MDs Protest New BCBST 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.

continued on p. 10

CVS Health Offers Genomic Testing for More Precise Care

Targeted therapies have made tremendous progress in oncology, with some products essentially rendering some cancers chronic conditions. According to the National Cancer Institute, the FDA has approved hundreds of targeted therapies across 30 types of cancers. Genomic testing can help determine whether a patient is a candidate for a particular therapy, and CVS Health has launched a program focused on boosting patient access to this.

In 2018, CMS finalized a national coverage determination (NCD) for diagnostic laboratory tests that use next-generation sequencing (NGS) for patients with advanced cancer in order to gain a comprehensive genomic profile. The NCD said that CMS will cover NGS in vitro diagnostic (IVD) tests for Medicare beneficiaries with advanced cancer who have not been tested with the same NGS technology. It also said CMS will cover FDA-approved or cleared companion IVDs “when the test has an FDA-approved or cleared indication for use in that patient’s cancer and results are provided to the treating physician for management of the patient using a report template to specify treatment options.”

But while payers often wait to see how CMS-led initiatives work out before eventually implementing the same policy, that hasn’t necessarily been the case with
With an eye on offering broad access to this testing, CVS Health recently unveiled its Transform Oncology Care program, which the PBM is offering via a collaborative with precision medicine-focused technology company Tempus. The program uses the testing results at the point of prescribing so patients are started on the treatment appropriate for them in a timely fashion. It also matches patients to clinical trials for which they are eligible. AIS Health recently spoke with Prem Shah, Pharm.D., executive vice president of specialty and product innovation for CVS Health, to learn more about the program.

**AIS Health: When did this program start?**

**Shah:** We announced the program on Dec. 12, 2019. The precision medicine strategy is now available to all health plans, regardless of whether the payer is a current CVS Health PBM client. In addition, Aetna has adopted the new precision medicine component of Transform Oncology Care for fully insured commercial populations and is rolling it out to participating Aetna provider networks in certain states.

**AIS Health: What was the motivation behind this program?**

**Shah:** Cancer care and management are challenging and expensive in today’s marketplace. In fact, it’s one of the top concerns we hear from health plans and our payer clients. We anticipate that these concerns will only grow as data shows that cancer costs are expected to rise to nearly $207 billion by the end of next year.

It is important to also understand that these high costs are exacerbated by the rapidly changing standards of cancer care, which can make it challenging for providers and patients alike to keep pace. For example, there were more than 700 updates made to the National Comprehensive Cancer Network, or NCCN, treatment and supportive care guidelines last year alone. As a result, only 15% of community oncologists regularly use clinical cancer pathways.

Further, there is a lack of patient access to advanced genetic testing. And, even when advanced testing is administered, patients often receive the less comprehensive single gene mutation test, which does not provide a patient’s complete genetic profile. Altogether, this can inhibit the start of the most appropriate treatment and result in poor outcomes and higher costs.

This first-of-its-kind precision medicine strategy, delivered in close coordination with oncologists, helps to solve these significant challenges in oncology management today. Transform Oncology Care uses genomic testing results at the point of prescribing to help patients start on the best treatment, faster and, in addition, matches eligible patients to clinical trials. The program also uses the company’s local footprint and unique assets to improve patient outcomes and lower overall costs at every point of the cancer care journey.

**AIS Health: Exactly what kind of genomic testing is done? Is this a full panel, or is it specific to the type of cancer someone is diagnosed with?**

**Shah:** Through a web-based provider portal built into their e-prescribing workflow, oncologists are prompted to order broad panel gene sequencing tests for patients with certain advanced stage cancers. Results of these sequencing tests then provide the oncologist with a more complete view of the tumor’s genetic profile in order to recommend the best treatment regimen for the patient.

**AIS Health: What kind of prior authorization is required for testing?**
Shah: We aim to have insurers cover these tests when clinically appropriate for patients, as our strategy can help offset those costs over time through more efficient cancer care spending.

AIS Health: When will testing be covered? Is it only for late-stage cancers? If so, do you consider those stage III or IV? When will testing not be covered?

Shah: As our program is just rolling out, we now have included 11 cancers, including non-squamous cell lung, breast, colon, pancreatic, ovarian, esophageal, esophagogastric, gastric, prostate and kidney in stages III or IV and at diagnosis for chronic lymphocytic leukemia and chronic myeloid leukemia. We anticipate that we will expand to other cancers in the future.

Often, many cancers diagnosed in early stages can be treated with very effective medications, regimens or surgeries that do not require advanced molecular testing, which is why we are only including certain cancer types (and in late stages) in our program.

AIS Health: How did you select Tempus as your partner?

Shah: Tempus is a technology company that is making precision medicine a reality by gathering and analyzing clinical and molecular data at scale. They are CVS Health’s vendor for both the genomic sequence testing and clinical trial management service for the oncology practices.

CVS conducted a rigorous review of genetic testing vendors in a number of critical areas, including innovation, customer service, cost, test turnaround time and clinical trial matching. Based upon that review, we determined that Tempus would be the best choice.

AIS Health: Could you please provide a breakdown of how the program works? I assume it starts with a cancer diagnosis — is that true? What happens next? And what is the time frame for the process?

Shah: The Transform Oncology Care program pulls together CVS Health’s enterprise capabilities to help address significant challenges at every point of the cancer care journey.

First, a web-based provider portal, built into the e-prescribing workflow, provides oncologists with real-time access to the latest NCCN guidelines at the point of prescribing, as these guidelines apply to 97% of cancers affecting patients.

For patients diagnosed with certain advanced stage cancers, the same provider portal informs oncologists about available broad-panel gene sequencing tests of the specific cancer at patient diagnosis, which are more comprehensive than the single-gene tests used regularly today.

The broad-panel tests identify the cancer’s specific genomic variants and can help the oncologist select appropriate treatment options specific to the tumor’s molecular and clinical profile. The testing results also match and help support the rapid enrollment of eligible patients in local clinical trials, facilitating broader access to experimental therapies.

Therapeutic regimens that align to NCCN guidelines, including those matched with the results of the broad-panel gene sequencing tests, will automatically receive prior-authorization approval, avoiding the need for additional approvals and speeding time to start of the therapy for patients.

AIS Health: The press release mentions value-based contracts. Could you talk about these — will CVS play a role? Are these between payers and providers or payers and manufacturers?

Shah: As part of the Transform Oncology Care solution, payers can also adopt value-based contracts that use provider networks to drive high-quality care and lower costs. Ultimately, the approach helps ensure better treatment for the patient by encouraging the physician to prescribe treatments aligned to the NCCN guidelines, choose high quality and lowest cost sites of care and recommend available care management programs to patients.

For example, participating network providers are reimbursed for quality and cost of care based on the NCCN standards and set in partnership with leading government organizations and clinical associations, including CMS, the American Society of Clinical Oncology and America’s Health Insurance Plans.

AIS Health: Is Aetna the only health plan that has adopted the program so far?

Shah: Aetna is the first health plan who has adopted our precision medicine strategy, but this is available to all health plans, and we are working to onboard additional payers.

AIS Health: Is there anything I’ve neglected to ask that you’d like to add?

Shah: CVS Health is working hard to make the latest in precision medicine accessible to more patients and further empower informed treatment decision making based on a patient’s individual cancer’s genetic profile to give them the best chance for successful treatment and improved quality of life. We plan to expand the scope of products and services as part of Transform Oncology Care in ways that help to better serve all customers,
including patients and payers. This includes supplementary programs that could bring important screening services to at-risk populations and additional innovative medical benefit medication management strategies, while also helping better drive quality oncology care through value-based programs.

Contact Shah through Christina Beckerman at Christina.Beckerman@cvshealth.com.

As ‘Deemed’ Transition Looms, Teva Makes Case for Copaxone

As the Affordable Care Act approaches the 10-year anniversary of its being signed into law, one aspect of the ACA is poised to finally take effect this month. When the Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the ACA, Congress left much of the details up to the FDA to determine. In addition to creating the 351(k) biosimilar approval pathway, Congress via the BPCIA intended to bring all biologics together under the same law, which it planned to do through the “deemed to be a license” provision.

While most biologics are licensed under the Public Health Service (PHS) Act and approved through a biologics license application (BLA), some protein products have gained FDA approval under the Federal Food, Drug, and Cosmetic (FD&C) Act through a new drug application (NDA). The BPCIA did two things to impact this: First, it modified the definition of a "biological product" to include a "protein (except any chemically synthesized polypeptide)." But the FDA later removed the "(except any chemically synthesized polypeptide)" language. The final rule (85 Fed. Reg. 10057, Feb. 21, 2020) confirms this, as well as changes in the Further Consolidated Appropriations Act, 2020 (FCA Act), defining a "protein" as "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size." In addition, the FDA interprets "chemically synthesized polypeptide" to mean any alpha amino acid polymer that is made entirely by chemical synthesis and is greater than 40 amino acids but less than 100 amino acids in size." Formalizing the definition through the final rule "will reduce regulatory uncertainty over whether certain products are regulated as drugs or biological products." This, in turn, says the rule, "will allow both FDA and private industry to avoid spending time and resources on case-by-case determinations for each product."

The final rule specifically clarifies that insulin falls under this definition of "protein." In a statement accompanying the rule, FDA Commissioner Stephen M. Hahn, M.D., noted that while insulin products are biologics, they have faced limited competition, "resulting in fewer choices and higher prices for patients. This transition will open new pathways for manufacturers to bring biosimilar and interchangeable versions of insulin and other transitioning products to market, facilitating greater competition in the marketplace. These critical therapies often carry a heavy price tag; the cost of insulin has risen over the past decade. Opening these products to increased competition is expected to bring down prices and help patients have access to more choices for these life-saving drugs. We will continue to communicate relevant information, including the resources we’ve issued today, to make the transition from one statutory framework to another as seamless as possible."

A Dec. 31, 2019, FDA list of shifting drugs reflects the updated definition. With 100 products included, the list added four products to the previous list:

✦ Ferring Pharmaceuticals Inc.’s Actrel (corticorelin ovine triflutate);
✦ Pfizer, Inc.’s Elase-chloromycetin (fibrinolysin and desoxyribonuclease combined [bovine], with chloramphenicol);
✦ Adlyxin (lixisenatide) from Sanofi; and
✦ Tesamorelin acetate from Theratechnologies Inc.

Multiple somatropin growth hormones, as well as Genzyme Corp.’s Cerezyme (imiglucerase), are among the products set to make the March 23 transition. Missing from the list of transitioning drugs, however, is Teva Pharma-
Teva: Copaxone Is Biological Product

In a letter submitted to the FDA on Feb. 19, Teva argues that Copaxone “falls squarely within the statutory definition of ‘biological product,’ and its approved New Drug Application (‘NDA’) for Copaxone should therefore be deemed to be a license under section 351 of the Public Health Service Act.”

Teva argues that Copaxone meets the 40-amino-acid benchmark. In addition, because Copaxone is a chemically synthesized polypeptide, contends Teva, the language excluding such products from the definition of a biologic means that Copaxone is a protein and biological product and, thus, should be transitioned over.

**Teva: Copaxone Is Biological Product**

The company “acknowledges that the FDA has previously stated, in another context (relating to generic ANDA approval, not biological product regulation), that glatiramer acetate is distinguishable from proteins because ‘it does not … have a defined and specific sequence.’ But since that time, the FDA has characterized other products with undefined and unspecified overall amino acid sequences as ‘proteins’ within the scope of section 351. Now that the FDA is considering whether COPAXONE fits the current definition of ‘biological product,’ it should conclude that the answer is yes.”

The company points to two drugs that will transition — Bausch + Lomb Inc.’s Vitrase (hyaluronidase for injection) and AbbVie Inc.’s Creon (pancrelipase) — as similar to Copaxone’s situation.

An industry expert who declines to be identified says the Teva letter should be considered in the context of the company’s nine citizen petitions arguing that the FDA should not approve any abbreviated NDAs (ANDAs) for generic versions of Copaxone (RSP 7/14, p. 11). The agency has denied the requests.

**FDA Has Approved Copaxone generics**

In the meantime, the FDA has approved ANDAs of glatiramer acetate from multiple companies, including Mylan Pharmaceuticals Inc. and Novartis AG unit Sandoz Inc. (RSP 10/17, p. 7).

In addition, the source points to the status change of synthetic peptides: “I would have argued that they did not fit the less than 100 amino acid definition of a peptide that FDA had created, but with the ‘except for synthetic peptide’ removed entirely by FDA from the definition of a biologic, then FDA’s leaving them as drugs is on its face quite reasonable.”

The source tells AIS Health that “I would have had more of an argument with FDA over enoxaparin, as you cannot get much more biologics a source than Chinese pig guts. But again they are sugars” (RSP 4/16, p. 4).

“More to the point, I suspect FDA made every effort that they could to ensure that none of the rollovers already had a therapeutic equivalence designation — and in both these cases there are already approved and marketed ANDAs,” the source continues.

“That would make for a problem for FDA were they to become BLAs, as none of the studies expected for an interchangeability designation would have been done. So Teva’s perspective is likely that to be rolled over would reduce competition. As we know that already seems likely for the insulins.”


**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 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 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

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

<table>
<thead>
<tr>
<th>CURRENT/ANTICIPATED OFFICE-ADMINISTERED NON-ONCOLOGY THERAPY PER DISTRIBUTION CHANNEL</th>
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<tbody>
<tr>
<td><strong>Q3 2019</strong></td>
</tr>
<tr>
<td>Specialty pharmacy: <strong>56%</strong></td>
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<tr>
<td>Buy-and-bill: <strong>33%</strong></td>
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<tr>
<td>Patient acquisition (brown bagging): <strong>11%</strong></td>
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<tr>
<td><strong>Q3 2020</strong></td>
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<tr>
<td>Specialty pharmacy: <strong>62%</strong></td>
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<tr>
<td>Buy-and-bill: <strong>28%</strong></td>
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<tr>
<td>Patient acquisition (brown bagging): <strong>10%</strong></td>
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Similar data for Medicare book of business

*Anticipated

Respondents belong to sample 2

Surveys collected 9/3/2019-10/7/2019

Contact sales@aishealth.com if you’d like to review our rates for group subscriptions.
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 “eliminates 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

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**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 that 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?”**

“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.
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.”

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

New FDA Specialty Approvals

✦ Feb. 10: The FDA granted final approval to Eagle Pharmaceuticals, Inc.’s Pemfexy (pemetrexed) for the treatment of people with locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy; and malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin. The drug, to which the FDA granted tentative approval in 2017, is a branded alternative to Eli Lilly and Company’s Alimta (pemetrexed). The two drugmakers reached a settlement in patent litigation on Dec. 13, 2019, that will allow Pemfexy to launch with a three-week supply on Feb. 1, 2022, then an uncapped entry on April 1, 2022. Dosing for the intravenous injection depends on the indication. For more information, visit https://bit.ly/2vkZBSi.

✦ Feb. 18: The FDA approved a new dosage form for Procysbi (cysteamine bitartrate) for the treatment of people at least one year old with nephropathic cystinosis. The Horizon Pharma plc drug is now available in delayed-release oral granules, as well as capsules. The granules, also known as microbeads, will be available in packets of 75 mg and 300 mg strengths in the first half of 2020. The agency initially approved the capsule in 1994. Dosing is weight-based. Website Drugs.com lists the price of 250 75 mg delayed-release capsules as $26,454. Visit www.procysbi.com.

✦ Feb. 26: The FDA expanded the label of Nerlynx (neratinib) in com-
sole vendor (RSP 5/06, p. 1). 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 (RSP 8/08, p. 1). CMS indefinitely postponed the program in 2008 (RSP 10/08, p. 1; 12/08, p. 1). Many of the challenges facing CAP, he tells AIS Health, may be similar to those with white bagging (see box, p. 7).

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.

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.”

“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

New FDA Specialty Approvals (continued)

bination with capecitabine for the treatment of adults with advanced or metastatic human epidermal growth factor receptor 2-positive breast cancer who have received at least two anti-HER2-based regimens in the metastatic setting. The agency initially approved the Puma Biotechnology, Inc. kinase inhibitor in July 2017 (RSP 7/17, p. 8). Dosing for the newest use is 240 mg via six tablets once daily on days one through 21 of a 21-day cycle and capecitabine 750 mg/m² twice daily on days one through 14 of a 21-day cycle until disease progression or unacceptable toxicities. Drugs.com lists the price of 180 Nerlynx tablets as $14,440. For more information, visit https://nerlynx.com.

✦ March 2: The FDA approved Sanoﬁ’s Sarclisa (isatuximab-irfc) in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed refractory multiple myeloma who have received at least two therapies including lenalidomide and a proteasome inhibitor. The agency gave the CD38-directed cytolytic antibody orphan drug designation. The recommended dose is 10 mg/kg as an intravenous infusion every week for four weeks and then every two weeks in combination with pomalidomide and dexamethasone until disease progression or unacceptable toxicity. Dosing for Sarclisa starts in the first cycle with a 200-minute infusion, which can be reduced to 75 minutes starting with the third cycle. The drug’s wholesale acquisition cost is $650 per 100 mg vial and $3,250 per 500 mg vial. According to Sanoﬁ, for a typical patient weighing 154 to 176 pounds, these prices correlate to $5,200 per infusion. The company says the drug “is expected to be available to patients in the U.S. shortly.” For more information, visit https://bit.ly/2PFt5RQ.
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?”

“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 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@cronline.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.

**BCBST Implements New Policy continued from p. 1**

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 Opt-In 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, says the plan already is receiving claims via the specialty pharmacy network.”

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Plan the 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.”

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.”

The letter maintains that while provider margins would decline, office’s 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. 5).

Letter Suggests Possible Treatment Delay

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.”

Consultant Questions Claims

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.

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.

BCBST Offered Provider Education

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."


Contact Chaney at Dave.Chaney@tnmed.org. Sullivan at wsullivan@specialtyrxsolutions.com and Wilson via John_Hawbaker@BCBST.com.

**News Briefs**

- **Walgreen Co. and Kroger Co. can continue to pursue a lawsuit (No. 19-1730) over Remicade (infliximab) against Janssen Biotech Inc. and its parent company, Johnson & Johnson, according to a decision by the U.S. Court of Appeals. The lawsuit claims that Janssen “used its size and bargaining power in the broader pharmaceutical market to enter into exclusive contracts and anticompetitive bundling agreements with health insurers that suppressed generic competition to Remicade, which in turn allowed Janssen to sell Remicade at supracompetitive prices.” The decision overturns a ruling by the U.S. District Court for the Eastern District of Pennsylvania (D.C. No. 2-18-cv-02357), which ruled in Janssen's favor in March 2019. View the decision at https://bit.ly/2Tx21pa.

- **The U.S. Preventive Services Task Force (USPSTF) gave a B grade to screening for hepatitis C infection in people between the ages of 18 and 79. The Affordable Care Act mandates that private insurers cover preventive services with a USPSTF grade of A or B. View the recommendation at https://bit.ly/38kJMxx.

- **PerformRx LLC and Geisinger Health Plan unveiled a multiyear agreement “to support better health outcomes, improve pharmacy experiences and lower costs for GHP members.” The arrangement is effective Jan. 1, 2021. Contact Scott Bluebond at mediarelations@performrx.com.

- **BrightSpring Health Services acquired Advanced Home Care’s (AHC) home health and specialty infusion units. AHC’s home health segment will join BrightSpring’s Adoration Home Health and Hospice businesses and operate as Advanced Home Health, and its specialty infusion segment will join PharMerica's Amerita division and operate under the name Advanced Home Infusion. Contact Lizzet Verdi at Lizzet.Verdi@brightspringhealth.com.

- **PEOPLE ON THE MOVE: Cigna Corp. promoted Dave Queller to president of Express Scripts. He previously led sales and account management at the PBM. Cigna also promoted Brian Seiz, Pharm.D., to president of pharmacy. Prior to that, he was president of Accredo. CVS Health named Alan Lotvin, M.D., president of CVS Caremark. He previously was executive vice president of CVS Health. He replaces CVS Caremark Executive Vice President and President Derica Rice. CVS Health also appointed Jonathan Maybey executive vice president, transformation. Most recently he was senior vice president for Aetna Markets. The Healthcare Distribution Alliance named Chester “Chip” Davis, Jr., J.D., president and CEO. He previously was president and CEO of the Association for Accessible Medicines. Walgreens Boots Alliance, Inc. named Richard Ashworth, Pharm.D., president of Walgreens. He previously was president of operations for Walgreens.