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DRUG BENEFIT NEWS

As More Therapies Flood the Market, Plans Worry About Rising Diabetes Costs

While PBMs have been giving significant attention to the rising cost of compounded medications, another traditional category that's driving trend at an alarming rate is diabetes. According to recent trend reports, PBMs observed double-digit increases in diabetes drug costs in 2013, largely due to inflation. And with a rich diabetes development pipeline that includes newer long-acting insulins and emerging therapies such as sodium glucose cotransporter-2 (SGLT-2) inhibitors, payers will continue to be challenged by that growth and seek ways to manage the overall health of their diabetic members.

"I think we're starting to see the wave, if you will, of increased costs directly related to the obesity epidemic and the aging of our population, because there's an incredible link between obesity and diabetes and heart disease and lipid disorders and those sorts of things," observes Craig Oberg, R.Ph., a managing consultant with The Burchfield Group. "Unfortunately, this is a therapeutic area where a lot of the things that are used to most effectively treat diabetes are still brands. The good news is that for those other therapeutic areas — heart disease, high cholesterol — there are some really good, solid therapeutic choices that can be purchased as generic products."

In its new *2014 Report on prescription drug costs,* Prime Therapeutics LLC reports that traditional diabetes medications were the second-largest driver of rising costs in 2013, with an increase of 63 cents per member per month (PMPM). Spending on diabetes medicines grew 10.4% in 2013, mainly due to an 11% jump in drug costs and 1.9% increase in utilization. Diabetes, as a category, has the highest expenditures and growth among traditional drug classes, with a total plan PMPM cost of $5.42 in 2013, adds the PBM.

And for the third year in a row, the U.S. spent more on diabetes medications than on treatments for any other condition, says Express Scripts Holding Co. According to that PBM's *2013 Drug Trend Report,* use of diabetes medications rose 2.4% in 2013, compared with a 1.5% increase in 2012. Meanwhile, diabetes drug costs jumped 11.6% in 2013, "accelerating from 9.5% in 2012." Express Scripts estimates that spending on diabetes medications will grow at an annual rate of 10% to 13% over the next three years.

BlueCross BlueShield of Tennessee, which uses Express Scripts as its PBM, says it has witnessed a 33% increase in plan cost on a PMPM basis for diabetes treatments between the first quarter of 2013 and first quarter of this year. "This is driven primarily by both an increase in membership, but also an increase in costs of products…primarily the insulin products, but also with the non-insulin drugs — generic products such as metformin seem to have taken a real jump — supplies (e.g., syringes) and glucose monitoring devices," observes Ned Giles, Jr., Pharm.D., manager of formularies for the Tennessee Blues plan.

To address these rising costs, Giles says the insurer annually re-evaluates the entire class of antidiabetics for potential rebate opportunities and tier placement, and continues to restrict certain products through step therapy and/or exclusion of certain products. "We know there have been significant increases in prices of products such as Lantus and certain generics, but it is very difficult for us to be able to control the rising AWP [average wholesale price] costs of products," shrugs Giles.

"With a rapidly aging U.S. population, growing obesity epidemic and subsequent increases in the prevalence of diabetes, the biggest issue for payers is how to curb the growing prevalence of the disease from a health/wellness perspective," points out David Calabrese, vice president and chief pharmacy officer for Catamaran Corp. "Also, how to ensure those that are diagnosed are managed to appropriate goals through active engagement in lifestyle and pharmaceutical interventions to prevent progression of disease and negative macrovascular (e.g., heart attack) and microvascular (e.g., blindness) complications" is an added challenge for payers.

In its *2014 Informed Trends* report, Catamaran said it experienced an overall trend in the diabetes class of 11.1%, including a 0.9% increase in utilization and a 10.9% increase in unit cost. The average cost per prescription for the antidiabetic class increased 9%, due to higher utilization of the more expensive antidiabetic drug Lantus, the PBM observed.

GBI Research estimates that the value of the global type 2 diabetes market could reach $38.8 billion by 2019. Sanofi's Lantus, a daily injectable long-acting

insulin, is currently the market leader for type 2 diabetes treatments, and achieved worldwide sales totaling $6.4 billion in 2012, according to GBI Research. But Sanofi will lose its patent on the active ingredient, insulin glargine, in Lantus in February 2015, although it has filed a patent infringement lawsuit to stop Eli Lilly & Co. from marketing a proposed rival treatment. GBI estimates that from 2012 to 2019, safer, more efficacious and newer classes of diabetes drugs will gain substantial market share.

Based on a survey of U.S. and European payers and physicians recently conducted by Decision Resources Group, U.S. physicians agreed that a greater reduction in body weight is the biggest unmet need relating to the treatment of type 2 diabetes. Surveyed U.S. payers, meanwhile, identified improvements in the drugs' ability to lower body weight and safely reduce the incidence of cardiovascular adverse events as key drivers of formulary inclusion.

One new class that payers and clinicians are watching for its potential to achieve weight loss while lowering glucose is the new crop of SGLT-2 inhibitors to treat type 2 diabetes. These are considered "breakthrough" medications because they work through a different mechanism by focusing not on the pancreas and beta cells to produce more insulin, as older medications do, but by increasing the excretion of absorption through the kidneys, explains Tim Blackstock, an analyst with Decision Resources Group. Two oral SGLT-2 inhibitors — Janssen Pharmaceuticals, Inc.'s Invokana (canagliflozin) and AstraZeneca and Bristol-Myers Squibb Co.'s Farxiga (dapagliflozin), received FDA approval in the last year, while others are in the pipeline.

"Thought leaders are excited about [SGLT-2 inhibitors] because they have the potential to be part of fixed-dose combinations or add-on therapies, as its mechanism of action represents less stress on the body," observes Blackstock.

Catamaran has established prior authorization criteria on both new SGLT-2 products to "ensure appropriate use of these agents by validating type 2 diabetes diagnosis, ensuring adequate renal function, confirming that there are no contraindications to therapy, and verifying that the patient has had a first-line trial (or contraindication) to metformin therapy, in line with American Diabetes Association (ADA) consensus treatment guidelines for this disease," explains Calabrese. Similarly, Prime Therapeutics says it requires the use of metformin before all other classes of antidiabetic drugs, including SGLT-2s. Meanwhile, Giles says BlueCross BlueShield of Tennessee has placed the new SGLT-2 inhibitors on different tiers but has not otherwise restricted these products.

Decision Resources' recent survey also suggests that fixed-dose combination (FDC) products offer physicians a way to improve convenience and medication compliance for those patients who are taking multiple pills for type 2 diabetes as well as other comorbidities. The research firm predicts that if approved, Novo Nordisk's Xultophy (degludec/liraglutide) will by 2017 emerge as the "clinical gold standard" among FDCs due to the "combined actions of the highly efficacious individual components on various measures of glycemic control." To conduct its research, the firm pitted five FDC products such as Merck's oral combination therapy Janumet (sitagliptin/metformin) against five emerging FDCs, and asked prescribers to rate them based on safety, efficacy and delivery method.

Meanwhile, Afrezza, a new short-acting inhaled insulin, was approved on June 27 to improve glycemic control in adults with type 1 or type 2 diabetes. Manufacturer MannKind Corp. says the "ultra rapid-acting" insulin offers a new option for patients with diabetes requiring mealtime insulin to control blood sugar levels, and is more fast-acting than injectable insulins such as Novo Nordisk's Novolog and Eli Lilly and Co.'s Humalog. The combination product features an inhalation powder that comes in single use dose cartridges and a small inhaler that will be used to help manage blood sugar levels at mealtimes. But it has a black box warning that the product shouldn't be used by patients with asthma or serious lung disease.

"This is not likely a game changer; rather, it is an alternative for individuals who do not want to inject insulin prior to every meal," asserts Craig Mattson, Prime's senior director of formulary development. "There remains a question regarding the long-term safety of inhaled insulin on the lungs."

Blackstock points out that none of these new agents at this stage "are likely to become first-line therapy, as metformin is still the dominant therapy because it's a good drug and it's had good efficacy, it's relatively safe and it's well tolerated." Nevertheless, there is a move to tailoring therapy to the individual patient, which could lead more physicians to consider the FDCs, he says.

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