Medicare & Reimbursement Advisor Weekly
Critical insight for managed markets professionals

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In this issue

Without access, expect to lose 90% of prescription volume in closed formulary

So what happens in a closed formulary? Here are some observations some formulary decision-makers have passed on.

The impact to a manufacturer is alarming financially. The National Drug Code (NDC) block in a closed formulary removes quite a bit of new prescriptions for a given brand. Your managed care customers are seeing migration to the generics and other formulary agents. Depending on how rigid a closed formulary is, your branded agent left out could lose between 90% to 95% of those scripts. Consider a company that invests in its salesforce and generates 1,000 new scripts in one month: with an NDC block, the scripts aren't filled, and, typically, the patient would end up with the generic or, in some cases, a script for the on-formulary brand.

If your company's managed markets strategy is to get access to your product with closed formulary plans, that's probably smart. Contracting is the key to access because without it, you could lose around 90%–95% of your volume (i.e., 950 out of those 1,000 scripts). With step edits, the effect is less, but you could still lose around 50%–70% in volume if your drug is restricted in this way.

Pharmaceutical manufacturers will need to adapt their contracting strategies to accurately determine a plan's level of control. It is imperative that manufacturers segment the market into plans with open versus closed formularies.

Most plans in Medicare D have some closed formularies as you know. Closed formularies and the use of NDC blocking are a great cost-control strategy for plans because they drive the brand cost down. —BC ■

Closed formulary takeaway

Losing new prescriptions if blocked out of a closed formulary has a kind of sentinel effect, according to some managed care plans, because at the point of clinical decision-making, behavior begins to change. The patient, pharmacist, and physician may file for a coverage determination or perhaps switch to a generic or an on-formulary brand because of messaging at the retail pharmacy, but clearly the brand will lose many new prescriptions.

DUR board outlines study gaps in setting PA decision

Wyoming's drug utilization review (DUR) board met January 29. The following is a rundown of some of the board's key decisions.

Class	Outcome	Notes
ADHD	Preferred agents: Adderall XR, amphetamine salts combination, dextroamphetamine, Vyvanse, Concerta, Focalin XR, dexmethylphenidate, methylphenidate, methylphenidate ER, and Strattera.	N/A

> p. 2

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Survey snapshot

72% *of managed care plan case managers who rate their opinion and influence in formulary decision-making as increased in the past two years, and 55% who rate their opinion as carrying "some weight" with clinical directors in the pharmacy or medical division. Based on a poll of 18 preselected case managers, part of HCPro Managed Care Advisory Board.* ***Interview highlights to be reported in upcoming issue.***

DUR board

< p. 1

Class	Outcome	Notes
Fibrates	Trilipix has a prior authorization (PA) until additional safety information is available.	Trilipix, indicated as a combo therapy with statins, was reviewed under the new drug policy. A Medline search was conducted January 24, 2009, revealing no head-to-head studies. An Abbott representative provided comment. Trilipix has fewer drug interactions than other fibrates and has not caused rhabdomyolysis. This may address an unmet need, according to the DUR board. Studies in combination with statins included more than 2600 patients. All primary endpoints were met. Using other fibrates with statins occurs at higher statin doses, the board said. The Trilipix studies failed to look at the drug in combination with high-dose statins, which is often how fibrates are used in practice.
Statins	Preferred: Lescol, Lescol XL, pravastatin, lovastatin, simvastatin and Lipitor. As a result, the criteria will be simplified to require only trial and failure of a preferred agent.	Vytorin requires a PA in favor of the use of simvastatin and ezetimibe (Zetia). Schering-Plough provided public comment. Vytorin patients are much more likely to see a decrease of more than 50% LDL and are also more likely to reach an LDL goal of < 70. The board asked that further information regarding the cost implications be provided in closed session. Following this discussion, the board agreed that it was reasonable to require use of the two separate agents prior to the combination product.
PPIs	Preferred agents as of April 1: Protonix, Prilosec OTC, and Prevacid.	Due to the expansion of preferred agents, the criteria will be simplified to require only trial and failure of preferred agents.
NSAIDs	Preferred agents as of April 1: diclofenac, etodolac IR, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketorolac, naproxen, oxaprozin, sulindac, ketoprofen, meclofenamate, mefenamic acid, nabumetone, and tolmetin.	Criteria will be simplified to require only trial and failure of two preferred agents. No changes to individual quantity limits or clinical edits.
CCBs	All preferred	No more PA criteria as of April 1
Overactive bladder	Preferred: Detrol LA, oxybutynin, oxybutynin ER, Enablex, Sanctura, Sanctura XR, and Vesicare.	Criteria will be simplified to require only trial and failure of a preferred agent or difficulty swallowing.

> p. 3

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DUR board

< p. 2

Class	Outcome	Notes
Somatotropin agents	Preferred agents: Genotropin and Nutropin	Proposed criteria discussed (final decision to come): PA for use outside of FDA-approved indications; evaluation by an endocrinologist is preferred; clinical evidence of improved growth will be required on a yearly basis to support ongoing utilization. Clinical evidence of need for growth hormone will be required for adult growth hormone deficiency and pediatric growth failure due to inadequate endogenous growth hormone. Genotropin has a patient support program called Bridges that the board asked for more information on.
Antidepressants	Claims for Cymbalta will require PA for **initial doses greater than 60 mg and doses of 120 mg and higher**	
Narcotic limits	PA required for: • Acetaminophen doses greater than 4 grams per day (for all acetaminophen-containing products) • Ibuprofen doses greater than 3200 mg of ibuprofen per day (for all ibuprofen-containing products) • More than one butorphanol nasal inhaler per month • Any narcotic utilization in combination with buprenorphine • More than sixty pentazocine/naloxone tablets per month • Fentanyl patches applied more frequently than every 72 hours • Marinol doses above 20 mg per day and for diagnoses except for AIDS and cancer	

Source: Minutes of Wyoming Drug Utilization Review Board session, January 29.

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Reporter's notebook

Drugs with better safety profiles may win in hospital pharmacy initiative

With patient falls rising steadily and payers pressuring hospitals to eliminate hospital-related injuries, **Peg Daly, RN,** director of education at North Adams (MA) Regional Hospital, says it has turned to its falls committee to research evidence and change how nurses assess patients' risks for falls and how to prevent them, specifically by revamping pharmacy protocols.

CMS generally follows the Joint Commission's (formerly JCAHO) guidelines, and the accreditor requires hospitals to reduce falls. "About 60% of our patients are covered by either Medicare or Medicaid, so we are predicting that in the near future payers (government and commercial) will not reimburse for injuries sustained as a result of a fall while in the hospital," says **Debbie Durant, RN, BSN,** director of the medical surgical unit at North Adams Regional Hospital.

That's one reason the hospital may try to ensure that the preferred medications aren't causing adverse effects or side effects that could increase fall risk. Medications with a better safety profile have an advantage, Durant says.

The goal is to reduce falls by 10% in one year; a single patient fall costs one of your hospital customers $33,785.00, according to a U.S. Department of Veterans Affairs analysis.

CHANGING PROTOCOL

In a new process, a pharmacist will conduct a more careful analysis of medications to check for potential drug interactions that could cause a patient to become disoriented and fall. "If they're at high risk for a fall, we want pharmacists to look at medications and make sure that the pharmacy review is a little more in-depth," Daly says, "but we're still figuring out what that mechanism is. We have to work this out with the pharmacy. It's possible that we would consider adjusting a medication policy or looking to the P&T committee for input."

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>
> ***—Peg Daly, RN,** on what her hospital may do under a plan to reduce the financial risk of patient falls.*

Working among the silos of a typical hospital will be a challenge, say Daly and Durant.

"When it comes down to it, patient safety isn't just the responsibility of nursing but all departments," says Durant.

No significant pharmacy data are available yet, but they will be reported in a future **MRAW.**

North Adams Regional Hospital also added new IV criteria to its process for assessing falls. Patients who were hooked up to IVs were being assessed in the same manner as those who did not have IVs. ■

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