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Indiana Medicaid DUR Board
402 West Washington Street
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Indiana Medicaid Drug Utilization Review Board Newsletter

Clinically Effective First-line Antibiotics That Are Cost Effective

At a time in which Indiana Medicaid drug expenditures are increasing at unsustainable double-digit rates, the DUR Board wishes to stress the obvious importance of prescribing that balances cost with clinical efficacy. As practicing clinicians, we are acutely aware of the cost/clinical efficacy dilemma presented to practitioners by the continuing emergence of drug resistant pathogens, complicated by the ever-higher costs of new drugs developed to treat the resistant organisms. Given those troubling circumstances, we thought the subject matter of this article to be timely, and we hope that it proves to be of assistance to you in your clinical practice.

The information in this article is intended as a reminder to practitioners of the drugs that are generally considered as constituting first-line treatment in the four disease state areas covered by the article. Ultimately, of course, the choice of drug deemed most appropriate to treat the patient's condition is up to the prescribing practitioner. As always, we welcome any comments that you may have.

Acute Otitis Media

Eight out of ten children will develop an episode of acute otitis media by the time they reach 3 years of age. Acute otitis media accounts for nearly half of all pediatric diagnoses and antibiotic use, resulting in an estimated 30 million office visits per year. The cost for treating otitis media in the United States is estimated to be between \$2-4 billion

per year.¹ The three major pathogens that cause acute otitis media are: *Streptococcus pneumoniae* accounting for 40-50% of the cases, *Haemophilus influenzae* accounting for 20-30% of the cases, and *Moraxella catarrhalis* accounting for 10-15% of the cases.²

Because of amoxicillin's effectiveness against pneumococci, it remains the first choice for therapy for acute otitis media. While the standard recommended dose of amoxicillin in patients at low risk is 40-45 mg/kg/day in three divided doses, doses as high as 80-90 mg/kg/day in two divided doses may be justified for patients at high risk for drug resistant *Streptococcus pneumoniae*.³

Pharyngitis

Group A streptococci is the likely cause of exudative pharyngitis. More commonly referred to as strep throat, symptoms typically appear suddenly and include sore throat, a general feeling of illness or malaise, chills, fever, headache, nausea, vomiting, and a rapid heartbeat. The throat will be reddened, with swelling of the tonsils and enlargement of the lymph nodes in the neck with tenderness. Treatment of pharyngitis caused by group A streptococci should begin promptly when symptoms appear and involves penicillin or erythromycin. Antibiotics are used to shorten the duration of infection and prevent serious complications such as rheumatic fever.

¹ Carlson D, Seay R. Acute Otitis Media Program Focuses on Antibiotics Usage. *Drug Benefit Trends*. 1999; 11(5): 40-42, 45-47.

² Barnett ED, Klein JO. The Problem of Resistant Bacteria for the Management of Acute Otitis Media. *Pediatr Clin North Amer*. 1995; 42: 509-517.

³ Recommendations for Management of Acute Otitis Media. *Clinician Reviews*. 1999; 9 (5): 93-96, 99-100.

Antimicrobial therapy will also help prevent spread of the infection to the sinuses and middle ear as well as to other people. The presence of a cough, inflammation of the larynx, and a stuffy nose are uncommon in streptococcal infections and are more symptomatic of a cold or allergy.⁴

Community-acquired Bacterial Pneumonia

Streptococcus pneumoniae is the most frequent cause of community-acquired bacterial pneumonia, identified in 20-30% of cases. Other "atypical" pathogens causing community-acquired bacterial pneumonia include *Legionella pneumophila* (1-15% of the cases), *Mycoplasma pneumoniae* (up to 20% of the cases), and *Chlamydia pneumoniae* (5-10% of the cases).⁵ The occurrence of *Streptococcus pneumoniae* is usually seasonal and seen in the months from October to April. Symptoms of *Streptococcus pneumoniae* develop acutely and resolve with treatment over several days. *Legionella pneumophila* is a water-related pathogen that should be suspected with the occurrence of pneumonia outbreaks, among patients with cardiopulmonary disease and immune compromise, and among those patients not responding to beta-lactam antibiotics. *Mycoplasma pneumoniae* occurs with no seasonal predominance, affecting particularly young adults with an onset of 7-14 days and featuring a persistent nonproductive cough. *Chlamydia pneumoniae* is an organism that is more commonly found in outpatients than in those patients treated in the hospital.⁶ All four organisms respond to erythromycin therapy with treatment durations that vary, depending on the pathogen.

⁴ The Merck Manual of Information – Home Edition 1997. Whitehouse Station, N.J.: Merck Research Laboratories; 1997.

⁵ The Medical Letter. The Choice of Antibacterial Drugs. October 22, 1999; 41(1064): 95-104.

⁶ Janoff EN, Rubins JB. Part 1: Clinical Approach to Community-acquired Pneumonia: Diagnosis and Etiology. *APUA Newsletter*. 1999; 14 (3): 1-4, 8.

Acute Uncomplicated Urinary Tract Infection

Bacterial infections of the lower urinary tract, including the bladder and urethra, are very common. Roughly five percent of adolescent girls develop urinary tract infections (UTIs) at some time, while boys at the same age rarely do. Among adults between the ages of 20-50, UTIs are about 50 times more common in women than in men. The occurrence of infections in men and women are more common in their elder years with less differences between the sexes.⁷ Acute uncomplicated urinary tract infections can be effectively and inexpensively treated, before identification of the organism, with trimethoprim-sulfamethoxazole. A three-day course of oral trimethoprim-sulfamethoxazole DS taken twice a day is often effective for acute cystitis in women.⁸

While the suggestions presented in this article for empiric antibiotic selection in common bacterial infections are evident in the literature, patients vary as much as severities of illnesses. Ultimately, antibiotic therapy is only cost effective if there is sensitivity to the antibiotic, compliance by the patient, and a sufficient dose/duration to achieve exposure with therapeutic concentrations at the infection site.

The Problem With "Brand Medically Necessary"

By Marc Shirley, R.Ph.
Office of Medicaid Policy and Planning

Prescribing practitioners and dispensing pharmacists are all likely aware that, under Indiana Medicaid, the prescriber's indication of "brand medically

⁷ The Merck Manual of Information – Home Edition 1997. Whitehouse Station, N.J.: Merck Research Laboratories; 1997.

⁸ The Medical Letter. The Choice of Antibacterial Drugs. October 22, 1999; 41 (1064): 95-104.

necessary" results in a Medicaid patients receiving a brand name drug instead of a typically less expensive, but therapeutically equivalent, generic product. There may be a number of reasons why a practitioner chooses to indicate "brand medically necessary" on a prescription for his or her Medicaid patient: patient demand for a brand name drug (perhaps furthered by the recent increase in "direct to consumer" advertising of brand name drug products), or a perception by a patient or practitioner that brand name drugs are somehow superior to generics, more effective marketing practices by brand name drug producers. Irrespective of the reasons for the prescribing practice, the following are *facts* about the impact of "brand medically necessary" on the Indiana Medicaid program:

- Each time Indiana Medicaid reimburses for a claim marked "brand medically necessary", payment is made at a rate commensurate with a brand name drug as opposed to at a rate representative of therapeutically equivalent, less expensive generic drugs.
- In calendar year 1995, there were 162,908 drug claims processed and paid that were specified as "brand medically necessary". The extra cost of these drug claims (cost over and above what would have been paid, had "brand medically necessary" *not* been indicated) was **\$2,677,773**. This translated out to an average extra cost to the taxpayers of \$16.44 for each "brand medically necessary" prescription.
- In calendar year 1996, there were 129,801 drug claims processed and paid that were specified as "brand medically necessary". The extra cost associated with "brand medically necessary" in that year was **\$2,355,644**. This translated out to an average extra cost to the taxpayers of \$18.15 for each "brand medically necessary" prescription.
- In calendar year 1997, there were 96,813 drug claims processed and

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paid that were specified as "brand medically necessary". The extra cost associated with "brand medically necessary" in that year was **\$2,125,362**. This translated out to an average extra cost to the taxpayers of \$21.95 for each "brand medically necessary" prescription.

The most current information regarding the cost impact to Indiana Medicaid of "brand medically necessary" is for claims paid in state fiscal year 1999 (July 1 1998 through June 30, 1999). For that period of time, there were approximately 77,000 drug claims processed and paid that were specified as "brand medically necessary". The extra cost associated with "brand medically necessary" prescriptions was approximately **\$2.1 million**. This translates out to an average extra cost to the taxpayers of about \$27.27 for each "brand medically necessary" prescription.

Related to the above, for the four-and-a-half year time period involved, the taxpayers of Indiana incurred an extra cost of approximately **\$9.3 million** for "brand medically necessary". You will notice that, for each year, the average extra cost per prescription for "brand medically necessary" increases.

In a letter dated April 16, 1997 from Roger L Williams, M.D., Deputy Center Director of Pharmaceutical Science, Center for Drug Evaluation and Research of the federal Food and Drug Administration, to Mr. Carmen A. Catizone, Executive Director/ Secretary of the National Association of Boards of Pharmacy, Dr. Williams stated, in part, "As you are aware, in the process of evaluating applications for generic drugs, the FDA makes recommendations via a document entitled *Approved Drug Products with Therapeutic Equivalence Ratings* (the *Orange Book*) that approved multiple source drug products, are therapeutically equivalent. This term indicates that they can be substituted with the full expectation by the patient and physician that they will have the **same clinical effect and safety profile** as the innovator drug." (emphasis ours)

If then, therapeutically equivalent generic drugs are as effective as their brand name counterparts, why is it necessary for the taxpayers of Indiana to incur an additional \$9.3 million in costs for brand name counterparts via "brand medically necessary" over four-and-a-half years? Please give this simple question due consideration the next time you consider specifying "brand medically necessary" on a prescription for your Medicaid patient

DUR Board Calendar

December 10, 1999
9:30 am, Indiana Government Center, South Training Center Room 1
DUR Board Meeting

For more information call Ms. Karen Baer at (317) 232-4391

Pro-DUR Alert Summary of September 1999's Submitted Claims

A review of the Pro-DUR alerts for September 1999 reveals that there were 6464 underutilization alerts (LR) involving anticonvulsants, insulin release stimulant-type hypoglycemics, and xanthines. Underutilization alerts are set when a recipient has refilled their medication at a date later than what was earlier dispensed. The Board hopes that the Pro-DUR alerts are a useful and helpful tool to the pharmacist in

determining when patient counseling is necessary and appropriate to assure patient compliance to their drug regimen.

There were 575 high dose alerts (HD) that occurred with non-steroidal anti-inflammatory drug (NSAID) prescriptions written to Medicaid recipients in September. Eighty-eight percent (505) of the alerts were overridden and dispensed. The alerts were generated when the daily doses for each claim exceeded the maximum dosage limit for each NSAID prescription. The table on the next page

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Pro-DUR Alerts (September 1999 Submitted Claims)

| <i>Alert Code</i> | <i>Alert Description</i> | <i>Alerts</i> | <i>Overrides</i> |
|-------------------|--|---------------|------------------|
| LR | Late Refill with Anticonvulsants | 4,569 | 4,045 |
| LR | Late Refill with Hypoglycemics (Insulin-release Stimulant Type) | 1273 | 1153 |
| LR | Late Refill with Xanthines | 622 | 582 |
| HD | High Dose with NSAIDs (Cyclooxygenase Inhibitor-type) | 575 | 505 |
| DD | Drug/Drug Interaction with Ciprofloxacin | 619 | 485 |
| DD | Drug/Drug Interaction with Norfloxacin | 43 | 40 |
| DD | Drug/Drug Interaction with Ofloxacin | 38 | 35 |
| DD | Drug/Drug Interaction with Lomefloxacin | 1 | 1 |

Indiana Medicaid Smoking Cessation Treatment Services Begin October 27, 1999

In October, Indiana Medicaid commenced paying for covered smoking cessation services. The service went into effect for claims with dates of service beginning October 27, 1999.

The services covered include reimbursement to providers for smoking cessation counseling and drug products, without prior authorization. The coverage is limited to a 12-week course of treatment per recipient, per calendar year. The treatment may include prescriptions for any combination of smoking cessation products and counseling.

Counseling is a requirement for smoking cessation treatment and may be performed by the prescribing physician. In addition, nurse practitioners, dentists, pharmacists, psychologists, and clinics may perform the counseling services, with an order from the prescriber.

Top 25 Drugs by the Total Dollars Paid In Third Quarter 1999

The top 25 drug products based on the total dollars spent for third quarter 1999, represented \$19,399,387 in Indiana Medicaid Payments to pharmacy providers. Antipsychotic agents topped the list with 7 products contributing to \$5,119,547 in Medicaid payments. Gastrointestinal agents and Selective Serotonin Reuptake Inhibitors represented 4 products each, with Medicaid payment amounts of \$4,462,960 and \$2,717,087, respectively. Anticonvulsant agents were the last group of products representing 3 products and \$1,614,051 in Medicaid payments. Details as to what products made the list are identified in the table below:

Top 25 Drugs for 3Q99

| Drug Product | Paid Claims | Quantity Dispensed | Total Payment |
|------------------------------|-------------|--------------------|---------------|
| 1. Recombinate 801-1240 | 359 | 2,351,411 U | \$2,607,060 |
| 2. Prilosec 20mg Capsule DR | 18,500 | 677,736 Caps | \$2,397,189 |
| 3. Zyprexa 10mg Tablet | 6,255 | 292,564 Tabs | \$2,163,959 |
| 4. Prozac 20mg Pulvule | 11,973 | 552,512 Caps | \$1,255,197 |
| 5. Prevacid 30mg Capsule DR | 10,510 | 373,858 Caps | \$1,250,359 |
| 6. Depakote 500mg Tablet EC | 6,536 | 569,703 Tabs | \$747,481 |
| 7. Celebrex 200mg Capsule | 8,426 | 317,164 Caps | \$694,327 |
| 8. Risperdal 1mg Tablet | 6,003 | 285,470 Tabs | \$633,466 |
| 9. Zyprexa 5mg Tablet | 2,941 | 115,597 Tabs | \$566,395 |
| 10. Risperdal 3mg Tablet | 2,348 | 128,023 Tabs | \$536,949 |
| 11. Claritin 10mg Tablet | 8,873 | 259,506 Tabs | \$530,473 |
| 12. Neurontin 300mg Capsule | 4,699 | 516,842 Caps | \$508,907 |
| 13. Zolof 100mg Tablet | 6,323 | 244,922 Tabs | \$503,853 |
| 14. Clozaril 100mg Tablet | 3,397 | 166,121 Tabs | \$503,562 |
| 15. Paxil 20mg Tablet | 6,465 | 235,184 Tabs | \$488,887 |
| 16. Zolof 50mg Tablet | 6,337 | 228,951 Tabs | \$469,150 |
| 17. Ultram 50mg Tablet | 9,929 | 653,548 Tabs | \$456,222 |
| 18. Propoxy-N/APAP 100-650 | 23,071 | 1,186,225 Tabs | \$449,660 |
| 19. Pepcid 20mg Tablet | 5,240 | 259,220 Tabs | \$412,585 |
| 20. Axid 150mg Pulvule | 4,731 | 258,032 Caps | \$402,827 |
| 21. Risperdal 2mg Tablet | 2,171 | 110,703 Tabs | \$394,243 |
| 22. Benefix 1000IU Vial | 55 | 400,376 U | \$391,081 |
| 23. Depakote 250mg Tablet EC | 5,626 | 489,113 Tabs | \$357,663 |
| 24. Lipitor 10mg Tablet | 6,247 | 207,935 Tabs | \$356,919 |
| 25. Seroquel 100mg Tablet | 2,027 | 149,349 Tabs | \$320,973 |

Pro-DUR Alert Summary

(Continued from Page 3)

lists the maximum daily dosage for the most commonly used NSAIDs as they appear in the drug files for the Indiana Medicaid Pro-DUR program.

Finally, there were 701 drug/drug interaction alerts (DD) involving fluoroquinolones. There is substantial evidence documenting how antacids, iron and zinc salts interfere with the GI absorption of fluoroquinolones, resulting in decreased serum levels. Approximately two-thirds of these interactions were overridden and dispensed. Concurrent use of multivitamins and antacids can lessen the effectiveness of fluoroquinolones when treating bacterial infections in Medicaid recipients. The Board hopes the alerts are useful to pharmacist in identifying patients that might benefit from intervention and consultation.

Non-steroidal Anti-inflammatory Agents

Maximum Daily Dose

| NSAID Drug Name | Maximum Dose |
|------------------------------|--------------|
| Ibuprofen | 3200mg/day |
| Naproxen & Naproxen Na | 1500mg/day |
| Ketoprofen | 300mg/day |
| Ketorolac Oral | 40mg/day |
| Diclofenac Na & Diclofenac K | 200mg/day |
| Sulindac | 400mg/day |
| Etodolac | 1200mg/day |
| Piroxicam | 20mg/day |
| Meclofenamate Na | 400mg/day |
| Tolmetin | 1800mg/day |

Visit the Indiana Medicaid DUR Board website at www.indianamedicaid.com