

TAKING CONTROL OF COMPLIANCE

The cost of biologic therapies adds urgency to the need to develop realistic compliance strategies. By engaging and educating both the physician and patient, some MCOs are working hard to address at what has always been a complicated and formidable issue.

BY SCOTT KOBER, *Contributing Editor*

For most of Thomas Morrow's life as a father with kids in the house, his grocery bills were relatively stable. Until his four children reached a certain age, Morrow could count on spending roughly the same

amount each month to fill his family's bellies.

But as the children became teenagers, especially the very athletic boys, Morrow's supermarket bills began to soar, which wasn't a surprise. His sons' biologic systems

simply required additional calories, which meant that Morrow had to buy them more food. As he puts it, "That's just part of life."

Morrow, who has served most of his professional career as a health plan medical director, used the story



PHOTOGRAPH BY STAN KAADY

Dose escalation is one of the thorniest adherence issues payers face, but in response to a biological phenomenon, it often might be unavoidable. Thomas Morrow, MD, says health plans looking at compliance issues from a financial standpoint could benefit from comprehensive educational techniques.

to illustrate part of the dilemma that MCOs are faced with as they attempt to control their biologic product costs. Although there are patients who will forever respond to a stable dose of a particular medication, others will require a higher and higher dose to ensure a regular response.

“There are a lot of reasons why an effective dose today may be ineffective tomorrow,” Morrow says. “Number one, the disease progresses — almost every degenerative disease gets worse over time. Two, the body upregulates receptors that need to be blocked or stimulated in many cases. Three, the body produces antibodies to many of the proteins that may neutralize a certain percentage of a drug, so you need to increase the dosage to overcome that neutralization.” There are probably a dozen other reasons as well.

“I can understand the concerns health plans have in this area, but theirs is a financial concern, not a biologic one,” he says. “Our bodies don’t care about finances, though. They care about biology.”

Taken in that context, controlling such medication compliance issues as dose creep may seem to be an impossible hurdle for MCOs to tackle. Although few experts would argue that both physician and patient compliance with MCO-recommended biologic regimens might be solved through one or two specific interventions, there are several techniques being introduced that are having a positive effect on bottom-line costs.

“You cannot solve these issues through one intervention, so you have to be creative as an organization to address them,” says Sharon

Levine, MD, associate executive director of the Permanente Medical Group, in Oakland, Calif. “You not only have to put the right people in place to gather and analyze information, you also have to ensure that you have the right mechanism in place to communicate that information to physicians so that they can use it effectively and pass it along to their patients.”

PHYSICIAN-CENTERED APPROACHES

Because of its structure as an integrated delivery system, Kaiser Permanente is able to operate in a somewhat different manner than other MCOs when it comes to setting guidelines for use of medica-

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— SHARON LEVINE, MD

tions, including biologics. Of the nearly 6,000 physicians in the Kaiser Permanente network, approximately 550 are involved in various formulary committees that set dose guidelines. That means in many cases, the physicians who are going to utilize a specific injectable or infused biologic are setting the general parameters of care.

Individual physicians maintain final control over the specific care of their patients, which naturally leads to some variation, Levine says, but, the peer-review structure of the entire organization enables Kaiser Per-

manente to keep that variation within a very narrow band. It is much more difficult, she finds, to ignore dose recommendations set by “Dr. John” who works down the hall than it is when those recommendations are passed down by “Dr. Johnson” who appears at the top of a masthead.

“Our approach changes the burden of proof,” Levine says. “If an individual in a department or a group of, say, dermatologists, is prescribing in a very different manner from their peers, it’s not the health plan that has deal with the situation, but rather the peers asking the physician, ‘Would you help us understand why your practice is different?’ or ‘What the basis is for the decisions you’ve been making?’ We don’t consider these encounters to be one-time events, but rather ongoing opportunities for dialogue.”

Levine understands that Kaiser Permanente’s specific approach cannot be replicated in most managed care settings where independent physician panels work with drug management committees. It cannot be overstated, she believes, how

important it is that the company have practices guided by colleagues who are known by their physicians. However, the one key element of Kaiser Permanente’s approach — regular and effective communication between the health plan and its physicians — is something Levine says every MCO can focus on improving.

“In this arena, you cannot over-communicate, but you have to make sure that your communication efforts are done in a way that ensures they are trustworthy, that the information is coming from credible

physician sources, and that there is an incentive from an efficiency, effectiveness, and quality perspective for physicians to pay attention to the information," Levine says.

Through a variety of mostly electronic communications vehicles, Kaiser Permanente ensures that its physicians are using the best and most appropriate information to guide their prescribing patterns for high-cost, high-impact biologics. Levine says that the company's approach is about giving physicians useful and honest information through the proper mechanisms at the appropriate time.

"Physicians have to trust the information that they are getting," Levine says. "It has to be credible, based on good science, and, when cost is a mitigating factor, MCOs have to be forthright about that. From our experience, physicians will support efforts to use the most cost-effective approach as long as they are confident that they are not being asked to compromise quality. When a formulary decision is merely a matter of 'We get a better price on this drug than its equivalent,' be honest about that."

The simple fact that there are formulary decisions to be made concerning biologics is something that many MCOs are currently using to their advantage. For such conditions as rheumatoid arthritis and multiple sclerosis, several biologic options are available, which gives MCOs some leverage during price negotiations, along with the op-

portunity to develop tiered medication criteria.

For instance, Harvard Pilgrim Health Care, in Wellesley, Mass., mandates that patients needing growth hormones fail its preferred tier 2 agent, somatropin (rDNA origin) for injection (Tev-Tropin), be-



Direct outreach case managers can improve overall compliance and adherence across several disease states, says Neil Minkoff, MD, of Harvard Pilgrim.

fore gaining covered access to one of the other three available growth hormones. It's a significant shift from even five years ago when MCOs' choices were limited to one-of-a-kind agents in a class.

"What we're hoping is that either the generic market opens up or more and more companies start coming out with these generic-type products like Tev-Tropin that give us management ability by having peo-

ple use that as the preferred product in lieu of a generic," says Neil Minkoff, MD, medical director, network services and pharmacy at Harvard Pilgrim. "We're just starting to get to that point where, in those few classes, we can be aggressive about having preferred agents."

PATIENT-CENTERED APPROACHES

Although educating physicians on the proper use of biologics is a vital piece of dose compliance, many MCOs are primarily focusing their resources on patient interventions. Levine identifies three core patient compliance issues that MCOs are being forced to deal with:

Finding ways to fit dosing and administration protocols into

members' schedules. Because many biologics require regular visits to a physician's office for an injection or infusion, it can become easily inconvenient for patients to stay on the required drug regimen. One missed appointment leads to two and three missed appointments, which eventually leads to treatment failures.

Devising realistic plan payment structures. Beneficiaries who are enrolled in a plan with a high deductible often balk at the upfront cost of biologics, especially if they are outpatients. Crafting a benefit design program that eliminates cost barriers for patients is essential.

Whenever possible, choose agents with limited side effects. Both Levine and Morrow agree — biologics with a laundry list of measurable side effects are often the ones patients balk at taking for several weeks or months. It can be difficult to convince patients to use products that are uncomfortable to inject or result in noticeable side effects, especially when they are not able to see the immediate benefits of the product.

"For example, if I make you impotent by giving you a beta blocker for your hypertension, you know that," Morrow said "But since you don't 'feel' your hypertension, you'll stop taking the drug because it is negatively affecting your quality of life. For biologics as well as for small molecules, it goes back to simple psychology — you have to create positive incentives to convince patients to continue with their therapies in the absence of quality-of-life improvements."

A number of different approaches are being used to address one or more of these compliance issues.

Harvard Pilgrim has chosen to attack compliance issues by investing in a rigorous case management program. In the 1990s, Harvard Pilgrim outsourced its case management to outside specialists. Although those vendors provided adequate levels of usefulness, Minkoff says, it made sense to pull those services back in-house as the need to gather better information on patient outcomes increased.

Today, Harvard Pilgrim employs a team of nurses with varying levels of chronic care experience to check in on patients. Depending on their level of individual need, case managers communicate with patients — sometimes daily — to provide them with the necessary level of external support.

“By taking control of the process, we know which of our case managers are doing what,” Minkoff says. “We have one integrated system where everyone is inputting their findings. We have a level of confidence in the ways our case managers are interacting with members, and we have the tools to be able to measure their effect on compliance.”

The efforts have paid off. Although the data detailing improvements in patient outcomes are not yet robust enough to be published, Minkoff says “The numbers are promising.”

“We’re seeing improved overall compliance and adherence across multiple disease states by having direct outreach case managers,” Minkoff says.

At Kaiser Permanente, the focus is on improving physician-patient communication. Although Levine noted that scans of particular drug classes are performed periodically

to identify any systemwide problems, it remains largely incumbent upon individual physicians to ensure patient regimen compliance.

Training and educational activities are regularly scheduled for Kaiser Permanente physicians, where experts are brought in to educate attendees on the most effective ways to communicate with increasingly well-informed (or in some cases, not-so-well-informed) patients.

“One of the sayings we use all the time in our organization is, ‘People don’t care how much you know until they know how much you care,’” Levine says. “Physicians have to establish a relationship of trust with each patient so that they can get the information they need to ensure that patients are going to be successful at following the prescribed regimen given the realities of their lives.

“It’s no longer just about a doctor giving orders to a patient. It’s about the value of having a conversation and, in the process, trying to elicit information that allows both parties to agree on a regimen that will make sense,” Levine says. “That’s a tectonic shift as physicians are becoming more responsible for health outcomes and not just the process of what happens in the examination room.”

SPECIALTY PHARMACY’S ROLE

The rise in the popularity of full-service specialty pharmacies serves as another signal of the increasing importance being placed on measuring biologic therapy outcomes. Specialty pharmacies are now offering “soup-to-nuts” care, with services for patients, physicians, and

payers. Through partnerships with various MCOs, those specialty pharmacies are finding new ways to measure patient outcomes and improve compliance.

“I’ve been preaching about the possibilities of specialty pharmacies for five or six years, and it’s nice to see that there are a number of them that are succeeding,” Morrow says. “They are recognizing that developing patient management programs gives them a competitive advantage. While they’d love to charge payers for the services they are providing, the reality is that most of the purchasers of pharmacy services are buying the primary service, which is distribution of a biologic at a low price, so specialty pharmacies are limited in the ability to absorb the extra costs for patient management programs. A few are starting to offer it just as a part of their business, which is really promising for the future.”

It is a future, most agree, that will continue to present special challenges as the biologic drug pipeline evolves and outcomes management programs generate enough data to be measurable over a long-term basis. No regimen will ever result in 100 percent patient compliance, but the focus on getting as close as possible to that figure isn’t going to slow down, either.

“You’ll never get to the point where things are black and white across the board where no one will have to use any judgment in prescribing treatment regimens,” Levine says. “You have to do what you can with the resources that are available.” **BH**

Scott Kober is Philadelphia-based writer specializing in healthcare issues.