MISSISSIPPI DIVISION OF MEDICAID

Pharmacy Update

Quarterly News Letter | Volume 1 , Issue 4 | Summer 2012

Inside This Issue

PDL Update (see pg. 7-8)

New Stable Therapy Requirements

All NEW non-preferred agents, as of July 1, will NOT be approved for stable therapy– a trial of 2 preferred agents must occur first. Stable therapy will not be considered until January 1, 2013.

Exceptions to this are: Lamictal XR, Bystolic, Jalyn, Pulmicort Flexhaler, Revatio, Prevacid Solu-Tab (Prevacid grandfathered ages 12 and under only). These drugs will be considered for stable therapy as well as any other associated criteria listed under the PA Criteria column on the PDL document.

Per Mississippi Legislature Ruling

PREFERRED BRANDS will not count towards the 2 brand monthly prescription limit as of July 1, 2012. They will however still count toward the 5 prescription limit.

TREATMENT OF HEAD LICE

Treatment of Head Lice

The agent of choice for treating head lice is permethrin 1%, with a cure rate ranging between 85% and 95%. Increasing resistance to permethrin 1% has led to the need for trials of alternative treatments, such as malathion. In December 2011, the FDA updated the labeling for malathion 0.5% lotion to include a warning about chemical burns including second-degree burns and stinging sensations. There are several new FDA-approved treatments for head lice, including Natroba Topical Suspension (spinosad 0.9%), approved for patients four years of age and older and Ulesfia Lotion (benzyl alcohol 5%), approved for patients 6 months of age and older. Natroba Topical Suspension (spinosad 0.9%) and Ulesfia Lotion (benzyl alcohol 5%) are applied to dry hair and should be rinsed off with water after 10 minutes. The labeling for Ulesfia requires a repeat application in 7 days, whereas Natroba may be repeated if live lice are seen after 7 days. Both agents contain benzyl alcohol (excipient in Natroba and active ingredient in Ulesfia), which has been associated with serious adverse reactions, including death, when applied topically to children less than 6 months of age. For more information, please refer to the FDA website for Postmarket Drug Safety Information.

(Continued on page 2)

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MEDICAID UPDATES

Treatment of Head Lice (continued…)

Antiparasitics (Topical) Excerpt from the PDL (Effective July 1, 2012)

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
ANTIPARASITICS (Topical)	EURAX (crotamiton) NATROBA (spinosad) permethrin	lindane malathion* OVIDE (malathion) ULESFIA (benzyl alcohol)	*Note: Non-Preferred drugs will deny at POS, PDL criteria are not listed for this rule as it pertains to Natroba only.* Natroba • History of permethrin in the past 90 days

PDL Changes: Antiparasitics (topical)

Effective July 1, 2012, several changes to the *Antiparasitics (topical)* category will be implemented, including adding Natroba (spinosad) as a preferred agent and moving malathion to a non-preferred agent. Because permethrin is still considered the agent of choice for the treatment of head lice infestation, Natroba will be covered if there has been a trial of permethrin in the previous 90 days. An excerpt from the Antiparasitics (topical) section of the PDL (effective July 1, 2012) is included above.

Federal Upper Limit Information

Federal Upper Limit and DOM Pricing Updates

Medicaid often receives questions regarding reimbursement for drugs with a CMS assigned federal upper limit, or FUL, price. Refer to the Federal Upper Limits' Page on CMS's website, where there is detailed information on CMS' FUL program. In the section entitled "Federal Upper Limits Prior to the Affordable Care Act", there are details about CMS' rationale for selecting drugs with a FUL and pricing methodology. To locate the most current FUL transmission and on this same webpage scroll down to this section in the fifth paragraph (see below in the boxed text):

Following a period of releasing the FULS in draft format, CMS plans to publish the final Affordable Care Act FULs. At that time, the prior FULs calculated using the methodology at 42 CFR 447.332 (FUL Changes Made To Transmittal No.37 and Transmittal No.37 – FUL November 20, 2001), as in effect on December 31, 2006, under the authority of the Medicare Improvements for Patients and Providers Act of 2008 will no longer be in effect.

See FUL Changes Made to Transmittal No. 37 dated September 25, 2009 which is the most recent update. Prices are noted on that page. DOM's pricing files are updated weekly.

Medicaid, I Have Questions!

Q: I like the new layout of the preferred drug list (PDL), but what are the "PA Criteria" that are now listed on the PDL?

A: As you have noticed, several improvements have been made recently to the PDL, including the addition of a "PA Criteria" column on the right-hand side of the document. Using input from Medicaid's P&T Committee, from the DUR Board, and from Medicaid's PDL vendor, Goold Health Systems (GHS), criteria were developed using FDA-approved labeling and extensive literature reviews to create evidence-based prior authorization criteria. These criteria help ensure that the Mississippi Medicaid drug benefit is clinically and fiscally sound. These criteria help to prevent safety-related issues identified by the FDA, as well as off-label prescribing of certain drugs with no medically-accepted use. When you receive a rejected claim, reviewing the PA criteria may help determine why the claim was rejected and whether you need to pursue a PA from the prescriber.

MEDICAID RESOURCES

Preferred Drug List Updates

The Mississippi Medicaid Preferred Drug list is updated two times per year, on January 1st and July 1st. The next update will become effective July 1, 2012. The July update reflects changes which have been recently reviewed by the Division of Medicaid's Pharmacy and Therapeutics Committee. It is important for providers to become familiar with changes to the Preferred Drug List (PDL) in an effort to prevent and reduce confusion and delay of patient care. The PDL is available for viewing at the Mississippi Medicaid website: www.medicaid.ms.gov/Pharmacy.aspx.

72 Hour Emergency Supply

A 72-hour emergency supply should be dispensed any time a PA is not available and the prescribed drug must be filled. If the prescriber cannot be reached or is unable to request the PA, the pharmacy should submit an emergency 72-hour prescription. The 72-hour emergency prescription counts against monthly service limits. A pharmacy can dispense a product that is packaged in a dosage form that is fixed and unbreakable (e.g., an albuterol inhaler), as a 72-hour emergency supply. Click Here

New 90 Day Maintenance List

Effective April 1, 2012, the Mississippi Division of Medicaid is offering a revised 90 Day Maintenance List of legend medicines which may be written for up to 90 days at a time.

There are two versions of this list:

1) 90 Day Maintenance, in alphabetic order
2) 90 Day Maintenance, Disease State Format

Please note that only the drugs included on this list may be dispensed in 90 day increments.

Prescription Services Limit

Currently Mississippi state law limits outpatient prescription drug coverage to five drugs monthly; of the five drugs only two may be a brand name medication. Beneficiaries up to 21 years old may receive more than the monthly limit provided proof of medical necessity. If a pediatric beneficiary has exhausted their monthly service limit, subsequent claims will be denied with the following message: "PA REQUIRED FOR AGE UNDER 21". These edits indicate that the beneficiary may qualify for additional benefits provided the submission of a Children's Medical Necessity prior authorization request. For more information, see www.medicaid.ms.gov/PharmacyForms.aspx.

Medicaid Provider Bulletin

The Mississippi Medicaid Bulletin is a quarterly publication aimed to provide timely information regarding policies that affect Mississippi Medicaid providers. The most recently published bulletins as well as an archive of previously published bulletins may be accessed at www.medicaid.ms.gov/Providers.aspx.

Products with Quantity Limits

A number of products covered by Medicaid have a restricted monthly quantity allowed. An up-to-date list of these products can be located by following the link at http://www.medicaid.ms.gov/Documents/Pharmacy/QuantityLimitsUpdate7-1-10.pdf

For assistance resolving issues related prior authorizations or coverage, please contact:

MISSISSIPPI DIVISION OF MEDICAID

Address:

Sillers Building, 550 High Street, Suite 1000
Jackson, MS 39201-1399

Telephone / Fax

Jackson area: 601-359-5253
Toll free: 1-877-537-0722
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DUR BOARD UPDATE

Low Molecular Weight Heparin (LMWH) Criteria — Effective July 1, 2012

The DUR Board has recommended the Division of Medicaid update the criteria for approval of low molecular weight heparins (LMWH). ***Effective July 15, 2012***, a point-of-sale approval criteria will be implemented for LMWH on the Preferred Drug List (PDL). As an ongoing effort to share information with Mississippi Medicaid providers, we wanted to make you aware of the **new criteria.**

SmartPA Criteria for LMWH duration:

Duration of therapy for LMWH will not be approved for greater than 17 days supply

- Exceptions to the 17 days supply rule will be:
  - History of cancer in the past 2 years
  - Pregnancy diagnosis in the past 280 days
  - History of a total hip replacement, total knee replacement or hip fracture surgery in the past 60 days **AND** the duration of therapy with this history is </= 35 days

A manual prior authorization will be required for situations other than the criteria above. Please see the "PA Criteria" column of the PDL for an expanded description of the new LMWH criteria. For the most recent version of the PDL, please go to http://www.medicaid.ms.gov/Pharmacy.aspx and select "Preferred Drug List" from the menu on left side of the page. Please refer to the Mississippi Medicaid website for any updates to the PDL.

Low Molecular Weight Heparins Excerpt from the PDL (Effective July 1, 2012)

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS
ANTICOAGULANTS	COUMADIN (warfarin) **FRAGMIN (dalteparin) SmartPA LMWH** **LOVENOX (enoxaparin) SmartPA LMWH** PRADAXA (dabigatran)* warfarin XARELTO (rivaroxaban) Clinical Edit	**ARIXTRA (fondaparinux) SmartPA LMWH** **enoxaparin SmartPA LMWH** **fondaparinux SmartPA LMWH** **INNOHEP (tinzaparin) SmartPA LMWH**

IMPORTANT INFORMATION

FROM THE MISSISSIPPI DIVISION OF MEDICAID

Pharmacy Changes — Effective July 1, 2012

Pharmacy program institutes a pilot program for ICD-9 codes at POS

The prescriber must write the valid ICD code on the prescription and no manual prior authorization is required. For the comprehensive list of valid ICD codes at POS, refer to Pharmacy Services' webpage at http://www.medicaid.ms.gov/Pharmacy.aspx, and select POS ICD-9 Codes. For other indications for the drugs listed below, a prior authorization request is required:

- Xarelto – limited to hip replacement
- Effient – *limited to unstable angina; STEMI (Segment Elevation Myocardial Infarction or heart attack), NSTEMI (Non-ST Segment Elevation Myocardial Infarction*
- Brilinta — limited to unstable angina; STEMI (Segment Elevation Myocardial Infarction or heart attack), and NSTEMI (Non-ST Segment Elevation Myocardial Infarction).
- Suboxone/Subutex — limited to opioid dependence.

Please note that instructions to pharmacies regarding point of sale placement of codes are included in the June Provider Bulletin and posted on the Pharmacy Services' webpage.

Postponement: Injectable Mental Health Drugs and Billing Changes

Since the following agents are administered in a clinical setting, effective **November 1, 2012**, injectable mental health drugs, including but not limited to antipsychotics and benzodiazepines, become solely a medical benefit and are to be billed as such. ***As of November 1, 2012, these drugs will be closed to Pharmacy Point of Sale (POS).***

The only exceptions are for Medicaid only beneficiaries residing in long-term care facilities such as nursing facilities (NF), intermediate-care facilities for the mentally retarded (ICFs/MR), and/or psychiatric residential facilities (PRTF). ***All pre-existing pharmacy prior authorizations for injectable antipsychotics and/or benzodiazepines, except for the aforementioned exceptions, become null and void as of close of business on October 31, 2012.***

Injectable antipsychotics include, but are not limited to:

- Abilify (aripiprazole),
- Compazine (prochlorperazine edisylate)
- Geodon (ziprasidone),
- Haldol Lactate and Haldol Deconate (compare to haloperidol lactate and haloperidol decanoate),
- Invega Sustenna (paliperidone palmitate),
- Prolixin decanoate (fluphenazine decanoate)
- Risperdal Consta (risperidone microspheres),
- Thorazine (chlorpromazine HCL),
- Zyprexa (olanzapine), and
- Zyprexa Relprevv (olanzapine pamoate).

Injectable benzodiazepines include, but are not limited to:

- Lorazepam (compare to Ativan), and
- Diazepam (compare to Valium).

SAFETY ALERTS

FDA MedWatch

Statin dose limitations with protease inhibitors **Warnings and Precautions**

[March 2012] The FDA clarified dosing and warning recommendations for citalopram. Citalopram should no longer be used at doses >40 mg per day due to potentially dangerous abnormalities in the electrical activity of the heart. Use at any dose is discouraged in patients with certain conditions due to risk of QT prolongation, and caution needs to be taken when citalopram is used in such patients. Lower doses should be used in patients >60 years of age.

Combination of aliskiren with ARBs or ACEIs in patients with diabetes or renal impairment **Contraindication**

[April 2012] The FDA notified healthcare professionals of possible risks when using blood pressure medicines containing aliskiren with other drugs called angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) in patients with diabetes or kidney (renal) impairment. Concomitant use of aliskiren with ARBs or ACEIs in patients with diabetes is contraindicated because of the risk of renal impairment, hypotension, and hyperkalemia. Avoid use of aliskiren with ARBs or ACEIs in patients with renal impairment where GFR < 60 mL/min.

Co-administration of boceprevir (Victrelis) and ritonavir-boosted HIV protease inhibitors **Precaution**

[April 2012] The FDA has revised the Victrelis drug label to state that co-administration of Victrelis with ritonavir-boosted Reyataz (atazanavir), ritonavir-boosted Prezista (darunavir), or Kaletra (lopinavir/ritonavir) to patients infected with both chronic HCV and HIV is not recommended at this time as concomitant use can potentially reduce the effectiveness of these medicines.

Zortress (everolimus) boxed warning for malignancies and serious infections **Boxed Warning**

[April 2012] The FDA has revised the Zortress (everloimus) label to include boxed warnings Increased susceptibility to infection and the possible development of malignancies such as lymphoma and skin cancer may result from immunosuppression

Gilenya (fingolimod) is contraindicated in patients with select cardiovascular conditions **Contraindication**

[May 2012] The FDA revised the Gilenya (fingolimod) label to include a contraindication for patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure. This contraindication also includes patients with a baseline QTc interval ≥500 ms, history or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless the patient has a functioning pacemaker.

For a complete listing of drug safety labeling changes, please visit the FDA MedWatch site at: http://www.fda.gov/Safety/MedWatch/

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The Mississippi Evidence-Based DUR Initiative (MS-DUR) performs the retrospective drug utilization review (rDUR) for the Mississippi Division of Medicaid. The MS-DUR advises the Mississippi Division of Medicaid Drug Utilization Review Board and provides educational outreach to health care practitioners on drug therapy to improve prescribing and dispensing practices for Mississippi Division of Medicaid beneficiaries. The goal of MS-DUR is to advance the discipline of drug utilization review (DUR) for federal, state, and commercial entities by developing and championing best practices in DUR. The MS-DUR is intended to be an information sharing and education-focused entity, not a punitive program. MS-DUR provides information for health care practitioners serving Mississippi Medicaid beneficiaries to assist with the continued evaluation and management of the patient's medication requirements.

The purpose of this newsletter is to provide new information relevant to providers serving Mississippi Medicaid beneficiaries and to "revoice" some of the information provided in the Mississippi Medicaid Provider Bulletin. You will occasionally receive communication from MS-DUR though Mississippi Medicaid, the Mississippi Pharmacist's Association, or from us directly. We hope this information is helpful to your practice and we value your comments and suggestions. Please email kdnull@olemiss.edu to provide feedback or to recommend topics for future newsletters. Please contact Medicaid (See Page 3) for assistance resolving issues related to prior authorizations or coverage.

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Mississippi Division Of Medicaid
Preferred Drug List Changes
P&T Meeting Dates: March 13 and April 17, 2012
PDL Changes Effective Date: July 1, 2012

The following changes will be made to the Preferred Drug List (PDL), effective July 1, 2012, pending recommendation and/or approval by the P&T Committee, DOM, and DOM's Executive Director.

For a comprehensive PDL, refer to http://www.medicaid.ms.gov/Pharmacy.aspx.

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for PREFERRED STATUS**
Anticoagulants	XARELTO (rivaroxaban)
Anticonvulsants	DIASTAT (diazepam rectal gel)
Anticonvulsants	VIMPAT (lacosamide)
Antiparasitics (Topical)	NATROBA (spinosad)
Bronchodilators, Beta Agonist	PROAIR HFA (albuterol)
Erythropoiesis Stimulating Proteins	ARANESP (darbepoetin)
Growth Hormone	NORDITROPIN (somatropin)
Hypoglycemics, Incretin Mimetics/Enhancers	TRADJENTA (linagliptin)
Hypoglycemics, Insulins and Related Agents	HUMALOG VIAL (insulin lispro)
Hypoglycemics, Insulins and Related Agents	HUMALOG MIX VIAL (insulin lispro/lispro protamine)
Hypoglycemics, Insulins and Related Agents	HUMULIN VIAL (insulin)
Lipotropics, Statins	atorvastatin/amlodipine
Ulcerative Colitis Agents	mesalamine

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for NON-PREFERRED STATUS**
Androgenic Agents	ANDRODERM (testosterone patch)
Angiotensin Modulators	COZAAR (losartan)
Angiotensin Modulators	EDARBYCLOR (azilsartan/chlorthalidone)
Antibiotics (GI)	DIFICID (fidaxomicin)
Anticonvulsants	diazepam rectal gel
Anticonvulsants	GRALISE (gabapentin)
Anticonvulsants	HORIZANT (gabapentin)
Anticonvulsants	LAMICTAL ODT (lamotrigine)
Anticonvulsants	LAMICTAL XR (lamotrigine)#
Anticonvulsants	ONFI (clobazam)
Antihistamines, Minimally Sedating and Combinations	XYZAL Tablets (levocetirizine)
Antiparasitics (Topical)	malathion
Antiparkinson's Agents	LODOSYN (carbidopa)
Beta Blockers	BYSTOLIC (nebivolol)*
Beta Blockers	DUTOPROL (metoprolol/HCTZ)
Bladder Relaxant Preparations	DETROL LA (tolterodine)
Bladder Relaxant Preparations	GELNIQUE (oxybutynin)
Bone Resorption Suppression and Related Agents	calcitonin salmon

Mississippi Division Of Medicaid
Provider Notice
Preferred Drug List Changes
EFFECTIVE DATE: JULY 1, 2012

NEW NON-PREFERRED DRUGS	
BPH Agents	CIALIS (tadalafil)
BPH Agents	JALYN (dutasteride/tamsulosin)*
BPH Agents	tamsulosin
Glucocorticoids (Inhaled)	AEROBID (flunisolide)
Glucocorticoids (Inhaled)	AEROBID-M (flunisolide)
Glucocorticoids (Inhaled)	budesonide nebulizer solution
Hypoglycemics, Incretin Mimetics/Enhancers	BYDUREON (exenatide)
Hypoglycemics, Incretin Mimetics/Enhancers	JANUMET XR (sitagliptin/metformin)
Hypoglycemics, Incretin Mimetics/Enhancers	JENTADUETO (linagliptin/metformin)
Hypoglycemics, Incretin Mimetics/Enhancers	JUVISYNC (sitagliptin/simvastatin)
Intranasal Rhinitis Agents	VERAMYST (fluticasone)
Leukotriene Modifiers	ZYFLO CR (zileuton)
Lipotropics, Others	ANTARA (fenofibrate)
Lipotropics, Statins	CADUET (atorvastatin/amlodipine)
NSAIDs	DUEXIS (ibuprofen/famotidine)
Pancreatic Enzymes	PANCRELIPASE
PAH Agents – PDE5s	REVATIO (sildenafil)*
Phosphate Binders	calcium acetate
Phosphate Binders	PHOSLYRA (calcium acetate)
Platelet Aggregation Inhibitors	BRILINTA (ticagrelor)
Proton Pump Inhibitors	PREVACID SOLU-TAB (lansoprazole)**
Ulcerative Colitis Agents	PENTASA 500mg (mesalamine)
Ulcerative Colitis Agents	SFROWASA (mesalamine)

NEW THERAPUTIC CLASSES/DRUGS	
NEW THERAPEUTIC CLASS	**RECOMMENDED for PREFERRED STATUS**
NONE	

*Existing users will be grandfathered

Grandfathered for seizure patients only

** No PA required for age 12 and under