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ANTI-INFLAMMATORY DEBATE TRIGGERS SAFETY CONCERNS

One of the responsibilities of pharmacy benefit managers (PBMs) is to evaluate the safety of the drugs they place on formularies. There is an expectation among plan sponsors that their PBMs prioritize the safety of drugs when deciding which drugs to identify as preferred drugs.

"Safety plays a primary role in formulary decision making that goes hand in hand with the clinical advantages of the drug," says Elizabeth G. Young, MS, PharmD, BCPS, director of formulary services for Walgreens Health Initiatives. "The best formulary products have a high degree of clinical merit, distinguish themselves in the therapeutic class, and reduce drug-related problems for patients."

"It's critical that payers have discussions with their PBMs and health plans about drug safety review processes," says John Wadkins, RPh, manager for Premera Blue Cross, a health plan with 1.3 million members in Alaska and Washington. "One of the best ways to learn how your PBM addresses safety issues is to ask for some examples of drugs that have been removed or excluded from the formulary

for safety reasons. This question also should be included in requests for proposal for PBM services."

"Plan sponsors should hold their pharmacy and therapeutics (P&T) committee accountable for clinical decision making," says Young. "Plan sponsors should request and review regular communication about what the P&T committee is doing, understand what they are doing, and get questions answered if something is unclear."

Case in Point

Despite the rigor of optimal pharmacy and therapeutics committee review processes, new drug safety concerns can and do surface about drugs that enjoy prescriber popularity and tremendous market share. A case in point is the selective COX-2 inhibitors (COX-2s).

Clinical data have recently been uncovered pointing to cardiovascular risks associated with anti-inflammatory drugs that are typically prescribed for arthritis, dysmenorrhea, and chronic pain. The

Anti-Inflammatory, continued on page 2

CONFERENCE OFFERS CONTINUING EDUCATION

The 2005 PBMI Prescription Drug Utilization Management Conference provides continuing education opportunities for human resources, benefits, and pharmacy professionals. PBMI's 10th annual meeting dedicated to the pharmacy benefit will be held from March 30 to April 1, 2005 at the Hilton Scottsdale Resort & Villas in Scottsdale, Ariz.

"The high number of conference attendees who return each year to the PBMI conference is a testimony to the educational and networking value of the meeting," said Michael H. Deskin, PBMI founder and president. "We are testing a new educational forum of tabletop exhibits to provide additional resources to conference attendees."

Conference, continued on page 2

Conference Passes Awarded

PBMI awarded free 2005 conference passes to benefits professionals from Cincinnati Insurance of Fairfield, Ohio; Decision Science of Baltimore, Md.; Goodyear in Akron, Ohio; and Starwood Hotels in White Plains, N.Y. The complimentary passes are a thank-you for completing PBMI's 2004 PBM Customer Satisfaction Survey and the 2004 Prescription Drug Benefit Cost and Plan Design Survey. All survey respondents were entered into the annual drawing for the complimentary passes.

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concerns include both COX-2s as well as the less selective nonsteroidal anti-inflammatory drugs (NSAIDs) like naproxen sodium. These data have resulted in one drug being pulled from the market (Vioxx®), stringent warnings for another (Bextra®), and voluntary cessation of direct-to-consumer advertising for yet another (Celebrex®).

“Managing the appropriate utilization of the COX-2s and NSAIDs is challenging because we are learning that their use is associated with increased cardiovascular and stroke risks but there are no clinical data to tell us what the indicators of those risks are,” said Tim Watson, PharmD, MBA, principal of PSG/AEL Rx in Irving, Texas. “There also is no clinical evidence to quantify if the benefits of these drugs outweigh the risks.”

The U.S. Food and Drug Administration issued the following prescribing guidelines for COX-2s and NSAIDs in a Public Health Advisory issued in December 2004¹:

- Physicians prescribing Celebrex® (celecoxib) or Bextra® (valdecoxib) should consider this emerging information when weighing the benefits against risks for individual patients. Patients who are at a high risk of gastrointestinal (GI) bleeding, have a history of intolerance to non-selective NSAIDs, or are not doing well on non-selective NSAIDs may be appropriate candidates for COX-2 selective agents.
- Individual patient risk for cardiovascular events and other risks commonly associated with NSAIDs should be taken into account for each prescribing situation.
- Consumers are advised that all over-the-counter (OTC) pain medications, including NSAIDs, should be used in strict accordance with the label directions. If use of an OTC NSAID is needed for longer than ten days, a physician should be consulted.

Plan sponsors should ensure they are managing the appropriate use of all anti-inflammatories in light of information linking long-term use or use in high risk settings following heart surgery with increased risk of cardiovascular events such as myocardial infarctions and strokes. Effective drug benefit management strategies are available to help ensure of formulary drugs are used as

Table 1: Strategies to Optimize Safety

Elements of Therapy Requiring Oversight	Management Strategy Options to Include in Plan Design
Prescribing Consistent with FDA-approved Drug Indications	Step Therapy Protocols Prior Authorization
Dosing	Quantity Limits Days' Supply Limits
Duration of Therapy	Quantity Limits Days' Supply Limits Retrospective Review of Excessive Utilization

safely as possible as shown in Table 1: Strategies to Optimize Safety.

Plan sponsors need to focus on the appropriate use of COX-2s and NSAIDs while the industry culls through data to better understand the risks associated with using these drugs. Because of the higher costs of COX-2s and the well documented gastrointestinal risks, many plan sponsors who cover them have placed the agents on the third or higher tier on a multi-tier formulary. The result of this formulary design is increased safety as well as an incentive to drive utilization toward lower cost generic NSAIDs.

Next Steps

The FDA reports it is analyzing the information from newly released studies about Vioxx®, Celebrex®, Bextra®, and naproxen as well as other existing data about both COX-2s and NSAIDs to determine if additional regulatory action is needed, according to the December 23, 2004 Public Health Advisory. The agency also plans to hold an advisory council meeting in February 2005 to discuss and assess the issues surrounding these drugs.²

Vigilance and effective clinical management will be critical as payers wait for the FDA's recommendations about the anti-inflammatories. ●

Footnotes

^{1,2} www.fda.gov/cder/drug/advisory/nsaids.htm accessed on January 26, 2005.

On-line Resources

Summary of clinical studies important in understanding the risks associated with COX-2 and NSAID therapies: <http://www.expresscripts.com/members/todaysbulletins/cox2/cox2Research.pdf>

U.S. Food and Drug Administration announcements, provider alerts, and safety tips: <http://www.fda.gov/cder/drug>

The Worldwide Employee Benefits Network (WEB) and the National Business Coalition on Health (NBCH) have endorsed PBMI's conference for several years. Both WEB And NBCH members are eligible for a \$50 registration discount just like PBMI members.

Pharmacy CPE

The University of Arizona College of Pharmacy, accredited by the American Council on Pharmaceutical Education, will award 14.7 contact hours of continuing pharmacy education credit to conference attendees participating in PBMI's conference.

CE for HR Professionals

The PBMI conference qualifies for recertification credit for the Certified Compensation Professional (CCP®), Certified Benefits Professional (CBPTM) and Global Remuneration Professional (GRP®) designations granted by WorldatWork Society of Certified Professionals. For more information visit the Society website at www.worldatworksociety.org.

The conference also has been approved for 12.75 recertification credit hours toward PHR and SPHR recertification through the Human Resource Certification Institute (HRCI). For more information about certification or recertification, please visit the HRCI homepage at www.hrci.org.

Agenda Available On Line

For a complete agenda and to register visit, www.pbmi.com/Conference.5.ASP. There are still conference sponsorship opportunities. For more information, call Ken Carpenter, vice president of sales for PBMI, at 480-874-2556. ●

EXAMINE INDUSTRY BEST PRACTICES AT PBMI'S 2005 CONFERENCE

PBMI's annual conference is the nation's premier meeting dedicated to curbing costs and maximizing quality in drug benefit programs.

Pre-Conference Workshop

Payers or plan sponsors—the coalitions, employers, health plans, TPA and union groups who provide prescription drug programs—will benefit from attending PBMI's pre-conference workshop to be held from 1 pm to 5 pm on March 30, 2005. Workshop topics include:

Using the Audit Review Process to Optimize Your PBM's Performance

The complexity of the PBM business model is driving the need for comprehensive audit reviews. Examine common PBM audit findings and their implications for your prescription drug program.

Creative Clinical Approaches for Leveraging Your Drug Benefit Investment

Managing drug mix is the best way to leverage your organization's investment in prescription drugs. Getting the right drug to the right patient at the right time and price requires effective clinical management. Evaluate up-to-the-minute strategies for using step therapy, quantity limits, days' supply limits, and dose consolidation as part of a comprehensive clinical management program.

Procurement Strategies for Specialty Pharmacy Vendors

Researching and selecting the right vendor partner is a critical first step in getting specialty pharmacy costs under control. Explore using a therapeutic class analysis to identify how best to manage these drugs and optimize patient care.

The Viability of Direct Rebate Contracting

Direct pharmaceutical rebate contracting may not just be for health maintenance organizations any more. Large employers are making headlines by announcing their intentions to contract directly with pharmaceutical companies for drug

rebates. Assess the benefits of this strategy to increase the cost-effectiveness of your drug benefit plan.

General Sessions

There are seven keynotes during the conference on March 31 to April 1, 2005. Topics are:

Retrospective: A Look at the PBM Industry's Coming of Age

It's been almost two decades since the *Wall Street Journal* coined the term pharmacy benefits manager or PBM. Review the history of PBMs and how the industry is weathering the current market climate.

Employers Health Purchasing Corp. of Ohio Case Study on PBM Procurement with Traditional and Transparent Pricing Options

The Employers Health Purchasing Corp. of Ohio structured its PBM re-contracting effort to ensure it could offer transparent and traditional PBM pricing models to its membership. Understand how an analytically driven procurement process led to successful contracting that will deliver overall benefit savings. Compare PBM pricing under traditional and transparent pricing models.

Disease Management 2005 & Beyond

Effective disease management programs arise from the integration of effective clinical, technology, and business strategies. Examine the industry's best practices for integrated disease management that combines medical and drug coverage to manage complete health care and overall benefit costs.

Medicare Part D Implementation Update:

Implications for Retiree Drug Benefits
As the Medicare Part D implementation deadline nears, employers continue to wrestle with drug benefit coverage issues. Assess progress made by CMS on Part D implementation and how it will impact retiree drug coverage.

Evidence-based Drug Copayments at Pitney Bowes Inc.

Pitney Bowes Inc. has defined and implemented evidence-based drug copayments in an employee and retiree population. Examine the positive impact this innovative plan design has had on emergency room visits, hospital stays, and overall benefit costs for patients with diabetes and asthma.

Today's Legal Climate for PBMs

PBMs face an increasing number of government investigations, proposed legislation, and private litigation. All of these issues have implications for how the sponsors of prescription drug benefit programs do business with PBMs. Identify the critical issues to monitor to stay informed about your PBM's operating environment.

Understanding Drug Pricing Methodologies

Discussions about drug pricing trigger a string of acronyms: AWP, ASP, and WAC. Compare these pricing methodologies and examine the role of database companies in the process. Question-and-answer session will focus on the implications of moving away from AWP pricing.

Breakout Sessions

There will be eight sessions on a breadth of topics critical to drug benefit management. Topics include integrating medical and drug data, physician attitudes about patients' out-of-pocket drug costs, medical adherence, over-the-counter programs, retiree benefits, patient drug safety, step therapy, and workers' compensation programs.

Register Now

Conference registration includes an attendee workbook as well as breakfast, lunch, and coffee breaks for the two-day conference. The complete agenda is on line at www.pbmi.com/Conference.5.ASP. ●

NEWS BRIEFS

ENJOY REWARDS OF BECOMING A MEMBER OF PHARMACY BENEFIT MANAGEMENT INSTITUTE

Join PBMI for research-based information on designing and managing pharmacy benefit programs. PBMI membership is open to plan sponsors, pharmacy benefit managers, and the organizations involved in drug benefit delivery. Join by visiting www.pbmi.com or calling 480-730-0814.

Transparency Debate Continues

The article titled, Evolution Triggers Transparency Debate, in the Winter issue of *PBM news* generated many reader comments about transparent PBM business practices. We want to hear from you, too, before we continue the transparency discussion in a future newsletter article. Please send your comments on PBM transparency to pbmi@pbmi.com. ●

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