RADAR on Specialty Pharmacy
Strategies and Analysis for Managing High-Cost Specialty Products

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Anthem Oncology P4P Program Boosted Evidence-Based Care

A recent study of Anthem's Cancer Care Quality Program (CCQP) treatment pathways found that an enhanced reimbursement to providers who adhere to on-pathway treatment regimens increased use of the drugs without changing the total care spending, supporting the payer's efforts to move the needle on value-based care. That program has since led to the insurer's launch of an oncology medical home this summer.

Anthem launched CCQP in 2014, rolling it out to 14 states through the next year *(RSP 6/14, p. 3)*. Administered by the plan's AIM Specialty Health subsidiary, the voluntary program provides enhanced reimbursement of $350 for a person's initial on-pathway treatment and then $350 every month after for a maximum number of months as specified by CCQP. Those payments are in addition to reimbursement for office visits and drugs. There's no penalty if a provider chooses an off-pathway regimen.

Researchers were trying to determine whether providers in the pay-for-performance (P4P) program were prescribing a CCQP-endorsed, evidence-based treatment regimen. They looked at pharmacy and medical benefit claims for people at least 18 years old diagnosed with breast, colon or lung cancer between July 1, 2013, and Sept. 30, 2017, and tracked them through March 30, 2018. More than 1,800 oncologists and 25,000 people were included across 14 states, and spending over a six-month episode period was evaluated.

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Study: 'Drug Super Spender' Members Doubled in Four Years

The United States is seeing a surge of innovative specialty therapeutics coming onto the market, many of which offer potential treatments for conditions that previously didn't have one. But many of these newer therapies are launching with expensive price tags, driving up spending on health care services. A Prime Therapeutics LLC study found a huge increase in people who have annual drug spend of at least $250,000 — so-called "drug super spenders"— from 2016 to 2019.

Researchers analyzed pharmacy and medical benefit claims from a commercially insured population of 17.9 million members between January 2016 and December 2019. They defined "cost" as plan and member cost share after network discounts but did not include manufacturer rebates or coupons. For drug super spenders, researchers used diagnosis codes to determine a clinical condition category based on their drug use.

In 2016, 2,994 members qualified as super spenders, accounting for $1.325 billion in drug spend, or 6.3%. But by 2019, the number of super spenders had almost doubled to 5,894 members, and they accounted for $2.579 billion, or 9.7% of all drug spend.

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More specifically:

✦ ***There were 2,317 members in 2016 with drug spend more than $250,000*** and less than $500,000. That number had risen to 4,572 by 2019.

✦ ***In 2016, there were 421 members with drug spend of at least $500,000*** and less than $750,000. By 2019, that had increased to 858 members.

✦ ***There were 256 members in 2016 who had drug spend of at least $750,000***. In 2019, 464 members hit that number.

Oncology drove the increase in spending, accounting for $662 million, or 53% of the total increase. Drugs for breast, kidney, lung, multiple myeloma and non-Hodgkin's lymphoma cancers were the main drivers within that class. Inherited single gene disorders contributed $377 million, or 30% of the total increase, driven by hemophilia A and B, congenital hypophosphatasia, cystic fibrosis, cystinosis, Duchenne muscular dystrophy, hereditary angioedema and spinal muscular atrophy.

Almost all of the remaining increase was in biologics for anti-inflammatory conditions, multiple sclerosis, pulmonary hypertension and three conditions in which Soliris (eculizumab) is approved: hemolytic-uremic syndrome, myasthenia gravis and paroxysmal nocturnal hemoglobinuria.

The research was presented at the Academy of Managed Care Pharmacy Nexus 2020 Virtual event, held Oct. 19 to 23.

The study's "major noteworthy finding was the growth rate of commercially insured drug super spender members," says Patrick Gleason, Pharm.D., assistant vice president of health outcomes at Prime and a co-author of the study. "When we conducted this same study a year ago, there were 4,869 'drug super spender' members, or 27 per 100,000 members. This year we found 5,894 members (32 per 100,000) in that category. In 2019, the 5,894 drug super spenders had over $2.6 billion in drug cost, accounting for $1 of every $10 in total drug cost for all 18 million members. If this trend continues over the next five years, we forecast drug super spenders will account for over 15% of the total combined drug spend through the medical and pharmacy benefits, for all members."

Biosimilar Savings May Not Be Enough

Asked if any of the conditions have the potential to decline in cost due to competition within the class, including biosimilars — notably, a Soliris biosimilar is expected in 2025 — Gleason says biosimilars "offer the potential to bend the cost curve for some high-drug-cost claimants. However, the extensive gene therapy, CAR-T and orphan drug pipeline will likely overwhelm biosimilar-associated cost reductions."

He points to the spinal muscular atrophy class. Biogen's Spinraza (nusinersen), an intrathecal injection, was approved in December 2016 for the treatment of SMA in pediatric and adult patients *(RSP 1/17, p. 5)*. The first-year price of the therapy is $765,000 and then $382,500 for subsequent years. It was the only approved drug in the class for a few years until May 2019, when the FDA approved gene therapy Zolgensma (onasemnogene abeparvovec-xioi) from Novartis Pharmaceuticals Corp. subsidiary AveXis, Inc. for people younger than 2 years old *(RSP 6/19, p. 1)*. Dosing for the treatment is a one-time 60-minute intravenous infusion, and its price is $2.125 million. And in August this year, the FDA approved Evrysdi (risdiplam) from Roche Group member Genentech, Inc. for use in people at least 2 months old *(RSP 9/20, p. 4)*. Dosing of the oral solution, which

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is administered by mouth or feeding tube, is based on age and body weight. The price of the drug is tied to a person's weight and is capped at $340,000 per year once someone reaches 44 pounds.

So now the pharmacy benefit drug Evrysdi will compete with the medical benefit drug Spinraza. "However, for many patients the annual maintenance cost of the new competitor risdiplam is priced minimally lower than nusinersen; thus, members utilizing these drugs will remain high-drug-cost claimants," Gleason says.

More One-Time Therapies Are in Pipeline

Looking ahead to conditions that may show up on the list over the next few years, Gleason tells AIS Health that Prime is "tracking 10 one-time therapy products (i.e., gene, cell or CAR-T) that could be approved in 2021, many of which treat conditions with little to no treatment options. Soliris received Food and Drug Administration approval for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive in 2019. In 2020, Uplinza (inebilizumab-cdon) and Enspryng (satralizumab-mwge) were approved for the treatment of NMOSD in adult patients with the same AQP4 antibody. With all three agents priced near to, and in some cases well over, $250,000 per year, there will be increased marketing and NMOSD provider education likely resulting in increased utilization and expense."

The top drug cost category in the study is more than $750,000 — but it may not be the highest category for long. "As the number of therapies with a cost over $1 million increases, we anticipate we will need to create additional dollar groupings," he says.

He questions whether high-cost drugs are priced to reflect their value, pointing to reports from the Institute for Clinical and Economic Research (ICER), most of which assert that these drugs "are over-priced to their value. To maintain affordable health care in America, health services and pharmaceuticals need to be fairly priced." One way to do this, he contends, is through the implementation of patient-centered value-based arrangements, which Prime outlined in an earlier report with Eli Lilly & Co. titled Advancing Patient Interests Through Value-Based Arrangements for Prescription Drugs.

The breakdown in spend between the pharmacy and the medical benefit remained consistent over the course of the study, reveals Gleason: "Just over one-third of super spender drug expense is through the pharmacy benefit, remaining stable from 2016 at 34.2% to 2019 at 34.7%. This, in part, reflects the current dominance of cancer drug therapies that are primarily billed through the medical benefit. Cancer drug therapies comprised 42% of drug super spender expense in 2019. It is important to point out that the health plan can choose which benefit, medical or pharmacy, a drug/gene therapy is to be billed."

Site-of-Care, Dose Optimization May Help

Payers, he says, can implement some strategies to make sure that drug spending is appropriate. For example, they "can identify cost of care improvement opportunities such as dispensing a drug from a more affordable setting (i.e., clinic vs. hospital) or working with the provider to optimize drug therapy (e.g., adjusting dosing to avoid waste). However, a more comprehensive strategy is to integrate medical and pharmacy data using machine learning and artificial intelligence (AI) to predict high-drug-cost claimants. Predictive modeling of potential high-drug-cost claimants can be performed by the PBM, if the PBM has integrated medical and pharmacy data, or health plan. Predictive modeling can identify potential high-drug-cost members early, prior to the member becoming a high-cost-drug claimant."

Specialized Pharmacist May Find Savings

He maintains that "because the number of identified high cost drug members is small (32 per 100,000 members), review by a specialized pharmacist providing detailed therapy assessment of the member's medical and pharmacy claims is warranted. The pharmacist can help determine appropriate and cost-effective regimens through communication with members and their providers. When Prime Therapeutics provided these services, one health plan saw $2.4 million savings in high-cost specialty medication and a 9:1 return on program investment" *(RSP 5/20, p. 10)*.

As far as takeaways from the study for payers, Gleason notes that being able to get such data "is only possible with a 'carve-in' model — when the PBM has access to both integrated medical and pharmacy claims data and a strong bond with the health plan where care coordination and warm handoffs occur. With a carve-in model, a managed care pharmacist integrated with the health plan can guide members and providers to access and use therapy in the most cost-effective manner, whether it be on the pharmacy or medical benefit."

For example, he says, "they can advocate for the use of generics, biosimilars or self-administration options where appropriate, optimize dosing or dispensing of medication, and monitor and resolve inappropriate

duplicate therapy. Integrated-with-in-the-health-plan managed care pharmacists may also have access to patient-specific elements outside of claims data that could lead to other cost-saving interventions as well.

"In addition, health plans should evaluate their benefits to help ensure member cost shares are promoting the use of benefit-agnostic drugs (e.g., autoimmune, asthma drugs) on the preferred/lowest cost benefit," he continues. "Payers should also rationally align the medical policies and utilization management policies across the medical and pharmacy benefits to promote cost-effective treatment pathways and prevent member and provider confusion."

View the research at https://bit.ly/34P13eM. Contact Gleason through Denise Lecher at denise.lecher@primetherapeutics.com. ✧

Cancer-Related Services Drop, Could Have Long-Lasting Impact

Years of advances in driving down cancer occurrences and deaths could be completely reversed by the COVID-19 pandemic. A recently published study shows screenings, diagnoses and treatment for various cancers dropped dramatically from March through July when compared with 2019 rates.

Researchers analyzed 6,227,474 claims from a provider clearinghouse representing 5% to 7% of the Medicare fee-for-service population. In April, at the height of the pandemic, screening for breast cancer was down by 85%; screening for colon cancer dropped by 75%; prostate cancer screening declined by 74%; and lung cancer screening was down by 56%. Hospital outpatient Evaluation and Management visits dropped 74% in April; new patient E&M visits fell 70%, and existing patient E&M visits declined 60%.

Breast biopsies were down 71% in April and 31% in July, while colon biopsies dropped 79% and 33%, respectively, and lung biopsies declined 58% and 47% during that time. Similarly, mastectomies were down in April through July, colectomies declined in April and May, and prostatectomies saw a decline in April and July.

Billing for Top MD-Administered Drugs Fell

In addition, billing for the top physician-administered drugs was down 26% in April and 31% in July.

The study, conducted for the Community Oncology Alliance (COA) by Avalere Health, was published in the November issue of JCO Clinical Cancer Informatics.

According to the study authors, it takes about three months for a person to have a cancer screening, then a biopsy and finally treatment.

"The COVID-19 pandemic and associated stay-at-home orders established across the U.S. limited patient access to in-person care and, in turn, impacted patients' ability to receive cancer care," write the authors. "Reduced access caused significant short-term disruptions in care delivery and, as an unintended consequence, may have long-term morbidity and survival implications for patients who missed cancer screenings and surgeries during this period. Delays in diagnosis can allow cancer to grow and progress to a more advanced stage, resulting in higher mortality rates."

And as rates of infection are anticipated to increase during the cooler weather, the study authors anticipate another wave of declines in cancer services.

"The data has been showing very scary trends, and if we don't come together and do something about this, it's not hyperbole to say that it is going to be a catastrophe," said Nick Ferreyros, director of communications for COA, in introductions for an Oct. 30 webinar on the study. "We need to act now and act quickly."

The "alarming decline" in cancer-related services has yet to return to normal, noted Debra Patt, M.D., Ph.D., executive vice president of policy and strategic initiatives at Texas Oncology and a study co-author, who said during the webinar that this indicated to her that many cancers have yet to be diagnosed this year.

Telehealth Has Helped but Not Closed Gap

Utilization of telemedicine has helped mitigate the declines somewhat, said Patt, who also is a COA board member. E&M utilization was down 73% without telehealth services as compared with a 58% decline with telehealth in April, researchers found.

"I think we've all been impressed with telemedicine during the COVID pandemic," said Patt. "It's provided an incredibly useful service and, I think, rich value in longitudinal care more broadly, but has it closed the gap? While telemedicine comprised a meaningful amount of services in the cancer care setting, it did not close the gap in comparison from 2020 to 2019. So while it is meaningful, it is not sufficient to close all the gaps that we have today."

As we move into the fall, "we can only anticipate that this problem is likely to worsen," said Patt. "I think that it begs the question, 'What can we do differently to make sure that we can avoid the natural consequences of some of these delayed diagnoses?'"

Patt pointed to an article in The Lancet Oncology that anticipates delayed diagnoses will result in a mortality increase after five years of as much as 9.6% in breast cancer, 16.6% in colorectal cancer and 5.3% in lung cancer in the United Kingdom.

The JCO Clinical Cancer Informatics article recommends that "in order to effectively diagnose and manage cancer, stakeholders should consider how to heighten awareness of the dangers of medical distancing and recover seniors' confidence in their ability to seek safe and appropriate care," including screening and treatment.

"With the incoming third wave, we are probably much better prepared," said Lucio Gordan, M.D., president and managing physician of Florida Cancer Specialists & Research Institute and a study co-author, during the webinar. "We understand about the disease COVID-19 much better. We know how to treat COVID-19 in terms of complication management; we have more PPE [i.e., personal protective equipment], and people are wearing more masks."

Environment Is Safer Now Than It Was

"In addition to it being a safer environment now" than it was in the early months of the pandemic, "I honestly feel like my cancer center — which still is not allowing visitors and screens every patient, pivots patients to telemedicine immediately if they fail a screen — is a safer place" because it immediately adopted guidelines from the Centers for Disease Control and Prevention, observed Patt. "I think we're going to be here for a while in this alternate environment, and I think it's important for people to know that it's safe and effective."

In response to a question about how long it will take to catch up and for volumes to get back to normal, Gordan, who also is a COA board member, replied that "it will take some time for normalcy again. We are about to see the incoming of a third wave, a vaccine is not here yet, and I think the backlog will increase and not decrease unless we're very proactive in communicating to individuals in the United States that it's safe to come to the clinics and get proper screening procedures so we don't stay at home neglecting symptoms and then allowing stage migration and progression of cancer and more suffering down the line."

COA Mulls Public Awareness Campaign

To that end, Ferreyros noted that COA is thinking about a "Get Screened Now" public awareness campaign "to alleviate patient fear and get things back on track." Gordon explained that COA and Avalere came up with the idea "to get the study information out to the whole United States to get people to feel comfortable in going back to the practices. We need to avoid medical distancing. People are literally dying at home" from neglecting symptoms.

"I think there's an enormous opportunity," he continued. "We are reaching out to our cancer care friends and partners in the industry, pharmaceutical companies, GPOs [i.e., group purchasing organizations], payers, others" to connect with COA in order to "fund or sponsor a very large national public service campaign to get all of us back to screening."

"I truly hope that all of us here" on the webinar "get behind this and help us push this forward," said Gordon.

Download the study at https://bit.ly/3ejRDv2. Contact Gordon and Patt through Ferreyros at nferreyros@coacancer.org. ✧

Survey: Oncologists Expect To Prescribe Onureg in AML

With the FDA's approval last month of Onureg (azacitidine), people with acute myeloid leukemia (AML) now have an oral version of a longtime injectable treatment within that class. Zitter Insights found that more than half of oncologists polled are likely to prescribe the drug as a maintenance treatment for the condition.

On Sept. 1, the FDA approved Bristol-Myers Squibb Co. unit Celgene Corp.'s Onureg, a tablet, for the continued treatment of adults with AML who achieved first complete remission or CR with incomplete blood count recovery following intensive induction chemotherapy and who are not able to complete intensive curative therapy *(RSP 9/20, p. 8)*.

The recommended dose of the tablet is 300 mg once daily on days one through 14 of each 28-day cycle. Drugs.com lists the price of 14 tablets, both 200 mg and 300 mg, as $22,098.57.

Vidaza Faces Generic Competition

The FDA approved Onureg's predecessor, Vidaza, in 2004. It is still available for administration by subcutaneous injection and intravenous infusion, and generic versions of the drug have come onto the U.S. market over the past couple of years.

For the Managed Care Oncology Index: Q2 2020, Zitter surveyed 104 oncologists between June 1 and June 30 about their likely prescribing actions. Sixty percent said they were somewhat and highly likely to prescribe Onureg, formerly known as CC-486, for the maintenance treatment of AML (see chart, p. 6). Almost half of the respondents said they were somewhat and highly likely to pre-

scribe it over some AML maintenance treatments. The therapies most likely to have Onureg prescribed over them were AbbVie Inc. and Roche Group unit Genentech USA, Inc.'s Venclexta (venetoclax) and Jazz Pharmaceuticals' Vyxeos (daunorubicin and cytarabine), both cited by 46% of 50 respondents.

AIS Health and Zitter are both owned by MMIT.

Zitter also polled 51 commercial payers with 129.6 million covered lives over the same time period. Payers with 88% of covered lives said they anticipated managing Onureg to label. And of 42 commercial payers with 100.1 million covered lives, those with 97% of lives said they will continue to cover existing AML therapies as maintenance treatment.

For more information on the Zitter data, contact Jill Brown Kettler at jbrown@aishealth.com. ✧

HOSP Forms to Advocate for Integrated Specialty Pharmacies

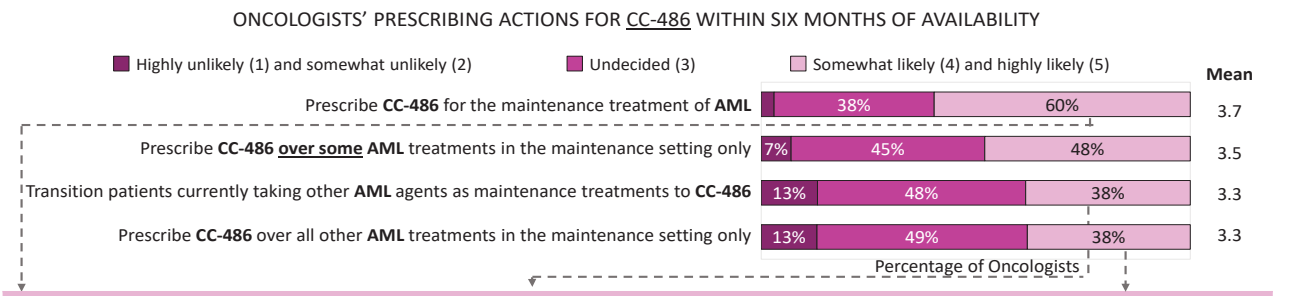
As the specialty pharmacy industry continues to grow, more entities within the health care system are boosting their capabilities in this area, and various health systems are implementing some form of a specialty pharmacy. These entities have some issues and challenges that may differ from those of traditional specialty pharmacies. In order to make sure their voices are heard, a group of seven health systems plus a specialty pharmacy integrator have joined together to form a new alliance known as the Health System Owned Specialty Pharmacy Alliance (HOSP).

In an Aug. 18 blog on his Drug Channels website, Adam Fein, Ph.D., CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc., shared information from the American Society of Hospital Pharmacists' survey of 487 pharmacy practices located in hospitals. That survey found that 26% of respondent hospitals in 2019 owned a specialty pharmacy, up from 20% in 2018 and less than 9% in 2015.

"The industry needs its own voice," contends Tanya Menchi, executive director of HOSP. "There is a lack of a single, objective platform to help educate and inform relevant stakeholders about the benefits of the integrated care model."

She tells AIS Health that the topic came up two years ago, when "informal meetings among groups of health systems and network providers of specialty pharmacy patient care began discussing the need for a new industry association dedicated to representing specialty pharmacies owned by health systems. The idea is that HOSP will

Sixty percent of oncologists are likely to prescribe CC-486 as a maintenance AML treatment, tied to perceptions of favorable efficacy



[1]Reasons to Prescribe CC-486 for the Maintenance Treatment of AML (n = 62)	[1]Reasons to Transition Patients Currently Taking Other AML Agents as Maintenance Treatments to CC-486 (n = 40)	[1]Reasons to Prescribe CC-486 Over All Other AML Treatments in the Maintenance Setting Only (n = 40)
"Based on the efficacy data." (17 similar responses)	"Reliable and safe." (2 similar responses)	"Clinical data driven" (4 similar responses)
"Better overall survival rate" (3 similar responses)	"Less adverse events"	"This is well-tolerated oral therapy"

Oncologists N = 104
Q: "Should CC-486 receive FDA approval, on a scale of 1 to 5 (1= highly unlikely and 5 = highly likely), how likely are you to take the following prescribing actions for CC-486 within six months of availability?"
Q: [1]"Please briefly explain why you are likely to take the following actions regarding CC-486 within six months of its anticipated launch."

Additional verbatim responses available upon request
Values less than 5% not displayed
Surveys collected 6/1/2020 – 6/30/2020

SOURCE: Zitter Insights, Managed Care Oncology Index: Q2 2020.

provide members an organization that focuses on integrated specialty pharmacy's unique issues and its commitment to patients and their care teams. With most major health systems owning specialty pharmacies or looking to create that capability, we expect interest in HOSP will be strong across the industry."

She maintains that this integrated specialty pharmacy approach "helps keep critical parts of patient care — such as medication management and treatment — inside the health system that is caring for the patient, instead of a more fragmented approach to care. This important care integration strategy helps improve medication adherence, reduce hospital readmissions and lower overall health care costs."

The founding members are Baystate Health, Berkshire Health Systems, CommonSpirit Health, Fairview Health Services, Hartford HealthCare, UMass Memorial Medical Center, West Virginia University hospitals and Shields Health Solutions, which helps hospitals implementing an onsite specialty pharmacy.

HOSP's board of directors consists of the following:

✦ ***Tim Affeldt***, vice president of specialty/infusion pharmacy operations at Fairview Health Services;

✦ ***Eric Arlia***, senior director of systems pharmacy at Hartford HealthCare;

✦ ***Neil Gilchrist***, chief pharmacy officer of pharmacy services at UMass Memorial Medical Center;

✦ ***Gary Kerr***, chief pharmacy officer at Baystate Health;

✦ ***Darlene Rodowicz***, executive vice president at Berkshire Health Systems;

✦ ***Jack Shields***, founder and chairman of Shields Health Solutions;

✦ ***Louis Sokos***, director of specialty pharmacy services at Allied Health Solutions, a West Virginia University hospital; and

✦ ***Marla Weigert***, system vice president of pharmacy services at CommonSpirit and president of CommonSpirit Specialty Pharmacy.

Menchi, who also serves as director of public policy for Shields, says that HOSP will advocate for the integrated specialty pharmacy industry and unite members around common interests and issues for the industry. Some of those issues include "educating stakeholders and policymakers on the benefits of the integrated model that result in better patient outcomes, sharing best practices for implementation and operation of the model, and advocating for common industry interests, like [the] 340B [drug pricing program], access to limited-distribution drugs and payer networks, and patient choice. In addition, HOSP will serve as a knowledge-sharing platform for members to collaborate and share data-based research focused on improved patient outcomes."

With an integrated specialty pharmacy, she maintains, "the health system can ensure a continuum of care that extends to financial assistance, faster delivery of medications, consistency of treatment and better coordination among providers. This results in both better patient care and better patient outcomes, which is truly what distinguishes health system-owned specialty pharmacies from nonintegrated, more fragmented options."

HOSP is a nonprofit organization, and it's open to any qualified health system.

If initial reactions to HOSP are any indication, the group isn't the only one that thinks the hospital-owned specialty pharmacy industry needs a voice: Since unveiling the group's formation, "the response has been overwhelming," says Menchi. "The inaugural board meeting was early in October, and HOSP was publicly announced on October 14. Twenty-four hours later we had received over 20 membership inquiries, which have continued to grow at an astounding rate. The interest has exceeded our expectations."

For more information, visit http://hospalliance.org.

Contact Menchi through Bob Olson at ROlson@virtualinc.com. ✧

Prime Launches Medical Benefit Management Tool MedSelect

While a variety of strategies are available to manage specialty drugs in the pharmacy benefit, that's not traditionally been the case with drugs that fall under the medical benefit. Prime Therapeutics LLC is adding to its offerings for medical benefit management with MedSelect, its newly launched national medical drug management list.

Prime has populated MedSelect with therapies based on their clinical efficacy and/or superiority and cost-effectiveness. It combines utilization management and site-of-care strategies to produce savings and appropriate drug use. The company says it expects the list will help Blues plans achieve a 4% to 7% reduction in medical drug costs.

Prime, which is collectively owned by 18 Blues plans, subsidiaries or affiliates of those plans, serves more than 30 million people.

Two options for the list are available. MedSelect – Managed offers more flexible strategies and more therapeutic

options, while MedSelect – Highly Managed has more selective tactics and is focused on the lowest net-cost options.

"As Prime Therapeutics focuses on total drug management, creating a medical drug list helps synchronize pharmacy and medical drug management," says David Lassen, Pharm.D., chief clinical officer for the company. "MedSelect is a vehicle by which Prime and our health plan partners can showcase national commercial medical strategies, promote appropriate use and better health outcomes, and manage costs by driving utilization to preferred, medical benefit drug products."

The list is updated quarterly "as strategies and positions are endorsed by our plan partners," he says. Prime maintains MedSelect, which it creates with input from its Blues plans throughout the development process, and "clinical efficacy is vetted through our Pharmacy and Therapeutics committee."

He tells AIS Health that implementation varies by client, which can choose a mix of Managed and Highly Managed tactics. In a situation where a client has members who are already on a medical benefit drug, "if an existing Blue Plan has adopted previous strategies, they can choose to keep those or align with MedSelect. Medical policies include continuation of therapy allowances when appropriate based on the disease or specific condition."

Prime has had a partnership with Walgreens Boots Alliance, Inc., AllianceRx Walgreens Prime, since 2017 that provides mail order and specialty

New FDA Specialty Approvals

✦ ***Oct. 7: The FDA expanded the label of BioMarin Pharmaceutical Inc.'s Palynziq*** (pegvaliase-pqpz) to increase the maximum allowable dose to 60 mg for the treatment of adults with phenylketonuria. The agency initially approved the drug with a maximum dose of 40 mg on May 24, 2018 *(RSP 6/18, p. 8)*. The recommended initial dosing of the phenylalanine (Phe)-metabolizing enzyme is 2.5 mg subcutaneously once weekly for four weeks. Then dosage should be titrated in a stepwise manner over at least five weeks to achieve a dosage of 20 mg once daily. That can be increased to 40 mg once daily after 24 weeks in people who have not achieved blood Phe control. Dosing can be increased to 60 mg once daily in people who have been on the 40 mg dose for at least 16 weeks and not achieved blood Phe control. Website Drugs.com lists the price of one syringe for all three doses — 2.5 mg/0.5 mL, 10 mg/0.5 mL and 20 mg/mL — as $541.94. Visit www.palynziq.com.

✦ ***Oct. 14: The FDA gave another approval to Harmony Biosciences Holdings, Inc.'s Wakix*** (pitolisant) for the treatment of cataplexy in adults with narcolepsy. The agency initially approved the selective histamine 3 (H_3) receptor antagonist/inverse agonist on Aug. 15, 2019 *(RSP 9/19, p. 8)*. Dosing in the first week is initiated with 8.9 mg once daily, then increased to 17.8 mg once daily in the second week and then increased to the maximum recommended dosage of 35.6 mg once daily in the third week. Website GoodRx lists the price of 60 17.8 mg tablets as more than $11,223. Visit https://wakix.com.

✦ ***Oct. 15: The FDA granted an additional approval to Merck & Co., Inc.'s Keytruda*** (pembrolizumab) for the treatment of adults with relapsed or refractory classical Hodgkin lymphoma (cHL). It also approved an updated indication for the treatment of pediatric patients with refractory cHL or who have relapsed after at least two prior lines of therapy. The agency initially approved the programmed death receptor-1 (PD-1) inhibitor in 2014 *(RSP 9/14, p. 4)*; it now has almost 30 approvals across more than 15 types of cancer. The newest approval was reviewed under Project Orbis via an FDA collaboration with the Australian Therapeutic Goods Administration and Health Canada. Dosing in cHL for adults is 200 mg every three weeks or 400 mg every six weeks via a 30-minute intravenous infusion. Dosing for pediatrics is 2 mg/kg, up to 200 mg, every three weeks. The list price for dosing every three weeks is $9,724.08; for every six weeks, it's $19,448.16, according to the Keytruda website. Visit www.keytruda.com.

✦ ***Oct. 16: The FDA gave full approval to AbbVie Inc. and Roche Group unit Genentech USA, Inc.'s Venclexta (venetoclax) in combination with azacitidine, decitabine or low-dose cytarabine*** for the treatment of newly diagnosed acute myeloid leukemia (AML) in people at least 75 years old or who have comorbidities that preclude the use

pharmacy services. And it recently entered an agreement with Cigna Corp.'s Express Scripts to offer its Blues plans the option of using that PBM's and specialty pharmacy Accredo's mail order and specialty pharmacy services. Kyle Skiermont, Pharm.D., Prime's senior vice president for specialty pharmacy and home delivery, tells AIS Health that the deal's purpose is to offer Blues plans an alternative to AllianceRx Walgreens Prime.

MedSelect's focus is on medical benefit drugs, says Lassen, "so while Prime is looking at facility, professional and home infusion use to determine if any site-of-care opportunities exist, there is minimal impact on our partnerships with Express Scripts and AllianceRx Walgreens Prime."

Biosimilar Treatment Depends on Tactic

Asked how MedSelect is treating the available biosimilars, Lassen tells AIS Health that with MedSelect – Managed, "oncology biosimilars are considered at parity with the originator to provide options for health plans and members that value choice. The Highly Managed offering prefers biosimilar products over the originator."

In categories that contain drugs for subgroups of patients based on biomarkers, does the list choose between available therapies, for example, Opdivo (nivolumab)/Yervoy (ipilimumab) vs. Keytruda (pembrolizumab) in metastatic non-small cell lung cancer expressing PD-L1 with no EGFR or ALK genomic tumor aberrations? "At the moment, these therapies are treated equally on MedSelect," he replies. "All Prime products follow a thorough clin-

New FDA Specialty Approvals *(continued)*

of intensive induction chemotherapy. The agency gave the companies accelerated approval for this indication on Nov. 21, 2018 *(RSP 12/18, p. 6)*; the B-cell lymphoma-2 (BCL-2) inhibitor's initial approval was on April 11, 2016 *(RSP 4/16, p. 11)*. AML dosing for the tablet is 100 mg on the first day, 200 mg on the second day, 400 mg on the third day and then 400 mg once daily of each 28-day cycle in combination with azacitidine or decitabine; in combination with low-dose cytarabine, dosing on days four and beyond is 600 mg once daily of each 28-day cycle. Blink Health lists the price of 30 100 mg tablets as more than $3,215. Visit www.venclexta.com.

✦ ***Oct. 23: The FDA approved Foundation Medicine, Inc.'s FoundationOne CDx*** to be used as a companion diagnostic for Bayer's Vitrakvi (larotrectinib). That drug is approved for the treatment of people with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment. The agency has approved the test for use with more than 20 targeted therapies. Visit https://bit.ly/31IkRPd.

✦ ***Oct. 27: The FDA expanded the label of Foundation Medicine's FoundationOne Liquid CDx*** to include its use as a companion diagnostic for three therapies: Novartis Pharmaceuticals Corp.'s Piqray (alpelisib), for use with fulvestrant to treat postmenopausal women and men with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK-3CA mutated advanced or metastatic breast cancer following progression on or after an endocrine-based regimen; Clovis Oncology's Rubraca (rucaparib), for use in adults with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube or primary peritoneal cancer who have been treated with at least two chemotherapies; and Genentech's Alecensa (alectinib), for use in people with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer. The agency initially approved the test in August *(RSP 9/20, p. 8)*. Visit https://bit.ly/3gINu3h.

✦ ***Oct. 29: The FDA expanded the use of Roche's cobas EGFR Mutation Test v2*** to include its use as a companion diagnostic for all five FDA-approved, as well as future approved, epidermal growth factor receptor tyrosine kinase inhibitors (TKIs) targeting EGFR mutations L858R and exon 19 deletions. Those therapies are AstraZeneca's Iressa (gefitinib) and Tagrisso (osimertinib), Boehringer Ingelheim Pharmaceuticals, Inc.'s Gilotrif (afatinib), Genentech's Tarceva (erlotinib) and Pfizer Inc.'s Vizimpro (dacomitinib). The test can identify 42 mutations in exons 18, 19, 20 and 21 of the EGFR gene. Visit https://bit.ly/2TCjYTG.

ical review process to ensure products including those based on biomarkers are available to our members."

MedSelect also has the ability to flag when a medication in the pharmacy benefit would be a better fit for a member than a therapy in the medical benefit.

"Prime's medical drug criteria, which is a major part of MedSelect, directs care to appropriate-use therapies," Lassen says. "These policies can cross benefits from pharmacy to medical or vice versa to guide members to the right medicine to optimize their health."

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Evidence-Based Care Increased

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According to the article, which was published on the Journal of Clinical Oncology's website Oct. 7, Anthem's program is the largest P4P program focused on the use of evidence-based oncology medications in the U.S. Over the study period, 97% of eligible providers opted to participate in CCQP.

Researchers found that prescribing an evidence-based regimen rose from 57.1% of patients to 62.2% of patients during the study period. In addition, spending on oncology drugs increased $3,339, and member out-of-pocket spending rose $253. However, "no significant changes in total health care spending" were detected.

Per the article, "Changing physician practice patterns is challenging. In the case of cancer drug prescribing, this may be a result, in part, of financial incentives in the buy-and-bill system, where physicians receive greater remuneration when prescribing higher-priced cancer drugs regardless of evidence. Our findings also revealed substantial variation in cancer drug prescribing. Physicians prescribed 402 unique drug regimens even though only 60 of those regimens were program-endorsed, evidence-based regimens."

"We are not aware of interventions at a national scale that have been as effective in changing cancer drug prescribing patterns as CCQP," maintains the article. "The success of CCQP in changing prescribing patterns is particularly relevant because P4P is widely used by insurers and health care delivery organizations as a means to improve quality, reduce costs, or both."

Findings Echoed Those of United Study

The article points out that researchers' conclusion that the program was associated with increased oncology drug spending was consistent with a similar finding in a study of a UnitedHealthcare oncology pilot *(RSP 8/14, p. 1)*. "Given the high cost of cancer drugs, including evidence-based cancer drugs, increases in evidence-based prescribing may not be enough to influence spending," concludes the article. "Collectively, these findings suggest that, in cancer care, paying physicians bonuses to prescribe evidence-based cancer drugs may improve care quality but may not yield savings. Furthermore, increases in evidence-based prescribing alone, regardless of intervention, may not be sufficient to bend the cost curve in cancer care, where unplanned acute care (hospitalizations and emergency department visits) also drives substantial spending."

"In this study, we found that a voluntary pay-for-performance program for oncology sponsored by a national insurer increased prescribing of evidence-based cancer drugs without changing overall spending," says the lead author of the study, Justin Bekelman, M.D., director of the Penn Center for Cancer Care Innovation at the Abramson Cancer Center and a professor of radiation oncology in the Perelman School of Medicine at the University of Pennsylvania. "This is a big deal, given how important evidence-based cancer drug prescribing is to achieving the best possible outcomes in cancer care."

Asked about some of the most surprising or noteworthy findings of the study, he tells AIS Health that "it was notable that even though the program worked — that is, it was effective in increasing evidence-based prescribing — it did not generate savings during the short-term, six-month episode of care we analyzed. This points to the need to evaluate longer-term spending, as evidence-based cancer drugs are not only more effective but also tend to be less toxic, likely reducing downstream costs of cancer care."

Longer Evaluation Time May Be Needed

In response to the same question, David DeBono, M.D., Anthem's national medical director for oncology and a co-author of the study, says, "we expected that this type of quality program would also drive lower costs because more effective and less toxic therapies tend to reduce downstream costs of care. Our expectation was based on our ongoing actuarial analyses of the full spectrum of pathways evaluated over a longer time frame of nine months or more where we clearly and consistently see downstream savings. However, based on the limited spectrum of clinical scenarios evaluated in this study and the short, six-month time frame used for the analyses of downstream costs, there were no differences in costs of care."

CCQP is "fundamentally unchanged" from how it was when it started, says DeBono. "However, as we collect data on practice patterns and share these data with practices in a collaborative manner, new opportunities have taken root, including an Oncology Medical Home initiative for which pathways are a foundational part of that new model. Making progress to new payment models and new quality metrics and initiatives was part of our expectation with this program. Three years after the inception of the Cancer Care Quality Program, Anthem established a practice engagement team where oncology nurses and pharmacists are deployed across the U.S. to work with individual practices in a collaborative fashion. These relationships have taken root and have allowed us to seamlessly launch the Oncology Medical Home in many markets across the U.S. in a variety of different practice settings."

Indications in Program Have Broadened

Another way in which the program has changed is that when it started, it was focused on pathways for breast, lung and colorectal cancer. But now, "there are now more than 20 cancers included and more than 80 common clinical scenarios for cancer treatment and more than 300 separated clinical pathways," says Michael Fisch, M.D., national medical director for oncology at AIM Specialty Health.

The high level of oncologist participation observed in the study continues to be seen today, says DeBono. "This is a program that is generally well-received, has limited administrative burden to practices and has now generated positive quality outcomes."

So what are important takeaways from the study for payers considering a similar program?

"First, understanding the clinical scenarios being treated and the full drug and supportive care regimens being prescribed sets the stage for comparing treatment patterns with current evidence and guidelines," says DeBono. "A common phrase in medicine is that 'you can only manage what you measure,' and knowing these details allows payers to have a transparent discussion about optimal, evidence-based prescribing. In addition, knowing these fundamental data allows payers to plan for the future as new drugs and therapies emerge and new opportunities for alternate payment models and new collaborative relationships evolve.

Program Was First Step in Shift to Value

"This program was meant to be a first step in an evolution to value-based strategies in oncology," he continues. "It was our intention to encourage practices to begin assessing their treatment decisions through a value lens. We understood that shifting toward a value-based environment would involve practice transformation, and the enhanced reimbursement part of the program was designed to support care coordination and treatment planning, as well as practice efforts to transform their practice patterns to reflect this movement toward quality and value."

According to DeBono, "just as drug development is based on sound concepts, pilot data and bio-plausible ideas, so are payer programs. But the same way that new drugs must be studied, novel payer programs need to be evaluated objectively. This type of collaboration between Anthem, its subsidiary companies HealthCore and AIM Specialty Health, and the University of Pennsylvania shows how such a research partnership can work. In this case, the evaluation showed a favorable effect of the program, but that finding could have been different, and Anthem was committed to publishing the results to share with the larger oncology community, regardless of the results."

Model Prompted Oncology Medical Home

One of the new models that evolved from CCQP is Anthem's oncology medical home, which started this past July with large oncology practices in California, Colorado, Connecticut, Ohio and Virginia for members with employer-sponsored Anthem plans in those states. The insurer expects more practices in those states, as well as others, to join in early 2021. Pathway adherence, avoided hospital admissions and emergency department visits, and appropriate antiemetic use are the current quality indicators.

In an interview with the American Journal of Managed Care, DeBono said the oncology medical home is aligned with the American Society of Clinical Oncology's (ASCO) Patient-Centered Oncology Payment model, which is focused on four components.

The first component is practice delivery requirements, which Anthem refers to as core competencies. "These are the type of care processes and comprehensive care that must be available to our members who are receiving oncology care, either within an oncology practice or a cancer center," he explained. The second aspect is participation in a pathways program. Anthem, he said, believes that its program "is encouraging value-based strategies in oncology and ensuring high-quality care for our members."

The other two components are tied to financial incentives for practices: a monthly care coordination fee and incentives for quality care and metrics. On the first aspect, the insurer designed the fee to be ascribed to members undergoing outpatient

chemotherapy or immunotherapy. "We believe that the monthly care coordination fee will help support the practice, as they transform their care from a fee-for-service environment to a value-based environment," stated DeBono.

On the last component, Anthem has incentives for practices that improve quality metrics and outcomes. According to DeBono, "we believe that encouraging the improvement of these quality metrics will move the oncology practice toward a higher-value care, without compromising on the exciting modern therapies of precision medicine in oncology."

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News Briefs

✦ ***CMS is delaying the start of the Radiation Oncology Model from Jan. 1, 2021, to July 1, 2021***. The move comes after CMS announced the launch date on Sept. 18, and multiple entities, including the American Society for Radiation Oncology and the Community Oncology Alliance, called for the start of the mandatory model to be pushed back in light of the COVID-19 pandemic. The agency said it intended to pursue rulemaking to implement the change. CMS proposed the program in July 2019 (84 Fed. Reg. 34478, July 18, 2019), and it initially proposed a start date in 2020 with an end date of Dec. 31, 2024. Participants will include physician group practices, hospital outpatient departments and freestanding radiation therapy centers for radiotherapy in selected Core Based Statistical Areas. The model will test whether changing from fee-for-service payments to prospective site-neutral, episode-based payments would save Medicare money and provide better care for beneficiaries. Episodes will cover 17 types of cancer and span 90 days. Visit https://bit.ly/2TDKoV9.

✦ ***Availability and use of biosimilars are increasing, and the products are on track to reduce drug costs by $100 billion over the next five years***, according to a study by the IQVIA Institute for Human Data Science. The report, titled Biosimilars in the United States 2020-2024 and released Oct. 6, found that the oncology biosimilars — which have reference drugs of bevacizumab, trastuzumab and rituximab — are expected to reach almost 60% market share by the end of their second year on the market. By June 2020 — one year after launch — biosimilar bevacizumab had picked up 42% of volume share. Download the report at www.iqviainstitute.org.

✦ ***Per-member per-month specialty trend rose 13.6% from 2018 to 2019***. That's according to Pharmaceutical Strategies Group's new report, State of Specialty: Spend and Trend Report, released Oct. 7. The fourth annual report analyzed 45 million pharmacy claims and 54 million medical claims. Contributing to that trend was a 10.3% increase in utilization and a 3.3% rise in costs per claim. Inflammatory disorders ranked No. 1 in terms of overall spend by therapeutic class, followed by oncology, multiple sclerosis, blood cell disorders and immunological disorders. Those categories were the same for 2019 as they were in 2018 and 2017. For more information and to download the report, visit https://bwnews.pr/2HUxyiJ.

✦ ***People should begin getting colorectal cancer screenings at the age of 45***, according to a draft recommendation from the U.S. Preventive Services Task Force (USPSTF), which gave the recommendation a B grade. That represents the first time the agency has recommended screening for all adults starting at 45. It continues to recommend screening for people between the ages of 50 and 75 years old, giving that an A grade. The USPSTF is accepting comments until Nov. 23 at https://bit.ly/2HYbJ1K.

✦ ***The FDA published a list of essential medicines, medical countermeasures and critical inputs that the U.S. needs to have available at all times***. The Oct. 30 move follows President Trump's so-called "Buy American" executive order that he signed Aug. 6 *(RSP 9/20, p. 1)*. Among other things, it calls on the FDA to identify a list of essential medicines within 90 days and speed up the approval or clearance of those products. The list includes 233 drugs, biologics and active pharmaceutical ingredients, as well as 96 medical devices such as diagnostic testing kits and personal protective equipment. Download the list at https://bit.ly/3mUQeyd. Comments may be submitted at https://bit.ly/2GovrmS.