Dealing with the Crazy Cost Curve in Dermatologic Drugs

Dermatologists, desperate for relief from the forces that have sent prices skyrocketing, are pushing for reform or exploring other options.

BY BONNIE DARVES

On a typical day at South Shore Dermatology Physicians in North Easton, MA, dermatologists and staff might spend hours on the phone with patients, pharmacies, or insurers trying to accomplish what used to be a relatively simple thing: prescribe an appropriate medication that their patients can afford. Now, with prices of commonly prescribed drugs—not just brand drugs but generics as well—skyrocketing and patients' copayments rising in tandem or fluctuating wildly, dermatologists and patients are finding themselves between a rock and a hard place.

It might take three or four tries before the dermatologist identifies an affordable option for the patient, and patients, increasingly frustrated and "sticker shocked," have no idea why their dermatologist doesn't know how much a medication will cost, according to Viraj Shroff-Mehta, MD, a dermatologist at South Shore. "We're well trained to start with the basic tried-and-true generics, but a few years ago patients started calling us, saying things like 'I can't believe you prescribed this medication. I went to the pharmacy and it was $400!'" she says.

Even explaining that she had been prescribing the same medication for decades at an affordable cost might not appease the patient. Plus, that conversation might just be the start of a labor-intensive process to arrive at a treatment that will be both effective and affordable.

"I've basically stopped prescribing clobetasol, which was my go-to Class 1 top strength topical steroid for decades. Now it's completely unavailable due to cost," said Dr. Shroff-Mehta. "What I explain to patients is that physician and patients are stuck between the pharmaceutical companies and the insurance companies, as they try to figure out who gets the dollars invested in healthcare."

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Last year, South Shore created a letter that addresses the issue and points patients to resources; the document is disseminated to new patients and is available to existing patients.

What many dermatologists want to know is this: What ever happened to their old-standby medications such as doxycycline, tetracycline, and fluorouracil that used to be available to patients for copays of $5 to $20? And why are there now prior authorization requirements for generic drugs that have been prescribed routinely, safely, and affordably, for decades? Dr. Shroff-Mehta estimates that her practice staff now spend approximately 11 hours a week simply managing prior authorization requests and denials, and other dermatologists interviewed for this article reported constantly increasing time outlays for a task that was once infrequent.

Maryam Asgari, MD, MPH, who directs the Massachusetts General Hospital High Risk Skin Cancer Clinic, says that even if she can't quantify the amount of time dealing with increasing drug prices and managing prior authorizations takes, she knows it's considerable. "I don't know that number, but I know that it's definitely much higher now. We're seeing prior authorization requests now even for simple medications that never needed approval before," says Dr. Asgari, who is deputy chair of the American Academy of Dermatology Drug Pricing and Transparency Task Force. She recently had an insurer decline fluorouracil, for example, for a skin-cancer patient. "So, I went back to the insurer and said, the alternative for me is to bring the patient back and cut out the cancer—which do you want?" she says.

For Mohs surgeon Marta Van Beek, MD, MPH, at the University of Iowa, the back and forth among insurers, physicians, and pharmacies is not just a hassle. It's also potentially detrimental to care and the physician-patient relationship, in her view. "My biggest frustration is that after I've gone through the evaluation and decided on the best medication considering my patient's comorbidities, I don't know what the patient's copay will be," she says. A drug might be covered but unaffordable, she explains, which means that she must go through arduous trial and error to figure out what is affordable.

"That delays onset of treatment," Dr. Van Beek says. "It also makes the entire encounter less satisfactory for the patient and for the physician because basically, it's extra work for something that's not improving care."

WHAT'S DRIVING DRUG COSTS?

Getting at the market factors that are driving up drug prices and fueling the prior-authorization frenzy is akin to using a very small screwdriver to open a very large black box. The pharmaceutical companies set prices for drugs in an environment that is largely unregulated and is driven primarily by supply and demand and competitive factors. Some drug-makers use legal mechanisms, such as the so-called patent fortresses or monopolies, to deter or prevent generic alternatives from getting to the market. (The recent EpiPen price scandal is a case in point.)

The pharmacy benefit managers (PBMs), whose initial raison d'etre was to negotiate lower drug prices for health insurers, increasingly hold the keys to the kingdom, industry observers claim. That's because drug-makers and suppliers must work with PBMs to get on insurers' formularies and thus increase their market share and access to insured patients. PBMs negotiate deals with manufacturers that sometimes involve rebates, undisclosed sums of money that go to health plans or PBMs and that critics liken to legal kickbacks because PBMs are exempt from antikickback statues that affect other healthcare sectors.

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Those rebates, whose details are shrouded, generally are not passed on to consumers. (PBMs are also permitted to charge health plans higher amounts for drugs than they reimburse pharmacies, a cost "spread" that is not disclosed and whose follow-the-money trail is elusive.)

"Spread pricing is probably most to blame for what's going on," says Mark D. Kaufmann, MD, associate clinical professor at the Icahn School of Medicine in New York and an AAD board member. "If a manufacturer wants to put a new drug on a formulary, they must go to the PBM, which usually suggests the price. If the manufacturer wants to come in at $2,000 a month [for a typical prescription], the PBM, for argument's sake, says that if the manufacturer provides it for $1,000 a month, they'll get it on the formulary."

What happens next is where the fuzzy business comes in, according to Dr. Kaufmann. The PBM, having gotten the drug for $1,000/month, goes to insurers and offers to sell the drug to them for $1,500, for example. "So the PBMs have the spread," Dr. Kaufmann says. "It seems like a good deal to the insurance companies because they're getting a $2,000 retail-price drug for $1,500, but the PBM is getting the spread. The savings in a system that's equitable should be going to the patients, but it isn't.

"It's become too difficult to actually wrap your head around, so physicians just throw up their arms and say, however you can get this drug to my patient, I'll do whatever you want," Dr. Kaufmann says.

The PBM sector claims that research finds no correlation between the prices that manufacturers set and the rebate amounts that PBMs negotiate and that manufacturers control prices. The pharmaceutical sector in turn contends that PBMs, which have consolidated market power through high-profile mergers, hold the price levers. Brand drug manufacturers who end up in less desirable positions within the PBM hierarchy frequently use coupon strategies now to increase their patient base.

Near the end of this dauntingly complex maze, health plans create formularies and set price-tiering and copayment structures, based on their costs and a host of market and other factors completely unknown to physicians and patients and outside their control. Thus, the relatively recent emergence of the market maneuver sometimes called "clawbacks," in which insured patients might end up saddled with a $50 copay for an acne drug whose actual acquisition cost is approximately $11.

WHITHER THE COST-SAVING GENERICS?

In the middle of this market-forces muddle, dermatologists historically prescribe generics whenever feasible, but that avenue for cost savings has narrowed, due to several factors. For one, as insurers move to require generics first, manufacturers have recognized that they can increase prices with relative impunity because of their preferred status. The other price-increase drivers are market forces and lack of regulation, Geoffrey Joyce, PhD, chair of USC's Department of Pharmaceutical and Health Economics in Los Angeles, maintains. In an October 2018 *Health Affairs* article that examined generic drug price hikes and Medicare patients' out-of-pocket spending, Mr. Joyce and coauthors found that the percentage of generic drugs that at least doubled in over a five-year period increased from one percent to 4.39 percent.

"You'll find examples of large price increases for generics in any therapeutic area, but I think that some of the creams and ointments dermatologists prescribe have been more aggressively hit by this strategy than other types of medications," Mr. Joyce says. In the end, he maintains, it's mostly about competition—or the relative lack thereof—and the fact that drug price setting is insufficiently regulated. When prices for generics drop significantly, smaller manufacturers might exit the market or be acquired, reducing competition.

The drugs that have seen the most dramatic price increases, Mr. Joyce says, are those for which little competition exists or the ingredient supplier base (often in India or China) is small or shrinking. When generic drugs are produced by just a few manufacturers, nothing stops suppliers from raising prices indiscriminately, even for drugs that have been used for decades.

"With branded drugs, it's a fight between the manufacturers and the PBMs—and Express Scripts and OptumRx and CVS have about 80 percent of market," Mr. Joyce says. "Generics are commodities, and although the US generic market generally functions OK, we have seen more market manipulation. You can't really raise your prices that dramatically unless you're pretty much the only game in town."

With brand drugs, Mr. Joyce adds, if a manufacturer's medication doesn't receive a preferential spot in the tiering structure, manufacturers might resort to using coupon strategies to increase their patient base by reducing patients' out-of-pocket expenses for their drug. "Couponing is a response—it's chicken and egg. The manufacturer says, 'If you put us in high copay or cost-sharing tier, we'll coupon it,'" he says. He and other industry observers contend that couponing is essentially a Band-Aid strategy to a big problem and that, in the long run, it doesn't help patients who must ultimately face the full price of the medication.

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LACK OF TRANSPARENCY: REGULATORY ANTIDOTE NEEDED

Regardless of what is actually going on and where in the market it's occurring, and despite the finger pointing, sources interviewed for this article say that one thing is clear: drug-price setting and negotiations are essentially happening behind closed doors with scant regulatory or public oversight.

"There needs to be meaningful reform and transparency because no one really understands what's going on [in drug pricing] except those people who have mastered it from the standpoint of revenue optimization," says Daniel Mark Siegel, MD, a clinical professor at SUNY Downstate in New York and a former AAD president. "Price transparency would be a wonderful thing. Because there's always going to be a good excuse for taking something that should be arguably close to free—in the case of generics—and jacking up the price sky high. And there are many guilty parties."

Dr. Siegel points to the PBM rebate activity and maneuvers as a good starting place for reform and regulatory action to undo legislation that legally enables the opaque dealings occurring between PBMs and health insurers. "Rebate is a misnomer. The term is kickback, and I wouldn't be surprised if there are kickbacks with generics, too."

Dr. Kaufmann concurs. He points to the bills introduced at state and national levels that would require greater transparency in drug pricing, especially by PBMs, and the recent rule proposed by the Office of Inspector General (OIG) that

would remove the safe harbor protection for rebates to PBMs or insurance plans. "The Academy is trying to battle this on all fronts—and transparency of PBMs and removal of PBMs, the antikickback statute, are two items very high on our list," he says. On the national level, H.R. 1316, the Prescription Drug Price Transparency Act, and S. 637, Creating Transparency to Have Drug Rebates Unlocked, are gaining support if not much traction yet. The AAD is also actively involved in efforts to address the ever-increasing problem of prior authorizations.

In Mr. Joyce's view, the government needs to act on several fronts to remedy the problem of rising prices, to ensure that patients can get generics affordably, and to address market factors that impede health competition and disadvantage consumers in the short- and long-run. For drugs where insufficient competition exists, as with some dermatologic drugs, and prices have risen dramatically, he suggests that the FDA should fast track generic applications. "This would mean that a proposed generic goes right to the head of the line and can get to market within 90 days," he says. He also supports the idea of allowing imports of undersupplied medication classes temporarily from countries with high safety standards, until a new drug is approved in the United States. "This has been a taboo topic, but it's one way to address the problem," he says.

Further, Mr. Joyce thinks that drug manufacturers and entities that supply drugs should have to justify, within 30 days, all price increases over a nominal percentage, such as five percent. "If a more drastic measure is needed, we could treat generics like public utilities—these are homogenous products, after all—and set a price floor, while allowing some profit," he says.

Regarding the market factors that have led to PBM dominance, all solutions going forward are necessarily, and unfortunately, retroactive, Mr. Joyce observes. "There's been incredible M&A [merger and acquisition] activity in healthcare, and I think the Federal Trade Commission and Department of Justice have done a terrible job regulating that," he says. "They let the No. 2 and 3 PBMs merge, and anybody who knew the industry said that this was not going to be good."

On the brand-drug level, efforts should focus on removing the artificial barriers to generics coming to the market, according to Kristine Grow, VP of Communications for America's Health Insurance Plans (AHIP), an organization whose members cover approximately 200 million Americans. "We're calling for government to address the shenanigans with brand manufacturers creating patent fortresses where they can file 100 patents to protect their medications, so other companies can never get through the thickets to issue the generic to meaningfully compete," she says. AHIP officials have also called out instances in which brand manufacturers, which are required to provide their drug to a prospective generic competitor for testing, manipulate the system to keep the request blocked in legal review.

RESPONDING TO CHALLENGES, DERMATOLOGISTS DEVISE OWN REMEDY

Many dermatologists who are simply trying to get patients the medications they need to treat their conditions or diseases are doing what they can to work within a seriously disadvantaging system. They're navigating the quagmire of prior authorizations and helping patients get coupons, as applicable. And they're desperately hoping that relief—in legislative, regulatory, or any other form—comes soon.

Some, however, aren't counting on that or waiting for it. Instead, they're resorting to strategies such as compounding to address the absurdly escalating prices for long-standing tried-and-true medications and the increasingly discouraging prior authorization process. One is New York City dermatologist Dhaval Bhanusali, MD, founder of Skin Medicinals. The company, essentially operating as a collective that also supports the dermatology nonprofit REAL, is working with a compounding entity to deliver compounded alternatives for some of the common drugs that are used to treat common conditions such as psoriasis, acne, melasma and pre-cancers and whose prices have gone through the roof in recent years.

Dermatologists can enroll in the program and essentially "build" medications by using a menu that includes only FDA-approved materials and ingredients, and the company adheres stringently to all regulatory requirements. Patients can then order the medications their dermatologists have selected, at prices ranging from roughly $30 to $50—where similar generics' costs might be triple that price or higher.

"We don't want to go through six prior authorizations—we want to get our patients better by giving them effective therapeutic options," says Dr. Bhanusali, an entrepreneur who seeks to use technology to bridge the gap between cutting-edge technologies and established paradigms. "And dermatologists are clamoring for options," he said, in the current fractured and frustrating environment.

In a mere seven weeks—the company launched last summer—hundreds of dermatologists from 46 states have signed on to Skin Medicinals, Dr. Bhanusali said, and thousands of patients have ordered their dermatologists' recommended treatments. "In its purest form, Skin Medicinals is dermatologists getting together and rallying for our patients." ■

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