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How have manufacturers of the most recent line extension products to hit the market achieved unrestricted access to them, be it a tier-2 position or tier 3, without any step edit or prior authorization? What strategy—clinical or contracting—works best?

The following is one view, suggesting a mixed approach:

- Reduce WAC (wholesale acquisition cost), compared to the existing product pricing
- Prove that the new product does not extend patent life

- Offer incremental discounts on both products

Note: That strategy was shared by a few plans who asked not to be named.

Other plans say line extensions offer little clinical value to a payer, which is why most manufacturers need to take a contracting approach—period, sometimes even to the point where the plan may lose all rebates on the existing product unless the line extension is included, or it may be a reduced rebate on the existing product. ■

Blocking access: Closed formulary article generates wave of letters

We received more than 30 letters and e-mails, including 13 from plans, in response to the closed formulary article in the February 4 MRAW.

Some managed markets readers say they have shared the article with their contracting folks to help them with forecasting. The idea that closed formularies can extend beyond the plan and change a physician's behavior across all plans is an important takeaway, which many of you agreed with.

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.

Paul Lakomski, RPh, MBA, a regional pharmacy director for WellPoint NextRx, agrees to a point. "I agree [with this], although I would not call a [National Drug Code (NDC)] block a sentinel effect. We usually refer to sentinel effect for a product that has an edit on it (like a step or NDC block), even though you most likely will approve the medication, but just knowing there is an edit reduces the number of requests for the drug that most likely would not be approved. Plus, only those that truly need the therapy would apply for one," he says. > p. 2



Survey snapshot

72% Of managed care plan case managers rate their opinion and influence in formulary decision-making as increased in the past two years, and 55% rate their opinion as carrying "some weight" with clinical directors in the pharmacy or medical division.

Note: This poll was based on 18 preselected case managers, who are part of HCPro's Managed Care Advisory Board. Interview highlights will be reported in an upcoming issue.

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DENIED ACCESS AGREEMENTS

Closed formularies create an environment that is difficult for manufacturers and prescribers to navigate.

For example, when manufacturers launch aggressive campaigns to contract for access, there are many plans that won't entertain access agreements for a period that ranges from six to 12 months. NDC blocks make trial and usage by patients and doctors really difficult in those situations.

When Lakomski was a director at a small plan, he implemented a moratorium period on any new drug. This was actually quite common in hospitals, and many of the P&T physicians had a self-imposed moratorium of six to 12 months on new drugs as well. The reasoning behind this is that clinical trials often do not reveal all of the potential side effects when used in a real-world population, so they did not want to use their patients as guinea pigs. There have been many instances where drugs once on the market have shown severe or even fatal side effects when used in the general population and not under the rigid control and guidance of a clinical trial, Lakomski says, citing Bextra/Vioxx and any of the other recently pulled drugs. This is a safety step.

"For drugs that are truly groundbreaking, there is always a way to get the medication through the appeals process, and this also limits the trial and error uses that could be potentially harmful to the patient," Lakomski says. "If we are talking about a new therapy that will extend life or significantly alter a disease state, there will be a way for the patient to get the medication.

If we are talking about the latest once daily anti-hypertensive with a novel mechanism of action when there are a multitude of options proven not only to reduce blood pressure but reduce morbidity and mortality (which is often not the case for the new entry), an NDC block or moratorium is appropriate."

Some plans ask why they would take a discount on a short-term basis to allow for the manufacturer to gain leverage. From the plan's view, manufacturers ought to rely on their clinical studies and product label if they want quick access. Plans also look at demand. If a plan has multiple coverage determinations for a new drug, they are typically more willing to consider a formulary position due to input from the prescriber community.

MRAW is investigating this issue for a follow-up story, and may follow some products that recently launched and about their market uptake. Contact me at bcote@hcpro.com with questions and your insight regarding this story.

CONCLUSION

A key point for the industry will be to separate the noise from control. Closed formularies with NDC blocks and step edits have a lot of control, and result in lower plan costs. An open formulary with a lot of communication produces noise, but not much control. Communication could be retrospective formulary change programs designed to move patients from tier 3 agents to tier 2 or generics. These communications (e.g., faxes, letters, coupon programs aimed at doctors or consumers) have a much lower conversion rate compared to a closed formulary, > p. 3

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but tend to be perceived as less disruptive. Pharmaceutical manufacturers need tools to determine whether a given plan manages with edits or just noise. Tools may be internal models to look at actual share migration when formulary positions are lost.

Manufacturers, if they haven't already, need to inventory a plan's ability to move share.

To read the first article in this series, see the February 4 **MRAW** or contact me for a copy. —BC ■

Reporter's notebook

Outlook on special needs plans

Medicare is attempting to change its special needs plans (SNP) to ensure that plans are, in fact, special needs. The agency wants to avoid an osteoarthritis type of plan that existed in the program's infancy. To do it, CMS now requires 100% of new members into a special needs plan to be people with special healthcare needs. These changes make the SNP model for plans less viable from a business standpoint.

The result is that the remaining SNPs will become much more aggressive in managing these members, a direct response to a withering of profitability. Smaller plans generally lack the infrastructure to case manage every special needs patient, so for plans with fewer than 100 members, it's likely they may begin to go away or there will be some consolidation.

Do not expect many of the bigger national players to go out acquiring small plans necessarily, unless the plan's membership fills a geographic and therapeutic niche.

CMS has set up the SNP rules to run through December 2010, but if after this time the government doesn't reauthorize this and SNPs go away, you may see more consolidation.

ACCESS RESTRICTIONS

Restricting access is getting more difficult. If an SNP or a Medicare Advantage plan restricts a drug, CMS has set up the rules to make it difficult to be creative with utilization management. As an arbitrary, fictional example, consider a drug indicated to treat rheumatoid arthritis and cancer (i.e., Methotrexate.) A Part D plan may only use a prior authorization (PA) for cancer, but since the drug is indicated to treat both diseases, CMS won't allow a plan to apply an edit such as a PA to just one indication; it can't be selective and limit a drug for certain indications. This ties a plan's hands on how to control its costs.

Where is this heading? With the possible choking of creativity on the utilization management (UM) side, some plans see the greater likelihood of a national formulary coming into play in five years. A current indication of that is that some plans are simply having to adopt the same formulary/UM approach as CMS suggests to them for certain classes, if the agency finds that they are a kind of outlier. However, limits on how to apply UM tools certainly appear to be more provider-friendly. ■

Source: Field reports.

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