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May 2021 VOL. 31 NO. 5
ManagedHealthcareExecutive.com

The rise in formulary exclusions

PBMs say exclusions are important for negotiating lower prices on behalf of health plans and members. Some payer and provider groups say they interfere with patient access to medicines. *by* **MHE STAFF**

Formulary exclusions — a decision by a PBM not to include a drug on its list of covered drugs, called a formulary — are not new, but they are increasingly in the spotlight, partly because the PBM industry is increasingly consolidated. CVS Caremark, Express Scripts and OptumRx, the three largest PBMs, collectively process about 3 out of every 4 U.S. prescriptions. Attention to exclusions has grown as the number of drugs excluded from the national formularies of the three PBMs has risen. In 2014, CVS Caremark and Express Scripts excluded a relative handful of medications — 134 between them. By 2020, the three largest PBMs combined excluded 1,195 medications. According to a tally by Adam Fein, Ph.D., a drug pricing and distribution expert, 1,343 drugs are excluded from 2021 formularies of the three major PBMs.

Employers, unions and other "plan sponsors" that contract with the PBMs don't have to follow the national formulary exclusions if they believe a drug should be covered for their employees or members. Still, the national formularies have clout, and the exclusions matter. PBMs say exclusions are a necessary check on the pharmaceutical industry's pricing power and a way of keeping patients and plan sponsors from having to pay for medications with a high price and little, if any, clinical value. Critics say the exclusions limit patient access to needed drugs and that PBMs use them to negotiate higher rebates.

Bargaining power, lower prices

Exclusions from national formularies may be making waves now, but they have been around for decades. In the late '90s, state Medicaid programs started to institute "preferred drug lists" that excluded select medications in major drug classes as a way to manage Medicaid drug expenditures and maximize the value of pharmaceutical company rebates, including the large "supplemental rebates" offered to these programs. When Medicare Part D got started in 2006, the federal government established rules that enabled the exclusions across most drug classes on Part D formularies.

According to the Pharmaceutical Care Management Association (PCMA), the trade and lobbying organization for PBMs, formularies ensure that payers, providers and PBMs "promote clinically sound, cost-effective medication therapy options and positive therapeutic outcomes." A study commissioned by PCMA showed that PBMs — in general, not just by using formulary exclusion — reduce prescription drug costs for health plan sponsors and consumers by 20% on average. Express Scripts says its national formulary and its exclusions saved clients and patients $14.5 billion between 2014 and 2020.

Jeannette Novatski, Pharm.D., a senior director of clinical program management at Express Scripts, described three scenarios in which exclusions might be used in an article posted on the company's website in 2019. First, if new generics come on the market, then their more expensive brand-name counterparts may be potentially be excluded. Second, if new brand-name drugs in a therapeutic class enter the market, then the company may be able to negotiate lower pricing for all medications in the class and potentially exclude high-cost brand-name competitors. Third, if the FDA adds new indications to a drug, then a drug that had a clinical advantage may lose that edge, "enabling Express Scripts to negotiate better pricing for medications in the therapy class and potentially excluding high-cost brands," according to Novatski.

Steve Miller, M.D., who was Express Scripts' chief medical officer for many years before Cigna bought the company in 2018 and he became Cigna's chief clinical officer, described Express Scripts' process for putting together a formulary in

a 2018 article. In Miller's account, a national pharmacy and therapeutics (P&T) committee consisting of 15 outside experts makes some initial decisions. A "value assessment committee" of company employees then conducts a review of the drugs that the P&T committee put in the "clinically optional" category that factors in cost, and those recommendations are sent back to the P&T committee for final approval. "Formularies are an effective strategy and, when used in concert with other cost mitigation programs, can yield significant savings for plan sponsors and patients while preserving access to medication," concluded Miller.

Many PBM have rules for certain therapy classes that "grandfather" the coverage of some medications even if they have been excluded from that year's formulary.

Although financial considerations shape exclusions and formularies, PBMs say their formularies and appeal procedures work to ensure access to needed medications. "Clinical appropriateness of the drug — not cost— is our foremost consideration," Express Scripts said in an emailed response to questions from *Managed Healthcare Executive*®.

What the critics say

The critics of formulary exclusions include patient advocacy groups and physicians, especially specialists who take care of patients with chronic diseases that are treated with medications coming off and on formularies.

Typically, formulary inclusions are based on complex negotiations among drug manufacturers, insurance companies and the PBMs, says Steven Newmark, J.D., M.P.A., chief legal officer and director of policy at the Global Healthy Living Foundation. A pharmaceutical company may bundle its medications and offer price concessions on some to get better placement on the formulary for others. One of the complaints about exclusions — PBMs more generally — is that those negotiations and their outcomes are secret. "PBMs and insurers do not publicly share this information," Newmark says.

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— STEVEN NEWMARK, J.D., M.P.A., CHIEF LEGAL OFFICER AND DIRECTOR OF POLICY AT THE GLOBAL HEALTHY LIVING FOUNDATION

Another objection to exclusions is that they can lead to "nonmedical switching": changing a patient's medications for reasons other than safety, efficacy or adverse effects.

"If you have a rheumatoid arthritis patient stable on drugs, you can't just switch them to a generic and expect the same results," says Robert Levin, M.D., president of Alliance for Transparent and Affordable Prescriptions, a group of rheumatology organizations pushing for more regulations of PBMs. "In a lot of patients, it causes worsening of medical conditions."

The American Journal of Managed Care® recently reported that Express Scripts offered patients a $500 debit card if they switched from Cosentyx (secukinumab), which it took off its formulary, to Taltz (ixekizumab) or other drugs for psoriasis and psoriatic arthritis. Cigna issued a statement that said patients were "offered several alternative medications that are equally effective and more affordable" and that it recommends that its clients offer an "efficient review process to assist those patients in obtaining a nonformualry medication in these instances."

Formulary exclusions can work against the financial interests of patients, say the critics, when the excluded drugs have a lower list price than the drugs the PBM kept on its formulary. "They claim they're watching out for patients and reducing costs. Reducing costs for whom? Not the patient. Prices keep going up," Levin says. (Express Scripts says most of the plans on its national formulary have a tiered benefit with flat copays so patients shouldn't experience a difference in cost.)

Patients need prior authorization for certain drugs, including those on the exclusion list. The insurer's internal review process can take weeks, says Levin: "It's a bureaucratic nightmare to get this stuff through."

To improve patient protections, some states have enacted laws that help physicians appeal exclusionary decisions and ask for a protocol exemption for an individual patient, Newmark says. "However, these laws vary widely across states, and there is no set of uniform methods for physicians to apply for an exemption," Newmark explains. The laws may also lack enforcement penalties, he adds.

Formulary exclusions don't expressly forbid patients from taking a medication. But if patients want access to an excluded medication, they must be able to pay out of pocket or their provider will need to seek a medical exception.

"Pharmacies are obligated to dispense prescribed medications aligned with what the patient's insurance coverage covers," Newmark says. "They cannot dispense an alternate medication — even with a prescription — that the health plan is refusing to cover unless the patient can pay for the full cost of the medication out of pocket."