ON THE HORIZON

MAKING PART D BETTER

Advocacy efforts are under way to improve patient access to medications.

BY ROCHELLE NATALONI, SENIOR STAFF WRITER

Forty years after enrolling its first beneficiaries, Medicare introduced a long-awaited prescription drug insurance program. Prior to that, Medicare paid for some drugs administered during a hospital stay (under Medicare Part A) or in a doctor's office (under Medicare Part B). But it did not cover outpatient prescription drugs until 2006, when the Medicare Part D prescription drug benefit was implemented, authorized by Congress under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Unlike Parts A and B, which are administered by Medicare, Part D is privatized, meaning that Medicare contracts with private companies that are authorized to sell Part D insurance coverage. Plans establish their own formularies; long-established medications and new medications are included, or not, based on negotiations between drug makers and the private companies authorized to sell Part D coverage. There is often a preauthorization process as well as an appeal process for members who are prescribed drugs that are not on their plan's formularies. Plans revise their formularies every year, adding new drugs and eliminating others. This adds a layer of administrative complexity because neither patients nor their physicians know whether a drug that is on the insurer's formulary when it is prescribed will remain so the following year.

Last year, Express Scripts Holding Company, the nation's largest pharmacy benefit manager, added a handful of medications to its list of drugs excluded from insurance coverage and simultaneously removed several medications from its exclusion list. Express Scripts has been excluding medications from its coverage list since 2014, citing concerns about costs to its health insurers and corporate customers. The aim of this exclusion process is reportedly to better negotiate lower prices with drug makers in an attempt to save customers money.

Erin A. Taylor, a Rand Corporation policy researcher, explained the rationale for this strategy.[1] "If insurers have the option to exclude certain drugs from the formulary, pharmaceutical companies may be more likely to offer lower prices for [a] medication," she wrote. "In turn, insurers can pass these savings on to enrollees in the form of lower premiums. If insurers were required to maintain the same formulary over time, pharmaceutical manufacturers could simply raise prices at will, and insurers would lack leverage to stop them."[1]

Despite this supposed limiting effect, 12 of the 20 most commonly prescribed brand-name drugs for seniors have gone up in price by more than 50% during the past 5 years, according to a report by the US Senate Homeland Security and Governmental Affairs Committee.[2] Six of the 20 were subject to price increases of greater than 100%.[2]

One reason for escalating Medicare D drug prices is that the federal government, which subsidizes Medicare D, is barred from negotiating cheaper prices for covered medications. Instead, the job of holding down costs is outsourced to the insurance companies providing the coverage. Critics say this results in the government spending tens of billions of dollars unnecessarily, while proponents defend it on free-market grounds.

The Pharmaceutical Research and Manufacturers of America, an industry group that represents pharmaceutical companies, has raised concerns about the accuracy of the Senate's report on drug prices. "This is yet another misleading report that ignores the robust negotiations that occur between Medicare Part D plans, middlemen, and biopharmaceutical companies," Juliet Johnson, a spokeswoman for the group, said in a written statement. "Negotiated rebates can reduce list prices by as much as 30% to 70%," she added.

BRAND-NAME VERSUS GENERIC DRUGS

Recently, researchers at the University of Michigan Kellogg Eye Center analyzed the annual $2.4 billion Medicare Part D prescription costs generated by eye care providers. They estimated that, if the government could negotiate drug prices similarly to the way the US Department of Veterans Affairs does, it could save $1.09 billion in annual ophthalmic drug costs.[3] Glaucoma medications made up half of all ophthalmic drugs prescribed, and dry eye medications comprised the next largest group, according to the study. With no generic equivalent, Restasis (cyclosporine ophthalmic emulsion 0.05%, Allergan) alone accounted

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for $371 million in spending and was the eye medication most often used by Medicare Part D beneficiaries. These two categories plus ocular inflammation and infection medications made up 96% of ophthalmic drugs prescribed and paid for under Part D.[3]

The researchers noted that brand-name medications are covered variably by insurers, so patients who are prescribed brand-name drugs often bear more of the cost through copays and deductibles; high costs, however, are associated with lower medication adherence.[4,5] Thus, they suggested that physicians should prescribe less expensive generics as first-line therapy whenever possible to help decrease the risk of cost-related medication nonadherence.[3]

The researchers reported that eye care providers turned to brand-name medications for 79% of total Medicare Part D payment claims, compared with 33% of claims among most other specialties. According to the study, these prescribing choices are typically made because (1) ophthalmologists often prescribe the drug with which they are most familiar; (2) there is an absence of comparative efficacy trials between brand-name and generic medications; (3) prophylactic use of brand-name drugs in response to concerns about potential infection is common; and (4) if patient care is optimized with a brand-name drug, physicians prefer to continue that treatment course. The report also suggested that physician acceptance of industry compensation for activities such as speaking and consulting can influence prescribing patterns, even if providers don't think they do.[6]

DEALING WITH COMPLEXITIES

The examination of Medicare Part D in this article is a rudimentary review of a program that is riddled with complexity, as any physician or beneficiary who has attempted to appeal the use of a nonformulary pharmaceutical knows. That complexity is one of the issues that ophthalmologists wish to see mitigated.

John P. Berdahl, MD, of Vance Thompson Vision, told BMC Vision, "Medicare Part D is a positive because it helps patients get access to drugs, but the challenges with the system can make it difficult for patients and doctors to navigate." Michael Greenwood, MD, also of Vance Thompson Vision, echoed those sentiments: "More access to medications is always better, so Medicare Part D is a good thing in general. It is nice to have options that we can fit to the patient's need. But I wish the system was easier—easier for patients, staff, and doctors to understand and navigate." Drs. Berdahl and Greenwood said Medicare Part D has little to no influence on which drugs they prescribe, but it does ultimately affect which medications patients get, depending on their coverage.

According to the American Medical Association (AMA), some practices of the Medicare D private health plans can get in the way of providing appropriate care and can impose administrative burdens on physicians, such as requiring prior authorizations. In an AMA survey of physicians, 75% of respondents described the burden associated with prior authorization on physicians and staff in their practices as high or extremely high, and 22% estimated that they spend in excess of 20 hours per week processing prior authorizations. Also, 90% of respondents reported that prior authorization delays access to necessary care, even though 79% of prior authorization requests are eventually approved. Further, 80% reported being sometimes, often, or always required to repeat prior authorization requests for medications after a patient is stabilized on a drug to manage a chronic condition.

FIGHTING BACK

Since the inception of the Part D prescription drug benefit, the AMA has frequently raised concerns about insurance plans' use of prior authorization and other drug utilization management (DUM) requirements as a means to reduce utilization and spending, even when there are no valid safety reasons for requiring these extra steps. In a recent letter to the CMS,[7] the AMA's CEO and executive vice president, James L. Madara, MD, noted that "[DUM] demands impose unnecessary administrative burdens on prescribers and unjustified access delays on patients." He continued, "Patients are enrolled in an enormous number of different Part D plans, each with [its] own formularies and prior authorization requirements. Physicians receive no compensation for the many hours of frustrating administrative time they spend trying to overcome hurdles that plans have placed before their patients' rapid access to their medications."

In the letter, Dr. Madara noted that glaucoma specialists in particular feel the effects of these obstacles to access. "Many Part D plans do not recognize that there are different classes for glaucoma drugs, so physicians who prescribe multiple medications to manage patients' glaucoma are warned against prescribing 'duplicate' therapy and face coverage restrictions," Dr. Madara wrote. He stated that glaucoma specialists experience numerous prior authorization and other DUM requirements, sharing examples that are outlined below.

Brimonidine. The active ingredient in Alphagan P (brimonidine tartrate ophthalmic solution, 0.1% and 0.15%, Allergan) is available in two generic formulations: (1) brimonidine 0.15%, which contains a suitable preservative and (2) brimonidine 0.2%, which contains benzalkonium chloride and has been associated with a 25% or higher incidence of allergic reaction.[8] Dr. Madara

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wrote, "A number of Part D plans consider brimonidine 0.2% the only generic they will supply, and ophthalmologists are forced to use it, despite the risk of allergy. If patients become allergic to the 0.2% solution, they can no longer use any of the alternatives because they will be allergic to those also."

Travatan Z. Travatan Z (travoprost ophthalmic solution, Alcon) uses a gentle preservative and, for some patients with dry eye, is a better alternative than generic travoprost, Dr. Madara noted. However, he asserted, it is difficult to get authorization for Travatan Z. Even when patients have been using the branded version for years, they often are made to switch to a generic. Also, generic travoprost recently became unavailable, leading to patient and pharmacist inquiries about whether they could switch to another drug. "If the generic is unavailable, it should be standard policy that patients get the brand-name medication," Dr. Madara argued.

Combigan (brimonidine + timolol, Allergan) and Simbrinza (brimonidine + brinzolamide, Alcon). These combination agents, which are available as brand-name formulations only, are often denied to patients who are already taking the component medications or who need an escalation of therapy with an additional medication, Dr. Madara noted in his letter. This, he explained, means that patients must continue to use multiple bottles and instill drops several times a day, rather than having access to a combination drug that might support improved adherence.

Prostaglandin analogues (PGAs). Patients must try a generic PGA before being approved to use a brand-name PGA, Dr. Madara wrote. "Even patients who have been documented as doing well during the previous year (or more) on a particular [brand-name] drug are forced to switch to a generic or pay higher copays because their plan has negotiated a better price for a different drug and the formulary has changed."

The AMA's advocacy efforts, including Dr. Madara's letter, tend to focus on getting CMS to require prescription drug plans to curtail their use of prior authorization and other DUM requirements. "The AMA recommends that policies be established to ease the process of complying with prior authorization requirements. Standard electronic transactions for prescription prior authorizations have been available since 2013 and are already mandated for use in certain states. These transactions allow physicians to prospectively complete pharmacy prior authorizations as part of the e-prescribing process, support significantly faster response times, avoid the hassles associated with re-entering data and remembering passwords for proprietary portals, and reduce administrative burdens for physicians and staff. A federal requirement for Part D plans to support these transactions could ensure faster patient access to medications and reduce substantial practice burdens across the country," Dr. Madara noted.

An equally important goal, according to Dr. Madara, is assuring the transparency of DUM requirements. He noted that all Part D plans, as well as pharmacy benefit managers, should be required to publicly disclose to patients and physicians, in a searchable electronic format, all drugs and medical services that are subject to coverage restrictions such as prior authorization, step therapy, formulary restrictions, and quantity limits; they should also be required to provide this information to electronic health record vendors to be displayed in their systems, Dr. Madara wrote.

SHIFTING PARADIGMS

As traditional private health insurance and government-subsidized health and drug insurance evolve, ophthalmologists are increasingly becoming aware of access issues. Elizabeth Yeu, MD, of Virginia Eye Consultants, told BMC Vision, "I think insurance companies are moving toward a piecemeal approach to meting out coverage, and I think the future of medicine will be impacted deeply by this model, where only the most basic elements of care will be covered for most patients." Dr. Yeu predicts that the services or drugs that insurers deem superfluous—whether a brand-name eye drop for a glaucoma patient or anesthesia for a cataract patient—will be available only to those who have a more expensive, enhanced add-on plan. ■

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