered diagnoses for use of clonidine are: ADHD, Hypertension, Hypertension in Congenital Heart Disease and Tics/Tourette's Disorder.
    - When the diagnosis code is not included in the list of covered diagnoses, the prescribing provider may call Louisiana Medicaid RxPA Operations at the University of Louisiana at Monroe School of Pharmacy at 1-866-730-4357 for guidance in establishing medical necessity.
    - When the diagnosis code is not included on the prescription AND when the pharmacist cannot reach the prescriber OR when the prescribing provider cannot reach the RxPA Center because it is closed, the pharmacist, using his/her professional judgment, may deem the filling of the prescription to be an 'emergency.' In these emergency cases, the pharmacist must indicate 'emergency prescription' on the hard copy or in the pharmacy's electronic recordkeeping system and may override the diagnosis code requirement by:

      Placing '03' in NCPDP field 418-DI (Level of Service)

      Compliance associated with program policy will be verified through the Louisiana Medicaid Pharmacy Program.

- For recipients 0 through 5 years of age:
    - On November 17, 2015, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana FFS Medicaid Drug Utilization Review (DUR) Board implemented clinical pre-authorization requirements for all medications used for behavioral health for recipients less than 6 years of age.
    - Clinical pre-authorization is <u>not</u> required for recipients less than 6 years of age who take clonidine for a diagnosis of Hypertension or Hypertensive Congenital Heart Disease. Claims for clonidine will bypass the clinical pre-authorization edit when one of the covered hypertension-related diagnosis codes is entered at the pharmacy.

The RxPA Center processes retail prescription prior authorization requests for providers of Fee-for-Service Louisiana Medicaid recipients and is open from 8am to 6pm Monday through Saturday.

Heart Failure Risk with Diabetes Medications Containing Saxagliptin and Alogliptin

In April 2016, the FDA posted a drug safety communication for the following medications:

- Onglyza® (saxagliptin)
- Kombiglyze XR® (saxagliptin and metformin extended release)
- Nesina® (alogliptin)
- Kazano® (alogliptin and metformin)
- Oseni® (alogliptin and pioglitazone)

ISSUE: An FDA safety review has found that type 2 diabetes medicines containing saxagliptin and alogliptin may increase the risk of heart failure, particularly in patients who already have heart or kidney disease. As a result, FDA is adding new warnings to the drug labels about this safety issue.
[This Communication is an update to the 02/11/2014 FDA Drug Safety Communication.]

BACKGROUND: Saxagliptin and alogliptin are part of the class of dipeptidyl peptidase-4 (DPP-4) inhibitor drugs, which are used with diet and exercise to lower blood sugar in adults with type 2 diabetes.

FDA evaluated two large clinical trials conducted in patients with heart disease. These clinical trials were also discussed at the FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting in April 2015. Each trial showed that more patients who received saxagliptin- or alogliptin-containing medicines were hospitalized for heart failure compared to patients who received an inactive treatment called a placebo (see Data Summary in the FDA Drug Safety Communication for additional information). In the saxagliptin trial, 3.5% of patients who received the drug were hospitalized for heart failure versus 2.8% of patients who received a placebo. This is the same as 35 out of every 1,000 patients compared to 28 out of every 1,000 patients. Risk factors included a history of heart failure or kidney impairment. In the alogliptin trial, 3.9% of alogliptin-treated patients were hospitalized for heart failure versus 3.3% in the placebo group. This is the same as 39 out of every 1,000 patients compared to 33 out of every 1,000 patients.

RECOMMENDATION: Health care professionals should consider discontinuing medications containing saxagliptin and alogliptin in patients who develop heart failure and monitor their diabetes control. If a patient's blood sugar level is not well-controlled with their current treatment, other diabetes medicines may be required.

Patients taking these medicines should contact their health care professionals right away if they develop signs and symptoms of heart failure such as:

- Unusual shortness of breath during daily activities
- Trouble breathing when lying down
- Tiredness, weakness, or fatigue
- Weight gain with swelling in the ankles, feet, legs, or stomach

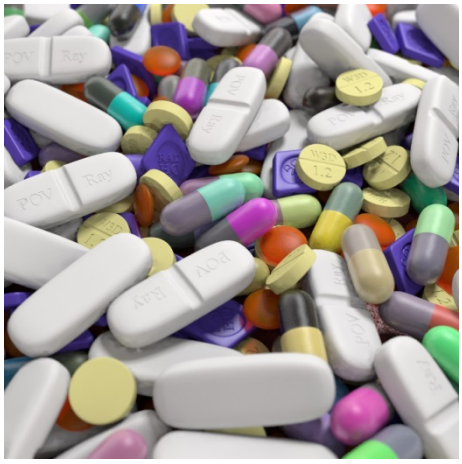
Patients should not stop taking their medicine without first talking to their health care professionals.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For more information:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm494252.htm

Brintellix ® (Vortioxetine) Name Change to Trintellix®



In May 2016, the FDA posted a drug safety communication for Brintellix® (vortioxetine).

ISSUE: FDA has approved a brand name change for the antidepressant Brintellix® (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta® (ticagrelor). The new brand name of the drug is Trintellix®, and it became available in June 2016. No other changes were made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals and patients may continue to see bottles labeled with the brand name Brintellix® during the transition period.

In a July 2015 MedWatch Alert, FDA warned that name confusion between Brintellix® and Brilinta® had resulted in prescribing and dispensing errors since Brintellix® was approved in September 2013. Due to continued reports of name confusion between the two medicines used for very different purposes, FDA worked with Brintellix® manufacturer Takeda Pharmaceuticals to change the drug's brand name.

BACKGROUND: Brintellix® (now Trintellix®) (vortioxetine) is used to treat a certain type of depression called major depressive disorder in adults. It is in a class of antidepressants called serotonin reuptake inhibitors (SSRIs) that work by affecting chemicals in the brain that may become unbalanced.

RECOMMENDATION: Health care professionals should check carefully to make sure they have prescribed or dispensed the correct medicine. During the transition to the new name change from Brintellix® to Trintellix®, prescribers can reduce the risk of name confusion by including the generic name of the medication they are ordering, in addition to the brand name and indication for use. Patients should make sure they have received the correct medicine. Trintellix® tablets look the same as the Brintellix® tablets. Those having any questions or concerns should talk to their prescriber or pharmacist.

Individuals responsible for ordering and stocking the medicine should be aware that Trintellix® has a new National Drug Code (NDC) number. It is important for drug information content publishers and medication-related electronic system administrators to use the new brand name Trintellix® and NDC number now that Takeda has made vortioxetine available under the new name Trintellix®.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For more information:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm498607.htm

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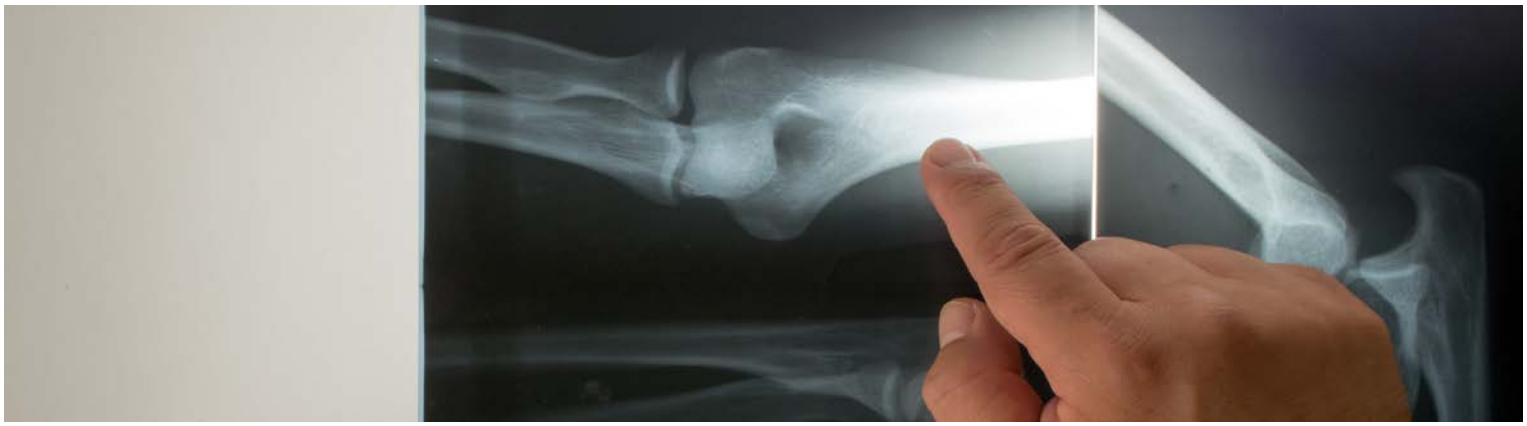
Request for Consideration of Medical and Dental Benefit Coverage for Louisiana Medicaid

This communication is to inform providers and vendors of a new process in regards to requesting coverage of a new service, technology or other benefit from Louisiana Medicaid. Please fill out and submit a request for consideration form in order to propose a benefit for review and consideration of coverage.

Please also attach supporting evidence based literature, free from industry sponsorship (publications, bibliography, or other documents) to a completed request for consideration form for a benefit to be considered for coverage by Louisiana Medicaid.

The form can be found on http://new.dhh.louisiana.gov/index.cfm/page/1456/n/382 under Quick links.

Services that are experimental, non-FDA approved, investigational or cosmetic will not be considered for coverage. A service may be deemed medically necessary and still not be covered under the Medicaid Program. The Medicaid Director, in consultation with the Medicaid Chief Medical Officer, may consider authorizing services at her discretion on a case-by-case basis.



Online Medicaid Provider Manual Chapter Revisions

Manual Chapter	Section(s)	Date of Revision
Applied Behavior Analysis	Title Page Section 4.1 - Covered Services Section 4.3 - Service Authorization Process Appendix D - Plan of Care (POC) Instructions and Form	07/14/2016
Professional Services	Title Page Section 5.1 - Covered Services - Anesthesia	07/14/2016

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

Archived Manual Chapter	Section(s)	Date of Omission
Applied Behavior Analysis	Title Page Section 4.1 - Covered Services Section 4.3 - Service Authorization Process Appendix D - Plan of Care (POC) Instructions and Form	07/14/2016
Professional Services	Title Page Section 5.1 - Covered Services - Anesthesia	07/14/2016

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	1-800-807-132		
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