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SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Specialty Products

Contents

Bill May Help Home Infusion Payment Gap, Allowing Beneficiaries to Continue Care

Almost eight months after a provision in the 21st Century Cures Act took effect, many home infusion providers are finding themselves under water, while some are not taking on new Medicare Part B patients. But a recently introduced bill, which has bipartisan support, could help plug a reimbursement gap that's causing issues within the industry. Without it, it's hard to say how much longer these providers can continue to support patients, who likely would be transitioned to receiving care elsewhere — assuming they continue to get care.

The Medicare Modernization Act established an average sales price (ASP)-based methodology for most Part B drugs. However, it excluded Part B infusible drugs furnished through durable medical equipment (DME) — such as chemotherapy administered with an infusion pump — from shifting to ASP, instead basing these therapies' reimbursement on October 2003 average wholesale prices (AWPs). The law went into effect Jan. 1, 2005 *(SPN 10/04, p. 7)*, and reimbursement for these therapies is still based on those same AWPs.

But Sec. 5004 of the Cures Act, titled "Reducing Overpayments of Infusion Drugs," changed the reimbursement methodology for Part B infusible drugs furnished through DME to ASP *(SPN 1/17, p. 1)*. So rather than being reimbursed at AWP -5%, these drugs will be paid at the ASP +6% rate used for most Part B drugs, which will lower the reimbursement for some drugs but increase it for others.

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CMS Proposes Slashing Medicare 340B Reimbursement, Prompting Outcry, Praise

Following years of scrutiny over whether the 340B Drug Pricing Program truly is functioning as it should be, CMS has proposed a dramatic change for the discount pricing program. The Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1678-P) is proposing that CMS pay hospitals a much lower rate for drugs they purchase under the 340B program. Some in the health care industry are hailing the decision, saying it will help curtail the rising prices of drugs, but others are warning that if enacted, the proposal could harm the very patients the program is designed to help.

The payment rate for hospitals now is average sales price +6%, regardless of whether the hospital purchased a drug at the discounted 340B rate. CMS is proposing that rate be reduced to ASP -22.5% "for nonpass-through separately payable drugs purchased under the 340B program." In addition, says the OPPS proposed rule, "we state our intent to establish a modifier to identify whether a drug billed under the OPPS was purchased under the 340B Drug Discount Program."

The 22.5% was based on a May 2015 Medicare Payment Advisory Commission (MedPAC) report that estimated hospitals in the program were getting a minimum

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discount of 22.5% of the ASP for drugs paid under the OPPS. A March 2016 MedPAC report pointed out that the HHS Office of Inspector General "estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs."

The 340B program has long been under fire from various sectors that are questioning oversight of the program and whether it is fulfilling its purpose, particularly since the Affordable Care Act expanded the types of facilities that could participate in the program *(SPN 6/13, p. 9)*.

The program was started as a way to help hospitals that serve a disproportionate number of low-income patients. Entities participating in the program can purchase most outpatient drugs from manufacturers at a discounted rate — sometimes as much as half off — and can treat all patients, both insured and uninsured, with those cheaper drugs but still be reimbursed by Medicare and other payers at higher rates. Because it's up to the covered entities to determine exactly to whom they sell the discounted drugs, this has led to criticism from manufacturers and members of Congress.

In recent years, 340B pricing has grown in profile on health plans' radar screens as more hospitals purchase smaller physician offices and as providers shift patients to outpatient hospital facilities, where care often costs twice as much as the same service provided in a community practice.

And it's not only plans that are concerned with the 340B program. Manufacturers must sell their drugs at deeply discounted rates, which can make a huge difference when it comes to expensive specialty drugs.

But hospitals participating in 340B maintain they serve larger populations of low-income, uninsured and underinsured people than do other hospitals and the lower costs help them make up any financial losses.

Various Studies Have Examined Impact

The proposed rule refers to various studies on the program that "highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost." One of them was a June 2015 report from the Government Accountability Office that recommended modifying the program so providers weren't incentivized to prescribe more or more expensive drugs to Part B beneficiaries treated at 340B hospitals *(SPN 7/15, p. 7)*.

Researchers looked at data from 2008 and 2012 from HHS's Health Resources and Services Administration, which oversees the 340B program, and focused on disproportionate share hospitals because they account for almost 80% of all 340B drug purchases. In both 2008 and 2012, Part B per-beneficiary spending, including on oncology drugs, "was substantially higher" at 340B hospitals than at those not participating in the program due to beneficiaries at 340B hospitals being "either prescribed more drugs or more expensive drugs than beneficiaries" treated at non-340B hospitals. So if the 340B hospitals were getting the drugs for less but getting reimbursed for them the same as non-340B hospitals, that could prompt 340B hospitals "to maximize the revenue generated by the difference between the cost of the drug and Medicare's reimbursement."

The report pointed out that "the differences we found did not appear to be explained by the hospital or patient population characteristics we examined." And while all the hospitals analyzed treated more people with cancer in 2012 than they did in 2008, beneficiaries at the 340B hospitals had the highest average spending on Part B oncology drugs.

In the proposed rule, CMS notes that "Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG

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found that, for 35 drugs, the 'difference between the Part B amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone…was greater than the amount a covered entity spent to acquire the drug.'"

According to the proposed OPPS, the changes "would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to share in some of the savings realized by hospitals participating in the 340B program."

In a press release on the proposed rule, CMS Administrator Seema Verma said, "CMS is committed to transforming the Medicare program and updating our policies to provide high-quality and affordable patient-centered care. These changes require innovative strategies, and we look forward to receiving stakeholder comment and incorporating new ideas in our final rule this fall. Additionally, the proposed rule takes a critical step towards fulfilling President Trump's promise to lower the cost of drugs, particularly for Medicare beneficiaries."

Report: Site-of-Care Costs Differ

Multiple studies have examined the growing trends of community oncology clinics closing down, as well as being acquired by hospitals, which some have tied to the 340B program. A report commissioned by the Community Oncology Alliance (COA) and released in April 2016 calculated that the shift in the site of care for infused chemotherapy from independent oncology practices to hospitals cost Medicare about $2 billion in 2014 *(SPN 10/16, p. 8)*.

That group hailed the proposed OPPS changes. "Since its inception 25 years ago, 340B has grown substantially, morphing into a profit-generating program for most hospitals that is drastically different from the noble, original program intended to help patients in need," it said in a statement. "Exacerbating an already bad situation with 340B, are the higher payments hospitals receive from Medicare for the identical services performed in physician-run community cancer clinics."

"We applaud HHS Secretary Price and CMS Administrator Verma for taking this bold step in curtailing hospital abuse of the 340B program and further addressing site payment parity," said Ted Okon, executive director of COA. "These proposals represent a good first step, but the Administration and Congress must take additional steps to address the alarming consolidation of cancer care that is fueling drug prices and driving up costs for seniors and taxpayers."

Other groups, however, denounced the proposed changes. For instance, Bruce Siegel, M.D., president and CEO of America's Essential Hospitals, said the rule proposes "deeply damaging policies that would harm vulnerable patients and their hospitals by cutting 340B savings and needed support for outpatient services in underserved areas."

CMS, he said, "states a desire to mitigate rising drug prices, but this policy would badly undermine that goal. The 340B program provides a buffer for patients and taxpayers against skyrocketing drug prices. The proposed OPPS policy would cripple 340B's value as a tool for lowering drug prices and disrupt access to care for those in greatest need, including low-income Medicare beneficiaries. The proposal also runs counter to Congress' intent for the 340B program: to help hospitals stretch scarce resources."

And according to Tom Nickels, executive vice president of the American Hospital Association, "The patients who benefit from the much-needed 340B program are the ones who will have their access to care threatened. Cutting Medicare payments for hospital services in the 340B program is not based on sound policy. Additionally, this proposed rule punishes hospitals for a policy outside of CMS' jurisdiction. It is unclear why the Administration would choose to punitively target 340B safety-net hospitals serving vulnerable patients, including those in rural areas, rather than addressing the real issue: the skyrocketing cost of pharmaceuticals. CMS repeatedly cites the fact that Medicare expenditures on drugs are rising due to higher drug prices as an impetus for its proposal....Yet, its proposed 340B policy change does nothing to directly tackle this issue. We strongly urge CMS to abandon its misguided 340B proposal and instead take direct action to halt the unchecked, unsustainable increases in the cost of drugs."

CMS is requesting comments on the proposed rule by Sept. 11.

View the document at http://tinyurl.com/yalwn5me. ✧

Most Health Plans Cover At Least One of Two Available Biosimilars

Almost two years after the first biosimilar became available in the U.S., the majority of health plans are covering at least one of these drugs, according to new research from Avalere Health. In addition, formulary coverage for the two available biosimilars is comparable to that of their competitors. And although neither drug has been designated as interchangeable with their reference products, plans seem to be comfortable with their use, which could help bring down payers' spending on costly specialty drugs.

Two of the five FDA-approved biosimilars are available on the U.S. market: Zarxio (filgrastim-sndz),

a granulocyte colony-stimulating factor (G-CSF) whose reference drug is Neupogen (filgrastim), and Inflectra (infliximab-dyyb), an intravenous anti-inflammatory biologic that is a biosimilar version of Remicade (infliximab). The FDA approved both biosimilars for all of the available indications of their reference drugs. Zarxio entered the U.S. market in September 2015 *(SPN 9/15, p. 8)*, while Inflectra launched in November 2016 *(SPN 12/16, p. 5)*.

Among the other FDA-approved biosimilars, two are embroiled in patent litigation: Erelzi (etanercept-szzs), a biosimilar Enbrel (etanercept) approved in August 2016 *(SPN 9/16, p. 9)*, and Amjevita (adalimumab-atto), a biosimilar Humira (adalimumab) approved in September 2016 *(SPN 10/16, p. 6)*. Renflexis (infliximab-abda), also an intravenous anti-inflammatory biologic, was approved in April 2017 *(SPN 5/17, p. 10)* and is expected to launch this year.

Many industry experts anticipated biosimilar prices at 25% to 30% off those of the reference drugs. So far, Zarxio and Inflectra are priced at about 15% less. Still, 50 respondents to an Avalere survey, who were from 45 health plans representing 183 million covered lives, cited biosimilars' cost relative to the reference drug as the top element they use to determine coverage of the drugs, with 95% citing this (see chart, below). The second and third most important elements were biosimilars' efficacy, cited by 80%, and their safety, selected by 73% of respondents.

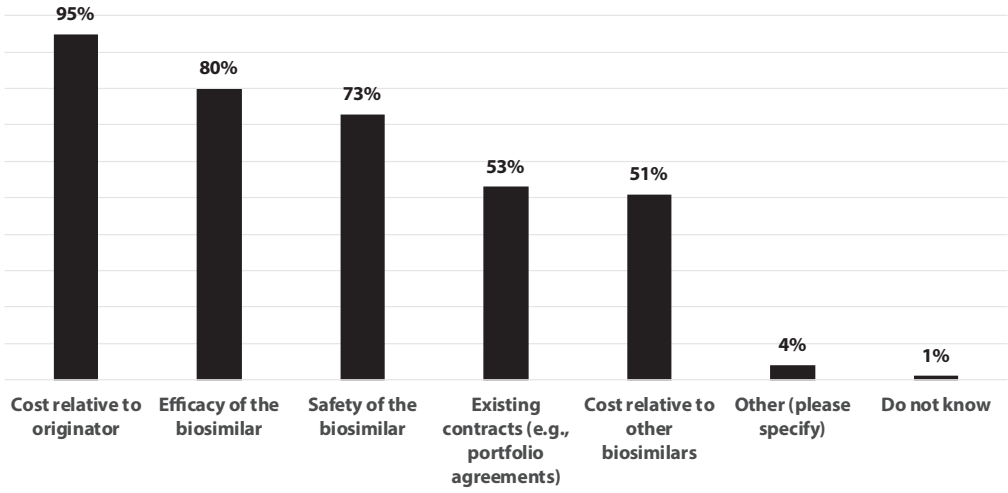
Avalere also reviewed how plans cover the biosimilars and found that 94% of employer-sponsored insurance plans say they are covering Zarxio, and 42% cover Inflectra.

The discrepancy could be due to a couple of reasons. According to Avalere's Sung Hee Choe, vice president, and Gillian Woollett, senior vice president, "time could be a factor, as Inflectra has been on the market for approximately seven months, versus Zarxio's approximately 22 months. Also, Zarxio has the benefit of extensive patient experience in Europe, which may have helped payers get comfortable with the product. Inflectra has also been on the market in Europe but [has] less experience than with Zarzio (as Zarxio is called in the EU)."

Zarxio is on the preferred brand tier for 42% of plans, compared with 45% for its competitors, which include Granix (tbo-filgrastim), Neulasta (pegfilgrastim) and Neupogen, according to an Avalere analysis based on data from Managed Markets Insight & Technology, LLC, which is the parent company of AIS Health. Thirty percent of plans have Zarxio on the non-preferred brand tier, compared with 23% for its competitors, while 22% have it on the specialty tier, compared with 21%. Only 6% of plans do not cover Zarxio, compared with 11% for its competitors.

Inflectra is on the preferred brand tier for only 7% of plans, compared with 36% for its competitors, which include Cimzia (certolizumab pegol), Enbrel, Humira, Orencia (abatacept), Remicade, Simponi (golimumab) and Xeljanz (tofacitinib citrate). Eighteen percent of plans have Inflectra on the non-preferred brand tier, compared with 28% for its competitors, while 17% have it on their specialty tier, compared with 21%. But while 14% of

Key Elements for Determining Biosimilar Coverage



SOURCE: Avalere Health, Avalere Policy 360, *Biosimilars: U.S. Payer Perspective*, released July 2017.

plans do not cover its competitors, 58% do not cover Inflectra.

It's interesting to note that the numbers are based on coverage in the pharmacy benefit only, so use of the biosimilars could be much higher when the medical benefit is taken into account as well. According to the 2017 edition of the *EMD Serono Specialty Digest*, G-CSFs and intravenous anti-inflammatory biologics are two classes for which coverage under both the pharmacy and medical benefits is most likely.

Among 58 commercial health plans representing 173 million covered lives, 12% covered G-CSFs in the pharmacy benefit only, 28% in the medical benefit only, and 60% covered them in both benefits. For IV anti-inflammatory biologics, 12% of plans covered them in the pharmacy benefit only, 47% in the medical benefit only, and 41% covered them in both benefits.

Choe and Woollett tell AIS Health that there are four main takeaways from the data: "(1) the vast majority of employer health plans cover a biosimilar product; (2) coverage of Zarxio is high; (3) plans are placing biosimilars on their preferred brand tiers at rates in line with the brand products; and (4) biosimilars are gaining coverage despite their not having interchangeable status from FDA, which has been viewed as needed for biosimilar acceptance."

The launch of the second Remicade biosimilar, Renflexis, is expected by October at the latest *(SPN 6/17, p. 11)*. Asked how the anti-inflammatory category may change with the addition of a second biosimilar, Choe and Woollett say, "There is a lot of interest in this launch, both for the initial pricing of the second entrant, and also because they will be the first biologics to share HCPCS codes."

Avalere noted that as of February, there were 64 drug development programs enrolled in the FDA's Biosimilar Products Development Program, "and the Agency has received meeting requests to discuss the development of biosimilars for 23 different reference products. So far, manufacturers have publicly disclosed the submission of 14 biosimilar applications to the FDA (including those already approved)."

View the Avalere data at http://tinyurl.com/y8v4p5qs. Contact Choe and Woollett through Frank Walsh at fwalsh@MessagePartnersPR.com. ✧

UnitedHealthcare Will Launch Online Prior Auth for Molecular Tests

Although UnitedHealthcare already requires prior authorization for genetic and molecular testing, the health insurer will roll out an online program nationally this fall for tests performed in an outpatient setting. The offering, according to the company, should help streamline the process and give insight into costs for multiple tests.

Providers requesting lab testing will need to complete the prior-authorization process themselves, while

ODAC Favors Approval of Biosimilars for Two Oncology Blockbusters

If the FDA chooses to follow the recommendation of one of its advisory committees, the agency could help clear the way for biosimilars of two blockbuster oncology treatments to come onto the U.S. market.

On July 13, the Oncologic Drugs Advisory Committee (ODAC) voted unanimously recommending approval of Amgen Inc. and Allergan plc.'s ABP 215, a biosimilar of Genentech Inc.'s Avastin (bevacizumab), and Mylan GmbH and Biocon Ltd.'s MYL-1401O, a biosimilar of Herceptin (trastuzumab), also from Genentech, a Roche Group company.

ODAC members voted for approval of ABP 215 for six of Avastin's indications — for colorectal cancer (two indications), non-small cell lung cancer, glioblastoma, renal cell carcinoma and cervical cancer — but did not consider its two ovarian cancer indications, which have orphan drug exclusivity until 2021 and 2023. Patents for the other indications expire in 2020.

The committee also voted in favor of approving MYL-1401O for all of Herceptin's indications: HER2-positive breast cancer in the adjuvant and metastatic settings and HER2-positive gastric cancer, an indication that has orphan drug exclusivity until Oct. 20. Herceptin's patents expire in 2019. ABP 215 has a Biosimilar User Fee Act target action date of Sept. 14, while MYL-1401O's is Sept. 3.

Avastin had worldwide sales of $6.783 billion in 2016, with $2.964 billion coming from the U.S. Herceptin had $6.782 billion in worldwide sales last year, with $2.509 billion in U.S. sales. Express Scripts Holding Co. has estimated $250 billion in savings over 10 years if 11 biosimilars, including ones for Avastin and Herceptin, are approved *(SPN 12/14, p. 1)*.

View the meeting materials at http://tinyurl.com/y9ggy7kq.

participating labs "will be responsible for determining if an authorization has been received," according to a network bulletin. Services performed that have not been authorized "will be denied and the member can't be balance billed," says the insurer. "If an authorization has not been granted, the participating laboratory staff should contact the ordering care provider to request a prior authorization."

The Genetic Molecular Testing Prior Authorization Program will go into effect for UnitedHealthcare's fully insured commercial members Oct. 1, says Lynne High, a spokesperson for the health plan. However, says the company, "Laboratory services ordered for members in Florida with a BeaconLBS logo on their identification card will not be required to participate in this requirement due to their participation in the UnitedHealthcare Laboratory Benefit Management Program."

To support the program, "we will be working with a vendor to provide an online genetic and molecular prior authorization intake system based on the UnitedHealthcare Medical Policies," High explains. She declines to identify the vendor with which United will work. In a recent network bulletin, the insurer explains, "The vendor will have an online prior authorization program available, and requests that meet our clinical criteria will be granted an authorization at the time of the request. UnitedHealthcare's medical policies, based on peer-reviewed, published literature, will be used for coverage determination. Our medical policies are reviewed and updated at least annually."

In the network bulletin, UnitedHealthcare says that "Laboratories that perform genetic or molecular testing will be asked to provide details on their genetic and molecular tests (i.e., test name, test ID number, codes used for billing, etc.) to our selected vendor starting in the second quarter of 2017. This information will be required for UnitedHealthcare to complete an authorization."

Prior authorization notification will be required for the following:

- ◆ Tier 1 Molecular Pathology Procedures
- ◆ Tier 2 Molecular Pathology Procedures
- ◆ Genomic Sequencing Procedures
- ◆ Multianalyte Assays with Algorithmic Analyses that include Molecular Pathology Testing
- ◆ CPT codes included in the prior authorization: 0001U, 0004M–0008M, 81161–81421, 81423–81479, 81507, 81519 and 81545–81599.

Training for the program and additional information will be available at UnitedHealthcareOnline.com around Sept. 1.

Program Will Help With Transparency

"Prior authorization is a key component to helping UnitedHealthcare members have access to quality, affordable health care," maintains High. "The online program for genetic and molecular testing streamlines the prior-authorization process (vs. having to place phone calls or send faxes) and provides cost transparency for a number of tests performed in an outpatient setting, including BRCA1/2, Hereditary Cancer Panels and Pharmacogenetic Panels."

"All utilization management activities will be managed by" UnitedHealthcare, she adds.

Contact High at lynne_m_high@uhc.com. ✧

Bill Could Help Plug Payment Gap

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And Sec. 5012, "Medicare Coverage of Home Infusion Therapy," established a reimbursement structure for the professional services that are provided with Part B DME infusible drugs. CMS currently reimburses for only the drugs provided, so this is a welcome development — but it does not take effect until Jan. 1, 2021. The payment will be per administration day of an infusion, and the rate will be determined by the HHS secretary.

Bill Would Take Effect in 2019

The Medicare Part B Home Infusion Services Temporary Transitional Payment Act (HR 3163) would create a temporary payment for those professional services that would begin Jan. 1, 2019. The bill, which was introduced by House Ways and Means Health Subcommittee Chairman Pat Tiberi (R-Ohio) and Rep. Bill Pascrell (D-N.J.) July 6, would be in effect until the day before implementation of the Cures payment.

The legislation, said Tiberi, "ensures that providers will receive necessary resources during the transition period until 2021 so that patients can continue to receive the home infusion therapies they need in the comfort of their homes."

Kendall Van Pool, vice president of government affairs for the National Home Infusion Association (NHIA), points out that commercial payers, Medicaid and Medicare Advantage all provide a services payment for home infusion. "It's a common-sense approach," he maintains.

He also clarifies that this "is not a reimbursement bill.…It's about patients." Providers "need to be able to refer these patients," says Van Pool. "This is the classic scenario of a patients-first approach." By receiving treatment at home, patients whose immune systems already are compromised are not at risk for hospital-acquired infections. In addition, a recent Option Care study showed additional benefits of home inotropic infusion, which is used to treat patients with severe congestive heart failure, in particular (see box, p. 10).

Patients Face Disruption to Care

"Without access to home infusion, patients who already face difficult health conditions now face a disruption to their care as they transition from hospital to home, or as they try to find alternate treatment options," says Paul Mastrapa, CEO of Option Care Enterprises, Inc. "Without a home infusion option, the hospitals and health systems that serve these patients also have limited options to ensure appropriate care is provided while costs are contained."

The Cures Act reimbursement change was enacted following the publication of three reports from the HHS Office of Inspector General (OIG) on the reimbursement methodology for Part B DME infusion drugs. The first report, issued in February 2013, compared the AWPs between 2005 and 2011 for Part B DME infusion drugs with ASPs and found the following:

"Overall, Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually. Most individual drugs had Medicare payment amounts that exceeded ASPs, many by more than two times, in each year. However, for as many as one-third of DME infusion drugs in each year, the payment amounts were below their ASPs, meaning that Medicare may be underpaying providers for these drugs.…If payment amounts for DME infusion drugs had been based on ASPs rather than AWPs between 2005 and 2011, total Medicare Part B spending would have been reduced by 44 percent (from $765 million to $431 million), a savings of $334 million."

The most recent OIG report, issued in September 2016, reiterates the recommendation from the 2013 and 2015 reports that "CMS take action to address payment issues associated with DME infusion drugs." Specifically, it maintains that AWP is "a flawed benchmark for determining payments, because it does not adequately reflect market prices. Paying based on flawed, out-of-date AWPs may create access issues for vital drugs or lead to excessive billing."

But the OIG reports had limitations, Bill Noyes, vice president of health information policy at NHIA, told AIS Health earlier this year, including that they assessed the therapies only on the basis of pricing, without taking into account the professional services needed to administer the therapies.

About 30 drugs have been affected by the change, including subcutaneous immune globulin, chemotherapies and inotropic agents.

According to a white paper by specialty infusion company Soleo Health, "The comprehensive cognitive services necessary to manage Medicare beneficiaries

NEW FDA SPECIALTY APPROVALS

◆ ***June 16:*** **The FDA expanded the approval of Dysport (abobotulinumtoxinA) for the treatment of lower limb spasticity in adults.** The agency approved the Ipsen Biopharmaceuticals, Inc. drug initially in 2009, and its indications include the treatment of upper limb spasticity in adults, as well as pediatric patients with lower limb spasticity. Dosing of the intramuscular injectable is based on indication. Website GoodRx lists the price of a 500-unit vial as almost $800. Visit www.dysport.com.

◆ ***June 16:*** **The FDA gave an additional approval to Darzalex (daratumumab) in combination with Pomalyst (pomalidomide) and dexamethasone for relapsed or refractory multiple myeloma.** The FDA initially approved the Janssen Biotech, Inc. monoclonal antibody in 2015, and it also is indicated for use in multiple myeloma as part of another combination of therapies and as a monotherapy. Dosing is based on body weight. Visit www.darzalex.com.

◆ ***June 22:*** **The FDA approved CSL Behring LLC's Haegarda (C1 esterase inhibitor subcutaneous [human]) for routine prophylaxis to prevent hereditary angioedema attacks in adolescents and adults.** It is the first subcutaneous therapy the agency has approved for this indication, and the FDA gave it orphan drug designation. Administration for the injectable is twice weekly. The company says the drug will be available "in the near future." Visit www.haegarda.com.

◆ ***June 22:*** **The FDA gave full approval to the combination of Tafinlar (dabrafenib) and Mekinist (trametinib) in people with metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test** (see brief below). The agency gave the Novartis Pharmaceuticals Corp. drugs breakthrough therapy designation and accelerated approval in July 2015 for this use. The recommended dose of Tafinlar capsules is 150 mg twice daily and for Mekinist tablets, it is 2 mg once daily. GoodRx lists the price of 120 Tafinlar 75 mg capsules as around $10,000 and 30 2 mg tablets of Mekinist as more than $10,600. Visit www.hcp.novartis.com/products/tafinlar-mekinist.

◆ ***June 22:*** **The FDA gave premarket approval to Thermo Fisher Scientific's Oncomine Dx Target Test to screen non-small cell lung cancer (NSCLC) tumors for biomarkers associated with three drugs: combination therapy Tafinlar (dabrafenib) and Mekinist (trametinib) (see brief above), Xalkori (crizotinib) and Iressa (gefitinib).** The next-generation sequencing-based test evaluates 23 genes associated with NSCLC, allowing physicians to match patients to the best therapy within days of the test, as opposed to weeks when screening samples only one biomarker at a time. Visit www.thermofisher.com/oncomine-dxtarget.

◆ ***June 22:*** **The FDA approved Genentech, Inc.'s Rituxan Hycela (rituximab and hyaluronidase human) for the treatment of adults with previously untreated and relapsed or refractory follicular lymphoma, previously untreated diffuse large B-cell lymphoma, and previously untreated and previously treated chronic lymphocytic leukemia.** The Roche Group company's subcutaneous injectable combines the same monoclonal antibody in intravenous Rituxan (rituximab) with an enzyme that helps deliver the drug. Administration time is now five to seven minutes compared with at least one-and-a-half hours for intravenous Rituxan. People can receive the new drug only after they have had at least one full dose of infused Rituxan. Dosing varies based on the indication. Blink Health lists the price for 30 milliliters of 1,600 mg rituximab/26,800 units of hyaluronidase human as $16,237.74. Visit www.rituxanhycela.com.

◆ ***June 29:*** **The FDA granted marketing authorization to Beckman Coulter, Inc.'s ClearLLab Reagents (T1, T2, B1, B2, M) to help detect several leukemias and lymphomas.** The test is used with flow cytometry to detect cancerous cells in blood,

requiring home inotropic therapy and subcutaneous immunoglobulin (SCIg) therapy are complex. These services include pharmacist sterile IV compounding and dispensing, clinically monitoring of patient's laboratory results and response to therapy, nurse monitoring of vital signs and weights for patients, pharmacist and nurse on-call availability to patients 24/7, and nurses teaching patients to administer their therapy."

During a May 4 conference to call to discuss first-quarter 2017 earnings, BioScrip, Inc. Senior Vice President, Chief Financial Officer and Treasurer Stephen Deitsch, in response to an analyst question about quan-

NEW FDA SPECIALTY APPROVALS (continued)

bone marrow and lymph nodes. It also offers information on what kind of leukemia or lymphoma is present by marking proteins on cells with fluorescent dyes. Visit www.beckmancoulter.com.

◆ ***June 29:*** **The FDA approved Illumina Inc.'s Praxis Extended RAS Panel to detect certain genetic mutations in RAS genes in people with metastatic colorectal cancer (mCRC) to identify those who may be eligible for treatment with Vectibix (panitumumab)** (see brief below). The next-generation sequencing test detects the presence of 56 mutations in RAS genes in the tumors of people with mCRC. Visit www.illumina.com.

◆ ***June 29:*** **The FDA gave an additional approval to Vectibix (panitumumab) to treat people with wild-type RAS metastatic colorectal cancer (mCRC) (see brief above) as a first-line therapy used with FOLFOX and as a monotherapy after the disease has progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan-containing chemotherapy.** The agency initially approved the Amgen Inc. drug in 2006; it also is used in combination with FOLFOX as a first-line treatment for wild-type KRAS mCRC. Dosing is 6 mg/kg every 14 days as an intravenous infusion over 60 minutes for doses less than or equal to 1,000 mg and over 90 minutes for doses more than 1,000 mg. Website Drugs.com lists the cost of a 20 mg/mL vial as around $1,180 with a discount card for a supply of 5 milliliters. Visit www.vectibix.com.

◆ ***July 6:*** **The FDA granted an additional approval to Orencia (abatacept) for the treatment of active psoriatic arthritis in adults.** The agency initially approved the Bristol-Myers Squibb Co. drug in 2005, and Orencia also is indicated for use with rheumatoid arthritis in adults and juvenile idiopathic arthritis. Dosing is weight-based, and the drug is available as both a subcutaneous injection dosed once weekly and an intravenous infusion given every four weeks after three initial loading doses. GoodRx lists the price of one carton of four 125 mg/mL syringes as around $4,000 with a coupon. Visit www.orencia.com.

◆ ***July 11:*** **The FDA gave full approval to Blincyto (blinatumomab) for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.** The Amgen Inc. drug also is approved to treat Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL. The agency had given the drug breakthrough therapy designation and accelerated approval. Dosing of the intravenous infusible drug is based on weight. Visit www.blincyto.com.

◆ ***July 13:*** **The FDA approved Janssen Biotech, Inc.'s Tremfya (guselkumab) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.** The injectable is the first biologic approved that blocks interleukin-23. Dosing is a 100 mg subcutaneous injection every eight weeks after two starter doses. The price for one dose is $9,684. Visit www.tremfyahcp.com.

◆ ***July 17:*** **The FDA approved Puma Biotechnology Inc.'s Nerlynx (neratinib) for the extended adjuvant treatment of early-stage, HER2-positive breast cancer in adults who have been treated with a regimen that includes Herceptin (trastuzumab).** The therapy is a kinase inhibitor that blocks several enzymes that promote cell growth. Visit www.puma-biotechnology.com.

◆ ***July 18:*** **The FDA approved Gilead Sciences, Inc.'s Vosevi (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) for the retreatment of hepatitis C infection in adults with genotypes 1 through 6 who have been treated with a regimen containing an NS5A inhibitor or adults with genotype 1b or 3 who have been treated with a sofosbuvir-containing regimen.** The single tablet is dosed daily over 12 weeks. Visit www.vosevi.com.

tifying the impact of the Cures Act, said the company "expected a full-year impact of approximately $24 million," according to Seeking Alpha.

"We've lost a significant amount of our reimbursement, and the service level didn't change," Drew Walk, CEO of Soleo Health, tells AIS Health. "We didn't make dramatic changes.…We needed to continue to serve patients and not abandon them," he says, noting the company "will take a hit." Already, he adds, Soleo Health has had to let some of its staff go.

But because providers continue to serve patients, this means that there hasn't been a direct financial impact on Medicare. "We're not seeing cost increases," points out Walk.

"All providers in the market are facing the same thing," he says. Health systems referring patients to home infusion providers "understand…their choices are more limited than they were before."

"If the legislation doesn't go through,…I can't imagine we can continue to manage patients at home," especially those receiving inotropic therapy. Soleo Health has taken a 90% cut on the provision of inotropic therapy, he says, with subcutaneous Ig also taking a big hit. And if the bill does pass, providers are facing another "14 or 15 months trying to work through this" until its 2019 implementation. Still, he says, "We'll survive as a company if they don't fix this." But generally speaking, if legislation isn't passed by the end of the year, "programs will have to be shut down."

Van Pool says that at this point, the information he has on the Cures Act's impact has been "mainly anecdotal." He tells AIS Health that "certain companies have started the process of not taking on new Part B patients in this space" and are "hoping they don't have to fully back out." NHIA is conducting a survey on its website of referral sources to determine whether they are having trouble referring people out. Initial returns show there are indeed some problems in this area, he says.

Multiple studies have shown that the cost for home infusion is much less than when a patient is treated in a hospital outpatient department, which is where they may be shifted under the current environment. For in-

Study: Home Inotropic Therapy Patients Have Higher Quality of Life

People suffering from heart failure who are awaiting a heart transplant or mechanical circulatory support are given intravenous inotropic therapy. And while this can be provided in a hospital or health care facility, recently unveiled research shows people receiving home inotropic therapy have a higher quality of life.

Option Care Enterprises, Inc. revealed these findings through a poster presentation at the National Home Infusion Association's annual conference in May. The study showed that "home inotropic therapy improved quality of life in advanced heart failure patients," said Kyle Walther, Pharm.D., lead author of the study and Option Care pharmacy resident. The study included 88 adults with heart failure who responded to 21 questions on the Minnesota Living with Heart Failure Questionnaire (MLHFQ) before starting therapy and again three months after home inotropic therapy.

When the initial results were compared with the subsequent ones, there was an overall 8.65% improvement in scores for all patients, a statistically significant finding. According to the researchers, the MLHFQ scores revealed especially beneficial improvements in reducing patients' shortness of breath, with a 17.13% improvement; decreasing hospital stays, which saw a 17.65% improvement; and reducing medical care costs, which had a 20.78% improvement.

An Option Care white paper explains that "in 2010, the average length of stay per heart failure admission was 5.6 days and in 2012, the average Medicare allowed cost per all-cause readmission following a HF admission was $15,667, equating to an average cost per day of $2,798." That compares with an average cost per day of about $350 for both the drugs and services associated with home inotropic infusion.

According to Walther, "Because inotropic therapy typically is provided long-term, it's invaluable that patients have the opportunity to receive this vital care in the comfort of their own homes, so they can continue to spend time with their families and enjoy the best quality of life."

"Medicare pays for the care involved in providing infusion of inotropic therapy, but only if it's provided in a hospital, nursing home or other health facility," said Tess Artig-Brown, co-author of the poster and director of Option Care's Heart Failure Program. "Few patients would choose to be in a facility receiving their care when they can be in their own homes, and our research suggests home infusion of inotropic therapy allows them to do that. Hopefully this will help draw attention to the benefits of improving patient access to high-quality home infusion."

Contact Walther and Artig-Brown through Lauren Kotarski at LKotarski@pcipr.com.

stance, the Soleo Health white paper notes that before the Cures Act's payment reduction, "the mean cost per patient infusion for Ig on average was $4,745 in the hospital outpatient setting versus $3,293 in the home or 31% less than the higher cost setting."

Act Impacts Various Stakeholders

But home infusion providers and payers are not the only stakeholders impacted by the legislation. Mastrapa says, "I invite people to view the patient and physician stories on the advocacy website www.keepmyinfusioncareathome.org." The Keep My Infusion Care At Home coalition started in response to the Cures Act, and sponsors include Option Care, NHIA, BioScrip, Soleo Health and the Healthcare Nutrition Council.

"Their stories," Mastrapa tells AIS Health, "are the best way to understand the unintended impact of the Cures Act on vulnerable patients and the physicians who care for them. The heart of our business is about improving the lives of patients and being a valued partner to physicians. This sudden change in reimbursement for certain infusion therapies has disrupted care for our patients and health systems partners. It brought about a dramatic reduction in Medicare reimbursement, effectively covering only the drug costs and providing no reimbursement for clinical services to administer certain infusion therapies in the home, creating an unsustainable gap in our ability to deliver on our promise to patients and physicians. That's why we are urging members of Congress to support this new bill, HR 3163."

The Cures Act, Van Pool clarifies, is "very robust; we're very happy with it." The law is "a great step in the right direction." Walk agrees: "The Cures Act really was a good thing," and "we all agree AWP pricing needed to change.…No one thinks we should go back to that." But "the four-year gap created a significant issue," which was "an unintended consequence."

When NHIA spoke with AIS Health about the Cures Act provisions in January, the association was hoping to move back the ASP methodology implementation two years and move up the service payment so they were implemented simultaneously in 2019. However, "For purposes of moving the payment forward, there was a problem with the implementation deadline," Van Pool explains, noting that there are steps that need to be taken before implementation, such as performing a market analysis of rates in the private sector. Those things "couldn't be done in the time we were looking at…so the temporary and transitional payment" was the best approach to take.

He describes the "straightforward" approach of the new bill, noting that it "serves the same purpose."

Following the bill's introduction, it was referred to the Energy and Commerce and Ways and Means committees. The Energy and Commerce Committee Subcommittee on Health has scheduled a hearing on it for July 20 at 10 a.m. EDT.

"On the House side, we're doing really, really well," says Van Pool, noting the "robust" list of co-sponsors, as well as others working behind the scenes. On the Senate side, particularly within the Finance Committee, members are familiar with the bill, so as it moves from the House to the Senate, there shouldn't be any surprises as far as familiarity with the legislation. "They're all very well aware of what's going on," says Van Pool, adding that this is "clearly going to be one of the bills everybody can rally behind."

As the bill undergoes congressional consideration, "I want members of Congress to know that patients, their families and the medical providers who care for them need their support on this legislation," says Mastrapa.

"We need them to understand that home infusion therapy for vulnerable patients requires expert clinical management, and clinical management services must be reimbursed to be sustainable," he continues. "This reimbursement gap must be closed so that we can serve our patients. Home infusion has several important benefits. Not only is it safe and effective, it also is often less costly than inpatient care at hospitals or skilled nursing facilities. It also plays an invaluable role in helping patients maintain their quality of life."

As of the morning of July 19, the Congressional Budget Office had not yet scored the bill, but supporters say they believe it will be "cost-neutral or low cost," Van Pool says. According to Walk, "dynamic scoring is difficult," but "that's the only challenge."

Bipartisan Support Is 'Big Deal'

"In the climate of Washington, D.C., today, we feel good" about support for the bill, he says. "To get bipartisan support on a health care bill is a big deal." He also lauds the "very strong coordination and collaboration among industry" stakeholders, including manufacturers, specialty pharmacies and home infusion pharmacies.

"We're excited that Congress is taking this up," says Van Pool, noting that there's been "a lot of work" for not only members of Congress but also their staffers. "Kudos to everyone on the Hill."

View the House hearing on July 20 at 10 a.m. at http://tinyurl.com/yawdqdan. View the BioScrip earnings call transcript at www.seekingalpha.com.

Contact Mastrapa through Lauren Kotarski at LKotarski@pcipr.com, Van Pool through Marilyn Tretler at Marilyn.Tretler@nhia.org and Walk at dwalk@soleohealth.com. ✧

NEWS BRIEFS

◆ **Fifty-two medicines and vaccines to treat and prevent HIV are in the drug pipeline,** according to a new report from the Pharmaceutical Research and Manufacturers of America (PhRMA) in partnership with The AIDS Institute. The products include 32 antiretrovirals and antivirals, 16 vaccines and four cell therapies, says PhRMA. View the report at http://tinyurl.com/yaeontyq.

◆ **Walgreens Boots Alliance, Inc. and Laboratory Corporation of America Holdings unveiled a deal that will allow LabCorp to develop and operate patient service centers within some Walgreens facilities.** Patients will be able to access lab testing in the locations and will check in at the pharmacy. The companies expect to develop seven of these locations, which will be known as LabCorp at Walgreens, this year: Five are planned for Denver, one for Morrisville, N.C., and one in Deerfield, Ill. The locations will be in addition to the approximately 1,750 existing LabCorp locations and will provide more options for access to the company's more than 4,800 tests, including ones in women's health, genomics, oncology and companion diagnostics. Contact LabCorp's Scott Frommer at investor@labcorp.com and Walgreens' Jim Cohn at jim.cohn@walgreens.com.

◆ **CMS proposed updated payment policies for the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2018.** The proposed rule (CMS 1674-P), issued June 29, covers payment rates for renal dialysis services furnished to Medicare beneficiaries starting Jan. 1, 2018, as well as rates for people receiving dialysis for acute kidney injury. In addition, the rule proposes changes for the ESRD Quality Incentive Program for payment years 2019 through 2021. Comments are due by Aug. 28. View the rule (82 Fed. Reg. 31190), which was published in the July 5 *Federal Register*, at http://tinyurl.com/ybako5dc.

◆ **McKesson Specialty Health and The US Oncology Network said they have expanded their agreement with the National Comprehensive Cancer Network (NCCN).** The deal will add five disease states to Value Pathways powered by NCCN: bladder, esophageal, gastric and kidney cancers, and myelodysplastic syndromes. Value Pathways powered by NCCN are offered through McKesson's Clear Value Plus clinical quality and regimen support system. The additions bring the total number of disease states offered through the provider tool to 27, and the companies expect to add up to 15 more disease states over the next three years. Contact McKesson's Claire Crye at claire.crye@mckesson.com and NCCN's Katie Kiley Brown at brown@nccn.org.

◆ **The Association of Community Cancer Centers (ACCC) has begun the second of three phases of a three-year initiative to develop an optimal care coordination model for Medicaid members with lung cancer.** During the first phase, which is being conducted throughout this year, an advisory panel is reviewing research and information gathered from five cancer programs. The second phase, running though September, will see ACCC preparing to beta test the model at seven ACCC member cancer programs. The third phase, which will be conducted from October 2017 to September 2018, will consist of testing the model. Learn more about the initiative at http://tinyurl.com/yan9s7e4.

◆ **Interpace Diagnostics Group, Inc. signed contracts with Premera Blue Cross and Aetna.** The Premera contract is for coverage of the ThyraMIR molecular test for thyroid nodules that standard cytopathological analysis has deemed indeterminate. The new Aetna deal is for coverage of ThyraMIR and ThyGenX and goes into effect Aug. 15. The payer has covered ThyGenX, which helps identify genetic alterations associated with papillary and follicular thyroid carcinomas, since June 2015 and ThyraMIR since November. Contact Redchip's Paul Kuntz for Interpace Diagnostics at paul@redchip.com.

◆ **DermTech, Inc. said it has signed its first payer contract with CareFirst BlueCross BlueShield and CareFirst BlueChoice.** Effective June 1, the health plan will cover the Pigmented Lesion Assay, DermTech's non-invasive biopsy and gene expression test to detect melanoma for its 3.4 million members. Contact DermTech's Sarah Dion at sdion@dermtech.com.

◆ **The Academy of Managed Care Pharmacy and America's Health Insurance Plans separately said they support the Pharmaceutical Information Exchange Act (H.R. 2026),** which would expand the ability of drug and device companies to share clinical and financial data with payers prior to FDA approval. View the bill at http://tinyurl.com/y8qxcdv5.

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