From The AIS Bookshelf:
From Chapter 8: Payer Strategies for Controlling Costs

This PDF includes a 24-page excerpt from a chapter on “Payer Strategies for Controlling Costs” from the AIS book *Specialty Pharmacy Trends and Strategies: 2016-2017 Edition*. For more information and to order the entire 352-page book, [click here](#).
PBM Strategies for Controlling Costs

PBMs Present Four Out-of-the-Box Solutions for Containing SP Costs

As plan sponsors grapple with soaring specialty pharmacy costs, health plans and PBMs are constantly on the lookout for ways to manage costs without shifting more financial responsibility to patients. During a session of the Academy of Managed Care Pharmacy Nexus 2015 conference, held Oct. 26-29, 2015, in Orlando, speakers from two health plan-owned PBMs identified four innovative solutions that are gaining traction and demonstrating success in the marketplace. They are:

1. **Adding a value-based review process to formulary evaluations.** When determining which new specialty medications to add to its formulary, Christiana Health Care System in 2011 established the Medication Value Subcommittee to evaluate drugs in four domains: efficacy, risk, cost and social benefit. For the latter, the Wilmington, Del.-based health system convened a panel of non-medical/community members that included two university professors, a high school teacher, a pastor and a community activist to provide insight into quality-of-life improvements associated with the drugs, said Jamila Jorden, Pharm.D., clinical pharmacist with PerformRx, the PBM subsidiary of the AmeriHealth Caritas Family of Companies.

2. **Partial fill programs.** Also referred to as “split fill,” these are focused mainly on self-administered oral oncology, for which only part of a 30-day supply is dispensed to ensure that the patient is compliant and can tolerate the medicine, explained Jorden. Multiple studies demonstrating the effectiveness of such programs, including one from Walgreens Specialty Pharmacy that showed a savings of about $1,300 per member for those opting in to the split fill portion of its oral chemotherapy cycle management program, have prompted PerformRx to begin implementing a partial fill program that will center on high-cost medications that have a high rate of discontinuation, she said. That program will provide members with 14-day supplies during the first two months of therapy, and the PBM will partner with its specialty pharmacy to make sure that members are taking the drug and are tolerant.

3. **Clinical pathway programs.** These are increasingly being implemented by insurers to standardize the use of evidence-based chemotherapy treatments, and make it easier to identify gaps in care, observed Jorden. She pointed to a retrospective analysis conducted by CareFirst BlueCross BlueShield looking at clinical data prior to and two years after it began a program with P4 Pathways. The study found that per patient drug costs rose from $16,494 pre-implementation to $16,906 two years after, with hospitalization costs dropping from $2,502 to $1,064 during that same time period. When adjusting for price increases, the pathways program resulted in $10.3 million in savings by participating sites, or $30.9 million for the entire health plan, said Jorden.

4. **Site-of-care solutions.** Regence, a group of health plans in the Pacific Northwest/Mountain State region, and Walgreens Infusion Services in 2013 piloted a voluntary site-of-care optimization program allowing patients on specialty infusion medications to utilize a Walgreens alternative treatment site or receive care in their home at a lower out-of-pocket cost. With certain exceptions, the plans have since mandated sites of care for fully insured members taking select agents for inflammatory conditions and intravenous immunoglobulin, and over a 10-month period saw a gradual decline in the use of hospital outpatient facilities and an average overall savings of $3,700 per infusion. Phase II mandated sites of care for patients on certain multiple sclerosis medications such as natalizumab. Interdepartmental collaboration was key to implementation, and both member and provider communications were needed to get the program off the ground, explained Alex Dong, Pharm.D., clinical pharmacist consultant with OmedaRx, which handles PBM operations for the affiliated Blues plans. Nevertheless, the program did face some pushback from providers, such as...
those affiliated with a health system, and some member disruption, with a few members griping on social media about the requirements around natalizumab, said Dong.

There’s no one perfect solution when it comes to specialty pharmacy, and plan sponsors’ approach will depend on the business setup, their members and their providers, added Jorden. “As you all know, there is an increasing number of specialty products and they are increasing in cost. We need to...make sure that our members are getting the appropriate care, so in doing this all at the same time, we want to make sure we contain the cost of the medication.” So what is the best approach? “All of the above,” she suggested. ✤
Digest: Plans Are Shifting Focus To Medical Benefit Management

Although some opportunities remain for health plans to manage specialty drugs under the pharmacy benefit, many plans now are focusing their attention on strategies for these therapies under the medical benefit, according to a 2014 study. Data in The EMD Serono Specialty Digest, which is now in its 10th edition, indicate that respondents’ focuses include creating limited or preferred infusion networks and managing site of care.

“Only about half the commercial plans in the survey have dedicated specialty cost-share tiers for specialty drugs covered under the pharmacy benefit,” a finding that is “pretty consistent with [2013],” says Debbie Stern, president of Rxperts, Inc. and editor of the digest, in April 2014. She notes that there “is a perception that everyone on a specialty drug pays a high cost share.”

Among the 33 commercial plans that said they had separate cost-share tiers for specialty drugs in 2013, 61% had coinsurance on these drugs, up from 56% of 36 plans in 2012. Likewise, the percentage of plans using a copayment for specialty tiers declined, with 39% in 2013 saying they used this, down from 44% in 2012. However, among these plans, there was an increase in ones using multitier cost sharing within the specialty tiers, where the lower tier is for preferred drugs, and the higher tier is for non-preferred drugs — 58% in 2013, up from 33% in 2012. This could indicate, says Stern, that plans believe there is “still the need for financial incentives for patients to utilize preferred drugs.”

Opportunity Exists in Preferencing

2013 saw an increase in designating preferred products within therapeutic categories, “but there are only three categories where more than half of plans have preferred products,” says Stern — growth hormone therapies, subcutaneous rheumatoid arthritis/Crohn’s disease/psoriasis (RA/CD/PS) drugs and intramuscular, subcutaneous and intravenous multiple sclerosis treatments.

“There is still a lot of opportunity it seems” for preferencing, she tells AIS. “It leaves me kind of scratching my head as to why plans aren’t taking advantage of this... There may even be other opportunities out there.” A small percentage of respondents said they preferred

Drugs within the oncology categories of chronic myeloid leukemia, renal cell carcinoma and multiple myeloma. “People are kind of putting their toe in the water,” but there hasn’t been widespread pickup of the practice in these areas, says Stern.

A question new to the digest in 2014 asked about the methodology behind plans’ preferring practices when therapeutic categories have drugs with multiple routes of administration and mechanisms of action. Almost three-quarters of respondents — 74% — said they would “select preferred products regardless of” the mechanism of action, and almost two-thirds, or 60%, said they would make a decision regardless of the route of administration.

“Traditionally with a unique mechanism of action,” such as ACE inhibitors and beta-blockers used to treat high blood pressure, “payers select a preferred product within each mechanism of action,” explains Stern. But survey respondents are saying they will “look across mechanisms of action rather than choosing one drug from column A and one from column B....Strategies will be more based on overall clinical outcomes, the uniqueness of a drug and its side-effect profile.” According to Stern, “This is one of the most interesting findings throughout the digest.”

**Plans Are Homing In on Medical Benefit**

Dispensing a limited amount of a newly prescribed drug is a management tactic that plans are using, but only 42% of plan respondents said they have a partial-fill program. Among those that have such a program, 84% have implemented it for oral oncolytics, followed by 42% for oral hepatitis C drugs and 24% for oral multiple sclerosis therapies. Reducing waste/decreasing cost, improving adherence and managing side effects were the top reasons cited for taking this approach, but when asked how many partial fills the plan allows, 55% said they limit for only the first fill. “If they want to improve adherence, reduce side effects” and cut down on waste and costs, “they really have to be doing this over a longer term,” contends Stern.

Overall for survey respondents, “the integration of the pharmacy and medical benefits is probably the topic of the day,” maintains Stern. Plans continue to be challenged in areas such as having consistent benefit design, cost share and reimbursement for services, as well as capturing accurate claims data. “The good news is there’s a lot of activity going on, but it’s a hard road to go down,” she says. For example, if “a drug is a drug is a drug, then why is that not easier to capture and reimburse?”

Another survey finding is a continued “split in how payers view prior authorization and managing this for specialty drugs” in different categories and benefits, “leading to a potential disconnect,” Stern says. For example, while responding plans said that the pharmacy department and PBM handled prior authorization for self-administered nononcology and oral oncology drugs the majority of the time, the medical management department had primary responsibility for management of nononcology and oncology drugs adjudicated under the medical benefit and companion diagnostics. “Drugs being managed in other departments can lead to confusion and a lack of consistency in the review methodology,” she warns.

“There was a lot of focus in 2014 on specialty drugs that are provider-administered,” notes Stern. That said, “I don’t see any major shift of coverage” from the medical benefit to the pharmacy benefit. However, between the digest edition covering 2011 and this one, reflecting data from 2013, three therapy categories did experience coverage shifts from the medical to the pharmacy benefits.

Drugs for hemophilia covered under the pharmacy benefit rose from 37% to 43%, medications for respiratory syncytial virus climbed from 23% to 40%, and pharmacy benefit coverage of intravenous medications for RA/CD/PS increased from 19% to 27%.

“Payers are starting to get savvier,” contends Stern. “Instead of making global changes, they are making changes where it makes sense” for all stakeholders.

When asked about medical benefit provider reimbursement strategies they either have in place or plan to implement, many respondents cited infusion-related tactics, including creating a limited/preferred infusion network, forming an ambulatory infusion network and recontracting their infusion network rate. “As plans move their focus to activities under the medical benefit, there’s kind of a black hole of information with infusion,” Stern maintains.

Managing the site of service was a “topic of high interest” among respondents, with intravenous RA/CD/PS therapy landing in the top therapeutic category targeted for site-of-service management. More than 80% said they either currently implement such a strategy (36%) or plan to implement it over the next 12 months (46%). That was followed by intravenous and subcutaneous immune globulins (39% for both categories of implementation) and Tysabri (natalizumab) for multiple sclerosis (34% for both). Intravenous oncology therapies were in the fourth spot, with 29% of respondents saying they have a site-of-care program in place now and 34% saying they will implement one in the next year. “I’m surprised that [overall oncology] number was as high as it was,” says Stern.

Of note was plans’ satisfaction with the services furnished by their specialty pharmacy providers. Distribution services, including access to limited-distribution drugs and reimbursement and eligibility coordination, received “reasonably good” satisfaction rankings, points out Stern. But for clinical/utilization management and reporting services, “satisfaction levels are dropping,” she explains. This could be due to various factors: “Payers
are not asking for what they want, payers are not getting what they want, or payers don’t understand what the specialty pharmacy is providing,” she says.

Respondents’ overall challenges with specialty drug management included variability in oncology treatment (71%), determining the value of therapy (68%), dealing with limited internal plan resources (66%), shifting sites of service (53%) and coordinating among departments at the plan (49%). “As more plans move into medical benefit management,” they are finding that it “takes a lot of time and coordination, which may impact the ability of plans to move forward,” says Stern. “Plans should look at where they will get the best return on investment in terms of time and resources” and focus their efforts there, she recommends.

Over the 10 years of the digest, Stern notes, the “tools that exist for traditional drug management have been effectively applied in most cases for specialty drugs under the pharmacy benefit.” But now plans are “moving to where they apply strategies under the medical benefit and have to deal with the complexities there.”

### Plans Should Look at Individual Data When Considering Medical vs. Pharmacy Benefit

Moving specialty drugs from the medical benefit to the pharmacy benefit has long been viewed as an effective management tactic by some industry experts. Others, though, contend there are good reasons to keep some drugs in the medical benefit. And while two 2014 reports have reignited that debate, the best advice for plans may be to determine what’s best for them based on an analysis of their own data.

In early March 2014, specialty drug services firm Artemetrx LLC released *An Evaluation of Specialty Drug Pricing Under the Pharmacy and Medical Benefit*, which was prepared by two Artemetrx employees. About a month later, the CVS Caremark Corp.-commissioned *Evaluation of Medical Specialty Medications: Utilization and Management Opportunities*, which was prepared by Milliman, Inc., was released.

The Artemetrx study looked at pricing in pharmacy and medical claims for Epogen and Procrit (both brand-ed versions of erythropoietin alpha), Neulasta (pegfilgrastim), Remicade (infliximab), Tysabri (natalizumab) and Xolair (omalizumab) among 10 different commercial plan sponsors. “These drugs were selected because they represent high aggregate expenditures and are frequently paid under both the medical and pharmacy benefits, allowing for direct comparison within the claims data,” says the report.

Researchers compared prices for the drugs when billed by physician offices or home infusion providers with those prices billed by pharmacies. Drugs in the outpatient hospital setting were not included because “it is widely recognized that drug pricing in the outpatient hospital setting is typically 2-3 times that of the physician office for commercial plan sponsors,” the report contends.

It found the “prices per unit dispensed” were higher for the drugs under the pharmacy benefit than for those on the medical side. “Across all plan sponsors, the mean price was 4% to 38% higher under the pharmacy benefit, depending on the drug,” says the report.

The Milliman study looked at multiple self-administered oral, inhaled and injectable drugs, as well as provider-administered injectables and infusibles that “represent 43% of medical specialty allowed cost.” Provider-infused agents did not include oncology drugs. There were 30 targeted categories, including allergic asthma, autoimmune conditions, erythropoiesis-stimulating agents, multiple sclerosis and respiratory syncytial virus, and more than 100 drugs included in the study.

That analysis was based on Milliman’s Health Cost Guidelines 2012 claims data and included commercial group members. The report found that shifting products in 14 classes of self- and provider-administered drugs from the medical benefit to the pharmacy benefit can save payers an average of 19%.

Of that percentage, the report claims that the following savings were shown when drugs were moved to the pharmacy benefit:

- **Injectable drugs administered in the hospital outpatient department** showed an average savings of 34%.
- **Drugs administered in the home setting** generated 19% savings.
- **Medications administered in physician offices** had 12% savings.

“Transitioning specialty medications from the medical benefit to the pharmacy benefit results in savings because payers can implement more effective management tools such as formulary design, utilization management, and preferred or exclusive networks under the pharmacy benefit,” Alan Lotvin, M.D., executive vice president of specialty pharmacy at CVS Caremark, told AIS in April 2014. “In addition, offering patients more convenient and cost-effective options by addressing where infusion care is administered can produce significant savings. We believe both strategies work together to help payers achieve optimal savings.”

He points to the report’s observation that 53% of specialty drug spending is in the medical benefit. “According to the Milliman analysis, implementing an effective transition — moving prescriptions from the medical benefit to the pharmacy benefit — can produce significant savings for health care payers by improving management of these complex and costly drugs,” says Lotvin.
Because claims in the pharmacy benefit are adjudicated at the point of sale, it is easier to apply various utilization management tactics in this benefit.

Brenda Motheral, Ph.D., president of Artemetrx and co-author of that report, maintains that “plans do have medication policies under the medical benefit for drugs that are high spend” that also can offer real-time adjudication. In addition, she says, the Milliman study “included a lot of self-injectables already under the pharmacy benefit.”

Some experts have questioned why Artemetrx excluded the hospital outpatient setting from its report and wonder if its contention that pricing in this setting is two to three times higher than that in the physician’s office is accurate. Motheral points to one of the Milliman analyses as being “very similar to what we did, at least on the surface.” Exhibit 12, she tells AIS, shows that “hospital outpatient cost is running about two times — sometimes a little more or a little less — versus the physician office.” That’s consistent with not only Artemetrx’s findings but also ones by Walgreen Co., the Pharmacy Benefit Management Institute and others, she says.

“More than a decade ago, PBMs tried to convince payers to move select drugs from the medical benefit to the pharmacy benefit,” observes Bill Sullivan, principal consultant with Specialty Pharmacy Solutions LLC. “The argument back then [was] ‘We can finally manage the utilization of these drugs now under ‘buy and bill.’” Many payers tried the tactic, but it presented a lot of problems.

The first issue, he says, is “changes intensified the friction between the medical and pharmacy benefit” because plan members had to make copayments for drugs that previously had been included in their physician visit copays. Second, “it required many plans to restructure their plan designs, often requiring state board of insurance approval. For many payers, that was a lot of states.” And the third problem, which Sullivan contends “was a doozie,” is that “physicians were really torqued off by payers ripping the margin out from under them for the drugs administered in the office. That battle set off a firestorm of recontracting — and the flames are still not out.... Trying to ‘kill’ off buy-and-bill,” he maintains, risks “further alienating network physicians who still depend on drug margin to a large degree.”

The bottom line, Sullivan says, is that nothing has changed since PBMs first tried to shift drugs into the pharmacy benefit. “All three problems still persist.”

“It’s a fine line with physicians,” agrees Motheral. Plans want them to have competitive rates, but the insurers have to be careful “not to squeeze them too hard.” When that happens, such as when physicians are forced to use a specialty pharmacy to get their drugs, providers may push administration to the hospital outpatient department, which is exactly where plans don’t want them to go.

Taking drugs out of “the hospital outpatient setting is where all the savings occur,” maintains Motheral. As far as what Artemetrx recommends, “there’s no question that we want to get drugs, when we can, out of the hospital outpatient setting” and into the physician office. This is “low-hanging fruit,” she contends. Making a wholesale move to shift all drugs from the medical benefit to the pharmacy benefit presents challenges that plans don’t really need to take on, she says. Shifting the site of service represents “more savings with less destruction.”

In addition, says Motheral, “We know class-of-trade pricing for physicians is better — about 15% to 20% better” — than pricing for specialty pharmacies, so plans likely are getting “a better rate from physicians. And once Medicare moved to ASP [i.e., Average Sales Price], the rates came down in doctors’ offices.”

One crucial point, contends Elan Rubinstein, Pharm.D., founder and principal at EB Rubinstein Associates, is that neither analysis “included manufacturer rebates, as both made clear in their reports. This is important when comparing the medical benefit drug to the pharmacy benefit drug allowed, because for competitive therapeutic classes — like several of the drugs analyzed in the Artemetrx report — PBMs often receive formulary rebates for pharmacy benefit drugs. A pharmacy rebate would reduce the average price per unit of these drugs — and recall that the Artemetrx conclusion is ‘the study found that prices per unit dispensed for specialty drugs were higher under the pharmacy benefit than the physician office or home infusion for the five drugs studied.’ But would inclusion of rebates have extinguished this difference?”

So what approach should plans opt for? There may not be a one-size-fits-all approach.

Rather than being in opposition to each other, the two reports “go hand in hand and illustrate the need to focus on strategy in plan design,” maintains F. Randy Vogenberg, Ph.D., principal at the Institute for Integrated Healthcare.

Indeed, says Motheral, if plans are “considering pulling drugs out of the medical benefit, they first need to analyze their own data” in order to determine the “true cost of care,” not just their spending on drugs.

“Do not make hasty decisions,” cautions Sullivan. Plans “need to do their own detailed analysis.”

According to Vogenberg, it “should not be seen as an either/or situation in terms of the pharmacy benefit vs. the medical benefit, and “other innovations need to be considered that could create more value to the plan.” Sullivan points to “the emergence of ISSPs [i.e., integrated single specialty providers] like Cardinal P4 for oncology, as an example of pulling whole therapeutic categories...
out of the standard model and overlaying a comprehensive medical/pharmacy management model that can ensure consistency and appropriateness, including right drug, right amount of drug, right length of therapy, right price, right utilization management, and right medication therapy management under both medical and pharmacy benefits.”

Medical Drug Management Is Increasing, but Is It Enough?

One of the main hurdles to effective specialty drug management is the ability for a payer to look at data in both the pharmacy and the medical benefit. But these benefits are siloed at many payers, so getting a comprehensive picture of a company’s specialty spend can be challenging. And while it’s relatively easy to get a complete understanding of the pharmacy benefit, that’s easier said than done for the medical benefit. With about half of specialty medications falling under the medical benefit — and a pipeline full of specialty drugs — payers need to implement strategies to get a handle on their overall specialty spend.

Now in its fourth edition, Magellan Rx Management’s Medical Pharmacy Trend Report looks specifically at drugs that fall under the medical benefit, with a section based on payer survey responses and one based on their claims data. The company collected data over a three-week period in June and July last year, receiving responses from 48 health plans managing 166.3 million lives.

Among the interesting findings is that “roughly 30% of respondents...weren’t performing any post-claim edits at all,” says Mostafa Kamal, senior vice president and general manager of the specialty drug division of Magellan. Although that’s down from about 40% in 2013, “that’s a pretty big number considering the size of the pool.” This is a “missed opportunity” for payers who fail to do this.

“Drugs billed on the medical benefit are sort of thought of in a siloed approach,” he told AIS in spring 2014. For example, he points to a drug trend report released by a PBM a few years ago that looked at only the pharmacy benefit. It said self-administered Humira (adalimumab) and Enbrel (etanercept) had an 80% market share within the inflammatory conditions category, but physician-administered Remicade (infliximab) had no spend. In fact, Kamal says, Remicade has a 40% market share within that therapeutic category when you consider both the pharmacy and the medical benefit.

“A lack of integration across benefits...creates a good amount of disconnect with what’s happening” in many therapeutic conditions, he maintains. “Full visibility” occurs when a “plan is being managed the way it should be.”

“Site of service continues to be an issue,” says Kamal. When physician-administered drugs move out of the physician’s office and into the hospital outpatient department, the same dose of the same drug may be “three, four, five, sometimes 10 times more expensive than in the physician’s office.”

Some payers, however, may be “more reluctant to tackle the issue,” particularly if it concerns larger hospitals because “they feel like they will get squeezed somewhere else,” he says.

The trend of hospitals acquiring oncology practices is “also a challenge” for payers, Kamal says. “Developing creative site-of-service strategies that drive patients to the physician’s office” is critical, and “rationalizing reimbursement in hospitals will be very important going forward.”

Some of the other noteworthy findings are the following:

◆ The incidence of off-label use among commercial plans was 6%, which is “not very dramatic,” says Kamal. But “in well-managed plans, this number should be 0% or 1%.” Payers should have programs in place to track this to ensure drugs are used and billed for appropriately. “Post-service edits is a good way to do this.”

◆ Approximately one-quarter of plans say they have a medical formulary in place, including using a tiered approach, preferring one drug over another and having prior authorization in place.

◆ “There’s a lot of room for plans to create more sophisticated strategies to incorporate genetic testing,” Kamal maintains.

◆ “Roughly half of plans that responded indicated they’re receiving rebates on medical drugs,” he says. But “that number should be closed to 100%...There is an opportunity for plans” to optimize rebates, he asserts.

Estimates used to be that specialty spend would make up half of overall pharmaceutical spending by 2025. Then it was 2022. More recently, 2018 is the projected year that will happen, he points out. “There are key, low-hanging-fruit areas that plans can get ahold of now,” Kamal contends. The pipeline is dominated by specialty drugs, which also “are being developed for common conditions,” such as high cholesterol. “Seventy million people have high cholesterol,” he points out. “Specialty management is just becoming more and more critical.”

But based on the report’s findings, “I expected plans would be doing more,” he says. “It’s a little difficult to compare each report in an apples-to-apples fashion because the payer set we survey changes year to year. But generally the trends are showing that generally speaking, plans are doing a little more every year, but it’s not enough.”
PBMI Survey Shows Advantages In Medical Benefit for Specialty Drugs

While utilization management strategies for specialty drugs covered under the pharmacy benefit continue to be widely used by plan sponsors — and in some instances are expanding in use — there lies untapped potential on the medical side for plans to manage rising specialty drug costs, suggests the Pharmacy Benefit Management Institute’s (PBMI) 2015 Specialty Drug Benefit Report.

According to the fourth annual survey of employers with more than 1,000 covered lives, prior authorization and clinical care management programs remain the top two most commonly used strategies for managing specialty drugs in the pharmacy benefit, and in 2014 were deployed by 86% and 76% of employers, respectively. The use of a separate cost-sharing tier for specialty drugs has seen significant growth in recent years, rising from 41% in 2013 to 62% in 2014. PBMI queried 366 employers covering an estimated 23.5 million enrollees, including active employees, retirees and their dependents, in October and November 2014.

In addition, 66% of respondents say they use a preferred drug list for all specialty medications. For those offering a preferred drug list, 15% say they exclude nonpreferred drugs from coverage, while 76% say those agents are covered at a higher cost-sharing amount.

Meanwhile, for specialty drugs going through the medical benefit, PBMI observes that opportunities exist to use “proven” utilization management tools such as step therapy and prior authorization to “help reduce cost while maintaining or increasing the appropriateness of care.” Fifty-seven percent of employers say they cover specialty drugs under both the pharmacy and medical benefits and 5% of employers report covering all specialty medications through the medical benefit. But only about one-half of respondents with medical benefit coverage of specialty drugs report using a step therapy or clinical pathway program, finds the report.

Nevertheless, use of such tactics in the medical benefit has grown in the last year.

Among respondents who cover at least one specialty drug under the medical benefit, 72% use prior authorization, 61% use care management and 54% use preferred products or a formulary, compared with 68%, 55% and 44% of respondents in 2013, respectively. ♦

Better Specialty Tactics Are Needed, but Payers Are Getting Creative

Even though payers seem to have a pretty good handle on the management of specialty drugs that fall under the pharmacy benefit, some continue to struggle with medical benefit drugs, with oncology in particular...
being a prickly therapeutic area to manage. However, payers are recognizing the need for innovative strategies and are moving to implement such tactics. Those are two of the overall themes of the most recent EMD Serono Specialty Digest, which includes data from 70 commercial health plans representing more than 100 million covered lives.

This 11th edition of the digest also marks a change of editors. Debbie Stern, formerly president of Rxperts, Inc. and now senior vice president of strategy and business development for CareCore National, has been responsible for the first decade of digests. But now she has handed off that responsibility to 2015’s co-editor, Brenda Motheral, Ph.D., president and co-founder of Artemetrx.

Asked about some of the most interesting findings of 2015’s digest, Motheral told AIS in April 2015 that one “is the lack of reporting capabilities for specialty drugs under the medical benefit. Less than 50% of payers currently have integrated specialty reporting across pharmacy and medical,” and 17% said this capability is in development. But with roughly half of all specialty drugs falling under the medical benefit, this is certainly an area that could use more attention. “Given that an understanding of the specialty spend, trend, and pricing is foundational to effective cost management, this represents a significant gap for payers,” she says.

Oncology Management Is Top Challenge

“Not surprising was that oncology management was identified as the top challenge for payers,” with 79% of respondents saying it was the No. 1 challenge, followed by determining the value of therapy, cited by 66% of respondents. “However, the fact that only 17% of payers felt they were effective at controlling drug costs is notable” — particularly since the category of reducing drug costs was at the top of the list of most important oncology goals, with 90% of respondents citing this. That category was followed by reducing emergency room visits and hospitalizations, with 87% choosing this but only 16% saying their plan was effective in this category. Similarly, 84% cited transitioning patients to hospice care when appropriate as the third most important goal, but only 21% said they had been effective. Next, 83% cited increasing use of palliative care when appropriate, with 19% claiming effectiveness. Also tied at 83% was using evidence-based guidelines. It was this goal that the most respondents, 46%, said they had been most effective in.

According to Motheral, “Payers are struggling with effective solutions for managing oncology, and the report found that more than 50% of payers have no plans to implement an oncology pathways program,” while only 21% of the 70 plan respondents said they currently use these. Of the 16 plans with pathways programs, 69% use a third-party vendor’s pathways, 38% work with oncologists to develop plan-specific pathways, 25% create their own programs themselves, and 19% use pathways developed by oncologists. “Of those payers that have implemented a pathways program, nearly one-third said they did not know what savings were being achieved, and another 44% said the savings were 0%-3%,” points out Motheral.

“One of the most insightful questions examined payers’ use of external vendors for specialty drug management services,” which were divvied up into topics under oncology, utilization management and provider management. “While 69% of payers currently or plan to utilize an external vendor for oncology pathways, only 9% of payers currently or plan to do so for site of care,” notes Motheral.

With the administration of many specialty drugs being shifted to the hospital outpatient department, where infusions can be three or four times the price for the same dose of the same drug in the physician office or through home infusion, site-of-care optimization increasingly has grown in popularity as a management tactic for infusible drugs. Recognizing that, 2015’s digest added the topic to the list of specialty drug management goals. “We were surprised to find that 71% of payers said that site-of-care steering was their top goal for 2015, yet only 37% of plans have pricing and utilization information by site of service to inform this type of program,” Motheral says. More than half of respondents cited the shift in site of care from the physician office to hospital outpatient department as one of their top specialty drug management challenges, and Motheral points out that among respondents, “about two-thirds are either currently recontracting their hospital outpatient rates or planning to do so in the near future.”

In addition, she says, “This was the first year that we asked payers if they actually knew their drug reimbursement rates for each of the sites of service. Surprisingly but consistent with the findings above, 41% of payers did not know (or could not disclose) their pricing in the outpatient hospital setting, while 30% did not know/ disclose their home infusion rates. Given the focus on site-of-service management, we expect this information gap to close over the next few years.”

Payers Are Moving to Innovative Tactics

As far as main takeaways from the digest for payers, Motheral tells AIS that “First, the findings generally reflect a shift in benefit management toward innovative models, such as bundled payments for episodes of care, vendor partnerships, clinical pathways for oncology, provider education and site-of-care redirection. Traditional tools, such as cost-sharing and utilization management, are still being used, but there is growing recognition that limiting benefit management to these tools may be insufficient to meet the goal of improving outcomes while maintaining an affordable specialty drug benefit.”
A second and related takeaway is that “payers recognize the importance of maintaining access to these therapeutically important medications. Although payers may lack the data that they need to make use of some of these innovative models, they are working to obtain the information they need to do so. Additionally, for many of the tools that we asked about, a large proportion of payers who don’t currently use the tools are making plans to do so in the coming 12 to 24 months.”

And on the topic of oncology management, with payers reporting fairly big divides between what their most important goals are and how well they think those goals are being met, “the survey findings suggest that oncology management is in its nascence,” says Motheral. “It is common in the early years of any innovation to have limited success, but as payers and oncologists gain experience with new models for delivering and paying for oncology care, the success in oncology management is expected to increase.”

**Legislation Seeks to Even Out Patient OOP Costs Across Benefits**

Members of both houses of Congress introduced the Cancer Drug Coverage Parity Act on June 11, 2015, with a goal of evening patient out-of-pocket (OOP) costs for self-administered drugs under the pharmacy benefit and provider-administered therapies that fall under the medical benefit. And while the bills could be signed into law, they may bring about some unexpected consequences, said one industry expert in May 2015.

Sens. Mark Steven Kirk (R-Ill.) and Al Franken (D-Minn.) introduced S. 1566, which was referred to the Senate Committee on Health, Education, Labor, and Pensions. Rep. Leonard Lance (R-N.J.) — along with five Republican and six Democratic co-sponsors — introduced H.R. 2739, which was referred to the House Committee on Energy and Commerce. The bills would “amend the Public Health Service Act to require group and individual health insurance coverage and group health plans to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for anticancer medications administered by a health care provider.”

Lance called for health insurance coverage to “keep up with innovation.” He noted in a press release that “Many patients are now using promising oral treatments but are forced to pay astronomical out-of-pocket costs or forgo treatment altogether. We have to fix this disparity in coverage so cancer patients are making health care decisions based on the best information, not which treatment fits into outdated guidelines.”

Rep. Brian Higgins (D-N.Y.), a co-sponsor of the House bill, pointed out that many people receiving treatment for cancer are doing so by taking an oral oncolytic rather than having to be infused by a provider in a facility. “Under the existing broken system, in some cases it is more costly to fill the prescription than spend hours in a medical facility under health care supervision. The Cancer Drug Coverage Parity Act levels the cancer drug playing field so patients can focus on fighting cancer, not fighting for coverage on life-saving medication.”

The issue won’t go away any time soon, as oral drugs comprise about one-third of the cancer therapy pipeline. More than 30 states have some form of parity laws, but they differ from state to state. Federal legislation has been proposed before but not passed. So might this time be different?

**Unexpected Issues Could Result**

“It is all politics of course,” says Bill Sullivan, principal consultant at Specialty Pharmacy Solutions LLC. “It doesn’t cost the federal government any money so there is less resistance to the idea. Since it is viewed as being patient friendly — and against those money-hungry health plans — it reads well in the media and with voters. While you could say it is more government regulation, it technically isn’t hurting anyone or adding bureaucracy, so even the right-wing conservatives may be open to it.”

He tells AIS that “there is an argument that by leveling the out-of-pocket costs for medications (pharmacy vs. medical benefit), patients nationally will be treated equitably. However, lower out-of-pocket costs under the medical benefit may actually increase to match the higher out-of-pocket costs now more typical under the pharmacy benefit. In that case the patient ends up worse off.

“The devil is in the details.”

**Magellan Rx Management Gives Extensive Overview of Medical Benefit**

Remicade (infliximab) continues to be the No. 1 specialty drug among commercial plans in the medical benefit by spend, seeing a 21% per-member per-month increase from 2012 to 2013 (see table, next page). Some decreases, however, were seen with drugs such as Eloxatin (oxaliplatin) and Taxotere (docetaxel), which faced generic availability. Those are only some of the findings of Magellan Rx Management’s fifth annual Medical Pharmacy Trend Report. View the report at www.magellanrxinsights.com.
### Commercial Top 25 Medical Benefit Drugs by Allowed Amount Per Member Per Month and Cost per Patient

<table>
<thead>
<tr>
<th>Rank</th>
<th>HCPCS Code</th>
<th>Brand Name</th>
<th>2012</th>
<th>2013</th>
<th>2012</th>
<th>2013</th>
<th>% Change</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>J1745</td>
<td>Remicade</td>
<td>$1.79</td>
<td>$2.16</td>
<td>$21,696</td>
<td>$24,647</td>
<td>21%</td>
<td>14%</td>
</tr>
<tr>
<td>2</td>
<td>J2505</td>
<td>Neulasta</td>
<td>$1.50</td>
<td>$1.60</td>
<td>$15,735</td>
<td>$16,856</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>3</td>
<td>J9035</td>
<td>Avastin</td>
<td>$1.17</td>
<td>$1.44</td>
<td>$19,452</td>
<td>$21,918</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>4</td>
<td>J9310</td>
<td>Rituxan</td>
<td>$1.02</td>
<td>$1.15</td>
<td>$27,044</td>
<td>$28,630</td>
<td>13%</td>
<td>6%</td>
</tr>
<tr>
<td>5</td>
<td>J9355</td>
<td>Herceptin</td>
<td>$0.87</td>
<td>$0.98</td>
<td>$36,341</td>
<td>$38,143</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td>6</td>
<td>J7192</td>
<td>Advate/Helixate/Kogenate/Recombinate</td>
<td>$0.57</td>
<td>$0.60</td>
<td>$173,272</td>
<td>$180,938</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>7</td>
<td>J1569</td>
<td>GammagardLiquid</td>
<td>$0.45</td>
<td>$0.47</td>
<td>$37,554</td>
<td>$41,605</td>
<td>4%</td>
<td>11%</td>
</tr>
<tr>
<td>8</td>
<td>J1561</td>
<td>Gamunex-C/Gammaked</td>
<td>$0.39</td>
<td>$0.45</td>
<td>$41,180</td>
<td>$53,117</td>
<td>15%</td>
<td>29%</td>
</tr>
<tr>
<td>9</td>
<td>J2323</td>
<td>Tysabri</td>
<td>$0.39</td>
<td>$0.43</td>
<td>$31,213</td>
<td>$33,887</td>
<td>12%</td>
<td>9%</td>
</tr>
<tr>
<td>10</td>
<td>J9263</td>
<td>Eloxatin</td>
<td>$0.65</td>
<td>$0.41</td>
<td>$23,919</td>
<td>$12,009</td>
<td>-37%</td>
<td>-50%</td>
</tr>
<tr>
<td>11</td>
<td>J9305</td>
<td>Alimta</td>
<td>$0.38</td>
<td>$0.40</td>
<td>$29,782</td>
<td>$32,973</td>
<td>7%</td>
<td>11%</td>
</tr>
<tr>
<td>12</td>
<td>J0897</td>
<td>Xgeva/Prolia</td>
<td>$0.23</td>
<td>$0.38</td>
<td>$5,046</td>
<td>$4,814</td>
<td>66%</td>
<td>-5%</td>
</tr>
<tr>
<td>13</td>
<td>J9228</td>
<td>Yervoy</td>
<td>$0.14</td>
<td>$0.35</td>
<td>$109,391</td>
<td>$168,471</td>
<td>151%</td>
<td>54%</td>
</tr>
<tr>
<td>14</td>
<td>J9171</td>
<td>Taxotere</td>
<td>$0.40</td>
<td>$0.35</td>
<td>$10,285</td>
<td>$9,197</td>
<td>-13%</td>
<td>-11%</td>
</tr>
<tr>
<td>15</td>
<td>J1459</td>
<td>Privigen</td>
<td>$0.19</td>
<td>$0.28</td>
<td>$34,787</td>
<td>$50,499</td>
<td>51%</td>
<td>45%</td>
</tr>
<tr>
<td>16</td>
<td>J2469</td>
<td>Aloxi</td>
<td>$0.26</td>
<td>$0.28</td>
<td>$2,106</td>
<td>$2,247</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>17</td>
<td>J2778</td>
<td>Lucentis</td>
<td>$0.20</td>
<td>$0.26</td>
<td>$9,604</td>
<td>$9,483</td>
<td>30%</td>
<td>-1%</td>
</tr>
<tr>
<td>18</td>
<td>J9041</td>
<td>Velcade</td>
<td>$0.23</td>
<td>$0.25</td>
<td>$26,671</td>
<td>$28,658</td>
<td>10%</td>
<td>7%</td>
</tr>
<tr>
<td>19</td>
<td>J1300</td>
<td>Soliris</td>
<td>$0.24</td>
<td>$0.23</td>
<td>$439,344</td>
<td>$416,593</td>
<td>-1%</td>
<td>-5%</td>
</tr>
<tr>
<td>20</td>
<td>J9264</td>
<td>Abraxane</td>
<td>$0.17</td>
<td>$0.22</td>
<td>$24,430</td>
<td>$22,217</td>
<td>27%</td>
<td>-9%</td>
</tr>
<tr>
<td>21</td>
<td>J9055</td>
<td>Erbitux</td>
<td>$0.22</td>
<td>$0.22</td>
<td>$36,746</td>
<td>$35,359</td>
<td>-2%</td>
<td>-4%</td>
</tr>
<tr>
<td>22</td>
<td>J0585</td>
<td>Botox</td>
<td>$0.18</td>
<td>$0.22</td>
<td>$1,917</td>
<td>$2,051</td>
<td>21%</td>
<td>7%</td>
</tr>
<tr>
<td>23</td>
<td>J2353</td>
<td>Sandostatin LAR Depot</td>
<td>$0.16</td>
<td>$0.19</td>
<td>$32,252</td>
<td>$32,190</td>
<td>22%</td>
<td>0%</td>
</tr>
<tr>
<td>24</td>
<td>J9033</td>
<td>Treanda</td>
<td>$0.13</td>
<td>$0.19</td>
<td>$27,497</td>
<td>$34,312</td>
<td>47%</td>
<td>25%</td>
</tr>
<tr>
<td>25</td>
<td>J2357</td>
<td>Xolair</td>
<td>$0.16</td>
<td>$0.18</td>
<td>$14,378</td>
<td>$15,190</td>
<td>17%</td>
<td>6%</td>
</tr>
</tbody>
</table>

**TOP 25 TOTALS**

- **Commercial**: $12.08
- **PMPM**: $13.70
- **Cost/Patient**: $20,974
- **PMPM**: $20,915
- **Cost/Patient**: $13%

**TOTAL MEDICAL PHARMACY**

- **Commercial**: $18.67
- **PMPM**: $21.07
- **Cost/Patient**: $1,371
- **PMPM**: $1,486
- **Cost/Patient**: 13%

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

In Lieu of Exclusions, Prime Promotes Preferred Specialty Coupons

When faced with monthly out-of-pocket costs reaching $250 or more, patients are more likely to walk away from their specialty multiple sclerosis or biologic anti-inflammatory treatment than those paying less than $50, according to Prime Therapeutics LLC. Copay offset programs offered by drug manufacturers can be used to get that cost share under $250, but what if they’re being used by members for nonpreferred specialty products?

That’s the conundrum Prime explores in a new paper appearing in the October 2014 issue of Health Affairs. “For the preferred formulary products, we absolutely believe that coupons have a role there in helping individuals avoid a high cost share, especially if they have to hit a deductible before their pharmacy benefit kicks in,” Pat Gleason, Pharm.D., director of health outcomes and one of the paper’s co-authors, told AIS in October 2014. “In the nonpreferred tier, coupons become disadvantageous or concerning because they’re going to circumvent the benefit design.”

In order to deter the use of coupons that will lead to increased payer costs, Prime recommends that plan sponsors implement specialty drug preferred tiers with a monthly out-of-pocket member cost share of $250 or less, and consider implementing prior authorization or step therapy that requires the use of a preferred specialty drug before a nonpreferred drug is covered.

Alternatively, plan sponsors can opt to exclude certain drugs from the formulary, but Prime has not “advocated heavily” for formulary exclusions. “If you put a drug on a formulary exclusion list, that means the member bears the entire drug cost. And in some cases, depending on how the exclusion is designed, it wouldn’t even apply to the deductible,” explains Gleason. “So we’d rather not [make exclusions]. But I will say that we are being asked more and more about formulary exclusion lists from both our fully insured business at each Blues plan and especially among our self-insured employer groups.”

Prime Therapeutics Specialty Pharmacy regularly applies specialty drug coupons for preferred formulary tier products. If the member has met the criteria to be on a nonpreferred product, the patient would qualify for that coupon as well. For example, copay offsets were applied to 35% of prescriptions for hepatitis C processed by Prime’s specialty pharmacy in the first half of 2014. This resulted in nearly $1 million in member costs offset by specialty coupons. Nearly three-quarters of hepatitis C prescriptions would have had a cost share higher than $50 before coupons were applied, whereas only 9% had a cost share higher than $50 after the coupon was applied.

Experts Discuss Payer Strategies For Specialty Copay Coupons

The following report was updated and adapted from a June 5, 2014, webinar sponsored by Atlantic Information Services, Inc., “Health Plan/PBM Strategies to Manage Specialty Drug Coupon Programs.” Attendees at the webinar got the chance to have their toughest questions answered by the following experts:

◆ Alaina Sandhu, consultant for the National Pharmacy Practice at Buck Consultants, LLC; and
◆ Steven Avey, vice-president of specialty programs from Medimpact Healthcare Systems, Inc.

Copay coupons are manufacturer-sponsored programs for patients with commercial insurance coverage. Because of anti-kickback statutes, coupons cannot be used on Medicare, Medicaid, TRICARE, The Department of Defense or Veterans Affairs programs or where prohibited by law. By contrast, patient assistance programs

<table>
<thead>
<tr>
<th>Impact of Hepatitis C Coupons on Member Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="chart.png" alt="Chart showing the impact of coupons on member cost share" /></td>
</tr>
<tr>
<td>SOURCE: Prime Therapeutics LLC</td>
</tr>
</tbody>
</table>
(PAPs) offer free or low-cost drugs to primarily uninsured patients who are financially eligible.

Most drug couponing programs have been geared toward non-specialty or traditional drugs. Insurers and pharmacy benefit managers (PBMs) believe these coupons generally undermine their health plan formularies and employer cost-sharing strategies because when patients use coupons to obtain brand-name medications, their own out-of-pocket expense is reduced, taking away the incentive to use a lower formulary-tier or generic medication.

Copay coupons do not change the medication’s true cost; as a result, payer spend may be higher because the patient is choosing a higher-cost product.

However, when it comes to coupons and discount programs associated with high-cost specialty drugs, many payers take a more cautious approach, since coupons may improve adherence to potentially unaffordable treatments, thus reducing overall medical costs.

The specialty pharmacy space has received increased scrutiny because of rising drug costs and the number of new drugs – about 900 – currently in the pipeline.

Seven to 10 of the top drugs by revenue will be considered specialty in 2016, up from about five in 2012. Trend increased 15% to 17% in 2012, 19% to 20% in 2013, and then in 2014, an increase of 22% to 25% is predicted.

The following four factors contribute to these changes:

♦ **No set definition for specialty drugs.** Although there is no standard definition for what constitutes a specialty drug, these drugs often are produced using recombinant DNA technology or require specialist expertise, handling or counseling.

♦ **Booming market.** Eight out of 10 drugs approved by the FDA in the next five years are expected to be considered specialty drugs. Biosimilars are not expected to produce the same price decrease as non-specialty generic drugs have.

♦ **Increasing utilization.** Utilization of specialty drugs is currently low – 1-2% – with respect to the total population but is expected to increase 10% or more in that next few years mainly because of new drugs, increased specialty drug use as first-line therapy and new indications for these specialty medications.

♦ **Increasing specialty drug spend and costs.** Specialty drug spend typically accounts for 12-30% of total drug spend and is predicted to increase to 40-50% by 2020. The average cost for a specialty patient is about $2,000 per month.

Prescription drug coupon programs have seen significant growth over the last few years. From 2012 to 2014, the numbers have jumped from 400 to more than 550 drug couponing programs. Specialty prescriptions have seen a particular increase in growth because of the increasing drug pipeline. Specialty coupon program availability varies widely by the therapeutic class. Because rheumatoid arthritis and multiple sclerosis are classes that have more readily available generic substitutes, they see more programs and greater use or availability and marketing efforts.

Plan sponsors do fear that use of specialty coupons might undermine their strategies with regard to formulary development, rebates or cost-share. Payers want to drive use of preferred brands to maximize rebates, for example, or drive lower cost alternatives. The use of coupons takes away the member’s incentive with regard to the plan design’s cost-share arrangement.

Specialty coupons can also help members, who are typically sensitive to the high cost-share of specialty drugs, especially with the prevalence of fourth-tier plan designs and the increasing use of high-deductible health plans. Members whose conditions require high-cost specialty medications are those hit hardest by increasing cost-shares, and use of specialty drug coupons can encourage more adherence among affected members. A recent Prime Therapeutics LLC study cited a positive impact of drug coupons in making medications more affordable, ideally leading to greater adherence and better outcomes.

Medication adherence is an especially big challenge in the specialty space, with the following contributing factors:

♦ **Side effects.** Many new specialty medications have distressing side effects, some of which can be serious and require the patient to be monitored carefully and coached.

♦ **Complacency.** In the absence of side effects, patients can still have a difficult time remaining on their prescribed therapies, sometimes because they’ve become complacent.

♦ **Cost.** The high cost of many specialty therapies is a contributing factor. However, even in the Medicaid arena, where copays are either specialty therapies or a few dollars, non-adherence is an issue, meaning cost is not the only barrier to medication adherence.

**Cost-Sharing Statistics**

Flat copays in the non-specialty area can range from $10-$40. Within that range, MedImpact’s analysis – which used a combination of different market segments, including managed Medicaid – showed that members paid almost 21% of the drug cost. In managed Medicaid, copays are only a few dollars, at most; taking out managed Medicaid business brought the member percentage to about 25% for non-specialty drugs, which fits with the typical national average.
For specialty medications, copays have a broad range of cost. A flat copay could be as low as $25 or as high as $150. For coinsurance, the amount the member pays could reach several hundred dollars.

The analysis showed that for specialty, the average member paid only 2.58% of the total cost of the medication, a figure that suggests that PBMs and insurers are showing restraint when establishing copay prices and setting them to reasonable levels. They have also instituted maximum out-of-pocket (OOP) limits, which help members. If the average cost for a specialty drug is $2,500, members who were charged the equivalent 25% of the cost (as in the non-specialty space) would pay a copay of $625.

In the past, prescription drug prices were determined by asking focus groups of potential patients what cost they would be willing to pay for a given therapy that relieves their symptoms and then analyzing those results and naming a price. Currently, pricing practices have little to do with the value of the product, although computer modeling of receptor sites in genotyping has improved this process for pharmaceutical companies.

For a new agent coming to market, pharmaceutical companies are expected to show payers and stakeholders a pharmacoeconomic model at the time of the product’s launch. These “cost offset models” show the relative value of a new medication and determine the therapy’s cost for one year, as well as an analysis to determine the cost offsets. Cost offsets include the reduction or elimination of hospital stays, ER visits or physician visits. A pharmacoeconomic cost offset model shows the total annual cost of the therapy and the total cost offsets, demonstrating the medication’s net value.

Cost offset models are not common in the specialty pharmacy arena because there is often no evidence to show a cost offset that is higher than the cost of the medications. For specialty, cost analysis compares a new medication’s efficacy against the other medications already available on the market. If the evidence shows that the new agent is clearly more effective, then that medication will get a preferred tiering on the formulary.

Most of the time, however, the evidence is not sufficient to determine that a new drug is superior to existing therapies. In this case, payers need to look at the medications in the therapy classes and determine which one has the best price. When choosing the tier for the medication, designers will first take into account the drug’s effectiveness and then the cost. The most valuable medications will be those that have the highest effectiveness by evidence and the lowest cost.

**Samples vs. Coupons**

Historically, pharmaceutical companies would offer free samples, in which a physician would give a patient a supply of medication for several weeks to determine how well the drug would work before writing a prescription. In some cases, there was abuse in that system, and the drugs were often not very effective.

For specialty medications, because of the expense of the drugs, pharmaceutical companies did not want to waste these expensive therapies by giving them to physicians and hoping that they would be used appropriately. A new approach was the concept of a copay assistance or coupon program, where there was a small risk to the person paying the copay to discover whether the new medication was going to be effective for them.

At this point, there is no clear consensus as to whether the coupon programs have a long-term benefit or harm in the specialty space.

Health plans and PBMs are using a variety of strategies to manage the use of specialty copay coupons, including:

- **Excluding specialty coupons.** For example, UnitedHealthcare Inc. publicized its decision to exclude coupons within their specialty pharmacy network. Plan sponsors can discuss the viability of this approach with their own health plan or PBM.
- **Drug exclusions.** Some PBMs have mandatory drug exclusions in their preferred drug lists in the specialty pharmacy space. For example, CVS Caremark Corp. excludes growth hormones, which fall under specialty pharmacy.
- **Preferred products and formularies.** This tactic is similar to drug exclusions. In it, the plan or PBM tiers different specialty brand products aligned with the preferred product and formulary placement to ensure that members are being driven to any existing lowest-cost alternative.
- **Step therapy.** For rheumatoid arthritis and multiple sclerosis – the two therapy classes with readily available generic alternatives – several PBMs and health plans have introduced step therapy programs. Members who want access to the non-preferred product have to step through the lower-cost therapies. Sometimes, this strategy drives higher rebate collection on behalf of PBMs and health plans for their plan sponsors.
- **Implementing a dispense-as-written (DAW) penalty.** This strategy makes members pay the difference in cost therapy if they select a higher-cost option.
- **Prior authorizations.** Health plans and PBMs can ensure that the member is receiving the appropriate medication for the appropriate diagnosis, particularly if the member is using the higher-cost or non-preferred brand medication within that specialty class.

Plan sponsors also have some strategies to consider, including:

- **Working with their health plans or PBMs.** For specialty therapeutic classes with lower-cost alternatives, spon-
sors can ask payers to help determine what solutions to offer members (preferred products or formularies, step therapy options or prior authorizations).

- **Leveraging the use of an inclusive or preferred pharmacy network.** Plan sponsors that want to basically exclude specialty drug couponing can adopt this method. In the current retail environment, there is no real way to hard-stop the claim or the coupon from processing, mostly because it processes as a secondary claim, and the retail pharmacy does not want to turn away its customers.

- **Member outreach and communication.** Once a plan sponsor has chosen a strategy, it should be sure to communicate that strategy to its members.

**CellCept® Copay Card Program**

One example of a copay assistance card is the “CellCept® Co-pay Card Program”. With this card:

- **The member pays the first $20,**
- **The pharmaceutical company pays** either up to $125 or up to $330 and
- **The member pays any remaining balance.**

### Even High Copays Are a Bargain on Specialty

<table>
<thead>
<tr>
<th>Non-specialty prescription costs</th>
<th>Specialty prescription costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>One client drug spend</td>
<td>Client drug spend</td>
</tr>
<tr>
<td>$2,445,455,896</td>
<td>$564,514,385</td>
</tr>
<tr>
<td>Copays collected</td>
<td>Client copay</td>
</tr>
<tr>
<td>$506,791,685</td>
<td>$14,551,301</td>
</tr>
<tr>
<td>Percent of member share</td>
<td>Percent of member share</td>
</tr>
<tr>
<td>20.72%</td>
<td>2.58%</td>
</tr>
</tbody>
</table>

For patients demonstrating financial need, the CellCept® copay card pays up to $330 a month, under the following circumstances:

- **The patient’s household adjusted gross income** is less than $100,000 per year.
- **Patients need to provide a verbal statement** to verify their income when they enroll, although documentation at a later date may be required.

### Setting the Stage: Specialty Drugs

**Definition:**

- No industry standard; varies by source
- Drugs produced using recombinant DNA technology
- Drugs that require specialized expertise, handling and/or counseling

**Market:**

- 300 specialty drugs in market with 900 in pipeline
- 8 out of 10 drugs approved by FDA in next 5 years expected to be specialty
- Biosimilars not expected to produce same price drop as non-specialty generics

**Trend:**

- 7 of 10 top drugs by revenue will be specialty in 2016 (5 in 2012)
- Expected to increase 15-17% (2012), 19-20% (2013), 22-25% (2014)

**Drug Spend:**

- Typically accounts for 12 - 30% of total drug spend, expected to be 40-50% (2020)
- Another 12 - 30% found in medical claims
- Average cost per patient is ~$2,000/month

**Utilization:**

- Typically 1 - 2% of population
- Utilization expected to increase 10% or more over the next few years, driven by new drugs; increased use as first line therapy; and new indications
An analysis of this copay coupon program was based on a 30-day supply or 90 tablets of CellCept, which is a transplant drug. (See box, below.)

### CellCept Pricing and Dosage

<table>
<thead>
<tr>
<th>Adult dosage</th>
<th>1.5 g/m per day (three 500 mg tabs per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AWP price per 500 mg tablet</td>
<td>$15.79</td>
</tr>
<tr>
<td>AWP monthly price for 90 tablets</td>
<td>$1,421.10</td>
</tr>
<tr>
<td>Typical discounted price per month</td>
<td>$1,193.72</td>
</tr>
<tr>
<td>Copay for the plan</td>
<td>$150.00</td>
</tr>
<tr>
<td>Copay assistance per month of therapy</td>
<td>$130.00</td>
</tr>
<tr>
<td>Patient pays</td>
<td>$20.00</td>
</tr>
<tr>
<td>Plan pays</td>
<td>$1,043.72</td>
</tr>
</tbody>
</table>

In this case, the copay was $150 to the plan, but because of the copay card, the member paid $20, the pharmaceutical company paid $130, and the payer ended up paying $1,043.72.

There is no copay assistance program on generics, but if the patient had used the generic mycophenolate, there is a substantial difference to the payer. (See box, below.)

### Mycophenolate (Generic CellCept) Pricing

<table>
<thead>
<tr>
<th>Adult dosage</th>
<th>90 tablets per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAC pricing per tablet</td>
<td>$0.89</td>
</tr>
<tr>
<td>Cost per month of therapy</td>
<td>$86.40</td>
</tr>
<tr>
<td>Copay for the patient</td>
<td>$10.00</td>
</tr>
<tr>
<td>Difference to the patient</td>
<td>$10.00</td>
</tr>
<tr>
<td>Difference to the payer</td>
<td>$967.32</td>
</tr>
</tbody>
</table>

Taking a maximum allowable cost (MAC) of $0.89, the cost of therapy for one month would be $86.40. The patient would pay $10, and the payer would pay $76.40. The difference between the brand-name CellCept® and the generic to the member would be $10; the member actually would pay less, and the difference to the payer was $967.32. Mycophenolate is an AB-rated generic medication — meaning that it meets bioequivalence requirements — and according to the FDA, there is no difference between the brand and the generic product except for the cost.

While some payers would require the generic drug to be used, this is not foolproof because in many states, the physician can override the generic requirement by writing “dispense as written” or similar language on the prescription.

Instructions to patients when they receive a copay assistance program typically say that, to help ensure receipt of the brand-name drug, the patient should ask the doctor to specify the brand with a note that states:

- **No substitution,**
- **Brand-name medically necessary or**
- **Dispense as written.**

The terminology is dependent on the state in which the patient lives. In these situations, pharmaceutical companies are telling their members to insist on a brand-name product because it is medically necessary, which is not the case.

Patients hear about these programs by receiving a card or a post card when they obtain the medication from their doctor, but in many cases, these programs are used by the specialty pharmacy.

Specialty pharmacies communicate their copay assistance programs by filling the prescription and explaining to the patient what the copay is. If the patient expresses any concern about the cost (or even if he or she does not), the specialty pharmacist can help the patient take advantage of one of these programs.

Specialty pharmacies are motivated to communicate with members about these programs and expedite the copay assistance because they don’t want to delay getting patients on to their medications. The payer shares this goal, but also is motivated to ensure that the most valuable medication is being prescribed and taken.

United Healthcare is one example of a company that has taken steps to address the use of copay coupons for specialty medications. The company started its program in September 2012, when it had a three-tier benefit program. At the time:

- **75% of its members using a tier-three (non-preferred) drug** were also using a copay assistance card program and
- **45% of the time, when a patient was using a medication on tier three,** a lower-cost alternative was available.

This situation costs the health care system more money, so for United, the copay assistance programs were providing a way around the formulary tiering, which is intended to financially incentivize patients to take the most appropriate medication and aim for the highest value.

United worked with its own specialty pharmacy and others in its network to stop allowing the copay assistance programs in four therapy classes:

- **Multiple sclerosis,** where United disallowed the programs for Extavia® and Gilenya®;
- **Autoimmune,** where United would not allow the copay programs for Humira®;
- **Transplant drugs,** where United disallowed the programs for CellCept®; and
Chapter 8: Payer Strategies for Controlling Costs

◆ *Hepatitis C*, where the company would not allow the copay assistance program for Victrelis® and PegIntron®. For each therapy class, other medications were available that, from United’s perspective, had higher value.

United developed a high-touch program to reach out to members and explain the new approach. The insurer also asked members if they would like a customer representative to contact their physician to discuss switching medications.

For Humira® and CellCept®, the new program meant an outreach effort to over 3,000 members. Upon receiving an explanation of the program and the invitation to contact the physician, 21% of the members said they would like that kind of assistance. Of the 79% who refused the service, only 3% indicated it was because they had already tried a lower-cost alternative. The majority indicated that “cost was not a concern.”

One-third of United members who asked for the specialty pharmacy to reach out to the prescriber saw that the medication was actually changed; 23% of members reached out to the prescriber on their own and were switched to the lower-cost drug.

When instituting a switch program, insurers need to keep an eye on how many people stop taking their medication. In the case of United’s TNF inhibitor class, 20% of the patients stopped taking therapy. While this could be considered a result of the switch, United did a similar analysis of a controlled group who was not affected by this program and found that 22% of those people stopped taking their medication in the same time period.

Because of that analysis, United concluded that the non-compliance didn’t result from the cost or the switching. The insurer did further analysis to see what impact total copay cost had on switching and found that members with more nominal copays ($50-$60) only switched about 10% of the time, while for those with much higher copays (such as a 25% coinsurance), the switch was made 40% of the time.

The final results of United’s program showed a five-point decrease in tier-three utilization and a market shift of 10% within the TNF inhibitor category. Because of the program’s success, the insurer has added 25 additional specialty medications to its list prohibiting the use of copay assistance cards.

**Purchasing’s Experience**

The Montana Association of Healthcare Purchasing (MAHCP) is an organization with multiple employers, both in and around the state of Montana, and is one of MedImpact Healthcare System’s clients. MAHCP uses a sophisticated seven-tier formulary benefit that exceeds what is normally seen in a commercial population. This benefit includes three tiers in specialty, and there are significant copays on the highest tiers of specialty benefit. MedImpact has worked with MAHCP to help the organization understand the influence of copay assistance programs on its formulary design.

For MAHCP’s client, the 2013 specialty spend was just over $9.7 million, and the copay expected was $678,212. The actual member contribution, after the copay assistance programs, was only $30,391, reducing the copays by 96%. Through this structure, members utilize much higher copays for medications that are extremely expensive, but show low clinical differentiation. Copay assistance programs counteract their benefit designs and thwart motivation to comply with the evidence-based formulary. MedImpact is working with MAHCP to develop a program similar to United’s that will help curb the influence of those programs when they are financially disadvantageous.

In some cases, copay assistance programs are being used to lower health care expenses. For example, hepatitis C medication Sovaldi’s manufacturer Gilead Sciences, Inc. uses a program for the drug in which the member pays $5 for the prescription, while Gilead pays up to 20% of the drug’s cost. MedImpact set up a benefit for a client where there was a 20% coinsurance with no member maximum. With the benefit, the client received a 20% discount on Sovaldi, and its members pay $5.

**Looking Ahead**

Expert projections suggest that within five years, specialty medications will represent about 50% of drug spend, meaning the cost of the medications will rise, but the percent of the member contribution will decrease. The 4-6% spend contribution by the member will represent 50% of the drug spend, presenting a double-edged sword for the payer.

Payers can combat this by establishing strict utilization management criteria and step therapy and by blocking non-valuable medications wherever possible. Beyond that, payers should also collect accurate data to determine where it makes sense to disallow copay assistance programs and selectively choose therapy classes and clients. Payers should also include a member education program in this effort to make it easier on the member as these switches occur.

**Independent Health Sees Big Savings via Integrated, Varied Approach to Coupons**

In an effort to combat manufacturers’ growing use of copay coupons to extend brand loyalty, Buffalo, N.Y.-based Independent Health and its Pharmacy Benefit Dimensions (PBD) PBM subsidiary in early 2014 developed a unique counter-detailing program that has had
a significant impact on network physicians’ prescribing habits. But recognizing that not all copay offset programs are bad, PBD and the specialty pharmacy subsidiary Reliance Rx opted to promote the use of patient assistance programs for a select set of specialty drugs in order to foster better adherence and achieve real savings.

Speaking at a session of the Sept. 16, 2015, AIS virtual conference, “Proven Pharmacy Benefit Strategies for a Rapidly Changing Marketplace,” Independent Health’s vice president for pharmacy services, Martin Burruano, R.Ph., explained that “there’s quite a differential in philosophy regarding copay coupons and patient assistance programs.” When it comes to manufacturer-sponsored coupons for brand-name drugs that have equally effective, less expensive alternatives, many insurers view these promotional efforts as “eroding” their efforts to control costs through the formulary and giving consumers a “false sense of savings.” Zitter Health Insights estimates that there were more than 700 brand-name drugs with copay offset programs in 2013, and 20% of those were for branded biologic products. And Independent Health found that nine out of 10 physicians in its network were prescribing many of those traditional products, said Burruano.

Building on previous mail-based efforts that targeted both patients and providers, Independent Health in early 2014 hired a seasoned pharmaceutical sales representative “who had vast experience in many of these disease states and drugs” and was “very effective in delivering a targeted message based on not only the clinical value but the economic value of prescribing more cost-effective medications,” said Burruano.

Working with its in-house PBM, Independent Health developed a “targeted campaign” that identified the physicians’ offices that were high prescribers of these medications and provided them with “actionable data” to promote prescribing in accordance with the formulary. “The tools that really had the most impact on the prescriber were data that includes peer-to-peer comparisons, almost like a report card, that provided cost transparency, because many of these prescribers really don’t appreciate what these medications actually cost,” shared Burruano. And many of the physicians were “quite shocked” at the cost of the coupon-associated brands they were prescribing, he said. Nevertheless, the company has found that it takes about five to six visits to “drill the message” and effect real change.

By resulting in more cost-effective prescribing in certain therapeutic categories, the counter-detailing program saved about $900,000 for the 2014 fiscal year, and a total of $1.6 million since its inception. Independent Health is in the process of expanding the program with one additional academic detailer to cover more providers and include messaging about several areas, including opioid utilization and Medicare Part D star ratings pertaining to certain measures.

On the flip side, PBD and Reliance Rx in 2014 developed the Specialty Copay Assistance Program (SCAP) for PBD’s self-insured customers that features a fourth tier of preferred specialty drugs. This originally included 10 drugs that had “very aggressive, yet low-barrier-to-entry copay assistance plans” and represented approximately 80% of overall specialty spend, explained PBD/Reliance Rx President Michael Reilly, R.Ph., who also spoke during the session. Effective Sept. 1, 2015, the program added six more medications, including Gilead Sciences, Inc.’s hepatitis C therapies, Harvoni (ledipasvir/sofosbuvir) and Sovaldi (sofosbuvir).

The SCAP drugs are each assigned a $500 copay that is adjudicated secondarily against a manufacturer assistance program, resulting in a $0 copay and “eliminating the financial barrier to compliance,” said Reilly. The program in 2014 generated $1.4 million in savings for patients alone, and a “much greater savings” for the employer groups; the company has a “shared savings model” through which it keeps 10% of the savings. As for whether the plan can capture rebates on the SCAP drugs, it varies from manufacturer to manufacturer, but some have allowed it in their contracts, he said. Reilly emphasized that none of these programs are about capitalizing on or maximizing rebates when those opportunities exist but are really about improving generic utilization and “driving to the lowest net cost.”
Percentage of Workers in Plans With At Least Four Tiers Drops Slightly

According to the 2014 Employer Health Benefits Survey released Sept. 10, 2014, by the Kaiser Family Foundation and the Health Research & Educational Trust, 20% of employees are now in a plan with four or more cost-sharing tiers. By comparison, only 4% of covered workers were in a plan with four or more cost-sharing tiers in 2005, and that has continued to rise every year until 2013, observes the 16th annual survey of more than 2,000 small and large employers conducted in 2014 from January to May.

Among plans with at least three tiers, copayments are much more common than coinsurance in the first three tiers, while coinsurance is more common in the fourth. Drugs in that tier have an average coinsurance of 29% for 2014, down from 32% in 2012 and 2013. 

Part D Analysis Finds Increased Coinsurance Use for Top Tiers

An analysis of Medicare Part D Prescription Drug Plan formulary data for 2015 finds that about two-thirds of stand-alone PDPs will apply coinsurance to at least two of their highest formulary tiers, which is up 84% from 2014, when only 32% of plans used coinsurance on their top two tiers.

In total, enrollment in plans with at least two coinsurance tiers increased from 6.4 million to 11.1 million from 2014 to 2015, estimates Avalere. In most cases, these plans include one specialty tier and apply coinsurance to the non-preferred brand tier, observes the consulting firm. All PDPs will use a specialty tier in 2015, adds Avalere.

The percentage of plans offering specialty tiers has steadily risen from 87% in 2012, finds the firm. But because they are not subject to the same cost-sharing

---

**Distribution of Covered Workers Facing Different Cost-Sharing Formulas for Prescription Drug Benefits, 2005–2014**

<table>
<thead>
<tr>
<th>Year</th>
<th>Four or More Tiers</th>
<th>Three Tiers</th>
<th>Two Tiers</th>
<th>Payment is the same regardless of type of drug</th>
<th>No cost sharing after deductible is met</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>4%</td>
<td>70%</td>
<td>15%</td>
<td>2%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>5%</td>
<td>69%</td>
<td>16%</td>
<td>2%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>7%</td>
<td>68%</td>
<td>16%</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>7%</td>
<td>70%</td>
<td>15%</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>11%</td>
<td>67%</td>
<td>12%</td>
<td>3%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>13%</td>
<td>65%</td>
<td>11%</td>
<td>1%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>14%</td>
<td>63%</td>
<td>11%</td>
<td>1%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>14%</td>
<td>63%</td>
<td>10%</td>
<td>1%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>2013*</td>
<td>23%</td>
<td>59%</td>
<td>10%</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>20%</td>
<td>60%</td>
<td>10%</td>
<td>4%</td>
<td>&lt;1%</td>
<td></td>
</tr>
</tbody>
</table>

* Distribution is statistically different from distribution for the previous year shown (p<.05).
† No statistical tests are conducted between 2006 and 2007 due to the addition of a new category.

limitations that are placed on specialty tiers, many of the non-preferred brand tiers offered by PDPs have cost-sharing rates ranging from 35% to 50%.

The trend toward more than one coinsurance tier has also been accompanied by a shift toward formularies with five tiers, observes Avalere. In 2015, 89% of plans will offer five or more tiers, up 53% from 2012.

**HHS Seeks Even Exchange Playing Field With Tweaks to Essential Drug Benefits**

In a new proposed rule on benefit and payment parameters for exchange plans in 2016, HHS suggests several key changes to essential drug benefits that industry observers say more accurately reflect market-based practices. The biggest and perhaps most welcome change is a proposed reliance on pharmacy and therapeutics (P&T) committees to develop formularies, which many managed care plans already use for their other lines of business.

Prescription drug coverage is one of 10 essential health benefits (EHB) that must be offered by plan sponsors of individual and small group plans sold on health insurance exchanges. For the 2014 and 2015 plan years, EHB plans have had to cover the greater of one drug per U.S. Pharmacopeia category and class or the same number of drugs in each USP category and class as the state-selected EHB benchmark plan.

In implementing that original standard, HHS explains in a proposed rule issued Nov. 20, 2014, (79 Fed. Reg. 27858, Nov. 26, 2014) that it meant to “require comprehensive coverage and establish a common organizational tool for plans to report drug coverage.” HHS now acknowledges that issuers have had difficulty developing formularies that conform to the USP system, which was developed for the Medicare population, and recognizes that “some drugs that are likely to be prescribed for the larger EHB population were not reflected.”

**HHS Proposes EHB Changes**

The Academy of Managed Care Pharmacy (AMCP), which has long championed the use of P&T committees in formulary development, is “very pleased” with the proposed shift from using the USP category and class design to “allowing P&T committees to actually design formularies based on what’s best for their patient population,” reports Mary Jo Carden, R.Ph., senior director of regulatory affairs at AMCP.

“We’ve always followed efficacy/safety criteria followed by pharmacoeconomics once the safety and efficacy have been established, and that would level the playing field for everybody,” echoes Martin Burruano, R.Ph., vice president for pharmacy at Independent Health, which offers individual and small group plans on and off exchanges in Western New York. The HHS proposal would ensure that “all the formularies would minimize the cost basis for developing a formulary and maximize the therapeutic efficacy first,” he suggested to AIS in November 2014.

Among other changes to essential drug benefits, HHS is now proposing two alternatives to the current USP standard:

1. **Replace the drug count standard with the requirement that plans adopt a P&T committee** and “use that committee to ensure that the plan’s formulary drug list covers a sufficient number and type of prescription drugs.” HHS asks would-be commenters whether it should adopt the P&T standards “in lieu of or in addition to” other standards it is proposing (see below). HHS also proposes setting P&T committee standards on membership, meetings, and establishment and development of the formulary, and recommends that issuers’ formularies provide “appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of and consistent with general best practice formularies in widespread use.”

2. **Replace the USP standard with a drug count standard based on the American Hospital Formulary Service (AHFS),** which HHS says is widely referenced in the private insurance market and frequently used for developing formularies for the population being covered by EHB. HHS observes that the AHFS system, which is
updated and published annually by the American Society of Health-System Pharmacists, “is more gradual and has more classifications than the USP system” and would ensure broader coverage of drugs.

Both proposals would be implemented for the 2017 plan year. HHS adds that plans could continue to use the existing USP drug count standard, and it would update that system to a more current version.

Through the proposed changes to drug count standards and other areas of the drug benefit, “HHS is acknowledging that the market will change faster than the regulatory paradigm can...and [is trying] to have the exchange plans reflect market practices,” observed Avalere Health, LLC, CEO Dan Mendelson in a November 2014 interview with AIS. “And it makes sense to the extent that the plans can be operating in a way that is consistent across different markets.”

Also contained in the rule is a proposal to establish “clearer and more uniform standards” for exceptions processes through which members can request and gain access to drugs that are not on formularies. This would include a secondary external review “if the first exception request is denied by the plan” regardless of whether that request is made on a standard or expedited basis.

While that enhanced process could create an additional burden for plans, it provides a level of transparency “that consumers need to be able to make informed decisions,” suggests Andrew Miller, director of business development at MeridianRx, a full-service PBM that supports small-group and individual plans sold by its sister organization, Meridian Health Plan, through the Michigan state exchange. “I think as long as a plan abides by the philosophy of providing the highest efficacy at the lowest possible cost, you’ll run into very few situations where you have members actually appealing things,” he suggests to AIS. “I think for the wrong type of plan, anybody can go ahead and reduce health care costs by just denying things, but you’re not really adding any value by just doing that.”

Miller says MeridianRx supports many of the proposals contained in the new rule for their potential to offer members more transparency, including one that would give enrollees the option to access their prescription drug benefit through retail pharmacies and not be subject to a mail order-only benefit. “I don’t think it’s fair for PBMs to necessarily force mail order on clients unless they really want it,” he contends. “There’s obvious concerns about mail order that can, quite frankly, cause confusion amongst members. Also on the health plan side, mail order can often actually end up costing more through churn and creep of the actual prescriptions.”

But if exchange plans must offer “most drugs” at retail pharmacies — as suggested in an HHS fact sheet that accompanied the rule — Burruano tells AIS he’s concerned that effective clinical management of specialty drugs could be lost if those drugs must go through any pharmacy. The insurer operates its own specialty pharmacy, Reliance Rx, which boasts a 90% compliance rate for the specialty medications it dispenses, he explains.

Burruano says there’s a lot of control in being able to drive members to that specialty pharmacy “because these high cost specialty drugs require a lot of clinical management, and the specialty pharmacy is able to provide that through frequent communication with our members regarding their medication profile, the other medications they’re on, their side effect management and working closely with their physicians if there are any adverse effect or compliance issues so they manage adherence and compliance for those members.” In addition, Reliance Rx routinely accesses manufacturer-offered or foundation-sponsored patient assistance programs, regardless of whether the drug is preferred or nonpreferred, which Burruano says is unlikely to happen with a retail pharmacy.

According to that section of the proposed rule, plans would still be able to restrict access to drugs that require “extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy,” or when the FDA has restricted distribution of the drug to certain facilities or practitioners (e.g., because of Risk Evaluation and Mitigation Strategies programs).

“Specialty could be a concern, but I think HHS is more or less talking about acute meds,” points out Carden. “I think what they’re steering away from is just a mail order-only benefit.”

Finally, HHS proposes adding a requirement that issuers publish an “up-to-date, accurate, and complete” list of all covered drugs on the formulary, including tiering information and any restrictions, in an easily accessible manner for the general public. HHS is seeking comment on whether such tiering information should include details on cost sharing.

Recent research conducted by Avalere shows that patients accessing specialty medications through exchange plans are more likely to experience higher out-of-pocket costs in 2015 than in 2014 through greater use of coinsurance.

“I think the issue is that HHS always has to balance the fact that this is insurance that people go online and buy in a comparison-shopping construct. So the thing I worry about is that the drug benefit can be a selection tool,” suggests Mendelson. “In other words, if a drug benefit is too generous, it might invite adverse selection and the plans are concerned about that, so sometimes CMS does have to level the playing field and make sure that there’s a minimum standard so that the drug benefit doesn’t completely erode. And that’s really the thing that they need to balance.”
Survey: Employers Are Open to Using Next-Generation Strategies

Most employers still turn to copayments and coinsurance to manage specialty drugs, but many of them are looking to implement new plan designs, according to the Midwest Business Group on Health’s fourth annual employer survey about specialty drug management tactics.

The group consists of more than 120 large self-insured public and private employers that have more than 4 million employees and spend more than $4 billion annually on health care for them. Between December 2014 and February 2015, 81 of those employers, representing more than 1.5 million employees, responded to the survey. It was conducted as part of the group’s National Employer Initiative on Specialty Drug Management, which began in 2011 with a goal of helping employers manage specialty medications more effectively.

All of the respondents agreed that they are concerned about the costs of specialty drugs and that they need “new and innovative solutions” to manage the specialty space. However, when asked if their PBM “does a good job managing specialty pharmacy costs,” only 12% said they strongly agree, while 39% agree, 41% somewhat agree, and 8% don’t agree.

The survey found that most respondents — 88% — have the traditional plan designs of copay and coinsurance in place, but they are open to shifting to new tactics. For instance, while 40% now offer vendor performance guarantees, 51% said they would consider offering them. Other plan design strategies they said they would consider offering include shifting costs to employees, carving out specialty and implementing a narrow network.

Forty-three percent of employers that had increased cost shares over the last three years reported increases of more than 50%. When asked about the impact of these increases, 21% said there was increased compliance to treatment, 17% said employees had complained about costs, 29% said there was no impact at all, and 37% said they did not know what the impact was.

And while they ranked site-of-care strategies to push employees to less-expensive locations as the fourth most...
effective cost management strategy, 63% do not have any kind of plan design element focused on this.

In oncology, the main plan design tactic used by respondents is an integrated PBM with a health plan that manages benefits (37% of respondents), followed by mandatory specialty pharmacy use for prescriptions, cited by 25% of respondents. None carve out oncology or use a narrow formulary with preferred cancer drugs.

“We’re excited to see that employers are willing to consider specialty drug strategies that are already being successfully used in health care,” said Cheryl Larson, vice president of the Midwest Business Group on Health, in spring 2015. “Performance guarantees help keep vendors accountable, and having providers assume shared risk for patient outcomes is part of the future market landscape. It just makes sense to align incentives across stakeholders for optimal plan performance.”

Larson tells AIS that “there are still opportunities left on the table by employers based on our recent survey through the National Employer Initiative. Most are not offering patient incentives — even for medication compliance or using less expensive sites of care. Low-hanging fruit tactics like incentives to appropriately use medications can help make a difference in employer-based population health.”

As part of the initiative, the group offers an employer toolkit online. The first section explains the specialty pharmacy landscape, the second discusses challenges with and tactics for plan design and vendor contracting, and the last part offers employers resources.

HHS Rules on Discriminatory Benefits, Mail Order Create Uncertainty for QHPs

As sponsors of qualified health plans (QHPs) fine-tune their product offerings for federally facilitated exchanges in 2016 and subsequent plan years, there are still two gray areas that may require plans to do a little extra work supporting the rationale behind their drug benefit designs. One is around potentially discriminatory benefits and the other is a 2017 prohibition of a mail order-only benefit; both present issues when it comes to specialty drugs.

According to the 2016 Payment Notice Final Rule (80 Fed. Reg. 10750, Feb. 27, 2015), issuers of essential health benefits (EHBs) are prohibited from implementing benefit designs that discriminate based on a person’s age, expected length of life, present or predicted disability and other factors. In both the rule and a Feb. 20, 2015, letter to QHPs, HHS clarified that placing most or all drugs for a certain condition on the highest cost tiers is potentially discriminatory.

While a specialty tier is “not on its face discriminatory,” HHS in the final rule said “placing most or all drugs for a certain condition on a high cost tier without regard to the actual cost the issuer pays for the drug may often be discriminatory in application when looking at the totality of the circumstances, and therefore prohibited.”

Helen Sherman, Pharm.D., vice president at Solid Benefits Guidance, predicts there will be variation as to how plans implement this guidance. “There are situations where ‘most’ of all drugs within a therapy class are on a highest tier (or disadvantaged through prior authorization or not on the formulary) because the medications within the class are interchangeable,” she points out.

For example, including two or three of nine growth hormone products on a preferred tier is a common medical management practice. “However, this practice could potentially be viewed as discriminatory since ‘most’ of the growth hormone products are disadvantaged,” she suggests.

As a result, Sherman is advising that at the very least, plan sponsors do the following:

1. Review their formularies and utilization management policies to identify situations where most medications in a therapy class or for a specific condition are on the highest tier or disadvantaged; and
2. When most of the medications for a condition are disadvantaged, maintain an objective, condition-specific/therapy class-specific rationale about why disadvantaged most medications for that condition (or therapy class) is reasonable medical management.

AIS asked nearly a dozen plans if this clause will force them to move any specialty drugs that would otherwise be considered nonpreferred to a preferred tier. Most were either unresponsive or quick to issue statements that they do not have discriminatory benefit designs.

In a June 2015 interview with AIS, Stephanie Yamamoto, Pharm.D., clinical pharmacy manager for Premera Blue Cross in Washington, says this is one of the regulatory pieces that the plan is “currently looking at and trying to figure out what we need to tweak in order to be in compliance with it by the dates that are stated.” She says Premera is confident that its evidence-based approach to tiering is not discriminatory, although what the plan considers to be specialty drugs may differ from how other plans categorize them.

If plans don’t err on the side of caution and keep the bulk of certain specialty medications in a nonpreferred tier, Sherman says she anticipates that “plans will need to demonstrate rationale on a case-by-case basis either through complaints and/or the formulary submission process.”

Also included in the final rule, but effective for the 2017 plan year, is HHS’s earlier proposal to prohibit plans from offering a mail-order only prescription drug benefit.
HHS in a November 2014 proposed rule said this means plans can charge higher cost-sharing amounts for drugs obtained from in-network retail pharmacies vs. mail-order pharmacies, although it changed the term “higher” to “different” in its Feb. 27, 2015, final rule.

Because specialty pharmacies are considered mail-order pharmacies, many commenters had expressed concerns about allowing beneficiaries to obtain specialty medications from retail pharmacies. HHS recognized in the final rule that “specialty pharmacies provide more integrated services, aimed at improving clinical outcomes while limiting costs relating to the delivery and management of the product, than a typical mail-order pharmacy or a brick and mortar retail pharmacy.”

As a result, HHS clarified that plans “may restrict access to mail order, which may include specialty pharmacies, for a particular drug” in either of two circumstances:

1. When the FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or
2. Appropriate dispensing of the drug requires special handling, provider coordination or patient education that cannot be met by a retail pharmacy.

But Martin Burrano, R.Ph., vice president for pharmacy services with Independent Health, says he’s still not sure this means there doesn’t have to be a retail option with the second instance. “With limited distribution drugs, members couldn’t access those drugs [through a retail pharmacy] anyway, but it’s still unclear as to whether in 2017 we have to allow open access to those members for specialty medications,” he remarks. “Can we mandate specialty pharmacy or can we not mandate specialty pharmacy for those members on the exchange? We’re all working with our local associations to get more clarification around that.”

Independent Health is also concerned about this requirement because of the level of clinical management that specialty drugs require. Sheila Arquette, R.Ph., director of pharmacy services with the Western New York insurer, says she hopes there will be additional guidance on the matter and opportunities through published studies to demonstrate that insurers are not “trying to restrict access, but trying to improve outcomes.”

“The industry standard position is that retail pharmacies are not able to deliver the necessary services, handling, and/or care for specialty medications, and therefore, specialty medications need to be dispensed by a specialty pharmacy,” observes Sherman. “However, there are significant variations across plans as to which medications are classified as ‘specialty medications.’ As such, it’s prudent for plans to have medication-specific, objective rationale in situations where the medication will only be covered through a specialty pharmacy.”

While still too soon to determine a course of action for 2017, Yamamoto says the requirement to offer both mail order and retail aligns with Premera’s “typical approach to give the member as much choice as they can.”

She adds, “specialty pharmacies are typically set up as mail order only access, but I know that there are specialty pharmacies out there that have retail or brick-and-mortar access as well, and that’s what we would look to leverage for this particular rule.”

While still too soon to determine a course of action for 2017, Yamamoto says the requirement to offer both mail order and retail aligns with Premera’s “typical approach to give the member as much choice as they can.”

She adds, “specialty pharmacies are typically set up as mail order only access, but I know that there are specialty pharmacies out there that have retail or brick-and-mortar access as well, and that’s what we would look to leverage for this particular rule.”

Formulary drug lists were collected by CMS as part of the initial QHP applications submitted by May 15, 2015.

Cigna Discontinues Mandatory Mail Order for HIV/AIDS Drugs

Cigna Corp. will discontinue its requirement that members obtain HIV/AIDS medications by mail.


“In addition, patients who paid more for their prescriptions as a result of the mail-order requirement may seek reimbursement of their out-of-pocket costs,” according to Consumer Watchdog. That organization and Whatley Kallas and have settled similar lawsuits with UnitedHealthcare and Anthem Blue Cross.

Report Analyzes Cost-Share Requirement Trends for Anti-Inflammatories

About a quarter of all commercial health plans require a 30%-35% coinsurance for anti-inflammatory drugs — Remicade, Enbrel, Humira, Cimzia, Stelara, Simponi and Otezla — according to an analysis of cost-sharing data from RxB, AIS’s Rx Benefit Data, published in a recent report on The Cost and Impact of Adverse Events: Anti-Inflammatory Drugs.

Analyzing the in-network retail cost-sharing requirements of more than 11,000 commercial plan designs, AIS researchers determined that another quarter of health plans impose a set copay amount for covered drugs in this class — most often in the range of $120-$200. Also popular for anti-inflammatories were plan designs imposing a 50% or 20% coinsurance requirement.
From The AIS Bookshelf:
From Chapter 8: Payer Strategies for Controlling Costs

This PDF includes a 24-page excerpt from a chapter on “Payer Strategies for Controlling Costs” from the AIS book *Specialty Pharmacy Trends and Strategies: 2016-2017 Edition*.

Like what you’ve seen in this chapter?
Order the complete *Specialty Pharmacy Trends and Strategies: 2016-2017 Edition* today!

**Order Form**


**Three Convenient Ways to Pay**

Charge my credit card

- $423
- $523

- VISA
- MasterCard
- AmEx

- Card # ________________
- Exp. Date ________________

Charges will appear as Atlantic Information Services, Inc.

Check enclosed for

- $423
- $523

Make payable to Atlantic Information Services, Inc.

- Purchase Order # ________________

**100% Satisfaction Guarantee**

Order *Specialty Pharmacy Trends and Strategies: 2016-2017 Edition* for a 30-day risk-free inspection and test for yourself the value of this information resource. If within 30 days you're not 100% satisfied, you may return it to AIS and receive a full, prompt refund. Refunds will not be made once the seal on the CD package has been broken. Please review your copy of the print version prior to breaking the seal.

**Three Easy Ways to Order**

1. Call toll-free 800-521-4323
2. Mail this completed form to:
   Atlantic Information Services, Inc.
   1100 17th Street, NW, Suite 300
   Washington, DC 20036
3. Visit the marketplace at www.AISHealth.com

*Signature ________________________________
*Phone # ________________________________
*Required for credit card and purchase orders