RADAR on

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Business Strategies and Analysis for Health Plans, Employers, PBMs and Pharma Companies

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New Payment Models for CAR T-cell Treatments Are Years Off

On Aug. 7, CMS announced that, effective Oct. 1, it would cover two types of CAR T-cell treatment, which use a patient's genetically modified immune cells to fight cancer. But private payers continue to reimburse providers for CAR T-cell treatment for patients on a case-by-case basis, experts tell AIS Health, and they expect that trend to continue until this treatment becomes a standard of care. That's likely to take more than three years.

In August 2017, FDA approved Novartis' Kymriah (tisagenlecleucel) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL). In October of that year, the federal agency approved Kite Pharma, Inc.'s Yescarta (axicabtagene ciloleucel) for adult patients with certain types of large B-cell lymphoma who haven't responded to or who have relapsed after at least two other kinds of treatment.

According to the National Cancer Institute, approximately 3,100 patients age 20 and younger are diagnosed with ALL each year; B-cell is the most common type of ALL. Kymriah is intended for patients whose cancer has been unresponsive to or has returned after additional treatment; this occurs in 15% to 20% of patients. Diffuse large B-cell lymphoma is the most common type of non-Hodgkin's lymphoma (NHL) in adults. Each year, approximately 72,000 new cases of NHL are diagnosed; diffuse large B-cell lymphoma constitutes about one in three newly diagnosed cases.

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Pediatric Managed Medicaid ACO Touts Role of Pharmacists

For a pediatric accountable care organization (ACO) that contracts with Ohio's Medicaid managed care plans, improving care for children would be a much more difficult job without the expertise of pharmacists who understand the unique needs of those patients.

"Our MCO partners are often really well versed in the adult patient population and chronic diseases that afflict their adult patients — but sometimes the pediatric population's chronic conditions are different, and those pediatric patients' needs are much different," Brigid Groves, a clinical pharmacist specializing in population health at Columbus-based Nationwide Children's Hospital, tells AIS Health.

Groves is one of two pharmacists employed by Partners for Kids (PFK), the ACO affiliated with Nationwide Children's Hospital that receives capitated payments from the state's five MCOs to manage care for 330,000 children in central and southeastern Ohio. She co-authored a recently published study that explores how PFK has "successfully leveraged pharmacists to provide population health management and medication management" to the children it serves.

As an example of how PFK pharmacists intervened to advocate for pediatric patients, Groves points to when the manufacturer of the inhaler Qvar (beclometasone dipropionate) changed the delivery mechanism for the steroid that's dispensed

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by the device — requiring patients to "use their own breath and pull in like they're drinking a thick milkshake through a straw to inhale that medication." Adults and teenagers can follow those directions, but for four- or five-year-olds, "it's pretty difficult to get them to put their socks on in the morning," let alone teach them how to use such a device, Groves points out.

"When the manufacturer changed that product, our MCO plans were just kind of like, 'great new product, put it on there' [their formularies]. And it really impacted a lot of our kids because they weren't able to get their steroid inhalers or use them appropriately," she says. But PFK's pharmacists explained the situation to the MCOs, and "our plans were then able to make appropriate changes on their formularies to allow our kids to have something that they could appropriately use that was clinically effective for the condition, as well as cost neutral."

One of the MCOs that contracts with PFK provided additional examples of the insurer-pharmacist relationship. CareSource is currently making changes to how it covers the immunosuppressive drug Remicade (infliximab), and "we've worked with Partners for Kids pharmacists on our clinical criteria for prior authorization with pediatric use of that medication, because it differs a little bit in pediatric use than with adult use," says Nicholas Trego, Pharm.D., associate vice president of pharmacy for the insurer's Ohio market.

CareSource also recently made some coverage changes on another immunosuppressive drug, Humira (adalimumab), and "PFK was able to provide us some very valuable feedback on the changes we were proposing" regarding appropriateness, best clinical practices and who should be grandfathered in for that medication going forward, Trego adds.

On the clinical side, PFK's pharmacists are spearheading a quality-improvement project focused on reducing asthma-related emergency room and inpatient visits by "ensuring that patients with asthma are appropriately diagnosed, evaluated and managed by pediatricians," according to Groves' study. In that effort, one measure Groves focuses on is patients' asthma medication ratio (AMR), which shows how often patients fill prescriptions for rescue inhalers compared to controller inhalers. Having an AMR above 0.5 — meaning 50% of the time or more, patients have a controller inhaler on hand — is associated with fewer ER visits, she notes.

So, "we work with our practices out in the community to help them identify which patients they should target for asthma-related interventions using their AMR value," Groves says.

As a result of that work, "we have seen changes in our AMR value as a network," which means that "more patients are under control with their asthma, therefore less likely to go to the emergency department or be hospitalized," she explains.

Initiative Targets ADHD Med Prescribing

Meanwhile, for the treatment of Attention Deficit Hyperactivity Disorder, PFK's pharmacists worked with community practices and the Nationwide Children's Hospital primary care network to increase the prescribing rate of preferred ADHD medications.

Interventions included sharing prescriber-specific data and feedback, presenting guidelines and data to attending physicians at section meetings and residents at monthly meetings, and developing ADHD-specific medication management interventions to review patient medications for appropriateness, effectiveness and safety, according to Groves' study. As a result, there was a 3% increase in network-level prescribing rates of preferred ADHD medications in 2017 compared to

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2016. Further, "sustained improvements in prescribing rates of preferred ADHD medications" have helped the ACO "realize cost savings without decreasing the quality of care," the study noted.

Pharmacists Advise on Specialty Meds

PFK pharmacists also collaborate with Ohio's MCOs on the use of specialty pharmacy products for the pediatric population. "Obviously, those are very high-cost agents, so we want to use them judiciously," Groves says. "When you have good relationships [with MCOs], you can work through those conversations and have a better impact up front on some of the prior authorization criteria."

That may involve explaining that "'these are the things our kids are experiencing,' or, 'this is the study that shows why they need this type of medication,'" she adds.

CareSource also sees value in that form of collaboration.

"They know what we're looking for on the prior authorizations," Trego says of PFK's pharmacists, and they help physicians by filling out the forms with the correct information that CareSource needs to get medication approved faster for members.

In addition to allowing practices to provide medications to patients more efficiently, "CareSource has probably seen administrative savings based on the fact that we're not going back and forth, back and forth, back and forth with prior authorization requests like we do with many other specialty clinics that don't have pharmacists embedded," adds Jennifer Szumowicz, director of specialty pharmacy at CareSource.

PFK's pharmacists also help advise patients and their families on how to use specialty medications, what side effects to expect and how to mitigate those effects, Trego notes.

"They honestly just teach the member and the member's family about the medication, which is of great value to us, so the member knows exactly how to use the medication, when to use the medication, what to expect from the medication — so we can expect the adherence to the medication to be very high as a result of that work that they do," he says.

While CareSource is not yet measuring how pharmacist-led interventions are improving medication adherence in the MCO's pediatric population, the organization is currently "working out the logistics" with PFK on such an effort, according to Szumowicz.

Personal Touches Can Improve Adherence

Even then, it would be difficult to fully quantify the effects of PFK's medication management, she adds.

"By having that pharmacist there, by them being able to walk out with the medication and know exactly how to use it — I really think that we probably have people who'd never even start their medication" in a traditional model, "whereas in PFK's model, I can guarantee that does not happen," Szumowicz says.

To the best of her knowledge, Szumowicz says, PFK's use of pharmacists is unique. But there are reasons to believe such an approach could spread, Trego adds. This year, a law went into effect in Ohio that grants pharmacists the status of health care providers, and CareSource has therefore been "actively working on a plan" to update how pharmacists are reimbursed, he explains.

"In the future, if a pharmacist could get paid independently," rather than have to bill under physicians to get paid for the work they're doing in clinics, "I think a lot more hospital systems would be open to his kind of model," Trego says.

View the study abstract at https://bit.ly/2z7z61g and contact Trego and Szumowicz via Gina Marcucci at gina@mediasourcetv.com. ✧

by Leslie Small

Pipeline of Million-Dollar Drugs Worries Large Employers

For large, self-insured U.S. employers, their No. 1 concern related to pharmacy benefits is how to finance treatments that come with seven-figure price tags.

That's one finding of the National Business Group on Health (NBGH) 2020 Large Employers' Health Care Strategy and Plan Design Survey, the results of which were unveiled on Aug. 13. Among the 147 employer respondents, 86% said they were either concerned or very concerned about "the impact of million-dollar treatments getting approved by the FDA," such as Novartis' $2.1 million spinal muscular atrophy treatment, Zolgensma (onasemnogene abeparvovec-xioi).

"The pipeline is looming — there are an estimated 14 new therapies in excess of $1 million each that are on the docket for FDA approval in the coming months and years," Ellen Kelsay, NBGH's chief strategy officer, said at a press briefing to review survey findings held in Washington, D.C.

No employer would argue that therapies like Zolgensma aren't valuable, but they still must grapple with how to cover those pricey drugs, she added. Nearly a quarter of large em-

ployers polled said that as of 2019, they are delaying the inclusion of newly launched treatments from their formulary to enable their PBM or health plan to better determine the treatment's efficacy and safety, the NBGH survey noted.

Purchasing stop-loss insurance for specific drugs and creating indication- and outcomes-based pricing contracts have not been as favored for 2019 or 2020, but 22% and 34% of employer respondents plan to take those approaches, respectively, for 2021/2022.

Companies Are Open to Government Help

Kelsay also highlighted the fact that 46% of employer respondents in the 2020 survey indicated they would consider a role for government in helping to negotiate prices for high-cost therapies.

"I think that's a reflection of the frustration employers have" with how to finance high-cost treatments, NBGH President and CEO Brian Marcotte said at the briefing. "It's not a question of are these good therapies. It's a question of what can society afford — not just what can employers afford."

When NBGH convenes a pharmacy benefit management committee to talk about such subjects, "employers start surfacing questions like, 'well, dialysis today is picked up by Medicare; are there certain conditions that should be, just based on what they are and what they cost,…somehow picked up in a different way than how they're funded today,'" Marcotte said.

NBGH's survey also revealed that large employers are increasingly taking a "defer to partners" approach to drive change in the health care system — or implementing what their health plan and PBM present as the latest innovations. Figuring out how to finance high-cost therapies is one of the key areas in which employers are looking to their health plan and PBM partners for assistance, Marcotte noted.

In general, Kelsay said, employers responding to NBGH's survey "placed a significant degree of emphasis and focus on what they're doing to manage their specialty drug spend."

When it comes to specialty drug management, the most notable area of growth is in the use of prior authorization (PA) for medications billed under the medical benefit — which typically are those therapies administered in a clinical setting. The share of employers using PA for drugs under the medical benefit rose from 36% in 2019 to 59% in 2020.

> **"The other concern they have is these copay cards bypass the plan design. So they weaken the integrity of the plan by not applying to the deductible, historically, and not applying to out-of-pocket maximums.**

Other popular options to tame specialty drug spending include site-of-care management and high-touch case management, Kelsay noted.

Employers Embrace Copay Accumulators

Another major area of concern for employers in the pharmacy-benefits realm is the impact of drug coupons and patient assistance programs on consumer behavior, the NBGH survey stated. While copay coupons can be beneficial to individual consumers, the problem is that such discounts can drive people to take higher-cost branded drugs over generic alternatives, Kelsay said.

"The other concern they have is these copay cards bypass the plan design," she said. "So they weaken the integrity of the plan by not applying to the deductible, historically, and not applying to out-of-pocket maximums."

Thus, many large employers are turning to "copay accumulator" programs, which generally apply the value of a copay coupon to an employee's deductible as well as their out-of-pocket maximum, according to Kelsay. Among respondents to NBGH's survey, 34% said they already had such a copay accumulator program in place in 2019, another 4% said they were adding one in 2020, and 15% said they were considering one for 2021/2022.

Meanwhile, 11% of large employers said they've implemented a copay maximizer program to address drug coupons. Usually, this involves creating a variable member copay to "smooth out" the value of the assistance over the course of the plan year, the NBGH survey noted.

Firms Mull Point-of-Sale Rebate Programs

The survey also addressed the subject of prescription drug rebates, which has been a top-of-mind topic this year given the now-tabled proposal to revamp the rebate system in Medicare Part D *(RDB 2/14/19, p. 1)*.

"Many of our employers said that they would prefer a rebate-free world, but in the world where rebates do exist, they're looking at bringing those rebates forward to the point of sale so that an individual that's taking a medication that is rebated actually derives the full value of that rebate," Kelsay said at the briefing.

Per the NBGH survey, 60% of large employers either have a point-of-sale rebate program in place or are considering doing so in the next three years. Among those that don't yet, the main challenge "remains how to financially account for the shift of rebate value from an overall plan benefit, thus reducing costs to all employees, to one

that more precisely benefits members filling rebate-enabled prescriptions," the report noted.

During a Q&A with reporters at the Aug. 13 briefing, Marcotte said employers' plans for rebates going forward haven't really been affected by the Trump administration's decision to pull its rebate proposal. That rule wouldn't have been very effective anyway since it relied on "the goodwill of the drug companies" to lower their list prices, he said.

Marcotte also argued that employers' move to high-deductible health plans is putting the spotlight on high drug costs. "Drug price has always been a challenge, but it was masked by copays for the consumer," he said. "Once consumers were exposed more to drug price, now you see a lot of energy and focus on drug pricing."

View the report at https://bit.ly/2yYVGsP and contact Marcotte and Kelsay via Ed Emerman at eemerman@eaglepr.com. ✧

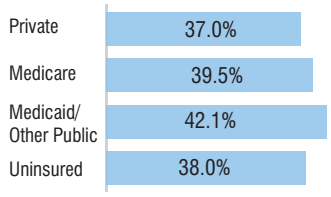
by Leslie Small

Few Patients Use Obesity Drugs

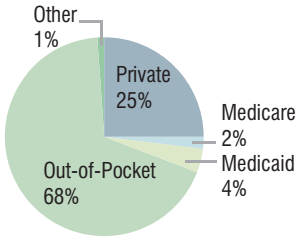
by Jinghong Chen

While about 38% of U.S. adults are obese, and the FDA has approved nine drugs to help treat obesity, relatively few people — about 660,000 annually — were estimated to have used an obesity drug between 2012 and 2016, according to a Government Accountability Office (GAO) report released Aug. 9. The GAO noted that coverage of obesity drugs varied across different types of health insurance. Patients' out-of-pocket payments made up most of the expenditures for these drugs (68%), while private insurers covered 25%, Medicaid 4% and Medicare 2%. State Medicaid programs or Medicaid managed care plans within states could choose to either cover or exclude obesity medications. In 2016 and 2017, over half of the prescriptions reimbursed under Medicaid were for the genetic obesity drug Phentermine.

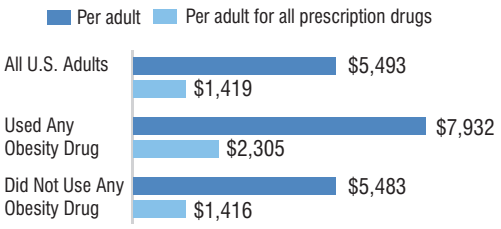
Prevalence of Obesity, By Insurance Type, 2013-2016



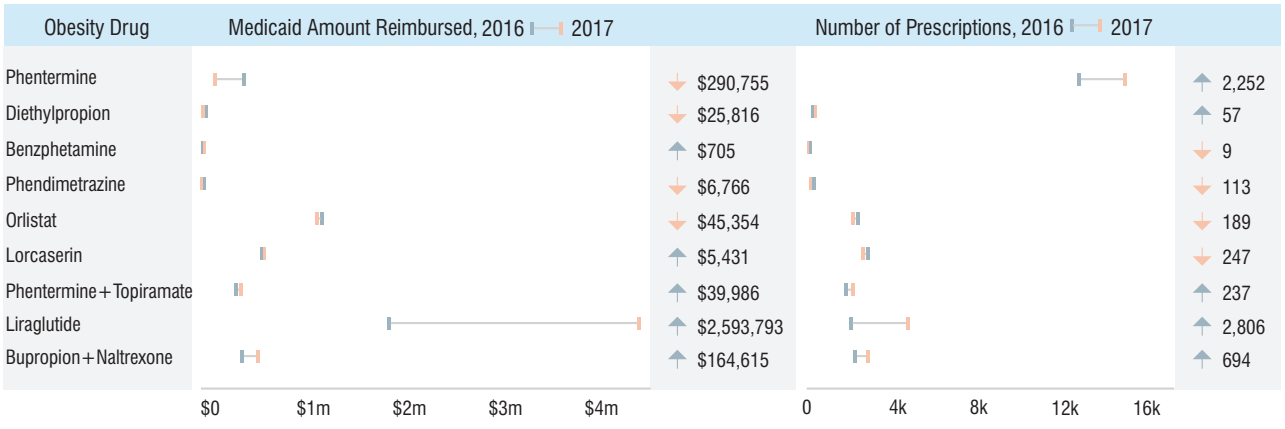
Estimated Average Annual Distribution of Payments for Obesity Drugs, 2012-2016



Estimates of Average Annual Medical Expenditures, 2012-2016



Medicaid Amount Reimbursed and Total Number of Prescriptions for Nine Obesity Drugs, 2016 & 2017



NOTES: The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care — because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payment amounts are not recorded as amounts reimbursed in CMS's Medicaid State Drug Utilization data. The number of prescriptions reimbursed includes 144 prescriptions for obesity drugs that showed zero dollar amounts for Medicaid reimbursement in CMS's Medicaid State Drug Utilization data.

SOURCE: U.S. Government Accountability Office, "Few Adults Used Prescription Drugs for Weight Loss and Insurance Coverage Varied." Visit https://www.gao.gov/assets/710/700815.pdf.