Drug Benefit News

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DRUG BENEFIT NEWS

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

Contents

PUBLISHER'S NOTE: The next issue of ***DBN*** *will be dated Jan. 8.*

Diabetic Ketoacidosis Warning Brings SGLT2 Concerns Into Focus for Plans

Thanks to a second FDA safety warning this year and newly revised labeling for the type 2 diabetes medications sodium-glucose cotransporter-2 (SGLT2) inhibitors, health plans are on high alert for evidence of diabetic ketoacidosis and urinary tract infections among their own members. But several plans tell *DBN* the warning may not require updates to existing coverage criteria, which are already tight given ongoing concerns about newer diabetes drugs and a preference for older, tried-and-true agents such as generic metformin.

The FDA had already warned of the risk of ketoacidosis in May in a separate Drug Safety Communication and said it would continue to evaluate this safety issue. Now, another safety review has resulted in the FDA adding new warnings to the labels of all three approved SGLT2 inhibitors to include the risks of ketoacidosis (too much acid in the blood) and serious urinary tract infections. Both conditions can lead to hospitalization, advised the FDA.

Not only is ketoacidosis a serious safety concern, it can be a significant cost driver for plan sponsors, asserts Jim Davis, executive vice president at Advera Health Analytics, Inc. The research and advisory firm monitors events reported to the FDA, including those not yet available to the public by making Freedom of Information Act requests, and calculates the downstream medical costs associated with adverse drug events.

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Express Scripts Targets Cancer Drugs, Brand Inflation Via SafeGuardRx Suite

Promising "to keep clients ahead of the cost curve" by targeting certain high-cost medication classes, Express Scripts Holding Co. on Dec. 15 unveiled the addition of two components to a growing suite of optional programs that include its Hepatitis Cure Value (HCV) Program and Cholesterol Care Value (CCV) Program. Encompassed under what it's now calling SafeGuardRx, Express Scripts next month will launch the Oncology Care Value (OCV) Program and the Inflation Protection Program to offer clients additional price protections in areas that have the potential to seriously squeeze plan sponsors' budgets.

Express Scripts earlier this year introduced an indication-based pricing model for cancer drugs, in which the PBM will pay different prices for the same drug, depending on the condition *(DBN 6/5/15, p. 1)*. The OCV Program includes that component, but it also involves other novel pricing arrangements that Express Scripts is now developing with additional manufacturers, according to spokesperson David Whitrap.

Beginning in 2016, the program will focus on prostate cancer, lung cancer and renal cell carcinoma, with other cancer categories likely to be included in subsequent years. In a Dec. 15 post to the Express Scripts Insights Lab website, Express Scripts Senior Vice President, Clinical, Research & New Solutions, and Chief Innovation Officer Glen Stettin, M.D., explained that cancer patients covered by plans that participate in this program will initiate therapy with "clinically appropriate and cost-effective medication for

a specific indication." Patients will also receive support through Express Scripts' Oncology Therapeutic Resource Center (TRC) and must exclusively obtain all oncology medications through the Express Scripts-owned Accredo specialty pharmacy.

Anticipating the approvals of the first PCSK9 inhibitors to treat high cholesterol, Express Scripts in June launched the similar CCV Program, which promotes the use of mail order for all cholesterol medications, involves a rigorous clinical review process for PCSK9 inhibitor requests, and provides member assistance and education through Accredo *(DBN 6/26/15, p. 1)*. The company said it's enhanced that program to include a per-member per-year plan cost cap on PCSK9 inhibitors that are obtained through Accredo for patients covered by a participating plan. Meanwhile, plans enrolled in the year-old HCV Program will receive an additional discount of at least $2,000 for every patient receiving the Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets), which Express Scripts selected as the exclusive genotype 1 hepatitis C option for customers that use the National Preferred Formulary *(DBN 1/9/15, p. 1)*.

Beginning Jan. 1, 2016, Express Scripts will also offer the new Inflation Protection Program, which Stettin said will "shield participating plans from the full cost impact of year-over-year price increases on brand drugs." According to the Express Scripts Prescription Price Index, the average price for the most commonly used brand-name drugs shot up 127% in the U.S. between 2008 and 2014. And last year, nearly 20% of brand drugs rose in price by more than 20%, says Express Scripts.

"Above and beyond our existing rebate arrangements that we have in place with our clients, this program provides both additional financial value and budget predictability for the future," adds Whitrap. All of these programs are available at no additional cost to Express Scripts clients, he stresses.

Josh Golden, practice leader of employer consulting at Pharmaceutical Strategies Group LLC, says of all four options, the Inflation Protection option is generating the most buzz among PSG clients. "Some kudos are due to [Express Scripts] for attempting to address an area of common concern among clients — unchecked brand drug inflation is definitely a pain point," he remarks via email. "But the value of the program may get a bit diluted in the details. The initial wave of Inflation Protection targets that we have seen have been set fairly conservatively, so we're probably not going to see frequent payouts on these in the near-term."

Golden adds that there are some "underlying concerns" about funding for the inflation program. "If [Express Scripts] is relying on pharma dollars to fund the Inflation Protection pool, then you could argue that this program is diverting value away from full pass-through rebate arrangements," he suggests.

As for the three disease state program components, Golden calls this a "tip-toe approach into exclusive distribution" and signals that the company is "willing to sacrifice some margin or assume some risk in exchange for greater utilization of Accredo."

Contact Golden at jgolden@psgconsults.com and Whitrap at dwhitrap@express-scripts.com or visit the Insights Lab at http://lab.express-scripts.com. ✧

To learn more about Express Scripts' indication-based model and other alternative drug pricing arrangements, join us at a Jan. 27 AIS webinar. Visit the AIS MarketPlace at www.aishealth.com.

UnitedHealth Foresees OptumRx Growth In Spite of Exchange Woes

While UnitedHealth Group may not be performing well on the public health insurance exchanges and recently lowered its 2015 earnings-per-share guidance to reflect that, the company's Optum health care services conglomerate is expected to boost revenue by 20% next year, driven in part by the recent addition of Catamaran Corp., executives said at a Dec. 1 investor conference.

Optum, which includes a health care information technology business and the OptumRx PBM, is expected

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to contribute more than 40% of UnitedHealth's operating earnings in 2016 and approach 50% of its earnings by the end of the decade, said the company at its Annual Investor Conference held in New York City. Providing an overview of 2015 performance, Optum Chief Financial Officer John Rex said the division is poised to deliver $67 billion in revenue, reflecting "strong organic growth across businesses as well as the Catamaran combination." UnitedHealth in March unveiled plans to acquire Catamaran and merge it with OptumRx, and completed the transaction in July *(DBN 4/3/15, p. 1)*.

For 2016, the company projected that Optum will deliver at least $80 billion in overall revenue and that earnings from operations will be in the range of $5.55 billion to $5.7 billion, up from an estimated $4.2 billion in 2015. That includes $57.8 billion in revenue and $2.5 billion to $2.65 billion in operating earnings from OptumRx. The PBM expects to process an adjusted 1 billion prescriptions per year.

That guidance includes several items that are not expected to materially impact UnitedHealth's bottom line, added Rex. These include large health plan customers forecasting lower Part D enrollment and one large customer transitioning to a claims-processing-only arrangement for a portion of its business.

PBM Focuses on Synchronization

During the conference, Optum CEO Larry Renfro said there is great potential for the PBM unit to expand as "employer, health plan and government clients look to more deeply integrate their medical and pharmacy benefits." And that integration is what the PBM is relying on as a key differentiator. While bringing the UnitedHealthcare business in-house from Express Scripts Holding Co., OptumRx in 2013 launched the Synchronization approach, drawing on its ability to integrate real-time medical and pharmacy claims data to address gaps in care *(DBN 3/11/13, p. 1)*.

Synchronization provides a "360-degree view of the whole person, all focused on driving better outcomes at a lower cost," explained OptumRx CEO Mark Thierer at the conference. He described the case of a 60-year-old patient recently hospitalized with a lung infection who arrived home with a "stack of discharge instructions and a stack of prescriptions." The patient placed a phone call to OptumRx and was routed to a nurse care advisor who had a "comprehensive view of her health history" and was then able to connect her with an OptumRx nurse and a pharmacist to resolve some of her medication-related issues and perform a "complete medicine cabinet review."

Synchronization members show a 5% to 15% reduction in both inpatient and emergency room admissions, and are 45% more likely to participate in clinical programs, added Renfro. Moreover, early results show these interactions can lower medical costs by up to $20 per member per month.

"Our key takeaways from the event were that the PBM is quickly maturing into a differentiated competitor to CVS and [Express Scripts] in [the] pharmacy services space," observed securities analyst George Hill in a Dec. 2 Deutsche Bank research note. "Unlike other PBMs, OptumRx is a PBM owned by a payer, with the majority of its PBM book of business in its MCO book of business. Optum contends that it will take a different approach to benefits management, focusing more on the best total treatment of the patient at lowest possible cost. This PBM model could be an interesting option to employers and other plan sponsors willing to try combining the medical and pharmacy benefit in the hopes of reducing total beneficiary medical costs, as opposed to splitting the medical and pharmacy benefit and trying to get the best cost from each."

Visit www.unitedhealthgroup.com/investors or contact Hill at george.hill@db.com. ✧

Lawmakers Seek Answers, Solutions For Off-Patent Drug Price Hikes

Just a year ago, lawmakers were making a lot of noise about generic drug price hikes that resulted from drug shortages, industry consolidation and manufacturing issues. But as the public debate over drug pricing has intensified in recent months, some members of Congress have narrowed their focus on an alarming trend of companies buying the rights to older drugs and then greatly inflating their price in the marketplace. In order to further understand this issue and consider policies to address it, the Senate Special Committee on Aging on Dec. 9 held a hearing at which it interviewed a panel of clinical and economic experts on sudden price spikes in off-patent drugs with no generic competition.

"For many decades, federal policy has sought to strike the right balance between maintaining the incentives needed to promote for innovation and the development of new drugs, and keeping medicines affordable," remarked Sen. Susan Collins (R-Maine), who chairs the committee, referring to patent exclusivity and the intent to promote competition once drugs go off patent. "That balance…never anticipated companies acquiring off-patent drugs and then jacking up their prices to enormous heights and doing so, as one executive essentially put it, 'Because I can,' but that is exactly what we have seen in recent months."

Collins was, of course, referring to Martin Shkreli, the 32-year-old former hedge fund manager who

founded Turing Pharmaceuticals and hiked the price of the toxoplasmosis agent Daraprim (pyrimethamine) by more than 5,000% after he acquired it. This was the first hearing in the Special Committee on Aging's bipartisan investigation into "sudden and dramatic" price increases of off-patent drugs, she explained. The committee on Nov. 4 sent letters to Turing and three other drug companies — Retrophin, Inc. (which was founded by Shkreli), Rodelis Therapeutics and Valeant Pharmaceuticals — seeking information about their rationale for the pricing of certain drugs. For example, the committee queried Valeant Chairman and CEO Michael Pearson about the respective 212% and 525% price increases for the recently acquired heart medications Isuprel (isoproterenol) and Nitropress (nitroprusside), which are also the focus of a separate probe by the House Committee on Oversight and Government Reform *(DBN 10/9/15, p. 4)*.

"Dramatic price hikes are seemingly business as usual for Valeant," asserted Sen. Claire McCaskill (D-Mo.), who is ranking member of the Special Committee on Aging. She referred to a report finding that Valeant this year has raised the prices of all its drugs by an average of 66%, and recalled questioning a Valeant executive at a hearing in July and being told the company conducted a "complex analysis" concluding that Isuprel was "significantly underpriced" before Valeant decided to raise its rate. "To me, there's a line at which these huge price increases on prescription drugs go from rewarding innovation to price gouging," stated McCaskill. "In particular, when these price hikes occur without any therapeutic change or improvement to the drug, it raise[s] troubling questions about whether companies like Turing and Valeant are taking advantage of the patients who depend on their products for survival."

What Daraprim, Isuprel, Nitropress and other drugs the senators are focusing on have in common is that they do not have market competition from generic alternatives, making them vulnerable to acquisition and price increases. And McCaskill said the senators are looking for solutions to prevent such a "market failure" from occurring while protecting patients.

Erin Fox, Pharm.D., director of drug information service at University of Utah Health Care, testified about the vulnerability of the generic injectable supply chain and said it was forced to remove Isuprel from about 100 crash carts stored throughout the hospital and make them available only in pharmacy back-up boxes that pharmacists bring in case of a critical emergency or cardiac arrest. She said the hospital has "no data yet on whether patients have been harmed [by this move], but it is concerning when we have to make decisions based on cost alone."

David Kimberlin, M.D., a pediatric infectious disease specialist with the University of Alabama, testified about the difficulties he and other health care professionals have faced when trying to administer a liquid form of Daraprim to infants born with congenital toxoplasmosis, which can cause brain damage, blindness, deafness and even death. Due to the high cost of the drug and a limited distribution arrangement put in place by Turing, sites that were previously able to compound the drug into the liquid have been unable to obtain it. A full 12-month course now costs at least $69,000, whereas previously it would run only about $1,200, he added.

But several strategies to mitigate rising costs and increase access to drugs in this type of situation were discussed, including one recently introduced by Express Scripts Holding Co. that Pharmaceutical Care Management Association President and CEO Mark Merritt said other PBMs are now pursuing. Express Scripts on Dec. 1 said it reached a deal with Imprimis Pharmaceuticals to offer members a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for $1 per capsule as an alternative to Daraprim *(DBN 12/4/15, p. 8)*.

Speaking at the hearing, Merritt said all PBMs are concerned about the recent price spikes and while they recognize it's not "indicative of the overall marketplace," they "take it seriously and are confronting it in real time." Merritt also mentioned PBMs' recent efforts to "root out corrupt pharmacies" like the Valeant-associated Philidor Rx Services LLC *(DBN 11/20/15, p. 1)* and thanked lawmakers for "resisting so-called any willing pharmacy mandates that would force payers like us to include bad actors like Philidor in our pharmacy networks whether they were good, bad or indifferent."

But to address the issue at hand, Merritt recommended that policymakers take certain steps. Among them:

◆ ***Approve generic drugs faster,*** said Merritt, referring to the FDA's average three-year review time and backlog of 4,000 applications.

◆ ***Establish a "special fast track" for abbreviated new drug applications for generics competing with off-patent brands*** and create new incentives for them to enter these markets; and

◆ ***Create a "watch list" of off-patent drugs that face no competition,*** "just simply to let the owners of the rights to these products and the potential hedge fund acquirers that we're watching, we know these are the targeted products and there's going to be a lot of scrutiny on it," said Merritt. "The hedge funds have these lists; the government might as well, too."

Also testifying at the hearing, Johns Hopkins University Professor Gerard Anderson, Ph.D., concurred that lawmakers should look into establishing priority reviews for drugs with no generic competition, and suggested — "as a last resort" — exploring importation from Canada and other countries where these drugs are less expensive. He also urged the committee to "take a very close look at how pricing works in the generic market, not just for these drugs but broadly" and consider making average manufacturer price information calculated by drug companies and used to determine Medicaid rebates publicly available to increase price transparency.

Visit www.aging.senate.gov. ✧

Plans Fret Over SGLT2 Issues

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Davis says Advera Health first identified ketoacidosis as a serious adverse event linked to this particular class of drugs more than a year prior to the initial FDA warning. Using its proprietary RxCost analytic, the firm estimates that the reported cases alone cost the health care system nearly $2.5 million overall in downstream medical costs related to the adverse event.

According to the Dec. 4 Drug Safety Communication, a review of the FDA Adverse Event Reporting System (FAERS) database from March 2013 to May 2015 found 73 cases of ketoacidosis in patients with type 1 or type 2 diabetes treated with SGLT2 inhibitors. And from March 2013 through October 2014, the FDA identified 19 reported cases of life-threatening blood infections and kidney infections that began as urinary tract infections in patients taking these drugs, all of which required hospitalization. A few even resulted in admission to an intensive care unit or dialysis in order to treat kidney failure.

As a result, the FDA has added new warnings and precautions to the labels of all SGLT2 inhibitors to reflect the two safety issues and provide prescribing and monitoring recommendations. Moreover, it is requiring that the makers of these products conduct "enhanced pharmacovigilance" studies that analyze spontaneous postmarketing reports of ketoacidosis in patients treated with SGLT2 inhibitors and perform "specialized follow-up" to collect additional information for a period of five years.

Davis says that increased monitoring is significant. "It's something that the FDA obviously feels strongly enough about where they're actually requiring the manufacturers to track it extremely closely over the next five-year period, so I think that's a pretty big signal right there," he tells *DBN*.

Laurie Wesolowicz, Pharm.D., director of pharmacy services clinical at Blue Cross Blue Shield of Michigan (BCBSM), says ketoacidosis is a "very serious side effect" and has been on the insurer's radar since an endocrinologist on its pharmacy and therapeutics committee brought it up as a concern prior to the FDA's safety communication in May. As a result, BCBSM has updated its prior authorization criteria for the class of drugs, but may tighten up that criteria even further based on the most recent warning, she tells *DBN*.

continued

"We require authorization for these drugs, not just for step therapy but also to document that the patient has diabetes [and] that they are in need of a diabetic therapy, and so we look for certain hemoglobin A1c levels" to demonstrate that, explains Wesolowicz. "It's one of those drug classes where we're always concerned when it's a brand-new type of drug but on the other hand we have a lot of discussion with our P&T committee [that] physicians, especially primary care physicians, are always looking for other therapeutic options for patients with diabetes. So we decided to take a more cautious approach and require prior authorization."

The insurer adopted a similarly conservative approach with dipeptidyl peptidase-4 (DPP-4) inhibitors and glucagon-like peptide-1 (GLP-1) agonists, which also are not traditional first-line therapies for diabetes. BCBSM first recommends that physicians prescribe generic metformin and consider insulin when members are in need of additional therapy. "But it's oftentimes really tough to get patients to administer insulin and so a lot of physicians will turn to the other agents," points out Wesolowicz. As a result, the insurer initially placed prior authorization requirements on those other newer drugs and with more experience "loosened up the criteria and preferred some of those agents."

Wesolowicz adds that BCBSM has not had any physicians in its Value Partnerships program report events of ketoacidosis or urinary tract infections in patients taking SGLT2 inhibitors, and that it will monitor medical claims going forward for any evidence of those adverse events.

Plans Have Not Seen Affected Patients

Likewise, PerformRx requires that patients utilize other preferred alternatives before trying any SGLT2 inhibitors and has very little utilization of drugs in the class at this time, according to Mesfin Tegenu, R.Ph., president of the AmeriHealth Caritas-owned PBM.

"We are currently monitoring the pharmacy and medical claims data to determine if there are any increased risks for our population," Tegenu tells *DBN*. "As is the case with all medications, risks must be weighed against the benefits of therapy. There are no treatment options for diabetic patients that are free of potential adverse outcomes. We will continue to monitor and determine if the risk of utilization outweighs the benefits." Tegenu adds that the entire class of drugs will be reviewed in early 2016 to determine if any coverage changes are needed in light of the FDA warnings and any other information.

Independent Health, meanwhile, says it is taking a "watch-and-wait" approach before re-evaluating formulary coverage in the class. The Western New York insurer has only one SGLT2 inhibitor, Invokana (canagliflozin), on formulary and has not yet identified any issues with members covered by its plans, and thus does not consider it a "deep concern" at this time, says Martin Burruano, R.Ph., vice president for pharmacy services.

The insurer's main course of action has been to communicate the new safety information to all providers. In response to the initial communication in May, the regional health plan has sent individual notices to all providers in its network as well as highlighted the safety warning in a spot on its physician and pharmacist newsletters devoted to black box warnings, MedWatch alerts, etc. issued by the FDA. In addition, it has incorporated the information into its medication therapy management program "so that the MTM pharmacist managing our diabetic patients share this information with either the member or provider or both, if it's applicable, and then also make recommendations to physicians if they see this may be an issue for the member," Burruano tells *DBN*. The insurer has also notified emergency room providers of the issue, because that's where patients presenting signs of ketoacidosis would generally end up.

Farxiga Poses Biggest Problem

According to Advera Health data presented at the American Society of Health-Systems Pharmacists' annual conference on Dec. 6 in New Orleans, a review of more than 99,000 "primary suspect" FAERS case reports for major type 2 diabetes medications found elevated reporting of ketoacidosis in all three newer classes of treatments. But SGLT2 inhibitors had a much higher reporting odds ratio, meaning they have a higher-than-expected reporting rate for the specified drug/adverse event combination, according to the poster presentation.

While cost information is not shown in the poster, ketoacidosis was the leading contributor to the RxCost calculation assigned to each diabetes drug in a May 2015 report. "It's important to note that our data do show a clear differentiation between the SGLT2s, so even though this is a classwide effect [and] they all do have increased and elevated reporting, there is a differentiation when you actually bring it down to an incidence level number," emphasizes Davis. "So we do see that Farxiga has the highest reporting incidence for ketoacidosis, and in turn has the highest RxCost of the other SGLT2s by quite a long shot." In that report, Farxiga (dapagliflozin) was shown to have an RxCost of $11.68, compared with just $2.66 for Invokana.

View the FDA alert at http://tinyurl.com/qhwjb2q. Contact Burruano via Frank Sava at frank.sava@independenthealth.com, Davis via Brenda Nashawaty at bnashawaty@adverahealth.com, Tegenu at mtegenu@performrx.com or Wesolowicz via Meghan O'Brien Edwards at mobrienedwards@bcbsm.com. ✧

Plans Have Work to Do on MTM CMR Star Ratings Measure

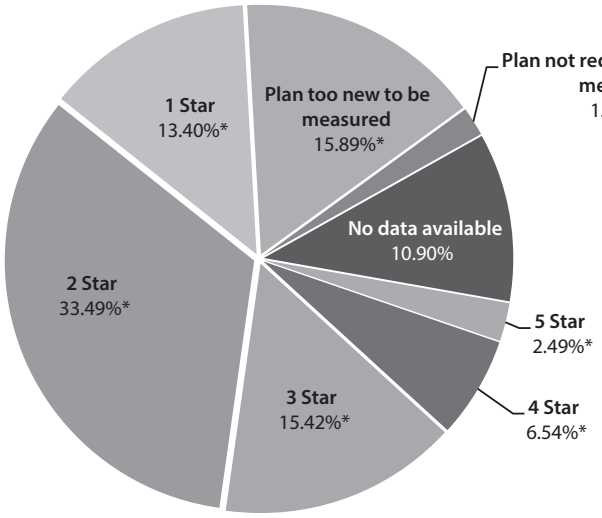
While Medicare Advantage plans showed continued improvements in the 2016 star quality ratings, Prescription Drug Plans experienced a significant decline in their overall average star ratings from last year, partly because of their performance on the three medication adherence measures *(DBN 10/23/15, p. 1)*. But both types of Medicare Part D plans were challenged by the new medication therapy management (MTM) comprehensive medication review (CMR) completion rate measure, which was moved from the display page for the 2016 ratings year. The bulk of plans achieved just two stars on that measure, according to a Solid Benefit Guidance analysis of 2014 data applying the 2016 cut-points for that measure.

"Plans have been behind the eight ball and now that it's a star measure and we can see what the results are, this needs to be a key strategic area," asserted Helen Sherman, Pharm.D., R.Ph., vice president, Solid Benefit Guidance, during the Dec. 10 AIS webinar, "Health Plan Strategies for Building an Effective MTM Program," at which speakers offered strategies on boosting CMR rates as well as considerations for selecting MTM vendors to help achieve that goal. CMRs are interactive, person-to-person or telephone-based medication reviews and consultations performed in real-time by a pharmacist or other qualified provider and must be offered to all beneficiaries who enroll in the CMS-mandated MTM program at least annually.

"As Medicare Part D has evolved and we're getting more specific requirements, plans…are generally a few steps behind," she continued. "It's a hard measure, it's a broad measure and plans are catching up. And many of the arrangements [between plans and MTM vendors] don't have requirements or necessarily alignment between what the health plan needs to achieve vs. the provider….Most plans have a very high-level arrangement today without a lot of guarantees and requirements. So as CMS's requirements are increasing, plans are recognizing that they need to do a more formal market evaluation and have more specifics in whatever arrangements they have."

Access to timely data is critical for conducting outreach and offering CMRs to beneficiaries, suggested Tasmiya Khan, Pharm.D., clinical consultant and pharmacist, Solid Benefit Guidance, who also spoke at the webinar. Having data as close to real-time as possible "really helps with the credibility when you outreach members and you engage them…vs. data that has a lag time in it."

MTM Landscape Based on 2014 CMR Results (642 Part D Sponsors)



2016 MTM Star CMR Cut-Points

5 Star:	≥ 76% CMR
4 Star:	≥ 48.6% to < 76%
3 Star:	≥ 36.2% to < 48.6%
2 Star:	≥ 13.6% to < 36.2%
1 Star:	< 13.6% (or <95% on data validation)

* of plans out of 642 Part D sponsors

SOURCE: Solid Benefit Guidance analysis of CMS performance data found at http://tinyurl.com/q4dtr5t, presented at the Dec. 10 AIS webinar, "Health Plan Strategies for Building an Effective MTM Program." For a recording and accompanying materials, visit the AIS MarketPlace at www.aishealth.com.

NEWS BRIEFS

◆ **After ending its controversial relationship with mail-order pharmacy Philidor Rx Services LLC *(DBN 11/20/15, p. 1)*, Valeant Pharmaceuticals International, Inc. has reached a 20-year deal with Walgreens Boots Alliance that will use the Walgreens drugstore chain to distribute Valeant's branded dermatological and ophthalmological products.** The agreement will feature wholesale price reductions of 10% that are being phased in over the next six to nine months, and lower out-of-pocket costs to commercially insured consumers. Valeant added that it plans to extend this distribution model to other independent retail pharmacies. The parties also struck a separate agreement through which Walgreens will distribute more than 30 branded products, where generics are available, in dermatology, ophthalmology, gastrointestinal and neurology/other therapeutic areas through Walgreens at generic prices. The reduced pricing for the branded products — which will be available to all patients beginning in the second half of 2016 — is expected to range from 5% to 95%, or a weighted average price decrease of more than 50%, said Valeant. The company has also come under fire for raising the prices of two recently acquired heart medications (see story, p. 3), but neither of those medications was mentioned in the Dec. 15 press release. Contact Renee Soto or Meghan Gavigan for Valeant at (212) 687-8080.

◆ **Avella Specialty Pharmacy on Dec. 14 said it would begin compounding a less expensive alternative to Daraprim (pyrimethamine), the toxoplasmosis drug that rose in price by more than 5,000% after it was acquired by Turing Pharmaceuticals (see story, p. 3).** Avella will make the therapy available for $1 per capsule to patients whose providers write a prescription for the compounded formulation. Express Scripts Holding Co. on Dec. 1 unveiled a similar deal with Imprimis Pharmaceuticals to offer members a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for $1 per capsule *(DBN 12/4/15, p. 8)*. Contact Avella Vice President of Marketing Todd Speranzo at todd.speranzo@avella.com.

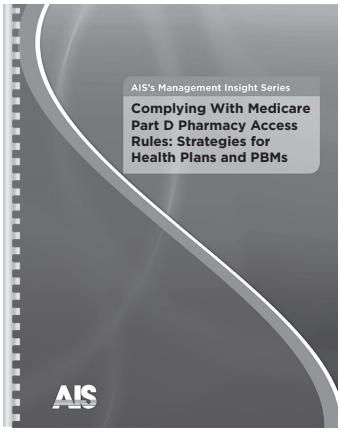
◆ **Employers are taking more aggressive steps to manage specialty drugs and are likely to intensify those efforts over the next three years as more expensive products come to market, suggests a new survey from Towers Watson.** More than one-quarter (26%) of the 487 large U.S. employers responding to the 20th Annual Towers Watson/National Business Group on Health Best Practices in Health Care Employer Survey confirm they are addressing specialty drug cost and utilization in their medical benefit, in addition to the tactics they are already employing on the pharmacy side. Specifically, 53% of employers have added new coverage and utilization restrictions for specialty pharmacy, such as requiring prior authorization or quantity limits; another 32% are expected to add these restrictions by 2018, finds the survey. In addition, 39% of employers said they exclude inappropriate compounds from their benefit coverage, and another 24% expect to do so by 2018. Visit www.towerswatson.com.

◆ **A new report aimed at tackling the prescription opioid epidemic in the U.S. recommends that pharmacies and PBMs play an expanded role in reducing opioid misuse and abuse.** The Johns Hopkins Bloomberg School of Public Health report, "The Prescription Opioid Epidemic: An Evidence-Based Approach," drew on the input of clinicians, researchers, government officials, pharmaceutical manufacturers, insurers and other stakeholders to devise a series of recommendations on prescribing guidelines, prescription drug monitoring programs (PDMPs), community-based prevention and other areas. That report suggested that, for example, PBMs' opioid management programs could be enhanced if companies had access to state-run PDMPs, which can have comprehensive controlled substances prescription records on an individual regardless of whether the person paid cash or filled prescriptions through multiple insurers and pharmacies. Download the report at http://tinyurl.com/ojkmfun.

◆ **Express Scripts and Premera Blue Cross on Nov. 30 said they reached an agreement for early renewal of Express Scripts' longstanding PBM deal with the Washington-based insurer.** After conducting a competitive review and selection process, Premera concluded that Express Scripts "continues to offer the best health plan integration and deliver the most overall value" for its clients and members, said the companies. Their partnership began in 1999, and will now extend through at least 2019. The two organizations have collaborated on multiple data-driven solutions to improve medication adherence and health outcomes for Premera's members, including a cross-platform mobile app. Contact Premera spokesperson Melanie Coon at melanie.coon@premera.com.

AIS's Management Insight Series

Complying With Medicare Part D Pharmacy Access Rules: Strategies for Health Plans and PBMs



As CMS steps up audit and enforcement activity, it is increasing scrutiny of complaints about beneficiaries not getting timely access to prescription drugs. ***Complying With Medicare Part D Pharmacy Access Rules: Strategies for Health Plans and PBMs*** analyzes the CMS requirements that are the subject of audit findings, and offers strategies plans and their partners can institute to prevent pharmaceutical-access problems.

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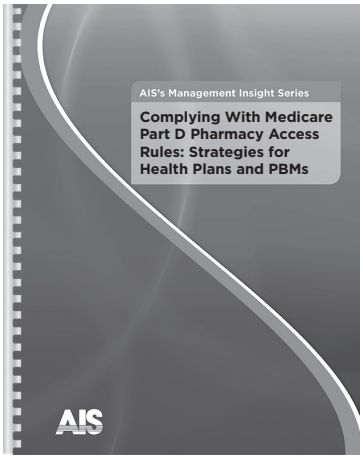
- What steps CMS expects Part D plans to take to monitor and oversee their PBMs.
- What specifically regulators are looking for in application of plans' policies on prior authorization, step therapy and transition supplies of medications, as shown in case outcomes.
- What regulators expect from plans in their handling of appeals of coverage determinations on pharmaceuticals.
- What CMS expects in terms of outreach to prescribers and beneficiaries on pharmaceutical-access issues, and what operational and other strategies plans should employ to accomplish this.
- How plans and PBMs should administer formularies to avoid access problems despite the necessity for frequent changes.

Written By

This report was adapted from a recent AIS webinar presented by Jane Galvin, managing director of regulatory affairs at the Blue Cross Blue Shield Association, Steve Arbaugh, managing principal and CEO of ATTAC Consulting Group, LLC, and Anne Hance, partner, McDermott, Will & Emery. It has been updated by AIS's editorial staff to include appendices filled with relevant background coverage of industry developments, federal agencies' guidance and preparatory materials, and other resources.

Get strategies for choosing vendors, administering formularies, making coverage determinations and other high-risk activities in the Part D program



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