

Provider Update

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Radiology Utilization Management Implemented

The Louisiana Medicaid Program has implemented Radiology Utilization Management (RUM) in order to promote the health of Medicaid recipients by ensuring appropriate utilization of Department-defined high-tech imaging studies by Medicaid providers and recipients. Medicaid has partnered with MedSolutions Inc. (MSI) to provide prior authorization, monitoring and management of medical imaging services.

Effective February 15, 2010, primary care and specialty care providers are required to request prior authorization for non-emergency outpatient Magnetic Resonance (MR), Computed Tomography (CT), and Nuclear Cardiac imaging. Reimbursement is contingent on the rendering provider obtaining prior authorization for these services. A list of the procedure codes that require prior authorization is available online at <http://www.lamedicaid.com/provweb1/RUM/RUMProcedureCodesListing.pdf>

Additional information about RUM, including a quick reference guide, can be found on the MSI website at <http://www.medsolutions.com/implementation/ladhh/index.html>

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Durable Medical Equipment Providers

Accreditation Required for Providers of Durable Medical Equipment

Effective for dates of service on or after April 1, 2010, all providers seeking reimbursement for medical equipment, supplies and appliances must be accredited by one of the following Medicare deemed accreditation organizations:

Organization	Website
The Joint Commission (JC)	http://www.jointcommission.org
National Association of Boards of Pharmacy (NABP)	www.nabp.net
Board of Orthotist/Prosthetist Certification (BOC)	www.bocusa.org
The Compliance Team, Inc.	www.exemplaryprovider.com
American Board for Certification in Orthotics & Prosthetics, Inc (ABC)	www.abcop.org
The National Board of Accreditation for Orthotic Suppliers (NBAOS)	www.nbaos.org
Commission on Accreditation of Rehabilitation Facilities (CARF)	www.carf.org
Community Health Accreditation Program (CHAP)	http://www.chapinc.org
HealthCare Quality Association on Accreditation (HQAA)	http://www.hqaa.org/
Accreditation Commission for Health Care, Inc.	http://www.achc.org/

A copy of the provider's approval letter with the certification dates from the accreditation organization must be submitted to the Provider Enrollment Unit at the following address by March 31, 2010.

Unisys Provider Enrollment
PO Box 80159
Baton Rouge, LA 70898-0159

Failure to provide verification of accreditation by the established deadline will result in the denial of prior authorization requests. The accreditation requirement for Medicaid providers shall become effective for prior authorization requests received by Unisys on April 1, 2010.

If you have any question regarding this policy change, please contact Stephanie Young at (225) 342-3935.

Dental Provider Link on LA Medicaid Website

The Louisiana Medicaid website now offers dental providers an all inclusive dental page that includes the following:

- Past and present dental policy updates,
- Dental Program Provider Manual,
- Claim forms and instructions,
- Fee schedules,
- Dental Periodicity Schedule, and
- Links to other useful websites.

Providers can access this page on www.lamedicaid.com by clicking on the "Dental Providers" link on the left side of the homepage. Questions about problems accessing this site should be directed to Technical Support at 1-877-598-8753.

Dental Provider Reminders

Providers are reminded to update their files each quarter by logging on to the Louisiana Medicaid website at www.lamedicaid.com under the "Provider Login" link to indicate whether they are accepting new Medicaid patients and to ensure their contact information is correct. This information on each provider is viewable to the public on the Department of Health and Hospitals website using the Provider Locator tool and the Insure Kids Now website as part of the Children's Health Insurance Reauthorization Act of 2009.

Changes or questions that may impact a provider's enrollment status should be directed to the Unisys Provider Enrollment Unit at (225) 216-6370.

All Providers

On-line Form Available for Requesting Spend - Down Medically Needy Notice

An optional new online form is available for providers to use when requesting initial or amended "Spend - Down Medically Needy Notices" (110-MNP). Instead of having to telephone Medicaid and request the 110-MNP form, providers now have the option of electronically completing a "Provider Request for Spend - Down Medically Needy Notice." This new form is available on the Medicaid website at www.lamedicaid.com under the "Forms/Files/User Manuals" link for "Online Forms or Files." Completed forms should be printed and faxed to Medicaid at 1-877-523-2987 for processing.

Questions regarding the use of this form should be directed to Lesli Boudreaux at (225) 219-1783.

Online Medicaid Provider Manual Chapters

The following Medicaid Provider Manual Chapters are available on the Louisiana Medicaid website at www.lamedicaid.com under the "Provider Manual" link.

- American Indian 638 Clinics
- Dental
- Mental Health Rehabilitation
- Multi-Systemic Therapy
- Personal Care Services
- Pharmacy

This list will be updated periodically as other Medicaid program chapters become available online.

Hospital Providers

Changes to Coverage for Newborns

The Children's Health Insurance Program Reauthorization Act of 2009 now provides immediate Medicaid coverage for all newborn babies born to mothers who are enrolled in Medicaid or the Children's Health Insurance Program (LaCHIP). Newborn babies are no longer required to live with or be a member of the biological mother's household upon discharge from the hospital to retain Medicaid coverage. Hospitals should complete an electronic "Request for Newborn ID Number" on ALL babies born to mothers with Medicaid coverage. Inquiries related to this change can be directed to the Medicaid Customer Service Unit at 1-888-342-6207 or (225) 219-1783.

Louisiana Drug Utilization Review Education

Black Box Warnings

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Many misconceptions exist in the medical community as to what a black box warning on a medication actually means. Some prescribers are unable to differentiate between a warning and a contraindication of a medication. The Food and Drug Administration (FDA) defines a contraindication as a clinical situation where the risk from the drug's use clearly outweighs any possible therapeutic benefit.¹ This is different from a black box warning, which is usually reserved for medications with potentially serious, life-threatening risks that may be minimized by detailing specific information to the physician. Medications with black box warnings require more patient-specific evaluation prior to use and intense monitoring from the physician after prescribing.³ These warnings are bolded and outlined in a "black box" and can usually be found in the first section of the prescribing information (package insert). There are currently over 500 medications in the United States that carry black box warnings. Table 1 gives examples of several medications (and classes) that carry a black box warning.

There are multiple criteria the Food and Drug Administration uses to determine whether a particular medication (or class) should be assigned a black box warning. These criteria may include:¹

1. There is an adverse reaction so serious in proportion to the potential benefit of the drug that it is essential that it be considered in assessing the risks and benefits of using a drug,
2. There is a serious adverse reaction that can be prevented or reduced in frequency or severity by appropriate use of the drug, or
3. FDA approved the drug with restrictions to assure safe use because the FDA concluded that the drug can be safely used only if distribution or use is restricted.

The FDA uses various types of evidence when deciding if a black box warning should be assigned to a medication.³ Evidence supporting the use of this warning can be obtained directly from randomized-controlled trials during the medication's approval process. Information received after the medication has already been approved and a particular adverse event is discovered during post-marketing reporting can also be used.³ If a new or more frequent adverse event appears after a drug is already on the market, the FDA may decide to review the data and will then determine if a new boxed warning is merited.⁴

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Pharmaceutical companies are required by law to update the product's prescribing information once a new boxed warning has been issued. This action may have severe detrimental effects on the medication's place in the market, as physicians are less likely to prescribe a medication with a new, serious warning.³ A good example of this occurred in the 1990s with the drug Seldane® (terfenadine). After the FDA placed a black box warning on the drug, sales decreased from \$700 million to \$450 million in one year.³

Additionally, the FDA may decide that a *Medication Guide* be included with any medication that receives a black box warning. This guide is different from the prescribing information, which is usually the official drug monograph. The prescribing information contains all of the product's labeling information and may have specific instructions for the patient, such as the directions that are dispensed with packs of oral contraceptives. The *Medication Guide* contains important information directed mainly toward the patient. The guide usually includes monitoring parameters, signs and symptoms of particular adverse reactions (usually the one responsible for the warning), and various other types of pertinent information.

The FDA uses multiple criteria to determine whether a drug needs a *Medication Guide*. If it is determined that increased labeling could prevent an adverse event, or strict adherence to the directions are vital for the drug's safety and effectiveness, a guide may be issued.⁴ These guides should be dispensed with the medication upon each new prescription and refill. It is the responsibility of the pharmacist to ensure that each patient who is prescribed a medication that has an accompanying guide not only receive the guide, but also receive the appropriate counseling when they pick up their prescription. The only exception to this rule is if the prescribing practitioner decides that receiving the *Medication Guide* is not in the best interest of the patient.⁴ A list of *Medication Guides* can be found on the FDA website (www.fda.gov/Drugs/DrugSafety/ucm085729.htm).

It is important for prescribers to be aware of a medication's (or class') boxed warnings and determine if the benefit of that particular therapy outweighs the potential adverse effect of the drug. The prescriber should adhere to any FDA-recommended monitoring parameters for the specific medication.

Louisiana Drug Utilization Review Education

Table 1. Common Medications with Black Box Warnings²

Medication or Class	Summary of Boxed Warning
ACE-inhibitors/Angiotensin-Receptor blockers (examples: enalapril, lisinopril, olmesartan, valsartan)	Should not be used in pregnancy, especially in second and third trimester due to risk of fetal injury or death
Amiodarone	Several potentially fatal toxicities, most commonly pulmonary (as high as 17%), and hepatotoxicity
Amphetamines (examples: dextroamphetamine/amphetamine, methylphenidate)	High potential for abuse, long-term use should be avoided
Antidepressants (examples: citalopram, fluoxetine, venlafaxine)	Increased risk of suicidality, especially in children, adolescents, and young adults
Antipsychotics (examples: olanzapine, risperidone)	Increased mortality in elderly patients with dementia-related psychosis, most due to cardiovascular causes
Beta blockers (examples: atenolol, metoprolol)	Abrupt discontinuation may exacerbate angina, myocardial infarction, and arrhythmias
Estrogen replacement therapy (example: conjugated estrogens)	Increased risk of cardiovascular events, endometrial cancer, and dementia if age 65 or older
Fluoroquinolones (examples: ciprofloxacin, levofloxacin)	Increased risk of tendonitis and tendon rupture in all ages, but higher if age 60 or older, on corticosteroids, or in transplant patients
NSAIDs (including COX-2 inhibitors) (examples: celecoxib, ibuprofen, naproxen)	Increased risk of serious cardiovascular thrombotic events, especially with long-term use, also increased serious gastrointestinal events (ulceration and bleeding)
Oral contraceptives (examples: ethinyl estradiol/norethindrone, mestranol/norethindrone)	Smoking increases risk of cardiovascular events
Promethazine	Should not use in children under 2 years of age due to potentially fatal respiratory depression
Salmeterol	Long-acting beta-2 agonists may increase risk of asthma-related death
Thiazolidinediones (examples: pioglitazone, rosiglitazone)	Can cause or exacerbate heart failure
Valproic acid (and derivatives)	Can cause liver failure (fatal), life-threatening pancreatitis, can cause teratogenic effects
Warfarin	Bleeding risk, can cause major (fatal) hemorrhage

References:

1. Food and Drug Administration. "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products-Content and Format *Draft Guidance*" January 2006. www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf Accessed December 8, 2009.
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3. Beach, J, Faich, G, Bormel, FG, Sasinowski, FJ. Black Box Warnings in Prescription Drug Labeling: Results of a Survey of 206 Drugs. *Food and Drug Law Journal*. 1998, issue 53: 403-412.
4. Products with a "Black Box" Warning. *Pharmacist Letter/Prescribers Letter*. 2006; 22 (3) 220332.



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 Baton Rouge, LA 70821

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FOR INFORMATION OR ASSISTANCE, CALL US!

Provider Enrollment	(225) 216-6370	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization			
Home Health/EPSTD - PCS	1-800-807-1320	LaCHIP Enrollee/Applicant Hotline	1-877-252-2447
Dental	1-866-263-6534		
	1-504-941-8206		
DME & All Other	1-800-488-6334	MMIS/Claims Processing/Resolution Unit	(225) 342-3855
	(225) 928-5263		
Hospital Pre-Certification	1-800-877-0666	MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Provider Relations	1-800-473-2783 (225) 924-5040	Medicare Savings Program Medicaid Purchase Hotline	1-888-544-7996
REVS Line	1-800-776-6323 (225) 216-REVS (7387)	KIDMED & CommunityCARE ACS For Hearing Impaired	1-800-259-4444 1-877-544-9544
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	Pharmacy Hotline	1-800-437-9101