Volume 15, Number 13 July 11, 2014

DRUG BENEFIT NEWS

PBMs Ramp Up Efforts to Curb Soaring Cost, Use of Compounded Medications

Express Scripts Holding Co. this month began what some say is the most aggressive approach yet to managing the rising cost of compounded medications by blocking coverage of more than 1,000 ingredients that are potentially driving up spend in this traditional category. But others like Catamaran Corp., CVS Caremark Corp. and the UnitedHealth Group PBM subsidiary OptumRx have launched initiatives to ensure that clients are not paying for compounded medications that have no additional clinical value over commercially available, FDA-approved medications without implementing sweeping edits.

Starting this summer, Express Scripts will begin blocking more than 1,000 ingredients that are commonly found in compounded medications. In a June 18 post to http://lab.express-scripts.com, Glen Stettin, M.D., senior vice president of clinical, research and new solutions, explains that the PBM is targeting bulk powders for which "prices have been greatly inflated but…provide no additional clinical benefit." These are primarily ingredients that are used in topical creams, and are most often found in treatments for acne, wrinkles and pain. The company stresses that it is not blocking coverage of sterile injectable compounds.

Express Scripts estimates that its new compound management solution will lower the costs in this category by 95% while affecting just 0.6% of its member population.

Battle Against Compounds Builds

At the same time, the company says it will ensure that patients who need compounds will be able to obtain them. The program is available free of charge.

According to a June notification sent to clients, Express Scripts also will monitor compound ingredient prices, "and if any ingredients increase outside of market-acceptable ranges, those ingredients will be excluded as soon as reasonably possible." Express Scripts will implement the new solution as soon as July 15 for plan sponsors that wish to block compounded ingredients right away and are comfortable doing so without notifying members. Otherwise, all clients will be enrolled by Sept. 15, giving them 60 days to notify members of the change, unless they opted out of the program before July 3. Express Scripts spokesperson David Whitrap says clients so far have been highly responsive to the new solution, and some are choosing to implement it next week.

Stettin charges that compounding pharmacies have "exploited a loophole" that enables them to charge "hundreds or thousands of dollars per gram of bulk powder or cream" included in a compounded medication. Since 2011, Express Scripts says it has witnessed a 30% increase in the number of compound prescriptions and a more than 1,000% increase in the total cost of these drugs.

Phil DeNucci, R.Ph., a managing consultant with The Burchfield Group, explains that in 2012, the National Council for Prescription Drug Programs (NCPDP) converted to an ingredient-based processing logic instead of the typical method of submitting compounds based on the highest cost ingredient and a multiplier. Payers continued to cover compounds because they hadn't experienced any problems under the previous processing logic, he says. But the new methodology led many compounding pharmacies — in collaboration with manufacturers — to begin submitting unique packaging and mixing oral or inhaled agents into topical products that contained multiple ingredients billed at inflated average wholesale prices, he suggests.

Compounding Industry Wants to Work With PBMs

The previous reimbursement methodology to some extent "disenfranchised" a lot of compounding pharmacies and was not entirely fair, contends Del Doherty, Pharm.D., director of managed care services at Professional Compounding Centers of America (PCCA). The company provides compound-related chemicals, devices, equipment, training and support for more than 3,900 independent community pharmacies across the U.S.

PCCA says it is working with PBMs and health plans to try to preserve compounded medications as a covered benefit and advise payers on the value of these specialized medications. "We want to achieve a common goal, which is we want compounds to be safe, effective and to produce the best quality of compounds out there…and we believe in a network of

highly credentialed providers," Doherty tells *DBN*. Meanwhile, a privately funded entity called the United Compounding Network has just formed in order to offer a limited, closed network of highly credentialed compounders that it contends will meet the quality standards of payers.

"The point that I think is important to make — and this is where PBMs tend to confuse this issue — is when the pharmacies put in the NDC [national drug code] for each ingredient in the compound, they are reimbursed on a pre-negotiated adjudication logic, so what the pharmacies are being reimbursed is based on a contracted rate," explains Doherty. "The only thing that changed is the fact that now the pharmacies are getting reimbursed for each and every ingredient in the compound. And when compounds are written, it's like any prescription — the physician writes for a given compound and specifies the ingredients in the compound. I cannot comment on what happens on an individual basis because these are personalized medications…but these are all coming from clinical decisions."

The problems that payers face, however, are not related to an increase in patients who actually need the drugs (e.g., pediatric patients with swallowing problems or people with allergies to the dye found in certain tablets). Rather, they stem largely from items such as topical pain medications that are essentially made by "prescription mills" and are being billed for as much as $10,000 per script, says DeNucci.

OptumRx Chief Medical Officer Brian Solow, M.D., and UnitedHealthcare Chief Pharmacy Officer Susan Maddux, Pharm.D., explain that the PBM and health insurer began tackling compounded medications in early 2012 when they noticed costs going up in this category, but even then, it wasn't among the top 25 cost drivers. From 2012 to 2013, however, UnitedHealthcare's carved-in customers saw a 35% increase in spend for compounded medications, which are now the No. 1 driver of spend.

"We have talked with lots of physicians who are getting solicited to write prescriptions for these compounding pharmacies and are getting paid for every compound prescription that they write," Solow tells *DBN*.

As a result, the two UnitedHealth Group subsidiaries began conducting targeted outreach to prescribers last year by engaging the top 100 prescribers of compounded medications by spend in "one-on-one, peer-to-peer discussions," explains Solow. "What we've found is that most of them were very surprised to hear the costs that were involved," he remarks. The companies also have sent letters to additional physicians about their prescribing as well as the cost of compounds and potential alternatives that may be covered.

Other strategies employed by UnitedHealthcare and OptumRx are:

◆ ***Identifying select bulk chemicals for formulary exclusion.*** UnitedHealthcare in July 2013 excluded the top 19 bulk chemicals responsible for the majority of spend where there was no evidence that they would actually be safe or effective in a topical form, such as chemicals used mainly for cosmetic purposes or ingredients that are available as a supplement or over-the-counter product. Maddux says the company is continuing to evaluate its data and enhance this program.

◆ ***Requiring notification/prior authorization for compounded medications that exceed a set dollar threshold.*** This was the first strategy deployed by the companies. "We continue to evaluate that threshold and adjust as it is appropriate," explains Maddux.

◆ ***Maintaining an extensive list of non-FDA approved bulk chemicals*** used in compounds to ensure that products are not approved. For example, if a topical compound contains an FDA approved ingredient that is not FDA approved for the compound indication or for which there is no off-label support for topical use, that requested compound would not be approved.

◆ ***Evaluating participation of compounding pharmacies*** to ensure that they abide by state and federal laws and are credentialed, accredited and licensed to practice. Solow points out that OptumRx has a network audit team that tracks and monitors high-dollar compounds, which may result in an in-depth investigation for fraudulent claims and termination from the network. OptumRx is also contemplating developing a compound network.

"We're not against compounding, and I don't think any of the PBMs are against it. It's just we need to make sure when it's medically appropriate and when it's safe and that the patient needs it, we'll make sure the patient gets it," adds Solow.

Meanwhile, CVS Caremark Corp. says it has developed a comprehensive strategy that PBM clients can choose to adopt within their plan design to help manage increasing compound drug utilization for specific, high cost, topical compounding bases and bulk powders. The resulting compounded drugs are applied topically (e.g., as creams, gels, lotions, ointments) for cosmetic use (e.g., anti-aging, scar diminishing, anti-wrinkle) or topical pain management. Effective July 1, PBM clients were given the option to select and customize this management strategy based

on their needs and drug utilization, according to a spokesperson.

But DeNucci says the Express Scripts strategy is the most aggressive he's seen "simply because it is at an NDC drug-specific, package-specific level." He adds that many of his employer clients have witnessed compounds become the No. 1 category in terms of cost. "Sometimes groups with as few as 10,000 covered lives are experiencing half a million dollars in compounded medication. So [this problem] was too large to address in kind of a traditional utilization management program."

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