

SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Specialty Products

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Medicare Part B DME Infused Drugs Just Took Reimbursement Hit From Cures Act

While many stakeholders within the health care industry hailed President Barack Obama's Dec. 13 signing of the 21st Century Cures Act (*SPN 12/16, p. 11*), one group that isn't very happy is home infusion providers. That's because the legislation changed the way that certain Medicare Part B infusion therapies are reimbursed — and some of these providers stand to take a big hit to their bottom lines. This, in turn, could impact patient access to care, according to the National Home Infusion Association (NHIA), which is pushing to get the Jan. 1, 2017, implementation date moved back a couple of years.

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 AWP.

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. So rather than being reimbursed at AWP -5%, these drugs will be paid at the ASP +6% rate used for most Part B drugs.

continued on p. 11

2017 Outlook

Novel Specialty Drugs Made News in 2016; Orphans, Focus on Value Expected Next

From new advances in medications including cancer drugs and biosimilars to changing reimbursement strategies, 2016 was a noteworthy year for the specialty pharmacy industry — and 2017 looks to be just as memorable. AIS Health spoke to an array of industry sources to find out what developments they thought were most important over the past year and what specialty trends they expect to see in 2017.

Noteworthy Specialty Pharmacy Occurrences in 2016

Stephen Cichy, founder and managing director, Monarch Specialty Group, LLC:
"The high cost of specialty drugs was probably the major theme of this past year, and this is likely to be a primary and continuing headwind going into 2017. Both increases in unit price and utilization will contribute to drive this growth trend.... Annual drug price inflation for specialty biologics on aggregate has historically operated at or above 10% per year over the past decade, and our view at Monarch Specialty Group is that this trend will not change substantially in the near term.

"Certain payers and PBMs are already taking efforts to counteract the financial impact of high-cost medications by increasingly excluding certain of these drugs from

formulary, and there's growing demand for restrictive formulary networks among certain employers and plan sponsors [SPN 9/16, p. 1].

"[In 2015], Novartis's Zarxio became the first biosimilar product to be approved by the FDA [SPN 3/15, p. 1], and is already replacing Amgen's Neupogen as the sole covered product among certain payer formularies as we lead into 2017. At the same time, certain PBMs are implementing increasingly strict network participation requirements at the pharmacy level, which will continue to present complex challenges for specialty pharmacies in 2017. Prohibition of pharmacy mailing (via USPS, UPS, Fed Ex, etc.), shipping and delivering are just some examples. Those that fail to comply with these new requirements may experience claim denials and recoups and, possibly, network termination.

"On the regulatory front...the 21st Century Cures Act [became law and included]...a change to the payment structure for infusion drugs under the Medicare Part B Durable Medical Equipment benefit from an average wholesale price metric to an average sales price payment methodology [see story, p. 1]...What's more, CMS issued earlier in 2016 its proposed Medicare demonstration project, which among other things set forth a proposed model to shift drug reimbursement under

Medicare Part B from a straight [average sales price]-based percentage to more of a semi-capitation model involving a fixed-fee component...[but] this proposal was ultimately abandoned by CMS in late 2016" (see story, p. 4).

David Lassen, Pharm.D., chief clinical officer, Prime Therapeutics LLC: "The approval of Exondys-51 [SPN 10/16, p. 1]. It was approved by the FDA for an orphan condition with minimal data, but there was a lot of pressure from advocacy groups for its approval. Prime evaluates all new and existing drugs on safety and efficacy, and we acknowledge the preliminary data does not show efficacy for this product. We will watch other drugs in similar situations to see if this trend continues. The launch of the first biosimilar for the autoimmune class, Inflectra, was also noteworthy [SPN 12/16, p. 5]. Despite the approval, Prime doesn't anticipate the price of Inflectra will decline quickly and offer any initial savings in 2017. Prime will continue to advocate for additional biosimilar approvals to increase competition which can help lower drug prices."

Eileen Pincay, senior pharmacy consultant, national pharmacy benefits practice, The Segal Group: "Looking back in 2016, probably the most noteworthy occurrences within the specialty pharmacy industry are the new treatments in cancer, hepatitis C and HIV. This was also a big year for first time generics, and some drugs were assigned breakthrough therapy designation, which expedites the development and review of drugs for very serious conditions...In regards to generic drugs, imatinib is the first generic for Gleevec, and both are indicated for chronic myeloid leukemia (CML). After exclusivity expires for the approved generic drug, payers may realize lower prices with increased generic competition..."

"A couple of other specialty medications that were granted breakthrough therapy designation and approved in 2016 were Venclexta for the treatment of chronic lymphocytic leukemia in certain patients [SPN 4/16, p. 11] and Eplusa that treats genotypes 1 to 6 in hepatitis C infection and was approved in June 2016 [SPN 7/16, p. 1]. Another drug that was approved for hepatitis C was Zepatier in January 2016 and treats genotypes 1 and 4 [SPN 2/16, p. 1]. Hence, for this past year due to the additional treatment options for hepatitis C, we can see an increase in competition in the hepatitis C space. This could mean an opportunity for formulary updates.

"Another area of interest in 2016 was the approval of Exondys 51. This is a controversial drug which was at one time not likely to get an approval but then ended up getting an accelerated approval by the FDA for the treatment of Duchenne muscular dystrophy (DMD) with mutated DMD gene amenable to exon 51 skipping, which is the most common type of muscular dystrophy."

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Elan Rubinstein, Pharm.D., principal, EB Rubinstein Associates: “More aggressive PBM formulary positions, in particular exclusions in categories with therapeutically similar biopharmaceuticals. Increasing pushback by health systems against specialty drugs assigned to limited distribution primarily for their manufacturers’ marketing purposes.”

Thom Stambaugh, vice president of specialty pharmacy, Cigna Corp.: “There have been meaningful developments regarding biosimilars. The inflammatory therapeutic class is a significant cost driver, and the 2016 introduction of the first infliximab biosimilar could significantly improve affordability of treating these conditions. Increased competition among drug manufacturers benefits our customers and clients, and we are seeing that with biosimilars. We now have a year’s claims history with Zarxio [SPN 9/15, p. 8]...and have experienced the cost advantages of biosimilars. Plan sponsors are also giving greater focus to how the site of a drug’s administration impacts affordability. Cigna works with treating health care providers regarding sites of care for specialty drug infusion therapy such as moving from outpatient hospital settings to a contracted doctor’s office. Our customers and clients also benefit from the trade purchase advantages physicians experience on many medical benefit specialty medications.”

Specialty Trends Expected in 2017

Cichy: “Over the next 10 years...[prescription drug] spending is expected to be up 6.7%. Increased utilization (especially for specialty meds), the specialty pipeline and drug inflation will be primary drivers of this trend.

“Over the last 20 months the U.S. market has seen 35 new restricted-access drugs...At the same time, certain payers are increasingly utilizing tactics to limit the size of their pharmacy networks. This means increased competition among pharmacies to be recognized on service panels, with authorization to service certain medications and be reimbursed. Common tactics for most payers to address specialty pharmacy utilization in 2016 has included prior authorization (PA), step-therapy edits to drive lower cost alternatives and quantity edits. In 2017, look for new innovations to include enhanced rule sets, [electronic health records] integration and possibly new integrations with clinical data to better understand clinical pharmacy outcomes. Expanding the PA process to reach across the pharmacy and medical benefit will be a focus for some payers in 2017.

“Formulary exclusions remain a key focus for many payers, and some are already moving towards either evaluating or implementing some sort of value-based contracting approach. Plan design changes will continue to be aimed at driving generics and biosimilars, includ-

ing use of tiered copays, where applicable. At the same time, some payers are already exploring the use of indication-based formularies. In 2017 look for early versions of this approach by certain PBMs to create increased competition by dividing up classes by indications. The integration of new technologies with pharmacy dispensing to help monitor drug utilization will continue to be explored in 2017 and beyond....

“It is becoming tougher to operate a specialty pharmacy business in today’s market. The industry is continuing to be affected by the industrywide slowdown in demand for hepatitis C drugs along with deep reimbursement cuts within this category and others, and certain specialty pharmacies are being forced to reconsider their product mix to manage their [gross profit]. At the same time, many will be reviewing their pharmacy reimbursement strategy to manage the forward magnitude of PBM [direct and indirect remuneration] fees, which will become more visible in 2017.”

Lassen: “Prime expects an increase in spend with orphan drug approvals. Specifically, we expect medical spend to increase because many specialty drug approvals will be administered on the medical benefit vs. the pharmacy benefit. However, the introduction of biosimilars in the autoimmune space may help mitigate trend through decreases in inflationary price hikes.”

Rubinstein: “Increasing payer reliance on evidence-based guidelines to drive drug preference decisions. Possible trend to using real world evidence to build guidelines and quality metrics, based on ‘big data’ analysis of what works in ‘real’ patients (for example ASCO’s CancerLinQ). Trend to embedding of evidence-based guidelines (but not necessarily those endorsed by payers whose patients physician serves) in physician EMRs, to facilitate product choice at the point of decision making.

“Confrontation between payer and prescriber drug preference will be made more complex in markets where prescribers and health systems have consolidated, have become dominant, and whose preferences payers serving those markets cannot ignore. Increasing consolidation of hospitals and health systems in major markets, to rival payers in market power within those markets — relevant to specialty pharmacies due to the potential conflict in

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drug preferences and policies and/or because those powerful consolidated health systems build their own specialty pharmacies preferred by member prescribers. For patients in consolidated markets, specialty pharmacies may find themselves working to satisfy differing drug preferences and policies, between powerful payer customers on the one hand, and powerful prescriber customers on the other hand. Uncertainty about pace and extent of movement away from fee-for-service to risk-based payment for health care services, if CMS becomes less aggressive in pushing pilot initiatives under the new federal administration.”

Stambaugh: “We expect plan sponsors will have continued focus on determining the overall value that specialty drugs are delivering for their costs. Not only is it important to determine if the specialty pharmaceutical achieved the clinical outcome as intended, but, beyond the prescription, did the outcome favorably impact the TOTAL medical cost of managing the medical condition? Physicians will be increasingly evaluated by health plans as well on value-based pharmacy-related metrics. These include prescribing lower net-cost specialty medications — whether through therapy prescribed and/or site administered, patient therapy adherence and clinical outcome achieved.

“From a therapeutic perspective, it is exciting to anticipate the approval of the first gene-based therapy to potentially cure a rare form of childhood blindness. Other gene-based therapies are in early stage development for specific cancers, cardiovascular disease, other monogenic heritable diseases including muscular dystrophies, HIV, macular degeneration and neurological diseases. As with other emerging innovations, it is important to also track the real-world performance of these medications to ensure that patients and their employers are obtaining value for their money. Having the ability to analyze integrated pharmacy and medical benefit claims data enables measuring the more immediate outcomes of a drug as well as its longer-term impact on total health quality and costs.”

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CMS Reverses Course, Drops Push For Part B Drug Payment Model

When CMS unveiled a proposed multipronged approach that would test a variety of alternative payment models for Medicare Part B last March, it was met with pushback from an array of stakeholders. And although it looked for a while as if at least the first phase of the pilot would be implemented, that didn’t happen, and CMS has now scrapped the Part B Drug Payment Model (81 Fed. Reg. 13230, March 11, 2016).

Phase I of the proposed model would have tested changing the add-on payment to the average sales price (ASP) of a drug (*SPN 3/16, p. 1*). Currently these drugs are reimbursed at ASP +6%, but the proposal would have changed the add-on payment to 2.5%, plus a \$16.80 per-drug per-day flat fee payment. The plan was to start this phase in 2016, with the second phase of the proposed payment model beginning “on or after” Jan. 1, 2017. It would have tested one or more value-based purchasing strategies, such as indication-based pricing or reference pricing. CMS proposed running the model for five years, with both phases in operation for three years.

CMS Cites Issues’ Complexity, Time Constraints

However, a CMS spokesperson confirms to AIS Health that “after considering comments, CMS will not finalize the Medicare Part B Drug Payment Model during this Administration. The proposal was intended to test whether alternative drug payment structures would improve the quality of patient care and the value of Medicare drug spending. While there was a great deal of support from some, a number of stakeholders expressed strong concerns about the Model. While CMS was working to address these concerns, the complexity of the issues and the limited time available led to the decision not to finalize the rule at this time. We appreciate the robust dialogue with our stakeholders on this important topic and value the feedback on this proposal and other CMMI [i.e., Center for Medicare and Medicaid Innovation] models.”

The initial phase of the program would have explored the impact of reimbursing providers at a lesser percentage than the current one, in an effort to do away with the “perverse incentives” of the methodology as it is now, under which providers are paid more to administer higher-priced drugs than lower-priced ones, said a CMS official during a media call when the program was first unveiled. And with Medicare paying \$22 billion in 2015 for Part B drugs, up from \$11 billion in 2007, CMS was looking to see if the model could reduce Medicare expenditures while “preserving or enhancing the quality of care” beneficiaries receive.

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But an analysis by Avalere Health released in early April showed that the majority of the most-affected therapies are drugs to treat cancer, and many of them do not have lower-cost alternatives (*SPN 4/16, p. 1*). In addition, while CMS was trying to encourage prescribing of less-expensive drugs, certain Medicare beneficiaries actually would have paid more out of pocket while providers received higher payments for lower-priced therapies.

Avalere determined that drugs costing providers more than \$480 per day would receive lower reimbursement than they are now, while ones below this threshold would receive higher reimbursement. "Because Medicare beneficiaries without supplemental insurance coverage are responsible for 20 percent of the payment, beneficiary out-of-pocket costs would increase for lower cost drugs (those below \$480)," said the company.

CMS received more than 1,300 comments — most of them negative — on the proposal. Still, it seemed that implementation remained on track.

In a May 17 note, Evercore ISI analyst Terry Haines maintained that the changes "are 80 per cent likely to be adopted by CMS in July 2016 and implemented in fall 2016 despite rising industry and congressional pressure to delay or stop it...CMS remains on track to adopt Phase I after public comments were received and has not backed off its timetable, although some small modification is not out of the question," such as making the geographical scope smaller, extending the time the model

will run or both, he said (*SPN 6/16, p. 8*). "We think CMS is unlikely to significantly change its timetable because the agency wants to get Phase I in place in this presidential administration and CMS believes Congress will not be able to stop it," wrote Haines.

And as recently as late June, Patrick Conway, M.D., CMS principal deputy administrator and chief medical officer, said during a Senate Finance Committee hearing, "We are reviewing the comments now and plan to make adjustments in the final rule" (*SPN 8/16, p. 8*).

"The overall basis of the proposed project was squarely centered around a working hypothesis that a smaller margin will have the potential to diminish what's believed to be a coercive incentive for physicians to prescribe the most expensive drugs on the market," says Stephen Cichy, founder and managing director of Monarch Specialty Group, LLC.

"The Medicare Part B Drug Payment Model, an effort to improve payment incentives and quality of care, was a major policy change masquerading as a pilot study," Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, tells AIS Health. "For a pilot study, the proposal was breathtakingly comprehensive and complex, with potential impact throughout the U.S. health care system. Although the Payment Model was withdrawn, the issues which it addressed are valid concerns. Unknown at this point is whether CMS under new leadership will view these concerns as priorities to be ad-

NEW FDA SPECIALTY APPROVALS

◆ **December 19:** The FDA gave accelerated approval to Clovis Oncology Inc.'s Rubraca (rucaparib) to treat patients with deleterious BRCA mutation-associated advanced ovarian cancer who have tried at least two chemotherapies. The agency also approved the FoundationFocus CDx-BRCA test companion diagnostic to identify people eligible for treatment with Rubraca. The agency gave the tablet breakthrough therapy designation, priority review and orphan drug designation. A 15-day supply of the drug will cost \$6,870. Visit www.rubraca.com.

◆ **December 27:** The FDA gave an additional approval to Adynovate (antihemophilic factor [recombinant], PEGylated) to treat hemophilia A in people less than 12 years old. The agency also approved it for use with adult and pediatric patients in surgical settings. The Shire plc Factor VIII treatment was initially approved in November 2015 for use in

people at least 12 years old (*SPN 12/15, p. 8*). Visit www.adynovate.com.

◆ **January 3:** The FDA approved Spinraza (nusinersen) to treat spinal muscular atrophy in children and adults. Biogen markets the injectable, and Ionis Pharmaceuticals, Inc. developed it. The agency gave the drug fast track designation, priority review and orphan drug designation. The therapy will cost \$750,000 for the first year of treatment and then \$375,000 for subsequent years. Visit www.spinraza.com.

◆ **January 5:** The FDA expanded the label of Lucentis (ranibizumab) to treat people with myopic choroidal neovascularization. Manufacturer Genentech USA, Inc. says it is the first anti-vascular endothelial growth factor therapy approved for the condition. The FDA gave it priority review, and it is the fifth indication the agency has approved the drug for. Visit www.lucetis.com.

dressed urgently — but public statements to date suggest a low likelihood that this will be an activist CMS.”

The Community Oncology Alliance (COA) was among the many groups that vehemently opposed the model (*SPN 4/16, p. 1*). After CMS confirmed that it would not move forward with implementation of it, Executive Director Ted Okon said, “Cancer patients and their providers across the country can breathe a sigh of relief now that the Part B experiment on cancer care is finally dead. It was encouraging to have such strong support from Congress to end this proposed model that was, at best, an overreach by CMS, created with no stakeholder input.”

Contact Cichy at scichy@monarchsp.com and Rubinstein at elan.b.rubinstein@gmail.com. Visit COA’s website at www.communityoncology.org. ✦

2017 Outlook

Specialty Pharmacy, Home Infusion Will Still Attract M&A Attention in '17

Merger-and-acquisition (M&A) activity in the specialty pharmacy and home infusion spaces in 2016 diverged a bit from that of 2015. In that year, both areas had a similar number of transactions, with specialty pharmacy notching 12 deals compared to infusion therapy’s 13. But 2016 saw specialty deals rise while infusion ones declined. According to one industry expert, though, both industries will remain strong and steady moving forward.

Looking back over 2016, “one of the big trends... was the peaking of the hepatitis C market from a specialty pharmacy perspective,” notes Reg Blackburn, managing director at The Braff Group. Late 2013 saw the first of the

Specialty Tier Average Cost-Sharing, 2016 vs. 2017, Silver Level, Individual Market (On Exchange)

| State | Average Copay | | | Average Coinsurance | | |
|----------------------|---------------|----------|------------|---------------------|--------|---------|
| | 2016 | 2017 | Change | 2016 | 2017 | Change |
| Alabama | \$244.00 | \$187.50 | (\$56.50) | 36.67% | NA | -36.67% |
| Alaska | NA | NA | \$0.00 | 31.79% | 40.00% | 8.21% |
| Arizona | \$330.00 | \$0.00 | (\$330.00) | 35.84% | 50.00% | 14.16% |
| Arkansas | \$190.40 | \$200.00 | \$9.60 | 21.25% | 24.00% | 2.75% |
| California | NA | NA | \$0.00 | 20.00% | 19.12% | -0.88% |
| Colorado | \$411.07 | \$463.75 | \$52.68 | 30.90% | 31.92% | 1.02% |
| Connecticut | \$60.00 | NA | (\$60.00) | 31.67% | 40.00% | 8.33% |
| Delaware | NA | \$0.00 | \$0.00 | 30.00% | 35.71% | 5.71% |
| District of Columbia | \$87.00 | NA | (\$87.00) | 36.36% | 24.00% | -12.36% |
| Florida | \$157.08 | \$0.00 | (\$157.08) | 26.59% | 36.06% | 9.47% |
| Georgia | \$232.96 | \$0.00 | (\$232.96) | 34.41% | 38.53% | 4.12% |
| Hawaii | \$150.00 | NA | (\$150.00) | 50.00% | 35.71% | -14.29% |
| Idaho | \$78.33 | NA | (\$78.33) | 32.38% | 27.26% | -5.12% |
| Illinois | \$165.65 | \$0.00 | (\$165.65) | 30.11% | 39.29% | 9.18% |
| Indiana | \$83.33 | \$0.00 | (\$83.33) | 25.52% | 29.78% | 4.27% |
| Iowa | \$133.33 | \$3.57 | (\$129.76) | 37.32% | 40.00% | 2.68% |
| Kansas | \$86.84 | \$100.00 | \$13.16 | 36.09% | 35.00% | -1.09% |
| Kentucky | \$0.00 | NA | \$0.00 | 32.65% | 39.58% | 6.94% |
| Louisiana | \$137.50 | \$150.00 | \$12.50 | 20.67% | 50.00% | 29.33% |
| Maine | NA | NA | \$0.00 | 28.23% | 45.56% | 17.33% |
| Maryland | \$125.77 | \$150.00 | \$24.23 | 31.90% | 30.00% | -1.90% |
| Massachusetts | \$71.54 | \$90.00 | \$18.46 | 20.00% | 40.00% | 20.00% |
| Michigan | \$186.67 | \$186.67 | \$0.00 | 30.06% | 31.85% | 1.79% |
| Minnesota | \$202.22 | NA | (\$202.22) | 23.38% | 27.38% | 4.01% |
| Mississippi | \$110.71 | \$0.00 | (\$110.71) | 32.63% | 32.14% | -0.49% |
| Missouri | \$159.38 | NA | (\$159.38) | 33.57% | 40.00% | 6.43% |
| Montana | \$153.42 | \$220.00 | \$66.58 | 0.00% | 35.00% | 35.00% |
| Nebraska | \$300.00 | \$0.00 | (\$300.00) | 32.96% | 30.00% | -2.96% |
| Nevada | \$225.00 | NA | (\$225.00) | 23.91% | 32.11% | 8.20% |
| New Hampshire | \$228.57 | \$210.00 | (\$18.57) | 36.19% | 44.29% | 8.10% |

new hepatitis C blockbuster drugs when the FDA approved Sovaldi (sofosbuvir) (SPN 12/13, p. 1), followed by Harvoni (ledipasvir/sofosbuvir) in October 2014 (SPN 12/14, p. 1) and then Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir) two months later (SPN 1/15, p. 1). A handful of additional drugs have since been approved, but it was really these initial ones that were game-changers for the condition.

“You had physicians holding patients back to wait for these drugs,” points out Blackburn. With their launch, there was “dramatic double-digit growth,” and the “high water lifted all boats.” But in 2016, this stopped. “The patients didn’t stop...but the bolus had gone through,” says Blackburn. “Companies flattened out.”

He tells AIS Health that “the other interesting trend from last year was the growth of hospital systems in specialty pharmacy” (SPN 5/14, p. 1). As consolidation among hospitals grows, they “have eyed specialty pharmacy,” entering the space “by either initiating their own programs or participating in equity programs.” And with a “robust” specialty drug pipeline, this trend is showing no sign of slowing.

The specialty pharmacy arena had 18.7 annualized deals in 2016, topping 2015’s 12 deals and 2014’s 17. The space “has been amazingly consistent,” says Blackburn, with “steady 10-plus deals a year.” The M&A activity in specialty pharmacy has demonstrated “an alternating pattern” in which there is “a bump-up from the baseline one year, and a drop the next,” he explains. However, that’s due “not to a lack of interest but supply patterns.... As companies get to the size that people are interested in buying,” they buy them.

For example, “hepatitis C drove companies to achieve a larger status,” which in turn prompted “people to buy them.” But the buyers “recognized this [hepatitis C market growth] was going to slow down, so they were willing to sell.”

Looking ahead to 2017, one continuing theme is that with specialty pharmacies, “bigger is better,” says Blackburn. “We’ll continue to see the big guys grow.” In addition, “on the small side,” new entrants will continue to enter the space, many specializing in a particular therapeutic area such as anti-inflammatory conditions or HIV.

continued

Specialty Tier Average Cost-Sharing, 2016 vs. 2017, Silver Level, Individual Market (On Exchange), continued

| State | Average Copay | | | Average Coinsurance | | |
|----------------|---------------|------------|------------|---------------------|--------|---------|
| | 2016 | 2017 | Change | 2016 | 2017 | Change |
| New Jersey | NA | NA | \$0.00 | 45.38% | 48.75% | 3.37% |
| New Mexico | \$161.54 | \$500.00 | \$338.46 | 41.67% | 36.43% | -5.24% |
| New York | \$70.17 | \$63.33 | (\$6.83) | 35.00% | NA | -35.00% |
| North Carolina | \$71.11 | \$80.00 | \$8.89 | 31.81% | 33.33% | 1.53% |
| North Dakota | \$200.00 | \$0.00 | (\$200.00) | 30.67% | 31.25% | 0.58% |
| Ohio | \$22.22 | \$20.00 | (\$2.22) | 29.70% | 36.85% | 7.15% |
| Oklahoma | \$153.85 | NA | (\$153.85) | 30.00% | 32.00% | 2.00% |
| Oregon | \$0.00 | NA | \$0.00 | 40.07% | 48.64% | 8.57% |
| Pennsylvania | \$173.91 | \$285.00 | \$111.09 | 38.10% | 45.16% | 7.06% |
| Rhode Island | \$121.67 | \$110.00 | (\$11.67) | NA | 50.00% | 50.00% |
| South Carolina | \$207.73 | \$0.00 | (\$207.73) | 31.64% | 28.46% | -3.17% |
| South Dakota | \$100.00 | \$64.29 | (\$35.71) | 39.23% | 40.00% | 0.77% |
| Tennessee | \$202.11 | NA | (\$202.11) | 26.96% | 43.33% | 16.38% |
| Texas | \$247.50 | \$0.00 | (\$247.50) | 34.67% | 35.36% | 0.69% |
| Utah | \$125.00 | NA | (\$125.00) | 31.98% | 38.18% | 6.20% |
| Vermont | NA | NA | \$0.00 | 50.00% | NA | -50.00% |
| Virginia | \$110.38 | \$36.67 | (\$73.72) | 35.13% | 38.00% | 2.88% |
| Washington | \$240.91 | \$25.00 | (\$215.91) | 32.99% | 40.63% | 7.64% |
| West Virginia | NA | \$1,000.00 | \$1,000.00 | 30.77% | 31.00% | 0.23% |
| Wisconsin | \$203.93 | \$363.40 | \$159.48 | 27.26% | 36.53% | 9.27% |
| Wyoming | NA | NA | \$0.00 | 26.36% | 29.17% | 2.80% |

Notes: Some plans require member to pay the deductible before cost sharing begins; all \$0 copays in this table require the deductible to be paid first. NA=No insurers in the state employ indicated cost-share strategy for silver-level plans. SOURCE: Compiled by AIS Health from AIS’s Rx Benefit Data online database. This analysis was performed using the full set of 2016 and 2017 on-exchange individual market health plans. Visit <http://aishealthdata.com/rxb> for more information; visit <http://aishealthdata.com/dashboard/rxb/demo> for an interactive demo.

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With the “mega players” — PBMs such as Express Scripts Holding Co. and CVS Health and payers such as UnitedHealthcare — having the ability to “direct policy-holders to their own pharmacies,...it doesn’t mean the other players can’t grow, but that they must be selective in where they grow,” he says.

“New drugs will continue to roll out,” many of them within the oncology space, where they often are limited-distribution therapies. Companies that can “offer a unified suite of drugs” will garner more business than those that can offer only a few of those treatments. “It’s been this way for a while, but [the trend] is accelerating.”

“Hepatitis C was kind of driving the train,” but now that “it’s normalized to a steady state, people are saying what else?” as far as therapies, says Blackburn. Companies may look to steady, long-term patient populations such as HIV, transplant, hemophilia and intravenous immune globulin (IVIG) for primary immune deficiency. Although they “get patients one at a time,” these “patients are staying around a long time.”

Infusion Has ‘Limited Supply of Sellers’

Last year the infusion therapy sector had 6.7 annualized deals, down from 13 the previous year but close to 2014’s eight deals. The space has been “relatively steady year over year but down a little” last year. That’s due to “a limited supply of sellers,” Blackburn states, as well as “private-equity roll-ups.” But this “doesn’t mean it’s going to go away.” For example, with larger infusion companies like PharMerica Corp. and Coram CVS Specialty Infusion Services, there “may be a gap” that needs to be filled to “round out their geographic footprint.” This “leads to a steady state of transactions,” particularly involving smaller infusion pharmacies.

However, the “middle ground” of companies providing home-infused specialty medications in areas such as IVIG and hemophilia are “interesting to both specialty pharmacy consolidators and home infusion consolidators,” he says. “People are still trying to grow these.” Infusible specialty drugs “are still growing like crazy.”

That said, Blackburn points to a “significant” recent occurrence: The recently passed 21st Century Cures Act “changed how home infusion companies are reimbursed for several different drugs in Medicare” (see story, p. 1). “If you’re a big player, you may have had millions pulled from your bottom line,” so potential buyers will need to “look at adjusted earnings.”

Private-equity investment within the overall pharmacy space that The Braff Group tracks — infusion therapy, specialty pharmacy and institutional pharmacy — slowed a bit in 2016. Last year saw 9.3 annualized follow-on deals, compared with 13 in 2015 and 11 in 2014. The 2.7 annualized platform transactions were

down from the seven deals in each of the three previous years.

For private-equity investors, home infusion and long-term care pharmacy “are good businesses to be in,” maintains Blackburn. “They’re not going away... But are roll-ups going to happen? Are there big enough companies to platform?” There is a “limit to the opportunities there.”

In the specialty space, “there’s a similar issue” in that the opportunities “haven’t gone away,” but buyers are looking for companies with larger revenues, he says. “We see a steady state in private equity,” which we’ll “see baseline again in the coming year as” companies grow into a size that makes them attractive to buyers. “The inventory will rebuild itself.”

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2017 Outlook

Emphasis on Value, Stricter Drug Management Tactics Are Expected

With the specialty pharmacy space continuing to become more of an issue for payers, AIS Health spoke to some industry experts about what they expect to see in terms of specialty drug management strategies for 2017. They anticipate tighter utilization management strategies and a continued focus on value.

Stephen Cichy, founder and managing director, Monarch Specialty Group, LLC: “In 2017, payers and specialty pharmacies alike will continue to be faced with significant challenges regarding drug coverage, cost, and reimbursement. A variety of strategies are already being utilized to address these challenges, and these will continue to evolve into 2017 as payers examine the specialty pharmacy landscape with increased scrutiny.

“High-priority disease states will include cancer, cystic fibrosis, hemophilia, hepatitis C, intravenous immunoglobulin and pulmonary arterial hypertension. Targeted strategies like drug-specific utilization management criteria, prior authorizations and step therapy will continue to be heavily relied on as tactics to control for utilization. Look for payers to increasingly explore a means to better manage specialty pharmacy expenditures across the medical benefit, as approximately 36% of total specialty spend operates in this area, and this is projected to grow to 55% by 2020. Additional approaches to be explored by payers may include (1) benefit design strategies including preferred-product selection, (2) use of preferred-pharmacy and site-of-care networks, and (3) care coordination, where applicable....

“All of these changes will continue to put pressure on specialty pharmacies as a whole, *vis-à-vis* increased reimbursement pressure and shrinking profit margins. More and more, specialty pharmacies will need to consider new lines of services or improve current services in order to deliver [a] quality, value-added proposition to their clients. Site-of-care optimization for certain specialty products will continue to drive opportunity for value differentiation, and this opportunity will likely favor certain home health, hospital (inpatient and outpatient), physician office, and other ancillary sites of care.”

Mike Einodshofer, chief innovation officer, Maxor National Pharmacy Services: “Care models are continuing to become more patient-centric and focused on outcomes that demonstrate value to the payer community. I think the specialty pharmacies that are focused on being the experts in specific disease states will be successful in winning carve outs from ‘one-size-fits-all’ specialty approaches. That is, I think you will see ‘sub-specialties’ emerging within the specialty pharmacy industry. I am seeing an increasing appetite within sophisticated health care purchasers to seek out the specialty pharmacies that offer expertise in specific disease categories. Pharma manufacturers gravitate to this approach too and I believe will build limited-distribution networks based on this level of specialization. Pharmacies that are best in class in particular disease states tend to have a higher level of patient empathy, tighter relationships with referral centers and better understanding of payer and foundational coverage — all of which results in a higher-quality patient journey.”

David Lassen, Pharm.D., chief clinical officer, Prime Therapeutics LLC: “There will likely be more exclusion strategies in 2017 as more ‘me too’ drugs come to market. Also, there will likely be tighter utilization management controls so the appropriate patient has appropriate use of therapy. Additionally, there may be more emphasis on medical policies implemented and strategies to prefer products on the medical benefit to control cost and use similar to current pharmacy benefit strategies.”

Eileen Pincay, senior pharmacy consultant, national pharmacy benefits practice, The Segal Group: “Given the expected double-digit increase for specialty pharmacy trend, plan sponsors should model the financial impact and develop a plan for management of these high-cost drugs. Cost-management options include requiring prior authorization, implementing step therapy, mandating use of a limited network of specialty pharmacies and identifying preferred treatments within disease categories and consider moving to an exclusive specialty arrangement and consider a more enhanced formulary strategy.

“There is also a movement for some PBMs to offer value-based pricing to support [a] rationale for setting different prices for different indications in the specialty space. A couple of key therapeutic categories where we have seen this, for example, are oncology (a few specific areas) and inflammatory conditions. This control may help leverage greater influence on pharmaceutical company pricing practices that help to lower future plan sponsor prescription drug claim cost increase; but we have yet to see the savings. Segal is just beginning to see more PBMs propose this new concept, and we are just beginning to evaluate and negotiate them for our clients.”

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Prime Data Help Drill Down on Appropriate Use of Treatment

Prime Therapeutics LLC is scrutinizing data such as whether use of a drug follows its indication and how long members persist on a therapy in order to help with managing some high-cost specialty drugs. By identifying areas in which drug utilization could be improved, the PBM can make sure members are getting the most effective treatment possible.

The PBM recently published data from a study that looked at patterns of use and persistency among people using Pfizer Inc.’s oral rheumatoid arthritis (RA) treatment Xeljanz (tofacitinib). Pat Gleason, Pharm.D., director of health outcomes at Prime and a co-author of the study, points out that the first author is a student at the University of Pittsburgh School of Pharmacy who is sponsored by Pfizer. Researchers looked at whether it “was used in accordance with its label...if methotrexate was being tried first” and if people had tried disease-modifying antirheumatic drugs (DMARDs) before trying Xeljanz.

Researchers analyzed data from 887 members of 12 Blue Cross and Blue Shield commercially insured populations who had at least one Xeljanz claim between Dec. 1, 2012, and Dec. 31, 2015 — the FDA approved the tablet Nov. 6, 2012 — as well as at least one medical claim that could be used to identify the member’s diagnosis. Almost all of them — 862, or 97.2% — had an RA diagnosis.

Xeljanz is indicated for use as a second-line treatment in people with RA who have not responded adequately to or who do not tolerate treatment with methotrexate. It can be used as a stand-alone treatment or in combination with methotrexate or other nonbiologic DMARDs, but it is contraindicated in use with biologic

DMARDs or “potent immunosuppressants such as azathioprine and cyclosporine,” according to Xeljanz’s label. Specifically, the label explains, “You should not take tocilizumab (Actemra®), etanercept (Enbrel®), adalimumab (Humira®), infliximab (Remicade®), rituximab (Rituxan®), abatacept (Orencia®), anakinra (Kineret®), certolizumab (Cimzia®), golimumab (Simponi®), azathioprine, cyclosporine, or other immunosuppressive drugs while” taking Xeljanz or Xeljanz XR because doing so may boost the risk of developing an infection.

Most Had DMARD Claim

Researchers found that in the year before members started Xeljanz, 771, or 89.4%, had a claim for any DMARD, and 432, or 50.1%, had a methotrexate claim. There are five tumor necrosis factor (TNF) inhibitors within the biologic DMARD class, and they make up some of the top specialty drugs in terms of spend: Remicade, Enbrel, Humira, Simponi and Cimzia. Researchers found that 375 members, or 43.5%, had claims for a TNF inhibitor.

Although nine of out every 10 members had tried a DMARD first, “we would like to see 100%,” says Gleason, who maintains there is “room for improvement.” Specifically, he says, tactics such as “step therapy and prior authorization can get that number higher.” For example, step therapy could require “evidence of a trial of methotrexate or another preferred product, and then the claim will go through,” while providers could be required to obtain prior authorization for the drug to make sure its use is appropriate before a claim is approved.

Use of Xeljanz ‘Has Increased Steadily’

With a wholesale acquisition cost of more than \$42,000 annually, Xeljanz is certainly not inexpensive, although its price is similar to those of other RA biologics. And, note the researchers, although Xeljanz “utilization has been low, it has increased steadily since the drug’s approval at a rate of 0.24 members per 100,000 commercially insured members per month.”

Data from the study were presented in a poster at a recent Academy of Managed Care Pharmacy event.

The study also examined rates of persistency on Xeljanz. Researchers considered the therapy discontinued when there was a gap of more than 90 days between the end of a claim’s supply and the filling of the next Xeljanz claim. Data showed that at the six-month mark, three of 10 members (30.2%) had discontinued Xeljanz, while more than four of 10 members (44.3%) had halted the drug at 12 months. At 18 months, 53.2% had discontinued and 57.1% at 24 months.

According to the poster, “As RA is a chronic disease, this is a high discontinuation rate after a short period of

therapy. Providers and payers should look for ways to improve persistency and consider outcomes based contracts where managed care organization reimbursement from pharmaceutical manufacturers is linked to tofacitinib adherence and persistency.” In addition, it said, “Payers should develop care and utilization management programs that encourage adherence, persistency and the most cost effective RA treatment strategies. These programs should emphasize the use of a nonbiologic DMARD, preferably methotrexate, as first line therapy in RA and prevent the use of tofacitinib with biologics.”

An article published in *Rheumatology* in 2015 included findings on discontinuation rates among people initiating treatment with a TNF inhibitor based on a meta-analysis of articles and abstracts for almost 100 studies worldwide. According to those researchers, the “overall discontinuation rates of TNF inhibitors at 0.5, 1, 2, 3 and 4 years were 21, 27, 37, 44 and 52%, respectively.” In addition, “Studies from registries conducted after 2005 and from countries with lower biologics access showed higher percentages of discontinuation.”

Prime Seeks Deals for When Drugs Fail

Gleason tells AIS Health that Prime is “pursuing outcomes-based contracts with pharmaceutical manufacturers” across multiple drug classes. Such deals would entail “reimbursement for treatment failures...If individuals are not going to be persistent, there should be reimbursement to the payer for the cost of the drug,” he says, adding that “\$40,000 is a lot to spend to try something else.” At Prime, “We want people to take the medication they’ve been prescribed and to feel better.”

“We are aware of the Prime Therapeutic analysis and have reviewed the abstract,” a spokesperson for Pfizer tells AIS Health. “It is important to remember that Prime’s formulary design requires failure of two preferred TNFs (Enbrel and Humira) prior to use of other agents,” based on data from Managed Markets Insight & Technology, LLC, which is the parent company of AIS Health. “Given that RA patients must fail both Enbrel and Humira prior to being placed on Xeljanz, Prime’s formulary design relegates use of Xeljanz to a more severe patient population potentially making comparisons of outcomes and adherence less meaningful given that Xeljanz is indicated post MTX [i.e., methotrexate]. The Prime analysis is an important reminder of why formulary design is so important to the effective management of patient care.”

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Parts of this article were excerpted from Drug Benefit News. Visit the MarketPlace at www.AISHealth.com for more information.

Payment Methodology Changed

continued from p. 1

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.

The reimbursement change follows 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 AWP 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 AWP 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."

Report: AWP Is 'Flawed Benchmark'

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 AWP may create access issues for vital drugs or lead to excessive billing."

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

Noyes says "approximately 30 drugs are affected" by the change, including subcutaneous immune globulin (IG), chemotherapies and inotropic agents.

There is "a wide variation in hits or increases in reimbursement" among the group of drugs, says Kendall Van Pool, vice president of legislative affairs at NHIA. "It's not all negative for all 30 drugs" as "certain drugs will get increased" reimbursement. But overall, the

"whole book of business definitely goes down." He tells AIS Health that "two drugs in particular" are the "most dramatically hit." Reimbursement for inotropic agent milrinone will have a decrease of about 92%. And subcutaneous IG Hizentra won't take as big of a hit in terms of a percentage decrease, dropping about 31%, but this is a high-dollar specialty drug, so the "actual bottom-line number" is highly impactful. Other subcutaneous IG products such as Gamunex and Gammagard will see hits between 21% and 31%, he says.

The Part B DME infused drugs were excluded from ASP reimbursement initially because of the recognition that "there needs to be a services payment around" them, says Van Pool. So the decision was made to "freeze reimbursement at the 2003 rates and fix this in the very near future." But as no services payment was implemented and reimbursement remained the same, "the frozen rate became more separate from the market."

The four-year gap between the shift to ASP and implementation of the services payment is because "some conservatives on Capitol Hill wanted every single year of the Cures bill to be offset," says Van Pool, an approach known as CUTGO, or cut-as-you-go, "a more onerous version of PAYGO," or pay-as-you-go. The approach "could accrue... needed savings for other programs," such as increased funding for the National Institutes of Health and FDA.

NHIA Calls for 2019 Start for Both

For its part, CMS said it needed to go through the rule-making process to implement the services payment, explains Van Pool, and said it needed the time to do that. "We think that CMS can do this faster than by 2021," he says. NHIA is hoping to have both the ASP methodology and the service payment implemented in 2019. "We think both are doable for CMS and Capitol Hill."

The Cures Act is "substantial new legislation intended to accelerate 'discovery, development and delivery' of medical therapies by encouraging biomedical research investment and facilitating innovation review and approval processes, among other things," notes Stephen Cichy, founder of and managing director at Monarch Specialty Group, LLC. But the reimbursement change for DME infusion therapies "will have [an] adverse impact to reduce reimbursement on impacted medications under Medicare Part B, and we may see the redistribution of the servicing of certain of these drugs by specialty and home infusion pharmacies from the home infusion setting to hospitals and/or post-acute care providers due to undesirable economics in 2017."

Those infusion pharmacies that have, for example, a lot of business in inotropic therapy "just took a hit," Reg Blackburn, managing director at The Braff Group, tells

AIS Health. "If you're a big player, you may have had millions pulled from your bottom line."

Indeed, the day after Obama signed the legislation, BioScrip, Inc. issued a press release saying it had "introduced a proposed Amendment" to its 2013 credit agreement, which it discussed for four paragraphs, followed by two paragraphs about the Cures Act. According to the infusion provider, "This legislation will potentially result in a significant reduction in Medicare patient access to inotropic and subcutaneous Ig therapies effective January 1, 2017. The company estimates that the Cures Act as written will result in reimbursement reductions impacting therapies representing approximately 3%-4% of total current revenue."

"We are actively analyzing the implications of the Cures Act and looking to undertake potential operational and strategic initiatives to mitigate the impact on our business," said Dan Greenleaf, president and CEO of BioScrip.

"The home site of care is cost-effective and safe," maintains Noyes. NHIA, he says, is "concerned about access to care" for Medicare beneficiaries who need these therapies. Van Pool points out that "in some circumstances where reimbursement is below the acquisition cost" for a therapy, those home infusion providers will

have to "make hard decisions," potentially making this "a very real patient-access issue." This, in turn, could mean "these patients could be going to other sites of care that are not appropriate" for them, such as the hospital outpatient department, says Van Pool. For instance, people receiving subcutaneous IG most likely have primary immune deficiency disorders, and in this setting, they are at risk of getting a health care-associated infection.

Many of these are "24-hour-per-day drugs," Van Pool notes. With many sites of care, "you can't just pop in and get milrinone....Otherwise, you're going to a skilled nursing facility....Patients don't want to be there, and they don't need to be there."

The reimbursement change also has "the potential to affect...care where a lot of patients start — in the hospital." If setting up home infusion proves difficult, patients may need to stay in the hospital longer, particularly if they've used up their skilled nursing facility stays.

"It's yet to be seen how this will impact the overall health care landscape," Noyes tells AIS Health, "but we estimate it will significantly impact it."

View the 2016 OIG report at <http://tinyurl.com/huyfw93>. Learn more about the issue at www.nhia.org.

Contact Noyes and Van Pool through NHIA's Marilyn Tretler at marilyn.tretler@nhia.org. ♦

NEWS BRIEFS

◆ **A U.S. district court on Jan. 5 granted Amgen Inc. a permanent injunction (No. 1:14-cv-01317-SLR) barring Sanofi US and Regeneron Pharmaceuticals, Inc. from infringing two patents for Amgen's PCSK9 Repatha (evolocumab) with their drug Praluent (alirocumab).** The judge gave the companies 30 days before the injunction takes effect "to allow defendants the opportunity to appeal and request expedited review of this ruling by the Federal Circuit, and/or to encourage the parties to reach an appropriate business resolution." On Jan. 9, the court denied Sanofi and Regeneron's motion to stay the injunction pending appeal. Visit <http://tinyurl.com/glktq7g>.

◆ **The FDA on Dec. 29 released Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product,** which finalizes draft guidance published in May 2014 (*SPN 6/14, p. 1*). The basic principles remain the same, but the new document updates language to clarify the four assessments of a biosimilar in response to comments. View the document at <http://tinyurl.com/n3qre4y>.

◆ **The Health Resources and Services Administration released the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation on Jan. 5.** The rule is effective March 6. View it at <http://tinyurl.com/hae9t7h>.

◆ **PEOPLE ON THE MOVE:** The National Association of Specialty Pharmacy named **Rebecca Shanahan** president and **Mike Agostino** president-elect. Shanahan is CEO of Avella Specialty Pharmacy; she succeeds **Burt Zweigenhaft**. Agostino is vice president, pharmacy innovation and business development for Hy-Vee, Inc....Prime Therapeutics LLC named **John Drakulich** chief sales officer. He most recently was senior vice president of business development for OptumRx. The company also appointed **Mike Kolar** senior vice president, general counsel. He previously was chief legal and administrative officer at Virtual Radiologic Corp....Therigy, LLC hired **Brian Roberts** as its director of data analytics. He previously worked in data warehousing and analytics for Express Scripts Holding Co.

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