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## Withdrawal of Unapproved Cough and Cold Products

On October 19, 2007, the FDA Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee recommended that all over-the-counter (OTC) cough and cold medications should not be used in children between the ages two-to-five years old. On January 17, 2008, as a response to a Citizen Petition pertaining to the potentially inappropriate use of OTC cold and cough medications in children less than 6 years of age, the FDA recommended not using such products in infants and children under the age of 2 years. Later in the same year, the Consumer Health Products Association (CHPA) announced that its members were to voluntarily re-label their products to warn parents against their use in children less than 4 years of age.

The movement against the use of such drugs commenced primarily due to scarce

safety and efficacy data. Study data has been limited by difficulty developing proper sample size and difficulty extrapolating adult data due to differences in adult and adolescent anatomy. The lack of sufficient data has led toward the recommendation of non-pharmacologic techniques as preferred treatment. Some suggestions include: adequate fluid intake, use of saline nasal drops/spray, use of humidifiers/ vaporizers, or topical antitussives.

On March 2, 2011, the FDA announced that certain unapproved prescriptions for cough, cold, and allergy drugs would be removed from the market due to a lack of safety and efficacy data. A list of the unapproved products maintained by the FDA can be found on the FDA's MedWatch Safety website:

<http://www.fda.gov/Safety/MedWatch/>

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\* (<http://www.medicaid.ms.gov/Documents/DUR/Packets/DURPackets05192011.pdf> )

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Name  
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City, State ZIP

# 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 scheduled update will become effective January 1, 2012. The January update will reflect changes which have been recently reviewed by the Department 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](http://www.medicaid.ms.gov). Follow the Pharmacy link located at the top of the screen, then click on "PDL" in the right column.

## Prior Authorization Update

As of January 1, 2011, Health Information Designs, Inc. no longer processes drug prior authorizations for Mississippi Medicaid. Providers may contact the Division of Medicaid Pharmacy Bureau at 601-359-5253 or visit the Mississippi Medicaid website at <http://www.medicaid.ms.gov/PharmacyForms.aspx> for more information regarding the appropriate procedures for prior authorization submission.

## 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](http://www.medicaid.ms.gov/PharmacyForms.aspx).

## OTC LIST

Mississippi Medicaid covers certain OTC medications with a written, telephonic, or electronic prescription. A list of the covered products may be found at <http://www.medicaid.ms.gov/Documents/Pharmacy/OTClistforweb.pdf>

## 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](http://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:



### 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  
Fax: 1-877-537-0720

# MEDICAID UPDATES

## FLU/ PNEUMONIA BILLING

The influenza and pneumonia immunizations are covered services in the MS Medicaid Pharmacy program. Beneficiaries must be 19 years of age or older and non-residents of a long-term care facility. The pharmacy must have a hard copy prescription on file and the immunization will count against beneficiaries' service limits. MS Medicaid will reimburse drug ingredient cost and dispensing fee, but administration fees will not be paid for.

Immunization for children 18 and younger must be handled through the Vaccines for Children program. MS Medicaid reimbursement will only be for beneficiaries in nursing facilities. Immunization cost for Medicare patients should not be included in the Medicaid cost report.

For additional information regarding immunization and Medicaid policies, refer to Medicaid's Provider Manual Sec. 77, <http://www.medicaid.ms.gov/ProviderManualSection.aspx?Section%2077%20-%20Immunization>

## SYNAGIS®

The Mississippi Division of Medicaid supports the administration of Synagis® for children meeting the American Academy of Pediatrics Redbook 2009 criteria for RSV prophylaxis. Starting October 24, 2011, prior authorizations may be submitted to DOM for administrations beginning October 31.

The Synagis® prior authorizations criteria and forms can be found on the Medicaid website and by clicking on "Pharmacy" and then "Prior Authorization" or you may find the file directly at: [www.medicaid.ms.gov/Documents/Pharmacy/Synagis.pdf](http://www.medicaid.ms.gov/Documents/Pharmacy/Synagis.pdf)

The forms should be accessed by selecting Synagis® 2011-2012 prior authorization form and criteria. Prior authorization for beneficiaries enrolled in **MississippiCAN** should be submitted to the respective MississippiCAN plan and not to Medicaid.

## MEDICAID, I HAVE QUESTIONS!

**Q: I get reject messages from Medicaid when I try to submit a claim for the generic for Adderall XR, BenzaClin, Prevacid, Xalatan, or Lovenox. Why does Medicaid only cover the brand name on certain products when the brand name is more expensive than the generic?**



**A:** We get this question a lot. In addition to clinical effectiveness, the cost of a drug is certainly an important consideration in what becomes

a "preferred" drug. Just like managed care organizations, there are times when Medicaid is able to negotiate a better price for some brand-name drugs compared to their generic counterpart. While not always, newly released generics are usually priced at about 80-90% of the brand name until more companies begin to manufacture the generic, so it is not too difficult for a brand name to cost less to Medicaid than a generic.

## COUGH AND COLD (CONTINUED)

Despite the recent FDA action, several cough and cold preparations are still available. Included in this newsletter is a "Medicaid Cough and Cold Quick List" that lists some examples of products that may be used to treat cough and cold symptoms, broken down by age categories. However, note should be taken that these products may have age-specific limits for use and may be contraindicated in children below certain ages.

The Division of Medicaid has recently revised the OTC coverage list following the FDA product removals. Some of the notable additions include: *Oxymetazoline Nasal Solution 0.05%*, *Phenylephrine Nasal Solution drops/spray*, and *Sodium Chloride Nasal Solution drops/spray*. The full OTC coverage list is located at <http://www.medicaid.ms.gov>.

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# SAFETY ALERTS

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## FDA MedWatch

### **Zofran (ondansetron): Risk of Abnormal Heart Rhythms**

[September 15, 2011] FDA notified providers and patients of an ongoing safety review for the anti-nausea product Zofran. Zofran may increase the risk of developing QT interval prolongation. Zofran should be avoided in patients with congenital long QT syndrome because of increased risk of Torsade de Pointes.

### **Reclast (zoledronic acid): New Contraindication and Updated Warning on Kidney Impairment**

[September 1, 2011] FDA notified healthcare providers and patients of an update to the drug label for Reclast regarding the risk of kidney failure. Risk factors for developing renal failure include underlying moderate to severe renal impairment, use of nephrotoxic drugs, or diuretics concurrently with Reclast. Reclast is contraindicated in patients with creatinine clearance less than 35mL/min or with evidence of acute renal impairment.

### **Celexa (citalopram hydrobromide): Abnormal Heart Rhythm**

[August 24, 2011] FDA notified healthcare professionals that the antidepressant Celexa should no longer be used at doses greater than 40mg per day. Doses of Celexa greater than 40mg can cause changes in the electrical activity of the heart. Celexa may cause dose-dependent QT interval prolongation. Patients with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, or predisposition to hypokalemia/hypomagnesemia are at higher risk.

### **Diflucan (fluconazole): Long-Term High-dose Use During Pregnancy May be Associated with Birth Defects**

[August 3, 2011] FDA informed the public that chronic treatment with high dose Diflucan (400-800mg/day) during the first trimester of pregnancy may be associated with rare and distinct birth defects. The pregnancy category for high dose Diflucan has been changed to **category D**. Pregnancy Category D means there is positive evidence of human fetal risk. FDA recommends patient counseling regarding Diflucan and the association to birth defects.

### **Zyvox (linezolid): Serious CNS Reaction Possible When Given with Certain Psychiatric Medications**

[July 26, 2011] FDA received reports of serious central nervous system reactions when Zyvox was given to patients taking serotonergic psychiatric medications. A list of the psychiatric drugs can be found in the FDA's Drug Safety Communication. Zyvox generally should not be given to patients taking serotonergic psychiatric medications, unless treating Vancomycin resistant enterococcus, nosocomial pneumonia, and MRSA.

### **Tamiflu (oseltamivir phosphate): Label Change-New Concentration**

[July 11, 2011] Labeling changes are being made to Tamiflu oral suspension. Product concentration was changed from 12mg/mL to 6mg/mL. Other changes included revised compounding instructions for the pharmacist to compound the 6mg/mL concentration from the capsules. Healthcare professionals should be aware that patients may receive prescription written for either concentration during the 2011-2012 Influenza season.

<http://www.fda.gov/Safety/MedWatch/>



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 pharmacists 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 through Mississippi Medicaid, the Mississippi Pharmacist's Association, or from us directly. We hope this information is helpful to your practice and we would love to receive comments or suggestions. Please email me at [kdnnull@olemiss.edu](mailto:kdnnull@olemiss.edu) to provide feedback or to recommend topics for future newsletters. Please contact Medicaid (See Page 2) for assistance resolving issues related to prior authorizations or coverage.

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# Medicaid Cough and Cold Quick List

Medicaid covers these over-the-counter (OTC) drugs pursuant to a written/verbal/electronic prescription

*This list is subject to revision*



Class	Generic	Strength	Common Brand Names	Dosage Form	Age				Rx/OTC Status
					<2	2-<6	6-<12	> 12	
1 <sup>st</sup> Generation Antihistamines and Combinations	Brompheniramine/Phenylephrine	1-2.5mg/ 5mL	Dimetapp Cold & Allergy Elixir	Liquid		✓	✓	✓	OTC
	Brompheniramine/Phenylephrine/ DM	1-2.5-5mg/ 5mL	Dimetapp DM Cold & Cough Elixir	Liquid		✓	✓	✓	OTC
	Brompheniramine/ Pseudoephedrine†	1-15mg/5mL	Q-Tapp	Liquid		✓	✓	✓	OTC
	Brompheniramine/ Pseudoephedrine/ DM†	1-15-5mg/ 5mL	Q-Tapp DM	Liquid		✓	✓	✓	OTC
	Chlorpheniramine	2mg/5mL, 4mg	Aller-Chlor Syrup, Tabs	Syrup, Tablets		✓	✓	✓	OTC
	Clemastine Fumarate	1.34mg	Tavist	Tablet			✓	✓	OTC
	Diphenhydramine	12.5mg/5mL, 25mg, 50mg	Benadryl	Capsule, Elixir, Liquid, Solution		✓	✓	✓	OTC
	Tripolidine/ Pseudoephedrine†	1.25-30mg/ 5mL, 2.5-60mg	Aprodine	Syrup, Tablet		✓	✓	✓	OTC
2 <sup>nd</sup> Generation Antihistamine Combinations	Cetirizine	1mg/mL, 5mg, 10mg	Zyrtec	Chewable Tab, Tablets, Syrup	✓	✓	✓	✓	OTC/Rx
	Cetirizine/ Pseudoephedrine†	5mg/120mg	Zyrtec-D 12 hour	Extended Release Tab				✓	OTC
	Loratadine	5mg/5mL, 5mg, 10mg	Claritin	Chewable Tab, Syrup, Reditab, Tablet		✓	✓	✓	OTC
	Loratadine/ Pseudoephedrine†	5-120mg, 10-240mg	Claritin-D 12 & 24 hour	Extended Release Tab				✓	OTC
Antitussives & Combinations	Benzonatate	100mg, 200mg	Tessalon	Capsules			>10	✓	Rx
	Dextromethorphan HBr	7.5mg/5mL, 15mg/5mL	Robitussin Pediatric Cough, Tussin Liquid	Liquid		✓	✓	✓	OTC
	Dextromethorphan HBr/ Phenylephrine	5-2.5mg/5mL	Triaminic Cold & Cough Liquid	Liquid		✓	✓	✓	OTC
	Dextromethorphan HBr/ Pseudoephedrine†	7.5-15mg/5mL	Triaminic Cough-Nasal Congestion	Syrup		✓	✓	✓	OTC
	Dextromethorphan Polystirex	30mg/ 5mL	Delsym	Suspension		✓	✓	✓	OTC
Expectorants & combination	Guaifenesin	100mg/5mL, 200mg/5mL	Robitussin, Diabetic Tussin Mucous Relief	Liquid	✓	✓	✓	✓	OTC
	Guaifenesin/ Codeine‡	100mg/10mg/5mL	Guaifenesin AC Cough Syrup	Liquid		✓	✓	✓	OTC
	Guaifenesin/ Dextromethorphan	100-10mg, 200-10mg/5mL	Robitussin DM, Robitussin DM Max	Liquid		✓	✓	✓	OTC
	Guaifenesin/ Phenylephrine	50-2.5, 100-5mg/5mL	Rescon GG, Triaminic Chest-Nasal Congestion	Liquid		✓	✓	✓	OTC
	Guaifenesin/ Pseudoephedrine/ Codeine†	100-30-10mg/5mL	Cheratussin DAC Syrup	Liquid		✓	✓	✓	OTC
Decongestants	Phenylephrine Oral	2.5mg/5mL, 10mg	Children's Sudafed PE, Contact D Cold	Liquid, Tablet		✓	✓	✓	OTC
	Pseudoephedrine†	15mg/5mL, 30mg/5mL, 30mg	Children's Sudafed Syrup, Sudagest, Sudafed	Syrup, Tablet		✓	✓	✓	OTC
Nasal Solutions	Oxymetazoline Nasal Solution	0.05%	Afrin, Sinex 12 hour Decongestant	Spray			✓	✓	OTC
	Phenylephrine Nasal Solution	0.125%, 0.25%, 0.5%, 1%	Little Noses Decongestant, Neo-Synephrine Mild Nasal, 4 Way	Drops, Spray	✓	✓	✓	✓	OTC
	Sodium Chloride Nasal Solution	0.2%, 0.65%, 0.9%	Ayr, Ocean	Drops, Spray	✓	✓	✓	✓	OTC

† Classified as Schedule III controlled substance in MS. Federally classified as OTC product and remains covered, pursuant to a prescription.

‡ Classified as Schedule V controlled substance in MS. Federally classified as OTC product and remains covered, pursuant to a prescription.

✓ Reflects medically-accepted indications as determined by drug compendia and clinical literature, and not exclusively for FDA-approved ages. Use clinical judgment.

*Last Revised: November 15, 2011*