MMIT RADAR

Spotlight on Market Access

Actionable understandings from AIS Health's in-depth coverage

April 20, 2020

As COVID-19 Highlights Pharma Innovation, How Might It Impact Opinions of Industry?

As the world struggles to deal with the COVID-19 pandemic, pharma is one of the main industries entrenched in the battle. And while drugmakers and other stakeholders within the pharmaceutical community are facing an array of challenges *(SMA 4/6/20, p. 1)*, the situation also is likely to result in permanent changes post-outbreak — and not all of them negative.

While it may be hard to see positive aspects of the current situation, some do exist. For one, "we should see better pandemic preparedness and other public health measures, more investment in that sector and more streamlined regulatory processes, for not only therapeutics but also for diagnostics (including tests to screen and detect SARS-CoV-2 antibodies)," says Junko Saber, managing principal at Innopiphany. "In addition, we should see movement towards acceptance and reimbursement for telemedicine, meaning 'virtual office visits' by phone or videoconference."

Some of the latter already is happening: CMS has temporarily expanded telehealth in Medicare fee-for-service and in Medicare Advantage has begun allowing diagnoses codes gathered from video-based visits to count toward risk adjustment.

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Providers Protest New Tennessee Blues Plan Policy Intended to Save Clients Money

BlueCross BlueShield of Tennessee, Inc. (BCBST) has found itself in the news recently but probably not for reasons the health plan might like: The insurer has received tremendous pushback from physicians on its decision to implement a policy requiring them to get provider-administered therapies from specialty pharmacies. But the health plan maintains that it has implemented the program in response to client demands and that the new policy will save money for its self-funded employers that opt into the program.

Providers traditionally have acquired therapies they administer through a practice known as buy and bill, by which they will purchase a drug from a wholesaler or distributor, keep it in their office and administer it to patients as needed, submitting a claim to the payer afterwards. Through this approach, providers can make a profit by marking up the drug.

But some payers mandate that providers purchase these drugs through a specialty pharmacy, a practice known as white bagging. This means the provider never takes ownership of the drug, and patients will pay their copayment or coinsurance to the specialty pharmacy after the physician orders the drug. The specialty pharmacy then delivers the medication directly to the provider. A third option, which is known as brown bagging, is when a patient receives the drug and brings it to the provider to be administered.

The Tennessee Blues plan says that it and the employers that it serves paid $900 million for provider-administered specialty therapeutics in 2018. In a Dec. 27 article, Henry Smith, senior vice president, operations and chief marketing officer at the insurer, said that while specialty products represented 1% of its covered prescriptions, the drugs made up approximately half of its drug spend. Smith also pointed to the specialty pipeline, which has numerous drugs that are expected to receive FDA approval in the next few years.

"Though these drugs are used by only a small number of patients, all insured people help shoulder the cost — and that cost is becoming unsustainable," he wrote on the company website. "Our customers are asking us to do more to help them manage these costs. Our solution is to require providers to order specialty medications from a pharmacy in our specialty network."

Plan Launched Program on Jan. 1

In response to those client requests to help save on specialty drug costs, the Tennessee Blues plan launched a white-bagging program on Jan. 1, with a six-month transition period, for self-funded employers who opt into it. Scott Neal Wilson, vice president of corporate communications and community relations for BCBST, confirmed in February that the plan already was receiving claims via the new process. An FAQ page on the plan's website clarifies that the program "does not apply to Individual/Marketplace, Medicare Advantage, BlueCare and BlueCare Plus plans yet. Members in these plans should simply follow the same process as before." While the policy change does not apply to self-administered drugs, Wilson also clarifies that it does apply to all locations where a provider may administer a therapy.

In a Jan. 8 article on the insurer's website, Natalie Tate, Pharm.D., vice president of pharmacy at BCBST, said that the policy will apply to about 5,500 of its 3.5 million members. Tate also said that 100 employer groups had opted in to participate. She clarified that the plan had not changed the provider-administered drugs it covers. (Download the list of affected drugs via the link at the bottom of this article.)

That network, according to Wilson, contains 28 specialty pharmacies. In addition, a sample letter on the company website adds that "for qualified providers, we're happy to talk about offering you a new dispensing provider agreement or adding you to the specialty pharmacy network."

"We estimate employer customers participating in our new program should save an average of 20% on these drugs. It's important to note that all of the savings go directly to those employers and the members covered by their plans — not BlueCross (or a PBM)."

Wilson adds, "it's also important to remember that we're covering the same drugs administered by the same doctors in the same facilities. And we're still paying providers for the services they provide to administer the drugs."

"We estimate employer customers participating in our new program should save an average of 20% on these drugs," he tells AIS Health. "It's important to note that all of the savings go directly to those employers and the members covered by their plans — not BlueCross (or a PBM)."

However, a great deal of press coverage, much of it negative, has occurred around the launch. Most recently, a Feb. 6 letter from eight medical societies asked the Tennessee Blues plan to reconsider the program.

The writers maintained that "practices currently engaging in the buy-and-bill model operate under thin margins," which would be eliminated with the

implementation of white bagging. Administration fees, they said, won't cover overhead costs associated with drug administration. They maintained that the results would be a shift in site of care from provider offices to the more expensive hospital setting, boosting costs for both the insurer and its members. Some hospitals even may refuse patients required to use white bagging, they said.

Information on the Blues' company website explains, "when you work with our specialty pharmacy network, you'll have access to patient care coordinators, educational materials and phone-based clinical pharmacists who can give advice."

"BCBST's new white bagging policy is a concern for physicians because of the potential adverse effects on patients. The focus of any new health plan policy should be to provide the best care at the best price with the best outcome. When insurance companies restrict the physicians' ability to do that, they compromise patient care."

The letter maintains that while provider margins would decline, offices' administrative costs would increase due to coordinating the timing of a drug's delivery and a patient's appointment, potential prior authorization of the drug and administration codes separately, and anticipated increase in patient calls about applying copayment assistance funds before a drug's administration. They asserted that the policy would result in drug waste since a white-bagged drug is specific to a patient, as opposed to buy and bill, which does not have patient-specific therapies. If a white-bagged therapy is unable to be administered, "then the medication is wasted as it is unethical and illegal to administer the medication to a different patient," they wrote (see story, p. 4).

This also means that there is a treatment delay for the patient, suggested the letter's authors. And they questioned how providers could verify a drug's supply chain. Finally, they cited "recent studies" showing that buy-and-bill drugs in Medicare Part B had price increases of 21% versus those in Part D, which had price increases of 45% due to rebates.

"BCBST's new white bagging policy is a concern for physicians because of the potential adverse effects on patients," Dave Chaney, vice president of the Tennessee Medical Association, tells AIS Health. "The focus of any new health plan policy should be to provide the best care at the best price with the best outcome. When insurance companies restrict the physicians' ability to do that, they compromise patient care."

In a Feb. 14 client alert, Bill Sullivan, principal consultant at Specialty Pharmacy Solutions LLC, questioned the societies' claim of "more red tape." He noted that with buy and bill, drugs are sitting on physician shelves while the providers try to get prior authorization for the products. "Manufacturers and payers would argue that it makes sense to merge logistic and administrative processes through a specialty pharmacy," said Sullivan. Then once prior authorization has been obtained and a patient's financial liability has been taken care of — something he said is "often the biggest delay factor" — "next-day delivery does not create an unreasonable or clinically dangerous delay," he wrote.

"These physician-infused medicines are the primary drivers of cost of care increases under the medical benefit. Coincidentally, these price increases also help bolster profit margins for physician practices."

According to Sullivan, the contention that specialty pharmacies cannot ensure the proper handling and safe delivery of drugs "is simply false." And he said that from 2014 to 2018, the average price of provider-administered drugs rose 73%. "These physician-infused medicines are the primary drivers of cost of care increases under the medical benefit," he wrote. "Coincidentally, these price increases also help bolster profit margins for physician practices."

In a Dec. 28 *Chattanooga Times Free Press* article, Roy Vaughn, a BCBST spokesman, said that "other insurance companies are employing more disruptive

strategies to control costs, such as moving patients to different sites of care." The policy will help BCBST keep prices down "because the specialty pharmacies have agreed to 'much more competitive pricing.'" He estimated that the policy "will save the state health plan between $9 million and $12 million in taxpayer dollars," stated the article.

"We're here to help our members get the treatments they need at the best possible prices."

Wilson says that ahead of the Jan. 1 start of the program, BCBST began offering information about the policy change in November.

"We first notified providers with a letter on Nov. 8, 2019, focusing on those who had specialty pharmacy claims for members who would be eligible for the new program. That letter instructed them to use our specialty network and listed the specialty pharmacies in the network," he says. The plan sent a second letter Nov. 26 to facilities that were treating eligible patients. That was followed by a Dec. 5 letter "to providers who weren't getting prior authorizations for these drugs, along with a list of drugs that require prior authorization."

Finally, a Dec. 18 letter was sent not only as a final reminder but also as a way to offer information on the transition period. Wilson adds that "during this two-month time frame, we also equipped our network managers with educational information so they could address this directly with the providers they support, whether in phone calls or in-person visits." BCBST included the six-month transition phase in order "to help providers get used to the new process and to allow us time to address some of their operational concerns," he explains.

Asked about how situations are handled in which a person with hereditary angioedema, for example, needs acute treatment, Wilson replies, "most often, provider-administered specialty drugs are given as part of a scheduled treatment regimen, and our in-network specialty pharmacies can deliver anywhere in the U.S. within 24 hours. We understand there are rare cases when a treatment needs to be administered immediately, and we're working on an exception process to meet those needs." Asked about provider-administered hemophilia therapies, he states that "the majority of hemophilia drugs have been and will continue to be covered as self-administered medications. There are a few exceptions, and if there is an immediate treatment need, an exception process would be used."

Wilson tells AIS Health that "specialty drug manufacturers have been raising prices for years, and we've been asking providers for help with this issue. We've had hundreds of conversations about specialty drug rates as part of our contract negotiations. When we've asked them to accept lower markups on the drugs, they often respond by asking how we'll make up the lost revenue for them. That's not our job; we're here to help our members get the treatments they need at the best possible prices."

View the medical societies' letter at https://bit.ly/2Tf82GP. View Smith's article at https://bit.ly/3816hlU and Tate's article at https://bit.ly/2SY6phN. View the list of affected drugs at https://bit.ly/2TdTBEd.

Contact Chaney at Dave.Chaney@tnmed.org, Sullivan at wsullivan@specialtyrxsolutions.com and Wilson through John Hawbaker at John_Hawbaker@BCBST.com. ✧

by Angela Maas

This story was reprinted from AIS Health's monthly publication RADAR on Specialty Pharmacy. *Visit https://aishealth.com/product/specialty-pharmacy.*

Experts Vary on Challenges, Benefits of White Bagging

As health plans seek to have more control over their spending on provider-administered specialty drugs, many physicians are pushing back, as seen most recently with BlueCross BlueShield of Tennessee's (BCBST) new program (see story, p. 1). But at least one survey of commercial payers shows that mandating the use of a specialty pharmacy to acquire these therapies is replacing the longstanding approach, a trend that respondents anticipate will continue even though

industry experts vary on the benefits and challenges of such an approach.

Providers traditionally have acquired therapies they administer through a practice known as buy and bill, by which they will purchase a drug from a wholesaler or distributor, keep it in their office and administer it to patients as needed, submitting a claim to the payer afterwards. Through this approach, providers can make a profit by marking up the drug.

But some payers mandate that providers purchase these drugs through a specialty pharmacy, a practice known as white bagging. This means the provider never takes ownership of the drug, and patients will pay their copayment or coinsurance to the specialty pharmacy after the physician orders the drug. The specialty pharmacy then delivers the medication directly to the provider. A third option, which is known as brown bagging, is when a patient receives the drug and brings it to the provider to be administered.

According to Dea Belazi, Pharm.D., president and CEO of AscellaHealth, white bagging is "somewhat common, and it varies by drug or disease state. It has become more common over the past few years than previous."

Surveys Anticipate Drop in Buy and Bill

A recent report from Zitter Insights would seem to support that contention: It shows that surveyed payers believe that white bagging will continue to gain traction in the commercial marketplace over buy and bill.

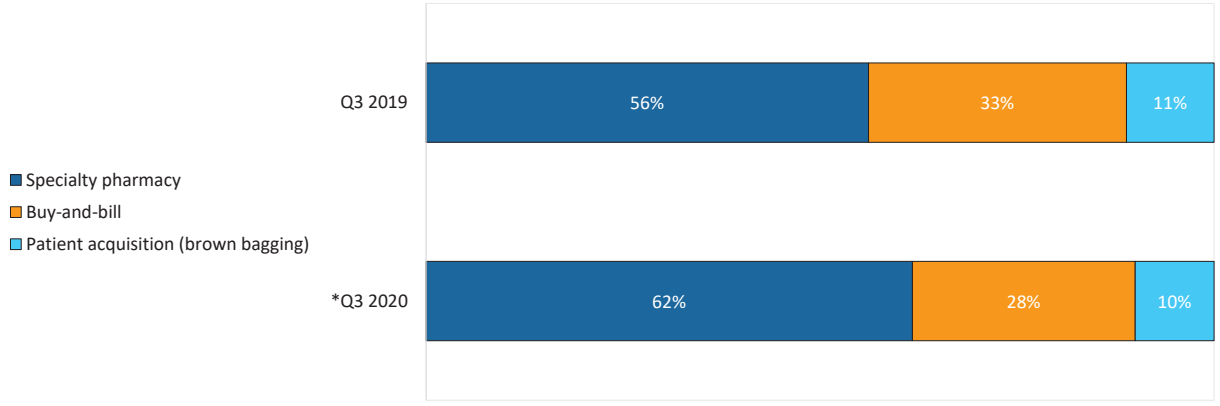
For the *Managed Care Biologics and Injectables Index: Q3 2019*, Zitter surveyed between Sept. 3, 2019, and Oct. 7, 2019, pharmacy and therapeutics (P&T) committee members who work for 51 commercial payers with 158.4 million covered lives. Asked about the volume of office-administered nononcology drugs that go through separate distribution channels, respondents estimated that more than half (56%) go through the white bagging process for third-quarter 2019, with one-third going through buy and bill (see chart below).

AIS Health and Zitter are both owned by MMIT.

The respondents estimated that the volume of these drugs distributed via specialty pharmacy would increase by third-quarter 2020 to 62%, while buy and bill volume would drop from 33% to 28%. They anticipated

Buy-and-bill distribution of office-administered non-oncology therapies is expected to decrease in the next 12 months

CURRENT/ANTICIPATED OFFICE-ADMINISTERED NON-ONCOLOGY THERAPY PER DISTRIBUTION CHANNEL



Payers (Commercial) N = 51; Covered Lives N = 158.4 million
Q: "Please estimate the percentage of your organization's office-administered/ infusible non-oncology therapy volume that goes through each of the following distribution channels currently."
Q: *"Please estimate the percentage of your organization's office-administered/ infusible non-oncology therapy volume that will go through each of the following distribution channels 12 months (by Q3 2020) from now."

Similar data for Medicare book of business
*Anticipated
Respondents belong to sample 2
Surveys collected 9/3/2019-10/7/2019

SOURCE: Zitter Insights, *Managed Care Biologics and Injectables Index:* Q3 2019.

that brown bagging volume would remain steady, at 11% in 2019 and 10% in 2020.

Similar numbers were found specific to oncology drugs. For *Zitter's Managed Care Oncology Index: Q3 2019*, the P&T members from 51 commercial payers said the volume of office-administered oncology drugs going through the white bagging process was 51% for the third quarter of 2019, with 40% going through buy

White Bagging Can Pose Array of Logistical, Contractual and Communication Issues

As the practice of white bagging grows, Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, tells AIS Health the approach has many potential issues that should be addressed in payer contracts with specialty pharmacies and providers:

- ***"If a drug is administered to the patient as prescribed*** and as supplied under white bagging by the specialty pharmacy, how is the payer informed — via a billing that shows administration of the drug's J-code and administered number of HCPCS [i.e., Healthcare Common Procedural Coding System] units, but with an indicator that this is for information purposes, not for reimbursement to the practice? If so, does the payer match up the specialty pharmacy billing with the provider billing to validate that the drug was administered as prescribed?"
- ***"What happens with excess drug*** if the dosage isn't exactly equivalent to a round number of supplied vials? Obviously, the open vial cannot be returned to the specialty pharmacy. But may a physician in the practice administer the excess drug to another patient, and, if yes, how is that billed since 100% of that drug was already paid for?"
- ***"A drug that…a specialty pharmacy ships to the practice/clinic*** remains property of the specialty pharmacy, since the physician practice or clinic on receipt has it in inventory but does not own it. As such, whose responsibility is maintenance of drug integrity? This involves questions like proper storage, chain of control, responsibility in the event of recall, responsibility for waste/loss.

"For instance, if the practice discontinues the drug that it received from the specialty pharmacy and returns a drug of the same name but of a different lot number and a different expiration date, is that OK with the specialty pharmacy? I really doubt it would be. What leverage does the specialty pharmacy have in such circumstances, since — I assume — the specialty pharmacy, under contract to the payer, does not have direct contractual relationships with the practices/clinics to which it ships drugs?"

- ***"One way to provide a white bagging program for a busy practice*** is for the specialty pharmacy to manage drug inventory on site at the practice, possibly through an automated drug cabinet. While this would avoid shipping cost, provide for on-site storage logistics and provide some access controls, the cabinet itself and its management would have a cost — if a cabinet is an option, would the specialty pharmacy or the payer be responsible [for it] and pay [costs associated with it]?"
- ***"The patient surely knows the name of the treating doctor/clinic*** but isn't likely to know the name of the white bagging specialty pharmacy, so if the patient gets a billing for cost share from that specialty pharmacy, will the patient be confused? Will the patient pay?"

"As the above show," he says, "there is substantial opportunity for confusion, misunderstanding, miscommunication, error and opposition in a white bagging program."

For more information, contact Rubinstein at elan.b.rubinstein@gmail.com.

and bill. For third-quarter 2020, respondents estimated that 58% of these therapies would reach physicians via white bagging and 34% through buy and bill. Brown bagging volume also was anticipated to remain steady year over year, at 9% in third-quarter 2019 and 8% in the third quarter of 2020.

Survey Respondent: 'Billing Is Clearer'

One payer respondent said their plan preferred to go through a specialty pharmacy for drugs administered in hospital outpatient departments since the specialty pharmacy helps with prior-authorization management, and "billing is clearer." Because the specialty pharmacy takes care of the billing, "that process is preferred."

According to Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, "white bagging provides payers the advantage of contracted specialty pharmacy product preferences based on evidence-based medicine and negotiated prices/rebates, prior-authorization management, direct payer billing and reporting, analysis and tracking of experience over time."

Another benefit, says Belazi, is for entities that pay for health care services, including health plans, employers and third-party administrators, as "they can procure these medications at a better price than allowing the health care provider" to obtain the drugs and bill the payer. For instance, BCBST says it expects that its employer customers will see an average savings of 20% on provider-administered specialty drugs via its new white bagging program.

However, Belazi points out, this benefit for payers poses a "major issue" to providers because "their ability to buy and bill the payer is a significant portion of their practices'/organizations' revenue." Not only does this approach remove the margin on provider-administered drugs, but it also "eliminat[es] margin as a factor in choice between drug therapy alternatives," says Rubinstein.

At AscellaHealth, Belazi says, "we advocate an approach to work with those health care providers and create alternative reimbursement structures to mitigate the impact of the financial loss." He tells AIS Health that the best way to introduce a mandatory white bagging policy to providers "must be a phased approach identifying areas where drug/provider administration is less impactful to a health care provider practice. Such a scenario would be one where the provider does few administrations, or the buy-and-bill practice is not a significant revenue driver for their organization. The second phase is to begin the conversation with providers where the financial impact is great and begin to identify areas of opportunities to start to introduce white bagging and perhaps reimburse greater for the administration of the drug and the care of the patient," he continues. "There are other alternative models such as letting the provider continue to buy and bill but [at a] lower cost."

Patients' out-of-pocket costs, Belazi asserts, "may not have to change or can be improved. Benefit designs that are centered around a percentage of the cost of the drug could result in a lower cost for the patient because the cost of the drug is lower. There are other scenarios that payers could do that reduce patient out-of-pocket costs if they participate in white bagging."

"Benefit designs that are centered around a percentage of the cost of the drug could result in a lower cost for the patient because the cost of the drug is lower."

However, Dave Chaney, vice president of the Tennessee Medical Association, refutes the notion of white bagging providing benefits to patients. "There is no discernable benefit(s) to the patient," he maintains. "In fact, patients will incur additional hassle and inconvenience to obtain drugs and get them administered." Patients' having to pay for drugs before they are shipped "can interrupt critical treatment" if patients cannot afford to pay for the therapies. But at the Tennessee Blues plan, "if the member is unable to pay right away, the specialty pharmacy will ship the drug to the provider and create a payment plan — or find copay assistance — for the member," maintains a Jan. 8 article on the insurer's website by Natalie Tate, Pharm.D., vice president of pharmacy.

"The only benefit is a financial savings for the health plans, which history shows do not pass along to their beneficiaries in the form of decreased premiums or out-of-pocket expenses," Chaney tells AIS Health. Scott Neal Wilson, vice president of corporate communications and community relations for BCBST, counters that "all of the savings [from the program] go directly to those employers and the members covered by their plans — not BlueCross (or a PBM)."

Rubinstein equates white bagging to the failed CMS Competitive Acquisition Program (CAP), which started July 1, 2006, with BioScrip, Inc. as its sole vendor. A little more than two years after the program's start, BioScrip — citing "unacceptable profit risk" — said it would not re-sign with CMS as a CAP vendor. CMS indefinitely postponed the program in 2008. Many of the challenges facing CAP, he tells AIS Health, may be similar to those with white bagging (see box, p. 6).

A major concern over both white and brown bagging is the potential waste. One of the respondents to the Zitter survey acknowledged that "coordinating delivery to the hospital and ensuring that the medication is delivered to the correct department and medication integrity is not compromised is the biggest challenge. Failed delivery, lost meds are also very common." Other respondents also cited the challenge of maintaining supply chain integrity.

"Coordinating delivery to the hospital and ensuring that the medication is delivered to the correct department and medication integrity is not compromised is the biggest challenge. Failed delivery, lost meds are also very common."

According to Steven Baak, M.D., a rheumatologist and medical director of the Arthritis Center in Bridgeton, Mo., "folks in the drug supply chain are not bothered by declining quality or safety because they get paid no matter what in a little game called 'fill and bill.'"

He tells AIS Health that his office "throws out around $100,000 worth of drug every six months due to PBMs shipping unwanted [prescriptions] to my office or my patients' homes. My patients bring it in to my office because 'they can't bear to waste expensive medicine.'" Baak says he also has experienced incorrect drugs being delivered, drugs shipped to the wrong place or a lack of PBM coordination with patients, resulting in missed doses.

Rheumatology, he tells AIS Health, includes "very complex clinical decision making," with patients often switching to other therapies. This also is a common occurrence in oncology patients receiving chemotherapy, notes Chaney. "Since drugs are dispensed for a specific patient and could not be used for another patient, that drug is now wasted at the patient's expense," as patients "will still be on the hook for payment."

"If a payer stipulates white bagging for drugs administered in the office/clinic, will this impact a physician's choice of injectable vs. oral therapy?"

"Medical practices will experience unnecessary financial burden under this policy," asserts Chaney, as "BCBST will allow physicians to continue to bill for specialty drugs only if they agree to the BCSBT's new contracted specialty pharmacy rates, a negotiation in which physicians have no input."

The plan has said that providers can apply to participate within the specialty pharmacy network. "Some medical groups also have their own specialty pharmacy as a convenience and benefit for patients, but on-site specialty pharmacies require expensive dual certification and an onerous re-accreditation process every three years," Chaney says.

Baak says that "PBM administrative burdens put on my staff are significant. It is more than one hour of my staff time per PBM patient per infusion, and I need my team to be doing patient care, not on hold with the PBM and being transferred, disconnected, etc. as they are made to jump through hoops."

Rubinstein wonders how much of an impact a white bagging program ultimately will have on the actual therapies prescribed. Amidst concerns that skinnied-down drug margins cannot support a practice, "will practices refer patients to more expensive

hospital outpatient centers for infusion of these drugs, and, if payer site-of-care coverage policies disallow infusion in these more expensive sites of care unless patient circumstances warrant, then where will the drug infusions happen?"

He points to the increasing amount of oral therapies available in areas such as oncology and rheumatology. "If a payer stipulates white bagging for drugs administered in the office/clinic, will this impact a physician's choice of injectable vs. oral therapy?" he asks. If providers shift from professionally administered drugs to self-administered ones, "what are the financial implications for payers and financial, access and clinical implications for patients?"

Contact Belazi via Nicole Dufour at ndufour@cpronline.com, Chaney at Dave.Chaney@tnmed.org, Rubinstein at elan.b.rubinstein@gmail.com, Sullivan at wsullivan@specialtyrxsolutions.com and Wilson via John Hawbaker at John_Hawbaker@BCBST.com. For more information on the Zitter data, contact Jill Brown Kettler at jbrown@aishealth.com. ✧

by Angela Maas

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What Will Be COVID-19 Changes?

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"Remote care and business may expand," says Mike DeLone, principal at Deloitte Consulting and U.S. life sciences sector leader, and "we may see payoff from fast tracking scientific discovery and potential new ways to leverage technology for digital transformation." For example, he tells AIS Health, companies are using AI "to comb through all the now open-source data from the scientific literature to gain insights. Technology partners are offering support to investigators to learn more about the virus, including variable responses to infection across geographies and demographics." In addition, the situation may give the pharma industry the opportunity "to rethink/re-evaluate the in-person rep model, and we may see an acceleration to alternative commercial models."

Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, says that "it may add some safety valves to the supply chain to be resistant to future supply chain disruptions." Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, agrees: "It appears likely that extended pharmaceutical supply chains, newly viewed as at risk of breaking, will be reconsidered, to be made more secure and perhaps shorter. Will the USA continue to rely on India and China for API [i.e., active pharmaceutical ingredients]?"

"In a crisis like this one, there is no single segment in health care that is equipped to handle it alone. Silos must be torn down and new partnerships formed for these types of catastrophic events."

Steven F. Robins, managing partner and principal at The New England Consulting Group, points out that many manufacturing and distribution decisions over the past couple of decades have "been dominated by cost efficiency....All aspects of the supply chain will be revisited, which will result in improved continuity of supply every day."

Also, he states, "many of the intercompany partnerships and public/private partnerships being developed to meet this challenge will create the opportunity to meet other worldwide health challenges. The conversion of different industries into health care manufacturers is also building a capability that has been lost since World War II. This reaffirms for many in pharma/medical devices that we are in an industry that tries do good, as well as make a profit."

It's also important to understand, maintains Robins, that "I think we tend to focus on specific industries in health care rather than looking at the whole system. In a crisis like this one, there is no single segment in health care that is equipped to handle it alone. Silos must be torn down and new partnerships formed for these types of catastrophic events."

"It's amazing to see how the entire pharma community and local, state and national government agen-

cies have rallied to collaborate and ensure the overall health care system can continue to provide ongoing patient care," asserts Richard Gourash, R.Ph., vice president of oncology at BioPlus Specialty Pharmacy. Information on therapies "needs to be relayed to the physician community and put into action by specialty pharmacies to help patients and caregivers with their treatments….Telehealth and digital communications have emerged as very effective ways to communicate to patients and caregivers during the COVID-19 pandemic," he tells AIS Health.

"We are seeing in real time the benefits of the massive innovation movement that has happened in diagnostics, life science tools and in biopharma over the last decade."

And as more companies join in the search for treatments and vaccines — at least 161 candidates were in development as of April 13, according to *Genetic Engineering & Biotechnology News* — the public is gaining a new appreciation of the pharma industry and the services it provides.

China first reported the outbreak in late December. Over the weekend of Jan. 11-12, Chinese authorities shared the sequence of the virus, a rapid process critical to both tracking and researching the disease. Clinical trials for vaccines and treatments began that month.

"We are seeing in real time the benefits of the massive innovation movement that has happened in diagnostics, life science tools and in biopharma over the last decade," points out Jeffrey Stoll, Ph.D., principal at KPMG Strategy. "The pace by which the disease was characterized (both its genomics but also its proteome and related inflammatory markers) and then the pace for which a wide range of [clinical trials were started for] therapeutics (vaccines, anti-viral therapeutics and testing of existing commercial drugs) has never happened at this [rate] before….Just five years ago, it would have taken three to six-plus months to profile COVID. It took weeks this time."

The COVID-19 pipeline "literally started within just a couple months," he continues. "Several of these pipeline drugs are totally novel, new entities that didn't exist two months ago. Moderna and Takeda, for example, both have programs that are going from discovery to clinical trials in record time….The pace that our life science industries have moved to find different solutions (e.g., 45-minute diagnostics, 50+ drugs, multiple clinical trial launches)…is a notable moment in human history," Stoll maintains. "It wasn't done at this scale and pace ever before."

Robins agrees, noting that both pharma and medical device manufacturers "have mobilized incredibly quickly" in the fight against COVID-19, "from diagnostics to ventilator manufacture to virus management to the search for a vaccine, and the daily news and publicity around these initiatives is bound to have some positive effect. However, at this point, all of these efforts will have little unless the vaccines developed are widely available at what is seen as reasonable prices."

The tone of the discussion between the administration and the pharma industry "has softened dramatically during this pandemic."

The situation also has boosted the image of an industry that has been criticized from various sources. Back in January 2017, president-elect Donald Trump accused pharma of "getting away with murder," a charge he would make more than once. And the assertion certainly wasn't the only time he took shots at the industry. Many members of Congress and the public also have not shied away from disparagement of pharma.

Less than a year ago, the pharmaceutical industry ranked last among 25 industries that Gallup collects data on annually through its Work and Education poll. Between Aug. 1 and Aug. 19, 2019, researchers polled 1,525 people at least 18 years old living in the U.S. and the District of Columbia. Respondents gave the industry a net-positive score of -31 — unseating the federal government in the lowest ranking, which had a net rating of -27.

According to Gallup, "Americans' net ratings for the pharmaceutical industry have never been lower since Gallup first polled on industries in 2001. Over the past 19 years, few industries have been rated lower than the pharmaceutical industry's current -31 net rating."

The tone of the discussion between the administration and the pharma industry "has softened dramatically during this pandemic," says Saber, pointing to a March 2 White House meeting that Trump had with multiple drugmakers in which the president called the pharma attendees "geniuses" and praised their progress in the search for treatments and vaccines.

"At this point, pricing legislation is likely going to be delayed at least until Nov. 30," she says. "If COVID-19 declines by that point, the tone could possibly change. It may be more likely that states will be more vocal with pharmaceutical companies since their budgets may be straining significantly from the impact of COVID-19."

"Public attitudes will change — are changing right now — toward the pharmaceutical industry, pharmaceuticals and particularly for vaccines. Consider the many 'antivaxxers' throughout the country now likely joining the rest of us in begging for the fast development and deployment of an effective vaccine against COVID-19."

"As an important part of the overall health care system, manufacturers play a key role in ensuring positive patient care," contends Gourash. "Organizations have invested heavily in financial assistance, free-drug programs, educational training and creating overall product-access pathways. Manufacturers have improved communications channels to their distribution and services partners to ensure fast and accurate product messaging reaches all industry stakeholders."

Sullivan points out that "recent reports suggest that pharma's image has positively spiked recently based on their visible efforts to join the fight on the virus." He points to the Drug Channels website as providing one example of this data. That blog's author, Adam Fein, Ph.D., CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc., polled nearly 700 followers during the week of March 16 on how they expected the pandemic to impact various industry stakeholders. Asked how the pandemic will impact the reputation of various industry stakeholders, respondents cited pharmacies as the No. 1 entity whose reputation will be improved (62%), followed by hospitals (59%) and pharma manufacturers (48%).

"All policymakers should take time and think about epidemic trends, our desire to find cures for cancers etc., and then think about why the pharmaceutical industry has been a real bright spot for the entire world during this time. We are seeing the benefit of having a well-capitalized, highly innovative pharmaceutical industry."

According to Rubinstein, "public attitudes will change — are changing right now — toward the pharmaceutical industry, pharmaceuticals and particularly for vaccines. Consider the many 'antivaxxers' throughout the country now likely joining the rest of us in begging for the fast development and deployment of an effective vaccine against COVID-19. Now development of an effective vaccine is a public health emergency, with all hands on deck in the effort, including organizations not normally involved in such things. And in the short run, manufacturers such as Gilead [Sciences, Inc., whose remdesivir is showing early potential as a treatment] are viewed as saving lives by making their experimental drugs available on an emergency basis. Finally, while Mr. Trump has repeatedly touted unproven drug therapies for COVID-19, the public message from this — despite Trump's irresponsible behavior — is that pharmaceuticals — and the researchers that discover them, the manufacturers that produce them, the distributors, the pharmacies, the entire chain of organizations and people needed to ensure that patients gets needed drugs — are essential to saving lives threatened by this virus."

"All policymakers should take time and think about epidemic trends, our desire to find cures for cancers etc., and then think about why the pharmaceutical industry has been a real bright spot for the entire world during this time," states Stoll. "We are seeing the benefit of having a well-capitalized, highly innovative pharmaceutical industry. The companies leading the charge on finding vaccines and therapeutic solutions are almost entirely coming from our highly innovative biotech companies (e.g., Gilead, Vir, Regeneron, etc.) or from our big pharma companies (e.g., Roche, Takeda, etc.).

"While drug pricing has been a hot issue for the past decade, it should not be lost on the world, and in particular U.S. policymakers, that it is not our generic manufacturers leading the way here," he continues. "The leading companies all either are U.S. companies or are global pharma companies who make the majority of their revenue and profitability (often 60% to 80%) from the U.S. market. The ability of these companies to turn on a dime and focus on COVID-19 is directly attributable to their financial health and ability to maintain world-class R&D operations. Pharma literally innovates to extend and save lives — most industries aren't so existentially tied to our survival."

"To win hearts and minds, pharma needs to continue to show the world that having healthy balance sheets, well-resourced development programs and well-paid world-class scientists and leaders protects all of society and not just investors. I hope we never get a better chance to prove it."

He tells AIS Health that "if governments logically thought through what industries drive the greatest benefit to society and, therefore, who they should want to keep well capitalized vs. those that can be more commoditized, innovative pharma really would be at the front of that list." He points to a 2018 report from the World Health Organization "that basically summarized how epidemics are now coming more frequently, spreading faster and more broadly than at any time in modern human history. This means COVID-19 is just one more example of the new normal we've entered."

Pharma companies need to strike a balance to meet this growing trend with the fact that "everyone still wants cures for diseases like cancer and Alzheimer's disease," says Stoll. "In this light, show me the last regional Canadian, EU or Japanese (first-world biopharma industries like the U.S.) that produced a highly innovative drug that had a meaningful impact or cure. The trend line would show it's either global companies that benefit from the U.S. or U.S. biotech that is driving 90% of this, and the rate of return from more regional biotechs has been diminishing over the last 15 years as Canada, EU and Japan clamped down on drug pricing. Everyone should look at the data and have a real discussion on what industries should be championed and what industries aren't helping but continue to earn government support so there is a better prioritization of how various government benefits are prioritized."

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Says Robins, "to win hearts and minds, pharma needs to continue to show the world that having healthy balance sheets, well-resourced development programs and well-paid world-class scientists and leaders protects all of society and not just investors.

"I hope we never get a better chance to prove it."

Read Fein's article at https://bit.ly/3a5hJy9. Contact DeLone through Ellen Conti at elconti@deloitte.com, Gourash at rgourash@bioplusrx.com, Rubinstein at elan.b.rubinstein@gmail.com, Saber at junko.saber@innopiphany.com, Stoll via Bill Borden at wborden@kpmg.com and Sullivan at wsullivan@specialtyrxsolutions.com. ✧

by Angela Maas

Reality Check: **Type 2 Diabetes (GLP-1 and Combo)**

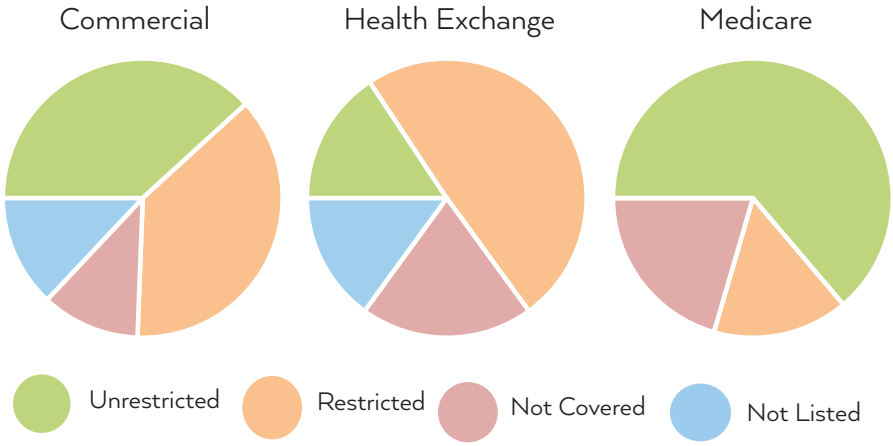
Our Point of View

Initial therapy for type 2 diabetes usually begins with metformin, says Jeffrey Casberg, R.Ph., director of clinical pharmacy at IPD Analytics. Other agents often are added on to help patients reach their A1c goal. Frequently used add-on products include dipeptidyl peptidase-4 (DPP-4) inhibitors such as Januvia (sitagliptin) from Merck & Co., Inc. and sodium-glucose co-transporter 2 (SGLT2) inhibitors such as Jardiance (empagliflozin) from Boehringer Ingelheim/Eli Lilly and Co. and Farxiga (dapagliflozin) from AstraZeneca plc. If patients' disease is more severe or they're not getting to their A1c goal with those classes, at that point primary care providers might refer patients to endocrinologists for treatment with insulin or a glucagon-like peptide-1 receptor agonist (GLP-1).

Coverage

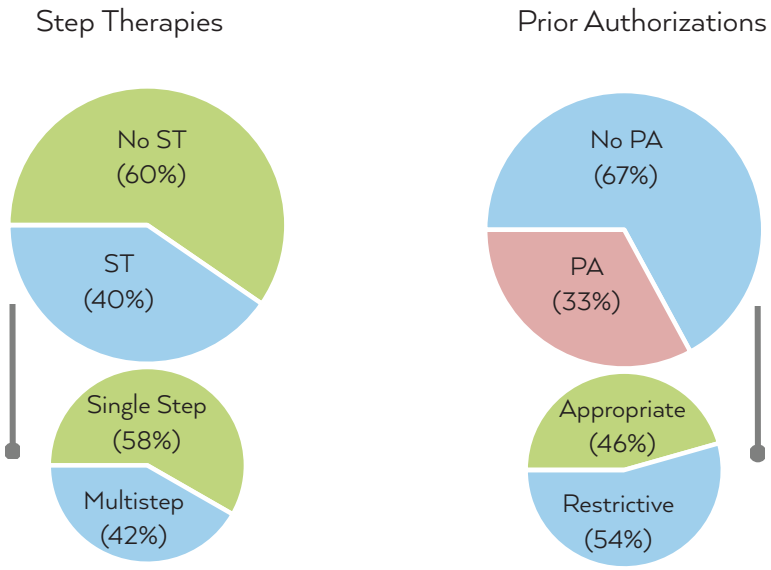
Pharmacy Benefit

Under the pharmacy benefit, almost 37% of the lives under commercial formularies are covered with utilization management restrictions. Around 21% of the lives under Medicare Part D formularies are not covered for at least one of the drugs.



Payers

For about 60% of the covered lives, payer pharmacy benefit formularies do not require step therapy (ST). Of the lives that require ST, 42% require multiple steps. Around 33% of payer-controlled pharmacy benefit covered lives require prior authorization, with 54% of those lives covered by policies that are restrictive as compared with a product's FDA-approved label.



DATA CURRENT AS OF Q1 2020

Reality Check: **Type 2 Diabetes (GLP-1 and Combo)**

AIS Health's View

According to Casberg, payers haven't put many restrictions on GLP-1s "because utilization hasn't blown up." The class recently welcomed the first oral therapy following the FDA's approval of Novo Nordisk's Rybelsus (semaglutide) in 2019. Rybelsus lists for $9,264 annually before rebates and discounts, which puts it in line with the other GLP-1s. But, notes Casberg, "the DPP-4s and SGLT2s are significantly less expensive," with annual list prices in the $6,000 range for Januvia and Jardiance. "When you get to the injectable GLP-1s, you're talking a $10,000 list price, so there's a significant price differential. You would think managed care would have put some type of management barriers in front of these GLP-1 products, but they haven't," he says. That's because specialist-driven utilization of the injectables has created what he calls an "artificial barrier" to broader use. The introduction of oral Rybelsus potentially could significantly shift utilization to GLP-1s, which "could really break the bank for these payers," Casberg tells AIS Health.

Trends From AIS Health

Express Scripts Coverage, FDA Label Update Boost Rybelsus


RADAR on Drug Benefits

May 25, 2018

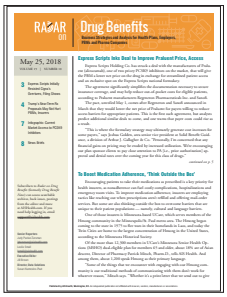
Express Scripts Inks Deal to Improve Prolonot Price, Access

To Boost Medication Adherence, 'Think Outside the Box'

Access to Novo Nordisk's Rybelsus (semaglutide) — the first oral glucagon-like peptide-1 receptor agonist (GLP-1) to treat adults with type 2 diabetes — got a major boost Jan. 17 when Novo said Express Scripts, part of Cigna Corp., will cover the agent. Rybelsus was approved in September 2019 and is available as a once-daily tablet version of the drugmaker's Ozempic (semaglutide), a weekly injection launched in 2018.

Subscribers to AIS's *RADAR on Drug Benefits* may read the in-depth article online

Payers Test Ways to Control Diabetes Cost


RADAR on Drug Benefits

May 25, 2018

Express Scripts Inks Deal to Improve Prolonot Price, Access

To Boost Medication Adherence, 'Think Outside the Box'

With the cost of diabetes drugs still growing, PBMs and payers are looking for more innovative strategies to hold down costs. For some, that might include a strategy similar to the one unveiled by CVS Health Corp.'s Caremark unit in 2020. The plan, called RxZERO, offers a slimmer formulary for the diabetes drug class, but with no out-of-pocket costs for members.

Subscribers to AIS's *RADAR on Drug Benefits* may read the in-depth article online

Blues Plans Focus on High-Tech Glucose Control


Health Plan Weekly

May 7, 2018

Amid Solid 1Q Results, Insurers Talk Up Deals, Partnerships

Genetics, Adherence Programs Can Ease Hypertension Costs

In May 2019, Blue Cross and Blue Shield of Minnesota signed a value-based agreement with device maker Medtronic plc that provides Blues plan members improved access to Medtronic's smart continuous glucose monitoring system. Blue Cross Blue Shield of Michigan also partnered with Mountain View, Calif.-based Livongo to offer personalized data and insights to members with type 2 diabetes using smart glucose monitors.

Subscribers to AIS's *Health Plan Weekly* may read the in-depth article online

Reality Check: **Type 2 Diabetes (GLP-1 and Combo)**

Key Findings

Competitive Market Landscape

Novo Nordisk versus Eli Lilly and Co. is the heavyweight fight in the GLP1 class, with most payers covering Lilly's Trulicity and Novo's Victoza and Ozempic, a next-generation weekly injection. An oral version of Ozempic, Rybelsus, launched in late 2019, making it the first oral GLP-1 on the market. Victoza likely will face generic competition in 2023. Other drugs in the pipeline include Intarcia's ITCA 650 and Hanmi/Sanofi's SAR439977. Most manufacturers promote on the lowest copay tier and provide cards for support. The majority of payers have preference for a franchise, and some payers exclude coverage for competitors.

Pharmacy Benefit Implications

Coverage for the drugs is via the pharmacy benefit. This is a heavily contracted class; costs are high, but so are rebates. Step-therapy restrictions are common, either alone or as part of prior authorization. Payers often require a step through a preferred GLP-1 for nonpreferred agents. For the combination products, policies can require a step through a GLP-1 analog or a long-acting insulin, while others require trial and failure of both.

Characteristics

Indications

Type 2 Diabetes (GLP-1 and Combo)

Step-Therapy (ST) Policies

Payer pharmacy benefit formularies require ST for roughly 40% of covered lives. Of those, 42% require multiple steps.

Prior-Authorization (PA) Policies

Roughly 33% of payer-controlled pharmacy benefit covered lives require PA, with 54% of those lives covered by policies that are restrictive as compared with a product's FDA-approved label.

DATA CURRENT AS OF Q1 2020

AIS Health's View

Casberg sees three potential approaches payers could take to manage GLP-1s. The first would be to "leave management the way it is, not putting any hurdles or step therapies in front of oral semaglutide and letting providers decide what they'll use." That would open the door to more use of oral semaglutide by primary care providers. Or, he says, payers could require a step through a preferred injectable GLP-1 to access Rybelsus. A more aggressive approach would be to require a routine step through SGLT2s or DPP-4s to access GLP-1s, which clinicians on a November 2019 Institute for Clinical and Economic Review panel said lacked clinical nuance, says Casberg, who represented the payer community on the panel. Concurrent therapy with an SGLT and GLP-1 is common, they noted.

About AIS Health

The mission of AIS Health — a publishing and information company that has served the health care industry for more than 30 years — is to provide readers with an actionable understanding of the business of health care and pharmaceuticals. AIS Health's in-depth writing covers the companies, people, catalysts and trends that create the richly textured contours of the health care and drug industry.

AIS Health, which maintains journalistic independence from its parent company, MMIT, is committed to integrity in reporting and bringing transparency to health industry data.

Learn more at https://AISHealth.com and https://AISHealthData.com.

About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today's rapidly changing healthcare market.

Our team of experts focuses on pharmaceuticals, business drivers, market intelligence and promotional behavior. Our products and services support brands approaching launch, commercialization efforts, pre-P&T market planning, launch strategy and readiness. We partner with hundreds of payers and manufacturers ensuring that our products continually capture and analyze formulary coverage and restriction criteria for more than 98% of all covered lives.

Learn more at https://www.mmitnetwork.com.