Report: "Specialty" drugs are by far the most expensive, but classification seems arbitrary

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The prescriptions with the most eye-popping price tags — like cancer meds that can cost more than \$20,000 a month — are usually classified as "specialty" drugs.

You'd think that since they're so costly, there would be clear criteria for putting drugs in the specialty category. But, according to a new report, you'd be wrong.

The issue might seem arcane, but it's hugely important. Specialty drugs account for only about 2% of the volume of drugs dispensed in the United States, according to industry estimates, but they also account for more than 50% of overall drug spending.

The report, by data analysis firm 46Brooklyn Research, found that the three largest drug middlemen in the United States often don't classify the same medicines as specialty. It also said that a large portion of the ones they do put into that category are generics — drugs that are usually no longer under patent and thus are supposed to be cheaper because multiple drugmakers can supply them.

"It is pretty bananas that there's so much commonality around our shorthand use of the word 'specialty' just in normal dialogue in drug pricing," said 46Brooklyn CEO Antonio Ciaccia. "But beyond that, for the definition of 'specialty' in contracts, that degree of ambiguity is kind of wide."

Understandably enough, when concerns are raised about the high cost of prescription medications, suspicion often falls on the companies that make them. And to be sure, drugmakers have been credibly accused of a number of anti-competitive practices that increase costs and their profits.

But less well known is the role played by middlemen known as pharmacy benefit managers. They contract with insurers to create pharmacy networks, create lists of drugs that are covered and negotiate rebates from drugmakers in exchange for putting their products on those lists.

Each of the big-three pharmacy benefit managers, or PBMs, has combined in recent years with a top-ten health insurer and now is part of one of the 15-largest corporations in the United States. So they're often contracting with a business that is part of the same corporation. And combined, they're estimated to handle more than 80% of all prescription transactions in the United States.

That level of dominance — or "market power" in econ-speak — and a lack of transparency about things like rebates, discounts and pricing have led the Federal Trade Commission to investigate them for <u>possible anti-competitive practices</u>. In addition, Ohio Attorney General Dave Yost in March announced <u>an antitrust lawsuit</u> against one of the big three, ExpressScripts.

Research has shown that as PBMs push drugmakers for ever-larger rebates and other discounts, they give the pharmaceutical companies an incentive to raise the list prices of their products. The report published Wednesday by 46Brooklyn suggests the PBMs might be pushing prices up another way — by arbitrarily classifying them as "specialty."

The analysts used lists of specialty drugs published by the big-three PBMs — ExpressScripts, CVS Caremark and OptumRx — and correlated them to National Drug Codes published by the U.S. and Food and Drug Administration. It then compared the PBMs' lists to one another.

Rather than finding uniformity, the analysts determined that roughly half the time, drugs on one PBM's list of specialty drugs didn't appear on at least one of the others'.

The analysis also found that a surprisingly large portion of the drugs on the specialty lists were generics — 42% to 54%. So despite the fact that they are normally off-patent and supposed to be cheaper as a result of competition, they were on high-priced specialty lists.

And high-priced they can be. For example, PBMs charged employers \$16,000 for an 180-supply of the generic multiple sclerosis drug <u>Tecfidera</u> at the end of last year. Meanwhile <u>Mark Cuban's Cost Plus Drugs</u> charges \$162 for the same prescription in a transaction not using insurance and PBMs.

As another example, PBMs charged employers \$6,250 for 30 tablets of the generic leukemia drug Gleevec in December 2022. Cuban's business charged \$39 when insurers and PBMs are excluded from the transaction.

But having lots of generics also means having lots of drugs that do the same thing. To control for that, the 46Brooklyn analysts grouped the generics that did the same things together.

They still found huge disparities between what the big PBMs regard as specialty drugs.

They all agreed that 971 drugs were specialty. But ExpressScripts listed 1,121 drugs in the specialty category that at least one of the two others didn't. For CVS, that number was 1,089 and for Optum it was 520.

A spokesman for a PBM industry group couldn't immediately be reached for comment. But the 46Brooklyn report said the conclusion was obvious.

"Yep, the drug supply chain just collectively decided to start calling a group of drugs 'special' and then commenced in complaining about how much these drugs cost," the report said.

As evidence of the "complaining," it cited a report by ExpressScripts' parent company that says, "Even though less than 2% of the population uses specialty drugs, those prescriptions account for a staggering 51% of total pharmacy spending."

It also cited a statement by Optum titled "Specialty drug prices giving you sticker shock?" It said, "Despite making up approximately 2% of overall prescription volume, specialty medications now account for 53% of total annual pharmacy spending."

But Ciaccia, the CEO of 46Brooklyn, said the PBMs failed to mention that their own lack of clarity about what specialty drugs are might be driving some of that.

"This is the latitude that allows for the overcharging for a lot of drugs," he said.

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