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

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Pilot Program Targets SDOH Barriers for Members With MS

Recently, health insurers have begun focusing on social determinants of health (SDOH) and the role these factors play on health outcomes. Then the COVID-19 pandemic put even more of a spotlight on the issue, disproportionately affecting people of color and low-income communities. Recognizing the impact that SDOH can have, AllianceRx Walgreens Prime is partnering with Highmark Inc. to launch a pilot outreach program focused on the impact of SDOH on people with multiple sclerosis (MS).

According to the Healthy People 2030 initiative from HHS's Office of Disease Prevention and Health Promotion, SDOH "are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks." These include financial strain, transportation needs, food insecurity and housing instability.

The program will apply to Highmark members with an MS diagnosis who use AllianceRx Walgreens Prime as their specialty pharmacy. To participate, these members must be willing to take part in a 13-question, voluntary survey conducted via telephone. SDOH-trained nurses from AllianceRx Walgreens Prime are contacting eligible members by phone and offering to administer the survey. Highmark will assess the survey responses to identify how it can design a specific care plan for each member facing SDOH challenges.

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Precision Oncology Solution Aims to Improve Patient Outcomes

With more and more oncolytics targeting specific alterations in tumors, the area of precision oncology is developing rapidly. To help bring some insight into this market, Magellan Rx Management, a division of Magellan Health, Inc., and Trapelo Health, a wholly owned subsidiary of NeoGenomics Bioinformatics, recently unveiled a collaboration aimed at helping both providers and payers navigate this complex space and ultimately improve patient outcomes.

The offering combines Magellan Rx's comprehensive oncology management solution and Trapelo's precision-medicine platform, which provides fast, accurate testing and treatment decision support. Trapelo links providers, laboratories and payers by providing access to molecular testing information, allowing providers to order tests from preferred labs and interpreting those results, including identifying appropriate, evidence-based treatments. It offers automated prior authorization, incorporates health plan policies and eliminates unneeded medical redocumentation. These services will support Magellan Rx's medical pharmacy program, which addresses various aspects of cancer care such as guideline-supported prior authorization, drug waste, personalized dosing, oral oncology management, post-service claim edits and provider network management.

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"Appropriate genomic testing and appropriate drug therapy selection in oncology are inextricably tied together," says Rebecca Borgert, Pharm.D., senior director of oncology clinical strategy and innovation for Magellan Rx Management. "It is impossible to ensure appropriate genomic testing without knowledge of available drug therapies, and, likewise, it is impossible to ensure appropriate drug therapy selection without a deep understanding of molecular genomic testing. The collaboration between Trapelo and Magellan Rx Management brings together our collective expertise in both of these areas and ties the entire process together. By providing clinical decision support for genomic testing and seamlessly using that data to drive appropriate drug selection, the promise of better patient outcomes through precision oncology is realized."

Citing the "tremendous growth" in precision oncology over the last 10 years, Borgert states that "we are now at a point where the majority of patients diagnosed with advanced cancer require some sort of genomic molecular testing in order to ensure high quality cancer care is delivered. The pace of knowledge growth makes it difficult, if not impossible, to stay abreast of the most recent science across all different types of malignancies. Additionally, this platform provides a service that will reduce administrative burden for oncology providers by bringing together genomic testing and drug utilization workflows into a single system."

Borgert tells AIS Health, a division of MMIT, that "the system is designed to offer clinical decision support that will lead to the most appropriate selection of both genomic testing options, as well as drug therapy. Often, there are multiple options that would be considered appropriate, and if the provider selects any of the appropriate options, the prior-authorization process will be streamlined. If the provider wishes to select another testing option or another drug therapy option, the system will default to the standard review for these items, which will be based upon the individual health plan's utilization management protocols and will often lead to a peer-to-peer review to discuss the individual patient's case."

Turnaround Time Can Be Challenge

"One of the current challenges with oncology precision medicine is turnaround time," explains Borgert. "The testing process often takes more than a week from when the order is placed until results are returned. This is an anxious time for patients and their families who are waiting on these test results. Anything that can be done to speed up the authorization process for testing will allow the lab to begin work immediately upon receipt of the order, and this will translate into a direct benefit for patients. Likewise, once the test results have been returned and a treatment plan identified, a quicker authorization process will lead directly to patients being started on personalized therapies as quickly as possible."

Trapelo also is helping speed up the process by suggesting appropriate therapies based on a molecular test's result. "Trapelo's actionable results viewer presents therapies ranked by level of evidence and payer preferences with participating health plans," says Clynt Taylor, president of Trapelo Health. "Effectively, Trapelo aims to provide every cancer patient the best chance at the best outcome by improving the speed and accuracy with which patients are matched to the optimal therapy."

Another challenge with molecular tests is that sometimes test results may be misinterpreted. Janine Morales, Ph.D., chief scientific officer at Trapelo Health, says the biggest issues with this are the following:

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✦ ***"Therapy alignments with test results can vary widely*** between laboratories.

✦ ***"Therapy alignments can be based on widely different amounts of evidence***, from preclinical data all the way to randomized controlled studies. In other words, some of the alignments are based on limited clinical evidence.

✦ ***"Lab reports, for the most part, do not offer clinicians a framework*** for deciding which, if any, of the therapies on the report are appropriate for the patient in front of them. So the risk is in the potential for confusion that leads to both overutilization and underutilization of molecular information to inform a therapy decision."

"These problems are sometimes addressed through the use of molecular tumor boards, experts who help translate the results into a treatment plan," Morales tells AIS. "These can be effective, but this human-intensive approach has scalability challenges."

However, she maintains that "improved information technology can help. Highly detailed reports in which individual therapy recommendations are presented in the context of a clinically evidence-based framework that takes patient clinical details into consideration, such as stage of disease, previous treatments, overall performance status, their interest in a clinical trial, their personal care goals and their tolerance for risk."

It's up to each health plan to decide how it would like to use the services within its oncology provider network, says Borgert. "Since the Trapelo business model also involves working directly with provider groups, we feel confident that oncology providers will recognize the value in this offering with regard to its ability to reduce administrative overhead for their practices."

According to Taylor, "the cost of this program is usually covered by the payer; however, Trapelo also offers the ability for oncology practices to adopt Trapelo clinical decision support capability more broadly and integrate it directly into the practice workflow through the EMR. In this configuration, there may be a cost for the practice as well."

Asked if pharmaceutical companies have a role to play in the program's success or ease of use, Taylor responds that while they do not have a direct role to play, drugmakers "do derive a significant indirect benefit through the success of the program. As the program is adopted by providers, it drives the appropriate testing of biomarkers for patients who need testing. This, in turn, gives more patients the opportunity to gain access to the most advanced and efficacious treatment therapies and clinical trials. This benefit has drawn the attention of pharma companies and opened dialogue with many of them regarding ways they can be supportive of the program."

Contact Borgert via Lilly Ackley at ackleyl@magellanhealth.com and Morales and Taylor via Karan Cushman at kcushman@trapelohealth.com. ✧

Study Finds Wide Variation in Payers' CAR-T Drug Costs

Chimeric antigen receptor T cell (CAR-T) therapies have been available in the U.S. since August 2017. While the list prices for the one-time treatments are known, a recent study from Prime Therapeutics LLC examined their total cost of care and clinical events following administration and found that payer costs for the therapies varied widely. Payers could use this information to help forecast costs for these drugs and strike value-based deals, says one author of the study, which was presented at the Academy of Managed Care Pharmacy's AMCP 2021 virtual conference in April.

Study Examined First Two CAR-Ts

Researchers examined the first two CAR-Ts on the U.S. market. Yescarta (axicabtagene ciloleucel) from Kite Pharma, Inc., a Gilead Sciences, Inc. company, was approved Oct. 18, 2017, for the treatment of adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy *(RSP 11/17, p. 8)*. The drug — which gained FDA approval for relapsed or refractory follicular lymphoma after at least two forms of treatment on March 6 *(RSP 4/21, p. 8)* — is priced at $373,000.

On May 1, 2018, the FDA approved Kymriah (tisagenlecleucel) from Novartis Pharmaceuticals Corp. — first approved on Aug. 30, 2017 *(RSP 9/17, p. 4)* for the treatment of people up to 25 years old with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or has relapsed at least twice — for the same large B-cell lymphoma indication *(RSP 5/18, p. 8)* and is priced the same for this use as Yescarta.

The process of administering CAR-Ts is complex and involves extracting a person's T-cells, shipping them to a facility where they are genetically reprogrammed and infusing them into the patient. Patients must stay near their infusion facility for a period of time afterwards to be monitored for any adverse reactions such as cytokine release syndrome and neurological toxicities.

Researchers examined integrated pharmacy and medical claims data among an average of 15 million com-

mercially insured members from January 2018 to June 2020 with a CAR-T drug claim line allowed cost of more than $250,000. Members had to be at least 18 years old and have a lymphoma diagnosis but not a leukemia or ALL diagnosis. They also had to be continuously enrolled through an 86-day CAR-T episode: 30 days prior to and 56 days following administration.

Members' nonfinancial outcomes were followed from the CAR-T episode date through Oct. 31, 2020. Members were separated into three groups:

- ***Experienced any claims-identified clinical event,***
- ***Disenrolled without experiencing an event*** or
- ***Remained enrolled and did not experience an event*** by Oct. 31, 2020.

Claims-identified clinical events were divided into any subsequent chemotherapy drug not including supportive medications, bone marrow transplants and death or hospice.

Researchers identified 74 members who met the study criteria. More than half — 59% — were male and ranged from 18 to 76 years old, with an average age of 55. The outcome events assessment follow-up period averaged 288 days after the CAR-T episode, ranging from 26 to 990 days.

The mean total cost of care for the 86-day episode was $711,884; the mean CAR-T drug cost was $527,547, while the mean non-CAR-T drug cost was $184,337. The median CAR-T drug claim was $411,711 and ranged from $275,244 to $2,101,934. The median cost for the total episode was $610,999, ranging from $358,980 to $2,235,658. Twelve percent of the episodes totaled more than $1 million.

Among the outcome events following the CAR-T episode, 29 of the 74 members experienced one, 21 disenrolled or ceased all claim activity without experiencing an event, and 24 remained enrolled and did not experience an event. Of the members experiencing a clinical event, 22 received chemotherapy, four had a bone marrow transplant, and 13 had an identified death or hospice. Nine members had more than one type of event.

"There has been little real-world data reported about the clinical and financial aspects of CAR-T therapy for adults with lymphoma," points out Joseph Leach, M.D., senior vice president and chief medical officer at Prime and a study co-author. "We went into this analysis with the goal of using the integrated medical and pharmacy claims data of over 15 million commercially insured lives to identify potential avoidable future costs and begin to assess real-world CAR-T therapy outcomes. Though we knew the CAR-T drug list price, we still expected variance, and it did vary.

Non-Drug Costs Previously Were Unknown

"Conversely, the non-drug costs, as they relate to what we defined as the 56-day 'CAR-T episode,' were unknown and therefore [this is] a noteworthy finding," he continues. "For example, we knew that stem cell transplantation was costly but needed to perform this analysis to understand what CAR-T drug plus all other costs would sum to, providing a potential expected financial range cost. Our clinical outcomes findings appear similar to those in the clinical trial findings."

Asked if payers could take steps to bring down some of the non-CAR-T costs, Leach replies, "The wide variation in payer CAR-T drug cost sticks out as an area for opportunity. The CAR-T drug wholesale acquisition cost (WAC) is consistent across all cases, but the total insurer payment showed substantial difference that has optimization potential. It's difficult to say the same thing for the non-drug costs knowing that patients may vary in their response to therapy, side effect management costs — for example, cytokine release syndrome — or hospital stay length."

As far as the CAR-T drug costs being higher than the WACs, Leach tells AIS Health, a division of MMIT, that those costs were paid "under the medical benefit through contracts or agreements held between the payer and hospital. It was anticipated that the real-world CAR-T drug cost would be higher than WAC, based on past drug pricing through the medical benefit observations, as drugs paid through the medical benefit are frequently priced higher than WAC."

Data Can Help Insurers With Forecasting

Leach maintains that "having an understanding of the CAR-T therapy median and range of drug and total costs may be useful as insurers forecast their own future costs for these or similar drugs. Payers may use these findings in contract conversations with providers, as well as value-based purchasing agreement conversations with drug manufacturers. This information provides real-world, integrated medical and pharmacy insurance benefits, fact-based data to negotiate pharmaceutical manufacturer–insurance payer value-based purchasing agreements ensuring the CAR-T therapy price to value is fair. It should be noted that value-based purchasing agreement reporting fulfillment will require comprehensive outcomes data and sophisticated analytic insurer/PBM reporting capabilities."

Earlier this year on Feb. 5, the FDA approved a third CAR-T for relapsed or refractory large B-cell lym-

phoma after two or more lines of systemic therapy: Bristol Myers Squibb's Breyanzi (lisocabtagene maraleucel) *(RSP 3/21, p. 8)*. With the approval, Leach says it's possible that payers may begin preferring one of the drugs, "especially if a value-based purchasing agreement with either manufacturer, provider or both results in fair pricing and cost-variation control."

That said, "although there are differences in the design of the available products, lack of comparative clinical trial data will make choosing a preferred CAR-T based on clinical efficacy challenging. Additional real-world studies such as this one may help inform differences in efficacy and toxicity. Value-based purchasing agreements based on meaningful endpoints such as duration of response and total cost may also be important factors in choosing a preferred product."

View the poster at https://bit.ly/3xMS4XZ. Contact Leach via Jenine Anderson at jenine.anderson@primetherapeutics.com. ✧

Report: Specialty Drug Spending May Be Slowed by Biosimilars

Based on invoice price levels, the IQVIA Institute for Human Data Science anticipates that the global medicine market will experience a 3% to 6% compound annual growth rate (CAGR) through 2025. Oncology and immunology are the top two therapy areas globally, and they are expected to grow 9% to 12% CAGR during the same time period, according to the company's recently released report titled Global Spending and Usage of Medicines: Outlook to 2025.

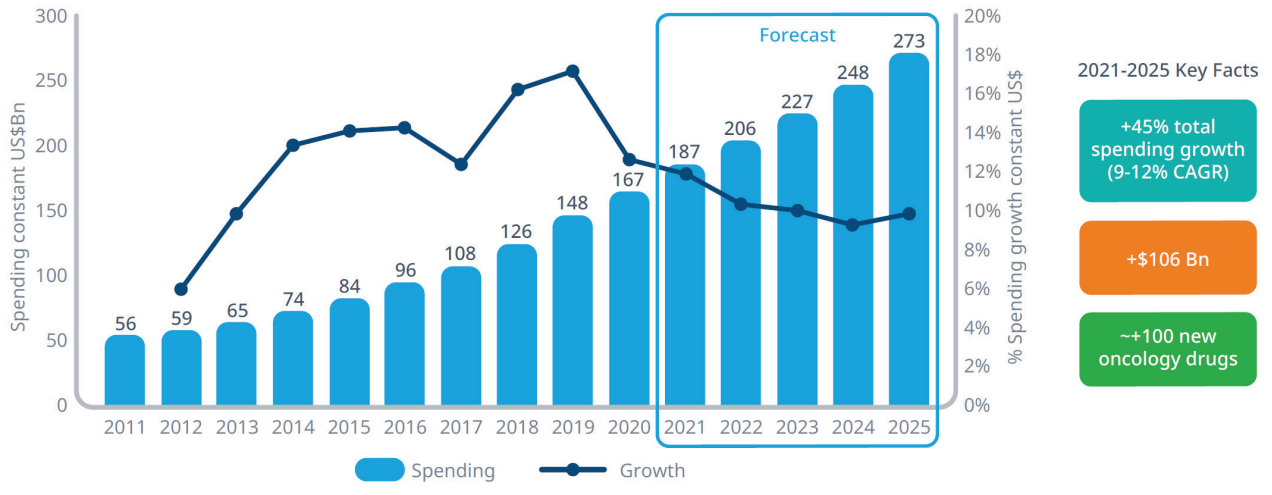
"Despite the pandemic causing significant disruption to health care systems and the use of medicines in the early part of 2020, the overall impact on medicine use was relatively modest during the year," says Murray Aitken, IQVIA senior vice president and executive director of the IQVIA Institute for Human Data Science. "This was in part because of significant stockpiling of chronic medicines in advance of movement restrictions and higher demand for some drugs used in the treatment of COVID-19 patients, which offset fewer new therapy starts and delays in treatment. The pandemic reinforced the resilience of the pharmaceutical sector and its adaptability, even in the most challenging of times."

The report projects that global spending on COVID-19 vaccines is projected to be $157 billion through 2025, "a small amount relative to the human cost and overall economic impact of the pandemic," he maintains.

"In total, specialty medicines will continue their steady increase as a share of the total drug market, especially in developed markets, where their share is expected to reach 59% by 2024," he tells AIS Health, a division of MMIT. The report forecasts that more than 100 new cancer drugs will launch by 2025, helping boost spending more than $100 billion to a total of more than $260 billion (see chart below).

However, Aitken notes that "savings from biosimilars are estimated to reach $285 billion over the next five

Global Oncology Spending and Growth



SOURCE: IQVIA Institute for Human Data Science, Global Medicine Spending and Usage Trends: Outlook to 2025, released April 2021.

years, reinforcing the critical role they play in supporting sustainable health systems, expanding access to patients and creating headroom for innovation.…Payers have the opportunity to capture these savings," as well as ones from increased generic competition to small molecule drugs.

Drug Competition Can Help in Contracting

"In most therapy areas, competition is intensifying among manufacturers, and this can provide opportunities by payers for more aggressive negotiating on price and conditions," points out Aitken.

"The evolution of the pipeline toward more precision medicines and drugs with orphan designations means payers should be prepared to allocate relatively higher shares of their drug spending towards relatively small segments of their membership," he says. "At the same time, a growing share of their members can have their diseases treated with relatively inexpensive medicines."

According to Aitken, "this year's five-year forecast includes more than the usual amount of uncertainty since the impact of the global vaccination effort and enduring effects of the pandemic are not fully known and could bring unexpected disruption to the medicine supply, health delivery systems and economic growth over the next five years. While we are forecasting 3%-6% CAGR, and the impact of COVID-19 has been relatively modest to date, we will also be monitoring global medicine use closely for any indication of more significant disruption."

Download the report at https://bit.ly/3nHFLrs. Contact Aitken via Keilani Finley at kfinley@10fold.com. ✧

Study Finds Good Adherence, Low ADE Rates With Oral DMTs

The multiple sclerosis (MS) therapeutic class boasts more than 20 disease modifying therapies (DMTs) that have various routes of administration. A recent study of oral therapies to treat relapsing-remitting MS (RRMS) found that they are well tolerated, have high adherence rates and have low rates of adverse events.

AllianceRx Walgreens Prime conducted the research in conjunction with Duquesne University School of Pharmacy. The study was presented at the Academy of Managed Care Pharmacy's AMCP 2021 virtual conference in April.

FDA Approved First Oral DMT in 2010

A progressive neurogenerative disease, MS impacts almost 1 million people in the U.S., and more than 85% have RRMS. The condition has no cure, and treatments are focused on slowing the progression of neurological impairment and disability, as well as speeding up recovery from attacks. Early therapies were either injected or infused, but the FDA approved the first oral drug to treat the condition, Novartis Pharmaceuticals Corp.'s Gilenya (fingolimod), on Sept. 22, 2010 *(RSP 10/10, p. 1)*, and others have come onto the U.S. market since then.

Researchers examined AllianceRx Walgreens Prime specialty pharmacy records of people with RRMS who were on FDA-approved oral DMTs. They analyzed use of the therapies, as well as switching trends, adherence and patient-reported adverse drug events (ADEs).

Participants in the study included people with RRMS who had been prescribed teriflunomide, fingolimod, siponimod, dimethyl fumarate and/or diroximel fumarate who completed initial clinical assessments and who had at least one MS refill clinical assessment between July 1, 2019, and Dec. 31, 2020. Patients were separated into six categories based on their therapy or if they changed to another DMT.

Researchers then categorized the drugs by class:

- ***Dihydroorotate dehydrogenase inhibitors (DHODHI): teriflunomide***
- ***Nuclear factor activators (Nrf2): dimethyl fumarate, diroximel fumarate***
- ***Sphingosine 1-phospahte receptor modulators (S1P): fingolimod, siponimod***

Adherence was measured by proportion of days covered (PDC) and required two fills on two different dates that provided at least 56 days' supply of therapy, as well as an index date that was not within the last 90 days of the study period.

Researchers defined patient-reported ADEs as "side effects reported in a clinical assessment conducted upon patient initiation and every refill," according to the study poster.

There were 10,370 patients who met inclusion criteria for the study. Most of them were female, between the ages of 40 and 59 and lived in the Midwest and South. The most commonly used therapy was dimethyl fumarate, while diroximel fumarate was used the least. Across the drug classes, the most used DMTs were Nrf2s, utilized by 45.4% of the patients used, followed by DHODHI at 28.3% and then S1Ps at 23.4%.

Only 2.48% of the patients switched to another DMT. Among those, 46.3% switched to a therapy in a different class, while 53.7% moved to another drug within the class. People most often switched from one Nrf2 to

another and least often from an S1P to an Nrf2. No formal guidelines exist on switching DMTs after an ADE.

The mean PDC among people who did not report an ADE and did not switch therapies was 81% for the DHODHI class, 78% for the Nrf2s and 83% for the S1Ps. Among those reporting an ADE, the most common within the DHODHI class was hair loss or thinning, while flushing was reported most often with the Nrf2s and abdominal pain for the S1P class.

Rick Miller, BS.Pharm., MS. Pharm., vice president of clinical and professional services at AllianceRx Walgreens Prime and an author of the study, says the study revealed a few noteworthy findings. First was that the DMTs in the study "were well tolerated based on the review of patient-reported ADEs. Reviewing the ADE data by individual drug class demonstrated patient adherence — as measured by PDC — was similar in patients who reported an ADE compared to those who did not. This may indicate other causes impacting non-adherence in addition to ADEs."

Study, Clinical Trials ADE Data Are Similar

And "because this study included such a large sample size, the data may be applied as a representative sample of patients taking oral DMTs to identify the current utilization trends for these medications. Finally, the patient-reported ADEs in the study closely matched the ADE data reported in the clinical trials. This means real-world ADE data was similar to the ADE data identified in the controlled clinical trials utilized for drug approval."

The FDA approved Mavenclad (cladribine) from EMD Serono, Inc., a Merck KGaA business, in March 2019 *(RSP 4/19, p. 8)*, prior to the study period. However, researchers excluded this oral DMT due to its dosage schedule: Dosing of the 10 mg tablets is 3.5 mg/kg divided into two yearly treatment courses, each of which is divided into two treatment cycles. Dosing is not recommended in the third and fourth years; beyond that, the safety and efficacy of restarting treatment have not been studied.

Cladribine Has 'Unique Dosing Schedule'

"We excluded cladribine because its unique dosing schedule makes it difficult to compare its PDC with the other oral DMTs," says Scott Carson, Pharm.D., program year one (PGY-1) resident at AllianceRx Walgreens Prime and lead researcher for the study. "The DMTs included in the study have once- or twice-daily dosing, whereas cladribine is two treatment cycles set about one year apart. Additionally, cladribine was approved March 29, 2019. Because of its unique dosing schedule, we were not able to calculate a PDC for those patients who started beyond Dec. 31, 2019, as they weren't scheduled to receive their second treatment cycle during the study period."

Asked if neurologists have a preference when switching a patient to another drug in the same class vs. moving them to another class, Carson replies that "though the study strengths include its large sample size and generalizability, it does not directly indicate which drugs are preferred among neurologists. However, according to our study, dimethyl fumarate was the most utilized drug and diroximel fumarate the least utilized. This could be due to their early and late approval dates. The most common switch was within the same drug class, from one nuclear factor activator to another. This clinically makes sense as diroximel fumarate tends to be a better tolerated version of dimethyl fumarate. In patients who switched, the most common switch from one drug class to another was to teriflunomide."

Research shows that MS is more common in areas further from the equator, but this study found the condition was more prevalent in the Midwest and the South. Carson says that finding is "surprising" and could be due to AllianceRx Walgreens Prime serving "a higher percentage of patients in the South as a result of third-party payer contracts in place, compared to other specialty pharmacies."

So what can payers do with these findings?

"These medications are expensive," points out Carson. "Knowing reasons for nonadherence is important so payers can partner with specialty pharmacies to address these barriers and improve adherence. As former Surgeon General C. Everett Koop stated, 'Drugs don't work in patients who don't take them.' This means a medication is only going to be as effective as a patient is adherent to the prescribed therapy, barring any ADE that impacts adherence. In addition, understanding the general trends for medication utilization and switching behavior provides one step closer to decreasing the knowledge gap of medication switching guidelines."

View the poster at https://bit.ly/3eihLIb. Contact Carson and Miller via Adrienne Foley at Adrienne.foley1@alliancerxwp.com. ✧

Integrated Medical, Pharmacy Claims Give Full View of AI Class

Some companies that analyze specialty drug spend do so with a focus solely on the pharmacy benefit. This approach, however, may fail to take into account a significant amount of medical benefit spending within cer-

tain conditions, including inflammatory diseases. A recent study by Prime Therapeutics LLC revealed trends across both benefits for the conditions, which account for almost 20% of all pharmacy and medical benefit drug expenditures among Prime's commercially insured book of business. It also demonstrated that the class may benefit from indication-based pricing.

The study was presented at the Academy of Managed Care Pharmacy's AMCP 2021 virtual conference in April.

The study examined the use of 29 drugs in both the pharmacy and the medical benefit across 12 autoimmune (AI) categories, including rheumatoid arthritis (RA), psoriasis (PsO), psoriatic arthritis (PsA) and Crohn's disease (CD). The AI class ranks No. 1 in terms of cost drivers among all drug health care expenses at Prime.

According to the study poster, these treatments represent about $1 in every $5 in pharmacy and medical benefit drug expenditures at Prime, but less than 1% of its commercially insured members use one of the therapies. Many of the drugs are approved for more than one indication, and the prices may have "significantly different average costs" depending on the condition. For this reason, the study also drilled down on drugs used for PsO and CD.

Researchers were focused on determining member use of the therapies and their costs in a commercially insured population of approximately 15 million members on a quarterly basis from January 2019 through June 2020 using integrated pharmacy and medical claims data.

For those members, Prime identified all medical claims from January 2018 to June 2020 for any goods or services with a diagnosis code for one of the 12 indications. Each member was assigned to one indication based on either utilization management in-

New FDA Specialty Approvals

✦ ***April 6: The FDA approved a new dosing regimen for Eli Lilly and Co.'s Erbitux*** (cetuximab) of 500 mg/m^2 as a 120-minute infusion every two weeks as a single agent or in combination with chemotherapy for people with K-ras wild-type epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer or squamous cell carcinoma of the head and neck. The previously approved 250 mg/m^2 per-week regimen remains an option. The drug's monthly list price is $13,596.20. Visit www.erbitux.com.

✦ ***April 7: The FDA gave full approval to Gilead Sciences, Inc.'s Trodelvy*** (sacituzumab govitecan-hziy) for adults with unresectable locally advanced or metastatic triple-negative breast cancer who have received at least two systemic therapies, including at least one for metastatic disease. The agency gave the antibody-drug conjugate accelerated approval on April 22, 2020 *(RSP 5/20, p. 8)*. The recommended dose of the intravenous infusion is 10 mg/kg once weekly on days one and eight of a continuous 21-day treatment cycle. Dosing for the first infusion is over three hours, which can be reduced to one to two hours if that dosing is tolerated. Website Drugs.com lists the price of one single-dose vial of 180 mg lyophilized powder as more than $2,173. Visit https://trodelvy.com.

✦ ***April 9: The FDA authorized marketing of Cosmo Pharmaceuticals N.V.'s GI Genius*** to help clinicians detect lesions in the colon in real time during a colonoscopy. The device uses artificial intelligence based on machine learning. The agency approved the product through the *de novo* premarket review pathway. Medtronic plc is the exclusive worldwide distributor of the module. Visit https://bit.ly/3scGZeL.

✦ ***April 12: The FDA approved Roche Group member Genentech USA, Inc. and Novartis Pharmaceuticals Corp.'s Xolair*** (omalizumab) prefilled syringe for self-injection across all its approved indications: the treatment of moderate to severe persistent allergic asthma, chronic idiopathic urticaria and nasal polyps. The drug, initially approved on June 20, 2003, had been approved for administration by a health care provider in a health care setting. However, in April 2020, Genentech, after consultation with the FDA, notified providers that due to the COVID-19 pandemic, they could allow certain patients to self-administer the drug temporarily. This approval makes that decision permanent. Patients must have no history of anaphylaxis and be closely observed by a provider for at least three injections with no allergic reactions. Dosing differs depending on the indication. Website InsideRx.com lists the price of a 75 mg/0.5 mL prefilled syringe as more than $648. Visit www.xolair.com.

✦ ***April 13: The FDA gave accelerated approval to Trodelvy*** for the treatment of adults with locally

formation or the most frequently coded diagnosis.

The analysis found that from first-quarter 2019 through second-quarter 2020, the number of members using an AI drug increased 17.0%, and drug costs rose 32.2%, from $23.89 per member per month to $31.59 PMPM. Members with an AI claim through the pharmacy benefit grew from 77.3% to 78.2%, and the proportion of drug payments through the pharmacy benefit rose from 78.6% to 83.2%. In addition, the mean quarterly drug payments increased from $13,662 to $15,436.

Among the 12 indications, seven accounted for more than 95% of utilization: RA, PsO, CD, PsA, ulcerative colitis (UC), ankylosing spondylitis and hidradenitis suppurativa. PsO and CD had the largest increases in PMPM drug expenditures, at $2.24 and $1.57, respectively. In PsO, the most common treatments were apremilast, adalimumab, secukinumab, ustekinumab subcutaneous (SC) and risankizumab. Within these five, apremilast had the lowest mean per-member per-quarter (PMPQ) cost, while risankizumab had the highest. In CD, the most common drugs were adalimumab, infliximab, ustekinumab SC, vedolizumab and certolizumab pegol. Within this group, infliximab had the lowest mean cost and ustekinumab SC the highest.

Within CD, ustekinumab SC had a mean PMPQ treatment cost of $39,579, compared with its mean cost in PsO of $17,271. And within CD, the $19,779 PMPQ mean treatment cost for adalimumab was higher than its $15,387 mean cost in PsO.

"Interestingly, this analysis shows $1 in $6 of autoimmune drug spend is billed through the medical benefit, yet frequently, drug trend analytics are completed using only pharmacy benefit claims. Without integrated medical and pharmacy drug trend analytics,

New FDA Specialty Approvals *(continued)*

advanced or metastatic urothelial cancer who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This was the second approval for the therapy in less than a week (see brief above). The recommended dose of the intravenous infusion is 10 mg/kg once weekly on days one and eight of a continuous 21-day treatment cycle. Visit https://trodelvy.com.

✦ ***April 16: The FDA approved another indication for Bristol Myers Squibb's Opdivo*** (nivolumab) in combination with fluoropyrimidine- and platinum-containing chemotherapy for people with advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma, regardless of PD-L1 expression status. Dosing is either 360 mg every three weeks or 240 mg every two weeks via a 30-minute intravenous infusion. The price of a 240 mg infusion every two weeks is $6,679. Visit www.opdivo.com.

✦ ***April 22: The FDA granted accelerated approved to GlaxoSmithKline plc's Jemperli*** (dostarlimab-gxly) for the treatment of adults with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test (see below brief), who have progressed on or following treatment with a platinum-containing regimen. Doses one through four of the PD-1 inhibitor are 500 mg via 30-minute intravenous infusions every three weeks; subsequent doses are 1,000 mg every six weeks. According to Endpoints News, a 500 mg vial will cost a little more than $10,000. Visit www.jemperlihcp.com.

✦ ***April 23: The FDA gave accelerated approval to ADC Therapeutics SA's Zynlonta*** (loncastuximab tesirine-lpyl) for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, DLBCL from low-grade lymphoma and high-grade B-cell lymphoma. Dosing for the CD19-targeted antibody drug conjugate is 0.15 mg/kg via a 30-minute intravenous infusion every three weeks for two cycles and then 0.075 mg/kg every three weeks for subsequent cycles. The wholesale acquisition cost for a 10 mg vial is $23,500. Visit https://www.zynlontahcp.com.

✦ ***April 23: The FDA approved Roche's Ventana MMR RxDx Panel*** for advanced or recurrent endometrial cancer patients to identify which ones are eligible for treatment with Jemperli (see above brief). According to the company, this is the first companion diagnostic to identify people with endometrial cancer who are eligible for a PD-1 inhibitor. Visit www.roche.com.

it is impossible to see comprehensive autoimmune specialty drug trend," observes Cathy Starner, Pharm.D., principal health outcomes researcher at Prime Therapeutics. "An alarming finding is the 33% autoimmune drug class expenditure growth in less than two years, which makes affordable health care sustainability a concern. It was a pleasant surprise finding that 98% of the time a member's medical claim diagnosis matched the prescriber-provided drug approval prior authorization diagnosis. This demonstrated confidence in assigning drug utilization to the member's diagnosis. There were important real-world AI drug cost variances per treated individual, within a drug and by the condition treated."

FDA Has OK'd Multiple AI Drugs Since '16

She says various factors helped increase expenditures, "including unit cost price inflation, increasing autoimmune specialty drug utilization and new products in the market, some with higher prices to treat the autoimmune conditions. There have been at least eight new drugs approved in this category since 2016: baricitinib, risankizumab-rzaa, sarilumab, upadacitinib, tildrakizumab, ixekizumab, brodalumab and guselkumab.

"Ustekinumab received FDA approval for Crohn's disease in late 2016 and then for ulcerative colitis in October 2019," she continues. "Ustekinumab has a higher list price than many other products to treat the same condition; however, it does have clinical trial results indicating improved outcomes over some of the other treatment options. Ustekinumab utilization for both indications has continued to grow at a steady rate. Guselkumab was first approved in 2017 for psoriasis and then in 2020 for psoriatic arthritis. As these drugs gain additional indications and become more widely used, providers may become more comfortable with prescribing them, and payers will need to ensure real-world outcomes justify their cost."

She says that while manufacturers offer rebates and coupons for products within the class, those discounts fail to offset the cost trend, "and not all utilization is associated with a discount."

ICER Has Conducted AI Drug Assessments

She notes that the Institute for Clinical and Economic Review (ICER) has conducted effectiveness and value assessments for RA, PsO and UC. For RA and UC, ICER concluded that "none of the targeted immune modulators (autoimmune drugs) included in the assessments fell within ICER's threshold value range of a $100,000 to $150,000 investment per single quality-adjusted life-year (QALY) gained. ICER found, based on the drug wholesale acquisition cost (WAC) after current market rebates, further cost discounts were needed to reach the value threshold price, ranging from further discounts of 29% up to 92%."

In the PsO assessment, ICER found that "five of the 10 targeted immune modulators assessed had prices meeting the QALY threshold," she explains. "We found certolizumab, ustekinumab and guselkumab cost more for psoriasis than other drugs used to treat psoriasis, and none of them met QALY thresholds in the ICER assessment. The ability to differentiate indication and evaluation of cost by drug provides the base knowledge to begin value-based contracting discussions."

ICER noted the "significantly lower prices" for infliximab and its biosimilar, Starner says. "There is potential for cost savings with broader availability and uptake of biosimilar treatment options. All health care stakeholders can collaborate to ensure autoimmune biosimilars have an increasing and comprehensive role in treatment of autoimmune diseases."

"With more biosimilars coming to market creating increased competition for various therapy classes, now is the time to double down on any and all efforts to encourage further use of biosimilars," said Joseph Leach, M.D., senior vice president and chief medical officer at Prime, in a statement hailing President Joe Biden's April 23 signing of The Ensuring Innovation Act and the Advancing Education on Biosimilars Act of 2021, laws aimed to increase adoption of biosimilars. "Prime is well positioned to help our clients with biosimilar adoption in their local and regional markets." Prime's pharmacy and therapeutics (P&T) committee "takes the position that biosimilars can be used in place of reference drugs in most clinical circumstances," the company said in a white paper released last month.

Site-of-Care Optimization Can Help

Site-of-care optimization could help bring down costs for infused therapies. "For infusible drugs, hospital outpatient facilities can be two to three times more expensive than other sites like home infusion, infusion centers and the provider's office. These opportunities are identified through medical drug review, so availability of medical claims data is required. Prime estimates a possible savings of more than $1 PMPM by optimizing site of care."

According to Starner, "It is incumbent upon insurers to optimize all discounts in the marketplace to ensure fair pharmaceutical manufacturer pricing to value. Insurers can input into the ICER report models their actual discounted costs, thereby determining

the real-world drug price to value for their insured population."

As far as the discrepancy in pricing between PsO and CD for ustekinumab, Starner cites a variety of reasons: "All Crohn's and ulcerative colitis cases are treated with 90 mg doses, but only a fraction of psoriasis and psoriatic arthritis use" that dose because it's indicated for people weighing more than 220 pounds. In addition, some people with CD and UC "are treated more frequently than the prescribing information-recommended dosing interval of every eight weeks (e.g., every four weeks), and we do not see this happening for psoriasis and psoriatic arthritis." Finally, the FDA approved dosing of ustekinumab in CD and UC "to begin with a one-time loading dose of intravenous (IV) ustekinumab, infused by a medical professional at a dose based on the individual's weight." After that, people can switch to ustekinumab SC.

Dosing Variance Exists Among Indications

"The most important reasons adalimumab is more expensive for inflammatory bowel diseases Crohn's and ulcerative colitis compared to psoriasis and psoriatic arthritis is the more frequent use of every-week dosing for IBDs vs. every two weeks for psoriasis and psoriatic arthritis," she says. "The more frequent IBDs' dosing is 80 mg per dose, as opposed to 40 mg per dose for psoriasis and psoriatic arthritis."

In setting up indication-based formularies, "the health plan and PBM would need to have an integrated medical and pharmacy claims database, integrated medical policy and utilization management review service and assignment of a member's diagnosis to the corresponding drug claim at the point of sale (either by the insurer or the provider submitting the claim)," she says. "Assigning a member to an autoimmune drug indication can help in designing indication-based, cost-effective formulary management strategies and value-based pharmaceutical manufacturer and/or provider contracting.…The results shown for psoriasis and Crohn's disease are an illustration of how reporting by indication may provide useful insights."

View the poster at https://bit.ly/33dnw3K. Contact Leach and Starner via Jenine Anderson at jenine.anderson@primetherapeutics.com. ✧

SDOH Pilot in MS Space Starts

continued from p. 1

The pilot will determine the success rate of a specialty pharmacy in administering the survey and the ability to address any member issues.

"Based on the self-identified needs of the member, the Highmark Social Work team will outreach to further assess the SDOH issue or barriers," explains Amy Shannon, director of health and wellbeing integration at Highmark. "In partnership with the member, our social worker will identify available resources to assist in reducing or eliminating the barrier."

The outreach, she says, "is the first step to help ensure members who are already facing health challenges have the support and resources they need to overcome barriers in other aspects of their lives which impact their health. By reducing or eliminating these barriers, people are free to be their best."

"This pilot demonstrates the continual evolution of patient care and collaborative efforts between key stakeholders," says Nebeyou Abebe, senior vice president of social determinants of health for Highmark. "Highmark recognizes that to understand and impact health, we must consider the physical, mental and social health of our members. Understanding, identifying and addressing SDOH factors that MS patients experience is a further commitment to improving their treatment journey and overall outcomes."

"SDOH can drive up to 80% of an individual's health outcomes," Shannon says. "It's imperative that we assess and provide support to members who are facing SDOH issues."

The nurses began making phone calls on April 19. Since then, AllianceRx Walgreens Prime already has identified some SDOH barriers among Highmark members, says Rick Miller, BS.Pharm., MS.Pharm., vice president of clinical and professional services at AllianceRx Walgreens Prime.

The pilot is focusing on seven domains, he explains: "social connections, financial resource strain, health literacy, food insecurity, transportation needs, safety and housing stability. While these SDOH domains may impact any patient with a health condition, in the short time the pilot has been live, we have already identified transportation needs, housing stability and financial resource strain as concerns within the MS population."

Companies Have Worked Together Before

Miller notes that AllianceRx Walgreens Prime and Highmark have worked together on "several innovative programs to support Highmark members receiving specialty medications, focusing on improving the quality of patient care, as well as addressing the overall cost of health care. The SDOH pilot was a project on which both organizations enthusiastically aligned as an area of focus."

According to Shannon, "since November 2019, Highmark has used a standardized SDOH survey to assess for barriers that health plan members

may be facing." More than 50,000 Highmark members have completed it.

As far as starting the program with a focus on MS, Miller says that both AllianceRx Walgreens Prime and Highmark already had "dedicated clinical and operational teams to support the MS patient population. With that infrastructure already in place, we selected MS as the initial disease state to pilot the SDOH survey process."

Miller explains that some metrics that will be tracked to measure the pilot's success include:

✦ ***"The number of Highmark members eligible for outreach*** by AllianceRx Walgreens Prime;

✦ ***"The number of Highmark members outreached*** by AllianceRx Walgreens Prime and the disposition of each outreach (e.g., could not reach, left voicemail, etc.);

✦ ***"The number of completed surveys***;

✦ ***"The number of Highmark members identified*** by AllianceRx Walgreens Prime as having an urgent member need(s) and referred to Highmark through an escalation process for immediate action; and

✦ ***"Of completed surveys with identified SDOH concerns***, how many Highmark members received support services."

While the survey is offered by telephone only at this time, Miller says that "other communication and technology options are being explored. Based upon the success of the pilot, these additional options may be considered for future development," such as digital-based solutions.

The program will run for one year. Depending on its success, additional patient populations may be included in future phases. "We are exploring a number of specialty disease states for future expansion," Miller tells AIS Health, a division of MMIT. "Initial expansion would focus on chronic specialty therapies, as well as specialty disease states, such as oncology and autoimmune diseases, that can be complex and challenging for patients to navigate through the health care system."

"Both companies are optimistic about the future of this program," says Miller. "The opportunity for improving the quality of life among people with rare and chronic conditions is why we do what we do and is professionally rewarding for all those involved. It also underscores the importance AllianceRx Walgreens Prime places on innovation and collaboration with partners like Highmark."

Contact Abebe and Shannon through Emily Beatty at emily.beatty@highmarkhealth.org and Miller through Adrienne Foley at Adrienne.foley1@alliancerxwp.com. ✧

News Briefs

✦ ***The FDA's Oncologic Drugs Advisory Committee voted to keep most indications for a handful of immune checkpoint inhibitors*** that target programmed death-1/programmed death ligand-1 (PD-1/PD-L1) and received accelerated approval pending further clinical trial data *(RSP 4/21, p. 1)*. Receiving "yes" votes were Tecentriq (atezolizumab) from Roche subsidiary Genentech USA, Inc. for certain triple-negative breast cancers and urothelial carcinomas and Merck & Co., Inc.'s Keytruda (pembrolizumab) for certain urothelial carcinomas and hepatocellular carcinomas. Keytruda received a negative vote for certain gastric cancers and Bristol Myers Squibb's Opdivo (nivolumab) did also for certain hepatocellular carcinomas. View the meeting materials at https://bit.ly/3uj4XqJ.

✦ ***Amber Specialty Pharmacy is partnering with MarkeTouch Media to enhance communication with patients*** via automated, targeted and responsive outbound notifications across services through the TouchPoint Management solution. The move frees up staff from performing routine tasks, allowing them to focus on patients, says the company. Visit www.amberpharmacy.com.

✦ ***AmerisourceBergen Corp. launched the Accelerate Specialty Network***, which the company says is the first specialty-focused pharmacy services administration organization (PSAO). Accelerate will help its members execute specialty contracts with payers and PBMs, provide data to allow members to optimize their businesses and offer services to improve operational efficiency. Members of the network include health system and independent specialty pharmacies, as well as medically integrated dispensing practices. Contact Francesca Gunning at fgunning@amerisourcebergen.com.

✦ ***PERSON ON THE MOVE***: Prime Therapeutics LLC named ***Karen DeZearn, Pharm.D.***, vice president of client success. She previously was vice president of national accounts, east at Express Scripts.