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DRUG BENEFIT NEWS

News, Data and Business Strategies for Health Plans, Employers, PBMs and Pharma Companies

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New Hep C Report Suggests Viekira Pak Is 'Wrong' Choice, Questions PBM Exclusions

A recent analysis of post-marketing data by Advera Health Analytics, Inc. suggested that AbbVie Inc.'s Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets) is the least safe option of three leading hepatitis C treatments and may be associated with at least $6.5 million in avoidable downstream medical expenses. In a blog post accompanying the release of the report, Executive Vice President Jim Davis questioned whether some payers made the right choice in exclusively covering the AbbVie drug on their standard formularies — a decision that Express Scripts Holding Co., for one, fiercely defends — while benefit consultants say this type of data is just one piece in a very complex puzzle of formulary decision making.

When Viekira Pak in December 2014 became the second oral agent in two months to receive FDA approval for the treatment of hepatitis C, Express Scripts immediately unveiled a pact to make that drug the exclusive genotype 1 hepatitis C treatment on its National Preferred Formulary *(DBN 1/9/15, p. 1)*. By early February 2015, at least 10 payers had disclosed exclusive or semi-exclusive deals with Gilead Sciences, Inc. to cover that manufacturer's hepatitis C agents, Harvoni (ledipasvir/sofosbuvir) and Sovaldi (sofosbuvir) *(DBN 2/20/15, p. 4)*. Express Scripts has said its aggressive stance on Gilead's pricing of those agents and bargaining with both drugmakers set the stage

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RxAdvance Aims to Disrupt PBM Service Model With Integrated Data Platform

By streamlining the often fragmented platforms used by PBMs to transact and analyze pharmacy, medical, laboratory and other data, RxAdvance is seeking to bring innovation to what its tech-savvy president and CEO, Ravi Ika, calls an "antiquated" industry. The Southborough, Mass.-based PBM in late 2014 completed building the Collaborative PBM Cloud, an "end-to-end" integrated platform that it is now actively marketing to health insurers and other plan sponsors along with 16 in-house PBM services.

"We looked at what are the avoidable medical costs in various buckets, analyzed the data with multiple health plans' data and integrated medical, lab and pharmacy data and said, 'These avoidable costs can be controlled if you have the right platform and you deliver the actionable intelligence at the point of care when the patient is in the doctor's office, and point of sale when he goes to pick up the prescription,'" explains Ika of building the platform.

Prior to launching RxAdvance in 2013, Ika in 2000 founded ikaSystems, which he says provided an integrated administrative management platform for health insurers that spanned all payer departments and business lines, lowered administrative costs for clients by as much as 50% and reduced avoidable medical costs. In an interview with *DBN*, he explains that the philosophies behind the two companies are similar: gather as much data as possible in one place to understand the payer's cost drivers

and find the "revenue maximization opportunities." On the medical side, that could mean tiering physicians and hospitals based on quality and cost; on the pharmacy side, that could mean pushing high-risk alerts, formulary savings opportunities or other "actionable information" to the physician at the point of care.

"When the doctor is trying to write a new prescription or renew an existing one through e-prescribing software or an EMR, we are taking advantage of the transaction and pushing actionable intelligence about the patient into his or her own workflow, so we are not asking the doctor to go to an outside portal," he explains.

One example of where the delivery of integrated information in real time may be effective is in Medicare Part D, in which plans must offer comprehensive medication reviews (CMRs) as part of medication therapy management (MTM) program requirements. By providing a "physician-led CMR," the Collaborative PBM Cloud prompts at the point of care to let the physician know that there's an opportunity to conduct a CMR and provide actionable information based on the member's condition(s) and the number of medications he or she is taking. The CMR can be completed in seven to 10 minutes, asserts Ika.

Other services include benefit plan design and modeling, claims processing, formulary management and modeling, pharmacy network contracting, analytics and reporting, compliance management and a fully integrated specialty solution to replace "buy and bill" with "authorize and manage." RxAdvance has also designed a disease-driven member app that members with certain chronic conditions can access through their smartphones to view cost saving and quality improvement opportunities. These services are available to insurers with commercial, Medicare and/or Medicaid lines of business as well as employer groups, accountable care organizations, state Medicaid programs and exchanges.

Without the PBM or the health plan having to outsource these various functions to other vendors, RxAdvance has operating costs that are about 40% less than those of other PBMs and passes those lower costs onto to the health plan in the form of administrative savings (i.e., charging a lower administrative fee) while keeping a smaller portion of pharmacy spread and rebate revenue than most PBMs, asserts Ika.

RxAdvance May Share Risk With Clients

In addition, RxAdvance offers clients an optional pharmacy risk-sharing model, in which the PBM will charge them based on pharmacy expenditures that are lower than what the plan is currently experiencing but the company projects the client can achieve. While no clients have taken the company up on that offer, four prospective clients are including that analysis in their requests for proposals (RFPs) now. RxAdvance's first PBM client was implemented in June 2015 and two more are slated to go live on Jan. 1, 2016.

RxAdvance now contracts with outside mail-order and specialty pharmacies, but will eventually look to build their own businesses. The company has also acquired a wholesaler license in order to account for generic inflation and be able to track the large variance in prices of about 15% to 20% of generic pharmaceuticals, so that if network pharmacies won't accept the maximum allowable cost prices for generics set by the PBM, they can obtain the generics directly from its own wholesaler, adds Ika.

Ika stresses that he's not selling the platform, like Argus Health Systems, Inc. or Catamaran Corp. (which was recently acquired by UnitedHealth Group) have for many years to other PBMs, and that it's the platform that differentiates his model. "The platform is streamlining all the operations within the PBM efficiently and is bringing real-time engagement of provider, pharmacist and member, and bringing in real time the clinical and pharmacy integrated actionable intelligence into the health plan to have a 360-degree view of the patient that they should act upon."

For more information, contact Ika via Steve Littlejohn at selj@climbthecurve.com. ✧

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2016 Star Ratings Show PDP Challenges With Adherence, CMRs

While Medicare Advantage prescription drug (MA-PD) plans continued to improve on star quality ratings, stand-alone Prescription Drug Plans (PDPs) experienced a significant drop in their overall average star rating from last year, according to new data from CMS. PDPs in particular struggled on the three medication adherence measures as well as the new medication therapy management (MTM) comprehensive medication review (CMR) completion rate, which also challenged MA-PDs.

According to 2016 star ratings data posted by CMS on Oct. 8, the average star rating weighted by enrollment for PDPs declined from 3.75 for 2015 to 3.40 for 2016. PDPs had made big gains last year when they improved from an average rating of 3.05 in 2014 *(DBN 10/24/14, p. 1)*. For 2016 there are 24 PDP contracts with overall ratings of four or more stars that will serve roughly 32% of PDP enrollees, down from nearly 53% of PDP beneficiaries last year.

CMS attributed the decline to the retirement of the diabetes treatment measure, on which plans had done well, and the inclusion of three measures that were not used for 2015. Measures pertaining to the call center — foreign language interpreter and TTY availability — and beneficiary access and performance problems were restored for 2016, while the CMR measure was for the first time moved from the display page to a star rating with a weight of 1 for 2016 *(DBN 5/23/14, p. 1)*. "Given the smaller number of measures for PDPs [15 vs. 44 for MA-PDs], these changes have a more significant impact," explained CMS.

Plans Have Trouble Keeping Up With Changes

In addition to certain measures being added and dropped for 2016, Tom Kornfield, vice president with Avalere Health LLC, cites several possible reasons for why there was such a significant decline in the average star ratings among PDPs. "To the degree that plans themselves aren't paid on the data I think affects how well they respond, because in general the overall ratings did go up, but you see these larger shifts for PDPs," he suggests to *DBN*. MA plans that earn four or more stars can receive a 5% bonus, while bonus payments are not available to PDPs. "It could also be that the PDPs are looking at low-income members, and that may be becoming a harder population to target."

Moreover, when measures are retired or new ones are introduced, because of the gap between the measurement year and the ratings year, "you could have plans that are really focusing a lot of efforts on certain measures thinking that will affect their star ratings and then that star rating is dropped or a new measure is added, and it's too late for them to [make a change] to really have an impact," adds Kornfield.

For 2016, both MA-PDs and PDPs scored an average rating of 2.3 on the CMR completion rate measure, which is based on the percentage of beneficiaries who met eligibility criteria for the MTM program and who received a CMR with a written summary in CMS's standardized format.

Helen Sherman, Pharm.D., vice president with Solid Benefit Guidance, says most plans find themselves continuously trying to catch up to meet annual CMS's changes for increasing CMR completion rates. "First it's challenging to forecast what CMR completion rate a plan should target given their desired MTM star result," she tells *DBN*. "With many plans using vendors for their MTM program, timeframes are challenging for plans with respect to when CMS's information is released, deciding upon a future CMR completion rate, updating vendor agreements and overseeing the vendor's execution to meet/exceed the target. It's difficult to align all the pieces, which is reflective in the scores."

MA Plans Continued to Improve

Meanwhile, CMS continued to observe increases in the number of Medicare beneficiaries in high-performing MA plans. MA-PDs that earned four stars or higher serve close to 71% of enrollees, an increase of almost 11 percentage points from 60% of enrollees in contracts with four or more stars the prior year. The average star rating weighted by enrollment for MA-PDs is 4.03 for 2016, compared with 3.92 in 2015, 3.86 in 2014 and 3.71 in 2013, said CMS.

Some of the big changes for plans this time were on Part D measures, and there were different trends among MA-PD plans versus PDPs. Medication adherence for diabetes medications, for instance, improved from 3.5 to 3.9 for MA-PDs but fell from 3.0 to 2.7 for PDPs.

Most of the moves, though, were in same direction, including appeals auto-forwarded (up from 3.6 to 4.5 for MA-PDs and from 2.5 to 4.1 for PDPs) and appeals upheld (down from 3.7 to 3.3 for MA-PDs and from 3.9 to 3.1 for PDPs). Stephen Wood, a principal in Clear View Solutions, LLC, suggests to *DBN* sister publication *Medicare Advantage News* that the downward movement in the latter category "has everything to do with drug prices," including substantial increases in copayments to help plans offset big price hikes and expensive new drugs.

Several analysts interviewed by *MAN* also said some of the scores indicated that plans must push their PBMs harder to aid them. The average stars score for price accuracy on the CMS Medicare Plan Finder, for example,

plummeted from 4.6 to 3.5 for the MA-PDs, and the MPF is a "PBM function," Wood remarks.

Out of 17 Medicare contracts that received five stars for their overall rating — thus earning higher performer icon (gold star) designation on the Medicare Plan Finder — two are PDPs, compared with three the year before. They are: Tufts Insurance Co., which is new for this year, and Wisconsin Physicians Service Insurance Corp., which also earned five stars in 2015.

Meanwhile, only six contracts received a low performer icon for consistently low quality ratings (i.e., 2.5 stars or less from 2014-16), down from seven the year prior.

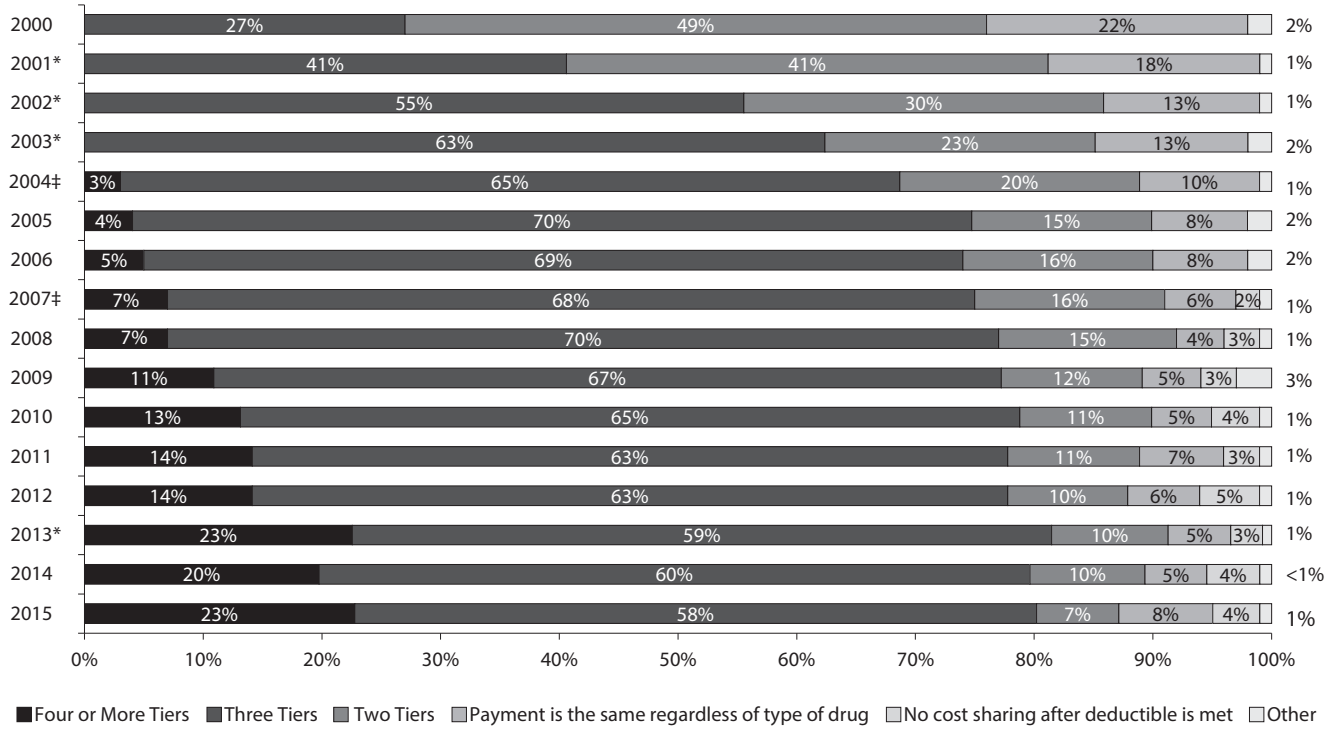
"I don't know to what extent the star ratings are really driving beneficiaries to make decisions to go from one plan to another," adds Kornfield. "And then if you have plans that are really kind of focused on low-income [populations], a lot of those folks are getting auto-assigned so they're not really making an active choice and from that perspective, the star rating may not have as much of an impact on the decision they make."

View the new data at http://tinyurl.com/ncfmomj. Contact Kornfield via Frank Walsh at fwalsh@gymr.com, Sherman at helen_sherman@ajg.com and Wood at stephen.wood@clrviewsolutions.com. ✧

Portions of this article were reprinted from DBN *sister publication* Medicare Advantage News. *For more information or to order, visit the MarketPlace at www.AISHealth.com.*

Distribution of Covered Employees' Different Rx Cost-Sharing Tiers, 2000-2015

According to the *2015 Employer Health Benefits Survey* released Sept. 22 by the Kaiser Family Foundation and the Health Research & Educational Trust, 81% of employees are now in a plan with three or more cost-sharing tiers, similar to the 80% observed in the prior year's survey. Meanwhile, the percentage of covered workers in a plan with four or more cost-sharing tiers continues to rise, reaching 23% in 2015, up from 20% the year before and 4% a decade ago, finds the annual survey of more than 2,000 small and large employers. Copayments are still more commonly used than coinsurance to cover workers' share of prescription drug costs, adds the report.



*Distribution is statistically different from distribution for the previous year shown ($p<.05$).

‡ No statistical tests are conducted between 2003 and 2004 or between 2006 and 2007 due to the addition of a new category.

NOTE: Fourth-tier drug cost-sharing information was not obtained prior to 2004.

SOURCE: *2015 Employer Health Benefits Survey*, The Kaiser Family Foundation and the Health Research & Educational Trust, published Sept. 22, 2015. View the full report at http://kff.org/health-costs/report/2015-employer-health-benefits-survey.

Health Plans and PBMs Continue to Deliberate on PCSK9 Inhibitors

This past summer saw the approvals of two highly anticipated agents in an emerging class of costly injectable drugs known as PCSK9 inhibitors that treat high cholesterol. While many industry observers had expected to see a scenario play out that was similar to when PBMs and health plans earlier this year pitted the makers of competing hepatitis C products against each other for exclusive formulary positioning (see story, p. 1), only ***Express Scripts Holding Co.*** thus far has unveiled its formulary strategy, while others say they are still reviewing the clinical data.

Express Scripts on Oct. 6 said its National Preferred Formulary will include both Regeneron Pharmaceuticals, Inc./Sanofi's Praluent (alirocumab) and Amgen Inc.'s Repatha (evolocumab), which were approved in July and August, respectively. Those drugs were introduced at an annual per-patient treatment cost above $14,000 *(DBN 9/11/15, p. 1)*. In an Oct. 6 post to the Express Scripts Insights Lab, Chief Medical Officer Steve Miller, M.D., explained that "collaborative discussions" with the manufacturers helped the PBM achieve the "best price possible for both products, without needing to exclude either."

Express Scripts Will Co-Favor Both New Drugs

Through a combination of discounts and a rigorous utilization management program for both drugs, Express Scripts estimated that its clients on the National Preferred Formulary will spend approximately $750 million on PCSK9 inhibitors in 2016 — "far lower than industry forecasts." That's because most of those clients enrolled in the Cholesterol Care Value program, which provides specialized patient care through the Accredo Specialty Pharmacy and guarantees a total cost cap for spending on PCSK9 inhibitors in 2016.

To date, the PBM has been rejecting the majority of pharmacy claims for Praluent and Repatha because they didn't require the necessary documentation to demonstrate that patients fit one of the profiles set by the manufacturers and the FDA, according to Express Scripts spokesperson David Whitrap. For example, physicians submitted prescriptions for patients who were statin intolerant when there was no prior evidence of them ever trying a statin. As physicians gain more familiarity with the products and Express Scripts' utilization management protocols, however, more claims may be approved, he says. "But that will be because physicians are better understanding our requirements, as opposed to us loosening those requirements," he adds.

DBN recently asked several PBMs and large health plans if they'd finalized their coverage strategy on the new cholesterol drugs. ***OptumRx,*** the PBM unit of UnitedHealth Group, responded that it is "still reviewing clinical evidence to determine the appropriate coverage policy," while ***MedImpact Healthcare Systems, Inc.*** said it plans to follow a similar "low net cost" approach as it did with the hepatitis C class rather than driving to rebates.

Likewise, ***Prime Therapeutics, LLC*** is in "active discussions" with manufacturers and is optimistic that it will "arrive at a decision that achieves the lowest net cost possible and helps ensure members can get the most appropriate treatment for their condition," according to Pete Clagett, senior vice president of integrated care and specialty with the Blues plan-owned PBM.

Script Volume Has Been Lower Than Expected

"The good news is uptake of these medicines has been very slow, so there's no need to rush decisions," Clagett tells *DBN*. "Prime's Cholesterol Best in Care drug management program is also effectively managing PCSK9 [inhibitors] to minimal use at this time and has already saved our plans millions of dollars. In addition to negotiating traditional discounts, Prime is working on a CareCentered Contract for PCSK9s that puts more skin in the game and holds manufacturers accountable for the overall performance of these products. This is a critical piece to our overall strategy. We will be discussing PCSK9s at our P&T committee meeting later this month and hope to finalize formulary placement in the next month or so."

"The PBMs appear to be taking a more deliberate approach with this class. Since the initial volume of PCSK9 prescriptions is a lot lower than originally anticipated, there is less near-term pressure on the PBMs to execute a quick decision on formulary strategy," observes Josh Golden, practice leader, employer consulting at Pharmaceutical Strategies Group LLC. "They can play the field for a bit, at least until utilization starts to climb for these products. That said, it's important to note that a delayed decision creates potential challenges for a smooth implementation of the strategy, assuming a January 1 effective date."

Contact Clagett via Karen Lyons at klyons@primetherapeutics.com, Golden at jgolden@psgconsults.com and Whitrap at dwhitrap@express-scripts.com.

Report Flags Viekira Pak Risks

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for other payers to secure discounts on these costly products, and that by excluding Harvoni, it has already saved clients more than $1 billion this year while expanding access to curative therapy for all patients with early stage hepatitis C.

In January 2015, Advera Health (then AdverseEvents, Inc.) issued a report suggesting that Viekira Pak may have a poorer safety profile than the other two products *(DBN 1/23/15, p. 4)*. That assertion was partly based on the number of adverse event terms — approximately 50 for Viekira Pak — on the approved labeling compared with only seven adverse events indicated on the labeling for Harvoni, which was approved in October 2014 *(DBN 10/24/14, p. 1)*. Since January 2015, Advera Health has filed seven separate Freedom of Information Act requests to obtain more than 11,000 adverse event case reports pertaining to Harvoni, Sovaldi and/or Viekira Pak.

Using its proprietary cost algorithm to calculate the RxCost, or average expected downstream cost associated with adverse event/drug combinations, Advera Health found that Viekira Pak's RxCost per prescription rose by 200% to $151 while the RxCost for Harvoni dropped 32% to $60.24 since the January 2015 analysis, according to the *Drug Safety Monitor* report published Oct. 12. These results included disease-related adverse events as well as adverse events not tied to the disease, but even excluding those disease-related events, Advera Health's overall conclusions about the relative safety of the three therapies remains unchanged, stated the report.

Advera Health also said the RxScore, which is depicted on a 100-point scale to reflect both the breadth and seriousness of side effects, for Viekira Pak increased by eight points to 73.93, "making it the riskiest option of the three drugs." At 68.98, Harvoni has the lowest RxScore of the three.

The report suggested that the jump in downstream medical costs per prescription related to Viekira Pak could be due to serious adverse event cases being reported for the first time. For the period between Jan. 1, 2015, and Aug. 25, 2015, Viekira Pak had the highest number (3,147) of primary suspect case reports — almost twice as many as Harvoni and 4.5 times as many as Sovaldi for that time. And despite being used in a "less risky patient group," Viekira Pak is linked with greater incidences of hospitalization and medical intervention due to an adverse drug reaction, observed Advera Health.

Using RxCost and prescription data obtained by its partner, The Evaluate Group, the firm conservatively estimated that if all Viekira Pak patients had taken Harvoni instead, the health care system would have saved $3.7 million in downstream medical costs that result from adverse events associated with Viekira Pak over that nine-month period, according to an Oct. 16 post to The RxReview Blog. Given that serious adverse events are underreported for Harvoni and Viekira Pak by a factor of 1.77, those savings could exceed $6.5 million.

"So were the payers who chose Viekira Pak wrong? These data suggest they were," wrote Davis. "Did they choose short term financial incentives over long term costs and more importantly patient safety? It seems to be so. Should patients, prescribers, insurers and government agencies care? Without a doubt. Can a positive impact be made both in terms of costs and outcomes…by reacting to these data? Definitely….[T]he numbers say patients with Hepatitis C should be provided with Harvoni over Viekira Pak, if safety is at all a factor."

Express Scripts Backs Formulary Decision

Express Scripts continues to stand by its strategy and emphasizes to *DBN* that the first consideration when making a formulary decision is always clinical and that in clinical trials, Harvoni and Viekira Pak demonstrated similar efficacy and safety profiles. "We will only consider a formulary exclusion in instances when our external P&T [pharmacy and therapeutics] Committee has already determined that there are multiple clinically equivalent products on the market," says Express Scripts spokesperson David Whitrap via email.

"As we do with all medications, our P&T Committee will continue to monitor all new clinical data as they become available, and we will use these findings to ensure that our formulary continues to deliver the best possible health outcomes at the lowest possible costs," adds Whitrap.

"The Advera Health report is a great example of the complex decisions that need to be made, and frequently re-evaluated on the formulary status of all drugs. Formulary decisions have historically been made based on clinical and financial information available at the time a drug is introduced to the market. Real-world data on drug-related adverse events and their downstream costs are definitely part of the total cost of the health care picture," observes Justin Weiss, Pharm.D., vice president of clinical services at Pharmaceutical Strategies Group LLC.

"I wouldn't look at the data at face value as a standalone decision-making point, but yet another example

of how Big Data can be used to assess the overall cost of care related to formulary decisions," he continues. "This type of analysis will continue to be required as we see more complex specialty drug regimens made available within a health care system that is struggling to manage costs and improve quality."

At the time of Viekira Pak's approval, some payers had expressed concerns about potential adherence issues, since patients have to take two fixed-dose ombitasvir/paritaprevir/ritonavir tablets once a day in the morning and one dasabuvir tablet twice daily with a meal, compared with the once daily Harvoni. "Given the short duration of these regimens, our P&T Committee — along with many other outside groups — concluded that the slightly higher pill burden for Viekira Pak is not a clinically significant factor for these patients," asserts Whitrap.

He adds that when dispensed through Express Scripts' Accredo Specialty Pharmacy, both products continue to demonstrate similar cure, adherence and side effect profiles to one another. "We are so confident that our Accredo specialists can help patients remain adherent to their Viekira Pak regimens that we financially guarantee this adherence for clients who participate in our Hepatitis Cure Value Program."

The report highlighted several potentially disease-related bleeding issues in patients taking Viekira Pak, including stoma site hemorrhage, gastric varices hemorrhage and scleral hemorrhage. While the first two conditions may be related to the underlying disease, the latter could be linked to the use of Viekira Pak, since it is a known adverse reaction among patients receiving interferon therapy for viral hepatitis, added Advera Health.

"I think the data likely has merit, and payers generally accept that treating and curing hepatitis C has a favorable impact on downstream costs, especially with avoiding liver transplants. However, data [demonstrating a negative or positive impact on downstream costs] will not necessarily change how and why a payer covers the hepatitis C drugs, because the member may not be with the same payer that pays for the drug long-term," suggests Helen Sherman, Pharm.D., vice president with Solid Benefit Guidance.

"Formulary exclusions are not going away and we will only continue to see more manufacturers lining up with PBMs to drive their products and maintain market share," adds Brian Anderson, a consultant with Milliman. "We will see these types of formularies being used across all lines of business in the PBM industry. The next issue that PBMs need to address is the price elasticity using their approaches of contracting using price protection to mitigate inflation. The exclusive formulary approach is effective but not the solution."

For more information, visit http://info.adverahealth.com/subscribe-drug-safety-monitor-center. Contact Anderson at brian.anderson@milliman.com, Sherman at helen_sherman@ajg.com, Weiss at jweiss@psgconsults.com and Whitrap at dwhitrap@express-scripts.com. ✧

NEWS BRIEFS

◆ **Reporting for the first time earnings associated with Catamaran Corp., UnitedHealth Group on Oct. 15 said third-quarter 2015 revenues for its OptumRx division jumped 80% to $14.5 billion.** The company attributed the improvement to a 59% increase in prescription volume to 226 million adjusted prescriptions in the third quarter, "driven by the acquisition of Catamaran and strong organic growth." For the three months ended Sept. 30, 2015, overall revenues were $41.5 billion, up 27% from the year-ago quarter, including an increase of 9% to $32.8 billion in the UnitedHealthcare division, while net income remained flat at $1.6 billion. "Market interest in OptumRx continues to grow in response to the value we can drive through more integrated downstream drug benefit and care management efforts, especially around the growing specialty pharmaceutical market," added Optum CEO Larry Renfro during an Oct. 15 conference call to discuss earnings. Visit www.unitedhealthgroup.com/investors.

◆ **The FDA on Oct. 16 granted accelerated approval to Praxbind (idarucizumab), the first agent approved specifically to reverse the blood-thinning effects of the anticoagulant Pradaxa (dabigatran).** Praxbind works by binding the drug compound to neutralize its effect and is for intravenous injection in emergency situations. In one of three clinical trials evaluating the safety and effectiveness of the new drug, 123 patients taking Pradaxa received Praxbind due to uncontrolled bleeding or because they required emergency surgery; the anticoagulant effect of Pradaxa was fully reversed in 89% of patients within four hours of receiving Praxbind. Pradaxa was approved in 2010 to prevent stroke and systemic blood clots in patients with atrial fibrillation, as well as for the treatment and prevention of deep vein thrombosis and pulmonary embolism. It is one of three "next-generation" anticoagulants that unlike their 60-year-old predecessor, warfarin, do not require regular blood monitoring or come with dietary restrictions. Because reversing the effect of Pradaxa exposes patients to the risk of blood clots and stroke from their underlying disease, the approved Praxbind labeling suggests that patients resume their anticoagulant therapy as soon as is medically appropriate, based on their health care provider's recommendation. Both agents are marketed by Boehringer Ingelheim.

◆ **The U.S. District Court for the District of Columbia on Oct. 14 ruled that drugmakers do not have to sell orphan drugs to covered entities participating in the 340B Drug Pricing Program.** The Pharmaceutical Research and Manufacturers of America (PhRMA) had sued HHS a year ago, saying manufacturers should not have to discount orphan drugs for nonorphan uses, as HHS had argued in an interpretive rule. The recent court decision vacates that rule, concluding that it contradicts the plain language of Section 340B(e) of the Affordable Care Act, which stated that any drug that is designated for a rare disease or condition is excluded from the 340B program. Visit http://tinyurl.com/oha4uwk.

◆ **Cigna Corp. on Oct. 9 agreed to reverse a policy that requires members to obtain certain HIV/AIDS medications through its mail-order pharmacy.** The decision came as a part of a settlement resolving a lawsuit (*John Doe v. Cigna et al.*, 15-cv-60894-DPG) filed by advocacy group Consumer Watchdog in April alleging that the mail-order requirement discriminated against HIV/AIDS patients and risked their health and privacy. The settlement will go into effect on Dec. 1, when Cigna members will be able to obtain their antiretroviral HIV/AIDS therapies except for Fuzeon (enfuvirtide) from any in-network pharmacy. The case was filed on behalf of a Florida man, although the group was seeking to represent a nationwide class of HIV/AIDS patients; Cigna agreed to the settlement before the court could certify the case as a class action. Consumer Watchdog said patients who would have paid more for their drugs than they would have through a local pharmacy as a result of the Cigna policy will be able to seek reimbursement under the settlement. A Cigna spokesperson declined to comment to Reuters. View the Cigna settlement at http://tinyurl.com/qbgxgjh.

◆ **Goold Health Systems, an Emdeon company, was awarded a multiyear contract to manage pharmacy benefits for the Ohio Medicaid program.** Goold, a health care management company focusing on Medicaid services, said it was selected by the Ohio Dept. of Medicaid to provide pharmacy claims adjudication, prior authorization, rebate management, preferred drug list and related clinical pharmacy services. The contract is for a multiyear project with an initial term through June 30, 2017, and three additional two-year optional renewals. Contact Emdeon spokesperson Heather McLarney at (615) 932-3690.

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