

PA No More?

Or are payers looking at other ways to manage high-cost specialty therapies? **BY LOLA BUTCHER**

Harvard Pilgrim Health Care killed it for a \$1,000-a-month biologic for asthma patients.

M-Plan laid it to rest for multiple sclerosis treatments.

SelectHealth gave it the boot for both MS and rheumatoid arthritis therapies.

Could it be that prior authorization — that oft-invoked strategy for managing the use of specialty pharmaceuticals — is going away?

Not on your life. But as health

plans gain experience with specialty therapies, they are fine-tuning utilization management strategies, even for products that come with high dollar amounts attached.

"I look at it as the atom bomb of management tools," says Charles Mihalik, Pharm D, director of pharmacy services for M-Plan, an Indiana HMO with about 135,000 commercial members. "We try to limit it to where we feel there's a real need."

While some plans continue to require prior authorization for any

therapy that exceeds a certain dollar threshold, the strategy — in some situations — is giving way to other management approaches.

"We might see some relaxing in prior authorization as we learn more about how to manage these products," Mihalik says.

That said, prior auth has a long history of success in pharmaceutical management, and it is not going away in the foreseeable future.

"Clearly if you put a PA or quantity limit on products, you're going



PHOTOGRAPH BY DENNY COLLINS

For the most part, prior authorization is not an effective management strategy, says Doug Matter, RPh, director of managed care at ICORE Healthcare. "It's an additional cost the health plan incurs. They really don't get much bang for their buck."

to decrease utilization of the products — no doubt about that,” says Robert Giles Jr., PharmD, senior manager for formularies and specialty pharmacy at BlueCross BlueShield of Tennessee. “It’s like charging \$5 for a gallon of gas. People are going to drive their cars less.”

Indeed, in the oncology category, health plans plan to increase their use of prior authorization, according to the Managed Care Oncology Index published by the Zitter Group earlier this year. Tom Baker, MPA, the group’s senior vice president of strategy and analytics, surveyed health plan executives in late 2006. The overwhelming majority of requests are approved, but prior authorization puts providers on notice that they are being watched.

“They have really just set up a sentinel system,” Baker says. “They are saying ‘I’m aware that there is a lot of economic incentive in cancer medicine.’”

The Tennessee Blues plan applies prior authorization to some of the new oral oncologics — and some intravenously administered drugs as well — to force physicians to make treatment decisions that correspond to evidence of their efficacy.

“We get lots of requests that don’t necessarily follow evidence-based medicine,” Giles says. “By putting bumps in the road, like prior authorization criteria, it makes you stop, step back, and look at the treatment of the patient. By doing that, we know we save some money, but we also don’t believe it negatively affects the care of the member.”

Doug Matter, RPh, director of managed care at ICORE Healthcare, represents many biotech companies in their relationships with MCOs. He estimates that up to 80

percent of claims for injectables are subject to prior authorization because of their high cost.

By and large, he thinks prior authorization is not an effective management strategy.

“Ninety-nine percent of the claims get approved because people aren’t going to abuse hepatitis medications or MS medications,” he says. “It’s an additional cost the health plan incurs. They don’t really get much bang for their buck.”

One exception is prior authorization for growth hormone for underdeveloped children.

“There is obviously a lot of abuse for growth hormone in antiaging and beautification, and health plans don’t want to pay for that. That’s a perfect example where prior authorization makes a lot of sense,” Matter says. “But a plan that prior auths hepatitis, especially for initial therapy? A gastroenterologist is not going to abuse interferon for a patient who is suspected to have hepatitis. It just doesn’t make sense.”

Mihalik says health plans use prior authorization as a first defense against physicians who are trying to push against the limits of knowledge. The fact that the overwhelming majority of prior authorization requests are approved does not mean the strategy is ineffective.

“I understand the physician’s perception that the vast majority of drugs are approved,” Mihalik says. “But the ones that are denied can reflect a significant reason for denial.”

Because of the health risk from inappropriate use of biologic therapies, M-Plan wants to limit their use to indications approved by the U.S. Food and Drug Administration.

“My plan is not very interested in what we would call experimental

use,” Mihalik says. “We felt that there was a lot of risk in doctors using them outside of their indication, because [of] ‘Well, they work for this, so maybe they’ll work for that.’”

Eric Cannon, PharmD, director of pharmacy at SelectHealth, applies prior authorization only for products he believes may be misused, not because they exceed a certain dollar volume. That is why SelectHealth, a 500,000-member not-for-profit insurer affiliated with Intermountain Healthcare in Utah, does not require prior authorization for RA and MS treatments, despite their high cost.

“We haven’t had prior authorization on those two categories now for probably two or three years, at least,” he says.

SelectHealth uses prior authorization only for six common categories of specialty drugs: growth hormones; asthma therapy; osteoporosis treatments; viscosupplementation agents; hepatitis treatment (to monitor the duration of therapy); and respiratory syncytial virus, or RSV, medication.

WHY? IT DEPENDS

At SelectHealth, the process for deciding prior authorization includes reviewing the number of times a therapy has been approved, the number of denials, the number of denials that are appealed, and the number of times those appeals have overturned the original decision. Those data vary from one therapy to the next, depending on the issues that should be considered with a specific pharmaceutical.

“Just because we’re doing a lot of prior authorizations and denying a lot of them doesn’t mean we’ll keep something on [prior authorization],

PA once topped techniques for managing specialty therapies

When researchers at the University of Maryland School of Pharmacy in Baltimore studied the evolution of utilization management for specialty pharmaceuticals at Blue Cross and Blue Shield plans across the country, one strategy emerged as the “go-to” favorite. From 2000 to 2004, prior authorization was the single most common strategy implemented by the 38 plans in the study. A survey conducted by the Blue Cross Blue Shield Association found that in 2003–2004, more than 83 percent of Blues plans used prior authorization as a management tool for specialty products. However, researchers found that other management techniques also were increasingly being used.

Management service	Developed in-house capacity		Used specialty pharmacy vendor		Did not use this service	
	Number	Percent	Number	Percent	Number	Percent
Prior authorization	22	73	3	10	5	17
Claims review	22	76	2	7	5	17
Formulary management	21	70	2	7	7	23
Utilization review	18	60	3	10	9	30
Purchasing or distribution of products to patients	1	3	20	67	9	30
Purchasing or distribution of products to providers/physicians	0	0	20	67	10	33
Specialty pharmacy benefit administration	14	48	3	10	12	41
Disease management	12	41	5	17	14	41
Rebate contracts	9	31	3	10	17	59

SOURCE: BLUE CROSS BLUE SHIELD ASSOCIATION
OUTPATIENT SPECIALTY PHARMACEUTICAL STRATEGY SURVEY, 2005

and just because we have some things on prior authorization and we approve all of them or most of them, doesn't mean we'll take it off," Cannon says. "But there are instances where, if we look at something, and we aren't denying any of the requests, we will seriously consider taking it off prior authorization."

Cannon thinks exenatide (Byetta) — which he says is “kind of on our radar” — may be similar to the biologics for RA and MS, which, over time, became viewed as the best treatment available.

“Our feeling has been that if it is an appropriate standard of care, then we need to make sure that there are only minimal hurdles to getting the product,” he says.

Harvard Pilgrim Health Care removed prior authorization for omalizumab (Xolair) after three years' experience with the asthma treatment. Approved to prevent allergic reactions that can prompt severe asthma attacks, omalizumab is injected in a physician's office, typically twice a month at a cost of about \$500 per treatment.

Like most health plans, Massachusetts-based Harvard Pilgrim applied prior authorization when omalizumab was introduced because it was concerned about off-label and inappropriate use, as well as the cost. The product is appropriate only for a small percentage of asthmatics who do not fare well with conventional medications. A review of prior authorization requests found physicians were prescribing omalizumab appropriately, prompting that barrier to be dropped.

At M-Plan, Mihalik considers

four issues when deciding whether prior authorization is appropriate:

- Will patients receive better care as a result?
- If they won't receive better care, will there be a significant effect on cost if prior authorization is removed?
- How much interference in practice would prior authorization cause?
- How much inappropriate or off-label use of the product is suspected?

"We use it very sparingly, because it takes a lot to administer a PA program," he says. "Many of the physicians who have to go through prior authorization are probably doing a good job to start with. So we're affecting a large population of practitioners, when in reality there may be a small benefit."

Mihalik discontinued prior authorization for MS treatments after a review of requests found no off-label use. "We don't want to hassle the docs if we don't have to," he says. "If they're using the drugs properly, and if there's very little risk for problems associated with them, why continue prior authorization?"

Mihalik is considering whether to remove prior authorization for RA treatments.

"As the guidelines have evolved in RA, biologic therapies are considered by many as first-line therapy," he says. "Are we actually not helping patients by requiring that they use other therapies prior to a biologic? That's a question I've been grappling with for quite some time."

Meanwhile, M-Plan is relaxing its rules for reauthorization of certain specialty pharmaceuticals.

"I've noticed that PBMs tend to put these reauthorization processes in, but there's not much objective evidence as to why you should do that," Mihalik says. "I've been dropping all my reauthorization (requirements) for cancer, because doctors aren't going to continue therapy if it's not working."

BEYOND PA

If not prior authorization, what? In oncology treatment, at least, look for two other approaches.

"I think we're going to move away from the term *prior authorization*, and we're going to start to see step therapy or protocols to treat each specific type of cancer," says Matter, at ICORE Healthcare. "We may call it a utilization review. But payers will be looking at those providers to make sure that they are treating various types of cancers under the approved regimen."

The approved regimen will be determined through discussions with physicians. Rather than dictate the use of a specific therapy, health plans increasingly will ask physicians to decide among themselves which treatment plan is appropriate for specific disease states — and then insist that they stick with it.

"The health plan is saying, 'All right, you are my oncologists in my network. You agree on the most logical way to treat small cell lung cancer, and that will be our protocol. We don't care how they do it at Mayo or Cedars-Sinai or whatever, but this is how you have agreed to do it, and that's how we'll implement our policy,'" says Matter. The oncologists would, contractually, be bound to adhere to the regimen, when appropriate, or receive lesser payment for going their own way.

Matter reports a handful of initiatives are already under way, and he forecasts that the trend will pick up speed quickly.

"I'd say in another 2 or 3 years, we'll be over 50 percent," he says, expecting that new provider contracts will offer payers the opportunity to implement the strategy. "By 2010, that will be the dominant way providers are reimbursed."

At SelectHealth, Cannon relies on physicians to advise on the appropriate use of specialty pharmaceuticals in a different way. The plan eliminated prior authorization for both RA and MS treatments after consulting with physicians who serve on steering committees for various medical subspecialties.

"Once or twice a year, we'll meet the rheumatologists or with neurologists and say, 'OK, where are you using these drugs?'" he says.

The physicians, motivated by their desire for fewer controls from the health plan, become a self-policing organization.

"If you've got somebody who is using something when they shouldn't be, the physicians themselves say, 'What's the data behind that?'" Cannon says. "They help us to establish the guidelines under which they're going to use the drugs."

Whether it's called a utilization review or an approved protocol, payers are not going to shirk their responsibility to review prescribed biologic therapies to keep specialty drug costs under control — and more importantly — ensure proper health care of their members. Not on your life. **BH**

Lola Butcher, who writes about health policy and the business of healthcare, lives in Springfield, Mo.