

Mississippi Medicaid Pharmacy Program Quarterly News

Winter 2009

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Welcome to the Winter 2009 edition of the “Mississippi Medicaid Pharmacy Program Quarterly News”, published by Health Information Designs, Inc. (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Mississippi Division of Medicaid (DOM) Pharmacy Program.

New Warnings for Propoxyphene

On July 7, 2009, the FDA notified health care professionals that it is enacting several proactive measures to reduce the risk of overdose in patients using propoxyphene-containing products because of data linking propoxyphene to fatal overdoses. In Europe, recent evidence has been discovered that indicates this medication may be more lethal in overdose situations than other pain medications. The agency will now require manufacturers of propoxyphene-containing products to strengthen the label's boxed warning to emphasize the potential for overdose when using these products and to provide a medication guide to patients stressing the importance of using the drugs as directed. Although a FDA advisory committee recommended a phased market withdrawal of propoxyphene products recently, the FDA concluded that the benefits of the medication for pain relief at recommended doses outweigh the safety risks at this time. In addition, the FDA found that differences in use patterns between Europe and the United States limit the applicability of the European data to the U.S. population. However, the FDA does recognize that there are unanswered questions about the safety of propoxyphene when used at doses higher than recommended on the label, as well as when used in the elderly population. The FDA is requiring new safety studies assessing the effects of propoxyphene on the heart at higher than recommended doses, the rates of fatalities and hip fractures among elderly patients taking propoxyphene/acetaminophen as compared to other analgesics. Findings from these studies, as well as other data, could lead to additional regulatory action. Beginning January 1, 2010, single entity propoxyphene products will be non-preferred for Mississippi Medicaid beneficiaries. This status change does **not** affect propoxyphene/acetaminophen combination products. More information regarding upcoming PDL changes can be found below.

Preferred Drug List Updates

The Mississippi Medicaid Preferred Drug List (PDL) is updated two times annually on January 1st and July 1st. The next update will become effective on January 1, 2010, and will reflect drug classes that have recently been reviewed by DOM's Pharmacy and Therapeutics Committee. Some of these classes include, but are not limited to, antipsychotics, ADHD agents, topical acne products and antidepressants. It is important for providers to become familiar with any changes to the PDL in an effort to prevent confusion and delay of care for patients. The PDL can be viewed at the Medicaid website, www.medicaid.ms.gov. Click on the Pharmacy Services link on the top of the screen. The link to the PDL is on the right side of the screen.

Xyzal®

Xyzal® is a minimally sedating antihistamine that is listed on the Mississippi Medicaid Preferred Drug List (PDL). However, as denoted on the PDL, this preferred agent is subject to an online edit for approval as a preferred agent. Patients attempting treatment with Xyzal® must have tried and failed treatment with either cetirizine, loratadine or fexofenadine. This trial must be reflected in paid pharmacy claims in order for the online edit to approve the Xyzal® claim. Pharmacists who are presented prescriptions for OTC cetirizine or loratadine for Mississippi Medicaid beneficiaries are encouraged to process these prescriptions rather than referring the beneficiary to purchase the products themselves. This will ensure that the paid claim for OTC cetirizine or loratadine will be found in pharmacy claims in the event a prescriber attempts treatment with Xyzal® for that beneficiary in the future.

RxPert™ Electronic PA System

RxPert™ is an automatic prior authorization system that operates behind the scenes to approve prescriptions for Medicaid beneficiaries. Saving time for both providers and beneficiaries, electronic PA is an important component of the prior authorization process. HID's RxPert™ has been in place for DOM for over three years and has successfully reviewed over 700,000 PA requests for DOM providers and beneficiaries.

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Drug Utilization Review: An Overview

The Omnibus Budget Reconciliation Act of 1990, better known as OBRA 90, created a federal mandate for the establishment of state drug utilization review (DUR) programs. The objective of certain sections of this legislation was to save taxpayer money by reducing the cost of drug therapy for Medicaid patients. Each state program must consist of 3 parts:

- ⇒ prospective drug review—OBRA 90 requires that pharmacists perform point of sale (POS) review of drug therapy prior to filling or delivering a prescription to a recipient, thereby increasing the pharmacist's responsibility for patient outcomes with drug therapy.
- ⇒ retrospective drug review—OBRA 90 defines RDUR as an educational tool to help physicians and pharmacists identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and Medicaid recipients. The purpose of RDUR is to prevent future drug utilization problems.
- ⇒ educational programs—OBRA 90 requires that each state plan must provide for ongoing educational outreach programs that educate prescribers on common drug therapy problems with the goal of improving prescribing and dispensing practices. These programs can be written, oral, or electronic communications.

HID is responsible for the administration of the last two parts of the Mississippi Medicaid drug utilization review program. Once a potential drug therapy problem has been identified through RDUR, an educational letter can be sent out to the prescriber alerting them to the potential problem and providing them with alternative prescribing choices. These letters are solely for educational purposes and are not part of any auditing program of the Division of Medicaid. The prescriber can choose to accept or ignore the recommending changes, and a voluntary response form is provided for prescriber feedback. While prescriber feedback is not required, the Division of Medicaid encourages all prescribers who receive one of these letters to provide feedback so that the Division can provide the best service possible to its provider community.

FDA Panel Recommends New Acetaminophen Limits

In June 2009, a U.S. Food and Drug Administration advisory panel convened in Maryland with the goal to determine ways to reduce incidences of liver damage associated with acetaminophen use in over-the-counter and prescription products. According to the FDA's Adverse Event Reporting System, acetaminophen continues to be the leading cause of drug induced liver failure in the United States. Eighty percent of acetaminophen products are available as over-the-counter formulations and with approximately 200 million acetaminophen-containing prescriptions dispensed in 2008, acetaminophen overdose continues to present a major problem in the United States.

The concern over acetaminophen stems from limited knowledge of an exact dose associated with toxicity. The onset of acute liver failure associated with acetaminophen can take several days and may not be easily identified due to non-specific, flu-like symptoms. Patients may not recognize acetaminophen is present in many over-the-counter products as well as some prescription pain relievers, increasing the risk of acetaminophen toxicity.

The FDA advisory panel recommendations include:

- Decrease maximum daily dose of acetaminophen from 4g/day (a new maximum daily dose has not yet been specified)
- Decrease maximum OTC single dose to 650mg
- Current maximum single dose (1,000mg) should be switched to prescription only
- Only one concentration of liquid acetaminophen should be available
- Prescription acetaminophen combination medications should be removed from the market
- Should prescription acetaminophen combination medications be left on the market, these products should contain a black box warning or "unit-of-use" packages should be required
- Rejection of a proposal to pull certain cold and cough medications due to minor role in acetaminophen overdoses

The FDA's Center for Drug Evaluation and Research plans to review the recommendations of the advisory panel and make its final determination in the future.

Medicaid Provider Bulletin

The Mississippi Medicaid Bulletin is published quarterly and provides timely information regarding policies that affect Mississippi Medicaid providers. The most recently published bulletin as well as an archive of past bulletins can be found at www.medicaid.ms.gov.

Acne

Acne is the most common skin condition in the United States. It is estimated that 40 million to 50 million Americans have acne, with most of these victims being teenagers or young adults. Each year, 85% of U.S. teenagers will have acne. While acne can leave permanent physical scars, the psychological effects of acne can be devastating as well, with poor self-image, depression and anxiety being common peripheral issues associated with acne.

Cause

While the exact cause of acne has not been determined, research of the condition has exposed four fundamental components for the development of acne: excess oil, clogged pores, bacteria, and inflammation. Sebum, the excess oil, is made by the body to prevent the skin from drying out. Androgenic hormones lead to significantly increased sebum production during adolescence, and clogged pores result when excess sebum cannot flow freely from the skin's surface. *Propionibacterium acnes* (*P acnes*), a gram-positive anaerobe that is a normal inhabitant of human skin, flourishes in excess oil, leading to inflammation. The degree of inflammation determines what type of acne appears on the skin. When sebum flow is blocked close to the skin's surface, minimal inflammation occurs and blackheads or whiteheads are the result. If the blockage occurs deeper within the skin, a pimple forms. Blockage at an even deeper level of the skin results in a pustule, or pus-filled pimple. A very deep blockage will lead to intense inflammation, resulting in a painful nodule or cyst. These are the most severe types of acne lesions.

Skin care

Excessive washing and scrubbing will not prevent or cure acne, and can actually make the condition worse by further irritating the skin. The American Academy of Dermatology (AAD) recommends gently washing the face once or twice daily with a mild cleanser and lukewarm water. This process helps to remove excess sebum, a critical step in controlling acne. Although it may be tempting to squeeze acne lesions, this is not recommended by dermatologists because it tends to make acne worse and can result in scars.

To avoid clogging pores, cosmetics, toiletries and sunscreens should be oil-free; oil-free products will be labeled 'non-comedogenic' or 'non-acnegenic'.

Treatment

According to treatment guidelines published by the AAD, topical therapy is the standard of care in acne treatment. Topical retinoids are considered to be important in acne treatment; combination of topical retinoids and topical erythromycin or clindamycin is more effective than either agent used alone. Benzoyl peroxide is a bactericidal agent that has proven efficacy in acne treatment, and it has the ability to prevent or eradicate the development of *P acnes* resistance. Combination products with erythromycin or clindamycin and benzoyl peroxide enhance efficacy due to the elimination of bacterial resistance. Salicylic acid is moderately effective in the

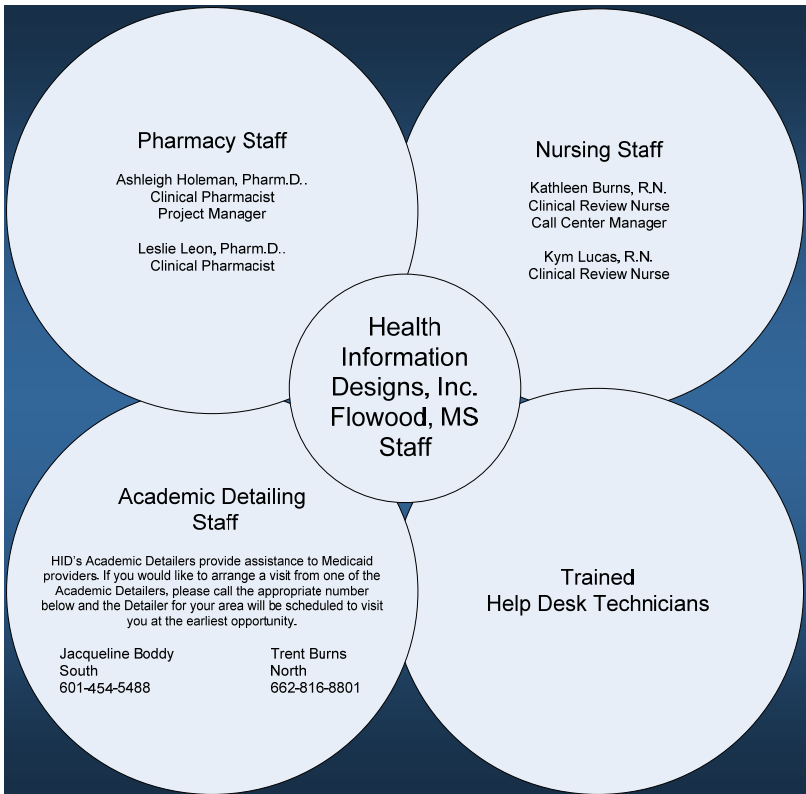
treatment of acne, and it is considered less potent than topical retinoids and as such, is often used when patients cannot tolerate skin irritation caused by topical retinoids. While azelaic acid has been shown to be effective in clinical trials, experts report it has limited efficacy compared to other agents. Data regarding the efficacy of sulfur, resorcinol, sodium sulfacetamide, aluminum chloride and zinc are limited.

Mississippi Medicaid

The Division of Medicaid realizes that there is a shortage of dermatologists throughout the state. In addition, DOM also understands that acne is not a benign disorder and can have deep psychological and emotional impacts. As such, DOM covers topical acne agents at the point of sale for beneficiaries under the age of 21. However, this class is addressed by the preferred drug list (PDL); those products that are non-preferred require trial and failure of two preferred products in order to obtain prior authorization approval. A listing of preferred topical acne agents is provided in the table on the right.

Therapeutic class	Preferred Products
Topical antibiotics	Clindamycin
	Erythromycin
Retinoids	Retin-A Micro [®]
Others	Azelex [®]
	Benzaclin [®]
	Benzoyl peroxide (Rx and OTC)
	Clinac BPO [®]
	Inova [®]
	Nuox [®]
	Panoxyl [®]
Zaclir [®]	

HEALTH INFORMATION DESIGNS



Health Information Designs, Inc. (HID) is contracted by the Mississippi Medicaid Pharmacy Bureau to provide Prior Authorization and Retrospective Drug Utilization Review services.

HID Helpful Numbers

HID Help Desk 800-355-0486
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