

IN THIS ISSUE

- 1 Value-Driven Partnerships Leading the Shift to Value-Based Care
- 2 Boehringer Ingelheim and Highmark Inc: A Value-Driven Partnership Focused on Outcomes in Diabetes and Cardiovascular Disease

Value-Driven Partnerships Leading the Shift to Value-Based Care

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Healthcare spending in the United States continues to soar, topping out at \$3.5 trillion in 2017.¹ A substantial proportion of that (\$327 billion) encompassed spending on diabetes care, including approximately \$37 billion for cardiovascular (CV) healthcare costs associated with diabetes.² Cardiovascular disease (CVD), including atherosclerosis, stroke, myocardial infarction, and heart failure, is the leading cause of death among adult patients with type 2 diabetes (T2D), with their risk of dying from a CVD-related event being 3 times higher than for an adult patient without T2D.³ Furthermore, patients with T2D who die due to CV events utilize 2- to 6-fold more healthcare resources in their final months of life compared with patients with T2D who die of other causes.⁴ The results of a 2016 analysis of all-cause costs relating to T2D and its complications demonstrate that 45% of healthcare resources go toward treatment of T2D, 28% to treatment of complications of CVD, 15% to management of renal complications, 6% to neurologic complications, and 6% to ophthalmic complications.⁵

Improvement in the clinical and economic management of patients with comorbid T2D and CVD remains a significant unmet need. Value-based care programs that focus on the total cost of care of these individuals and the value of the care provided are one way to address this need. Multiple strategies exist to move toward value-based care; examples include provider-facing initiatives such as accountable care organizations and reference pricing, as well as patient-facing programs such as value-based insurance design.⁶ Aligning clinician and provider incentives is critical to improving patient-centered outcomes and efficiency in the delivery of care.

Value-based care programs require partnering organizations—and their healthcare providers and patients—to think differently about

addressing unmet needs in disease management, both clinically and economically. These programs are shifting the focus to therapeutic options and care programs that will bring the highest return on investment in terms of cost of care and patient-centered outcomes. For example, value-based care for chronic conditions, such as diabetes, must go beyond management of glycated hemoglobin levels.

To improve patient health and possibly reduce total cost of care for patients with T2D and established CV disease, value-based care models should prioritize measurement of hospital admissions due to MI, stroke, or HF. Two drug classes with proven CV benefit—sodium-glucose cotransporter 2 (SGLT-2) inhibitors and glucagon-like peptide 1 receptor agonists—have demonstrated potential to help meet these goals in patients with comorbid T2D and CVD. These agents impart significant reductions in major adverse CV events. And, although not indicated, both classes of agents have additional nonglycemic benefits, including systolic blood pressure reduction and weight reduction.⁷

These agents make it possible to improve the management of adult patients with T2D and established CVD. The American College of Cardiology and the American Diabetes Association recognize the CV benefits of these agents and have updated their guidelines to recommend them in concert with first-line agents for patients with comorbid CVD and T2D, when indicated.^{7,8} This inclusion further reinforces the importance of CVD risk management in diabetes care and sets the stage for innovative value-driven partnerships that capitalize on these recommendations to decrease total cost of care and increase positive patient outcomes. Boehringer Ingelheim is the first organization to pursue these innovative value-driven partnerships based on CV outcomes and total cost of care. •

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AJMC
THE AMERICAN JOURNAL OF MANAGED CARE

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Boehringer Ingelheim and Highmark Inc: A Value-Driven Partnership Focused on Outcomes in Diabetes and Cardiovascular Disease

Editors from *The American Journal of Managed Care*® (AJMC®) sat down with Kayse Reitmeyer, manager, pharmaceutical manufacturer relations and rebate administration, at Highmark Inc (Highmark), to learn about Highmark's experience creating a value-driven partnership (VDP) with Boehringer Ingelheim centered around Jardiance® (empagliflozin) tablets, a sodium-glucose cotransporter 2 (SGLT-2) inhibitor for type 2 diabetes (T2D), which was shown in the EMPA-REG OUTCOME trial to

reduce the risk of cardiovascular death in adults with T2D and established cardiovascular disease (CVD).¹ The interview focused on Highmark's experiences in creating and managing the VDP, including their rationale for participation, areas of focus, expected benefits, and organizational challenges and solutions.

The goal of Boehringer Ingelheim's VDP is to enable the systemic change from volume to value that health plans in the United States are in a unique

INDICATIONS AND LIMITATIONS OF USE

JARDIANCE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: History of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE, severe renal impairment, end-stage renal disease, or dialysis.

Please see additional Important Safety Information throughout and accompanying Prescribing Information for Jardiance (empagliflozin) tablets, including Medication Guide.

position to drive for their clients, employers, providers, and their communities. Boehringer Ingelheim believes that the use of products with robust clinical trial evidence, such as JARDIANCE, translates into better outcomes for appropriate patient populations who use these products and that those outcomes will translate into total cost-of-care savings. Boehringer Ingelheim’s innovative value-based contract centered around JARDIANCE has demonstrated an annual total cost-of-care savings of \$13,704 per patient per year, primarily driven by an up to 50% reduction in medical costs across all sites of care (see Figure).² If, at the end of their contract period, Highmark does not realize a total cost-of-care savings after utilizing JARDIANCE in the appropriate patient population, compared with another T2D treatment, then Boehringer Ingelheim will retrospectively adjust the net price accordingly.

Boehringer Ingelheim is dedicated to ensuring that JARDIANCE and their other approved products supported by robust clinical evidence and meaningful economic outcomes are accessible to those who would benefit from their use. Partnering with organizations like Highmark offers a way to do so while continuing Boehringer Ingelheim’s larger commitment to innovating life-changing advances in medicine. A focus on total cost-of-care savings places Boehringer Ingelheim on the cutting edge of innovation as healthcare evolves from volume to value.

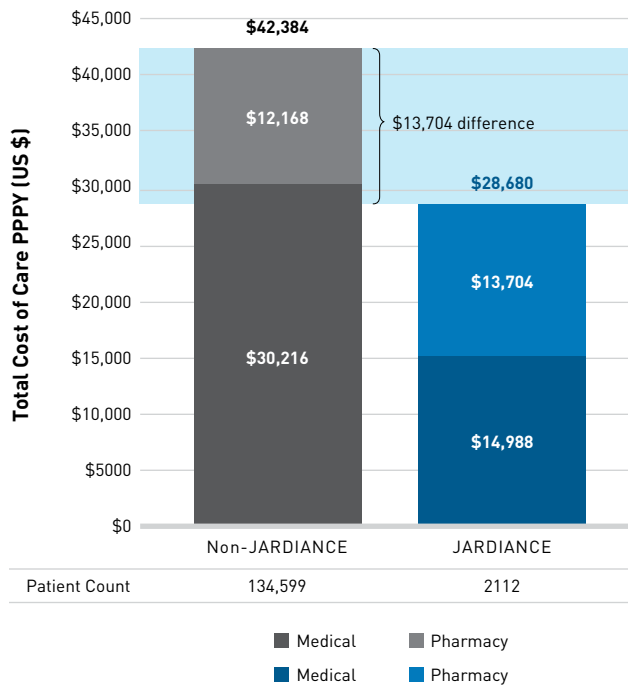
Highmark and its health insurance subsidiaries and affiliates collectively are one of America’s largest health insurance organizations. Together with its Blue-branded affiliates, Highmark comprises the fourth-largest overall Blue Cross and Blue Shield-affiliated organization in the country based on capital. Highmark and its affiliates operate health insurance plans in Pennsylvania, Delaware, and West Virginia that serve approximately 4.5 million members and hundreds of thousands of additional individuals through the BlueCard program. Its diversified businesses serve group customer and individual needs across the United States through dental insurance, vision care, and other related businesses.

The interview with Reitmeyer appears below.

AJMC®: Can you discuss the interventions that Highmark is using to promote value and drive value-based health outcomes?

Reitmeyer: At Highmark, we find value in companies that will stand behind their product and its performance. Value-based care and

Figure. Expected Outcomes and Annual Total Cost-of-Care Savings of Boehringer Ingelheim Value-Based Contract²



PPPY indicates per patient per year.

outcomes-based contracts align well with that idea because manufacturers are willing to put guarantees and contract language around their product’s performance and stand behind that performance. By contracting this way, we can ensure our members have the right tools—in this case, medications. It is the way things are going and the way they should be going.

At Highmark, we are constantly performing value analyses and tracking and reviewing real-world evidence. We are also looking to enter into contracts that make sense for our business in that way.

**IMPORTANT SAFETY INFORMATION (CONTINUED)
WARNINGS AND PRECAUTIONS**

Hypotension: Empagliflozin causes intravascular volume contraction and symptomatic hypotension may occur. Before initiating JARDIANCE, assess and correct volume status in the elderly, and in patients with renal impairment, low systolic blood pressure, or on diuretics. Monitor for hypotension.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

We want to work with pharmaceutical manufacturers that are willing to be transparent and design concepts that are innovative and add value to our business.

From a value-driven contracting perspective, we are typically presented with a few different pharmaceutical manufacturer partnership options, such as the total cost-of-care concept that we entered into with Boehringer Ingelheim. This contract design tracks total costs—in terms of the product, pharmacy costs, and medical costs—compared with other competitors in its class, to uncover the overall cost for our member population.

In terms of patient-focused initiatives, we currently have case management and patient outreach programs in place, and we are working to engage with employer groups on certain disease state programs.

AJMC®: What gaps in care currently exist within Highmark regarding the management of T2D and CVD?

Reitmeyer: We have done a lot of work in diabetes and CVD specifically over the last few years, creating pathways for patients to ensure they are receiving the right medications at the right time during their healthcare journey. As a result, we have made huge strides in managing diabetes and CVD among our members.

One difficult area for many organizations to manage is the size of the population with diabetes and the involvement of primary care physicians [PCPs] in treating the population. Not that it's inappropriate—there absolutely is a valued place for PCPs in the patient journey—but it makes connecting and recommending interventions challenging due to the size of the patient population with diabetes and/or CVD and the number of PCPs treating these

patients. However, we have had success in managing diabetes and CVD through collaborative disease state pathways, which provide a more consistent and predictable journey for our members. Diabetes and CVD remain a large focus for all plans and I'm sure that programs to target them will continue to be an area of interest for the foreseeable future.

AJMC®: What are some of the gaps in therapy that Highmark targets in this patient population?

Reitmeyer: Adherence, as a gap in therapy, continues to be a difficult area in this patient population, because payers typically have to base the tracking of adherence off of fill data. Every plan, every provider, would likely agree that adherence is one of the most difficult areas to track and determine real outcomes since you cannot know for sure if patients are taking their medications every day.

Although adherence is still an area of focus for us, we also focus on access to care. We want to ensure that patients are getting the right product at the right time and that we are not inappropriately delaying their access to effective medications that have positive outcomes for our members.

AJMC®: What led Highmark to explore a collaborative VDP with Boehringer Ingelheim?

Reitmeyer: We have had a long-standing partnership with Boehringer Ingelheim and have worked well together in the past. They brought forward a good opportunity, and they were willing to brainstorm with us to design the contract. And so it was the right opportunity for both of us. That is what we look for in a partner. We want to work with pharmaceutical manufacturers that are willing to be transparent and design concepts that are innovative and add value to our business. Boehringer Ingelheim had released new data on the CV outcomes [related] to Jardiance® (empagliflozin) tablets, and these clinical updates are something that we stay on top of and carefully consider when we review drugs at Highmark. We were in alignment with Boehringer Ingelheim standing behind their product and its performance. Companies that are willing to commit to their products and their product portfolios and put these types of value-based frameworks around them are usually the right partner in these types of agreements.

IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)

Acute Kidney Injury and Impairment in Renal Function: Empagliflozin causes intravascular volume contraction and can cause renal impairment. Acute kidney injury requiring hospitalization and dialysis has been identified in patients taking SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating JARDIANCE, consider factors that may predispose patients to acute kidney injury. Consider temporary discontinuation in settings of reduced oral intake or fluid losses. Monitor patients for signs and symptoms of acute kidney injury. If it occurs, discontinue JARDIANCE and treat promptly.

Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Before initiating JARDIANCE, evaluate renal function and monitor thereafter. More frequent monitoring is recommended in patients with eGFR <60 mL/min/1.73 m². Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m².

AJMC®: Aside from transparency, did any clinical results have a bearing on entering into this VDP with Boehringer Ingelheim centered around empagliflozin [JARDIANCE]?

Reitmeyer: We already had supported empagliflozin [JARDIANCE] from a clinical standpoint and the other products from Boehringer Ingelheim. The product was preferred on our formulary, and we were covering the product in the lowest tier for branded agents. This outcomes-based contract opportunity was a nice way to put more value around the product and showcase how it performs compared with other products in the class.

AJMC®: How do you think setting up the partnership would have run differently if the product was not yet on formulary?

Reitmeyer: We have always stayed away from using these outcomes-based contract opportunities to drive formulary decision making. Clinical efficacy and safety are always the most important for us. We always think, “clinical first.” We will vet and make sure that the product makes sense from a clinical perspective before we ever bring financial topics into the discussion. Then, when we are thinking about entering into an agreement with a pharmaceutical manufacturer, we want to track outcomes for products that we are already supporting to capture real-world evidence and effectiveness.

AJMC®: Did you vet the product in terms of total cost-of-care savings prior to entering into discussions about the partnership as well?

Reitmeyer: Yes. We typically have a high-level preliminary analysis completed beforehand so we have some basic comfort level entering into the contract before we commit to the full, in-depth analysis. We were willing to stand behind their product clinically, based on where we placed it on our formulary, and so it made sense to add on this additional opportunity to track the total cost-of-care outcomes in our commercial population.

Interestingly, Boehringer Ingelheim came to us with a proposed framework without doing a baseline analysis with our data. They were confident in the clinical performance of the product and put a framework around it for the total cost-of-care component. They were confident that the total cost of care for empagliflozin [JARDIANCE] would be equal to or less than existing antidiabetic therapies.

AJMC®: How did you get buy-in from the top down to enter into this partnership?

Reitmeyer: This was not our first VDP, and that helped to break down some of the internal barriers. It took us 18 months to get our first outcomes-based contract in place, and during that time, we worked closely with our privacy, legal, and data governance teams to get a contract in place that we were all comfortable with. The successful process established for that initial contract set the stage for future discussions on outcomes-based contracts.

As a result, when we were presented with the value-based contract opportunity with Boehringer Ingelheim, we experienced a quick turnaround, and it was a good experience for all parties involved. Internal approvals are typically not quick to obtain because there are so many teams involved in the process, especially for these outcomes-based designs. We were able to expedite that process by being transparent and collaborative.

For example, traditionally, for a standard contract, we would go through our legal team and provide a business review through our pharmacy contracting team. These contracts have to go through data governance, data security, privacy, and legal; there are a lot of people reviewing the contract before being able to ultimately sign it.

We have had a longstanding partnership with Boehringer Ingelheim through traditional contracting, but this was the first time we expanded on that with them and turned it into an innovative total cost-of-care contract.

AJMC®: What concerns were raised by the internal stakeholders that were involved in approving this contract?

Reitmeyer: The internal stakeholders raised many questions about the data points that were being shared and why they were being shared. We had several conversations around getting the data set to a point where all parties were comfortable. Most companies are protective of and careful with their data flow and how and where information is being shared. This is different from negotiations for a standard contract, which tend to focus only on formulary positioning and market share totals.

These issues were resolved relatively quickly, however, because of a willingness to negotiate on both sides. Boehringer Ingelheim

IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)

Urosepsis and Pyelonephritis: Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene): Serious, life-threatening cases requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

“Companies that are willing to commit to their products, and their product portfolios, and put these types of value-based frameworks around them, are usually the right partner in these types of agreements.”

came to us with a reasonable request for data, which made it an easier conversation from the start.

AJMC®: If you were a smaller organization that had to outsource these discussions and data analyses, do you think the process to set up the partnership would have gone as smoothly?

Reitmeyer: Analytic support can be an issue when identifying an opportunity for outcomes-based contracting, depending on the organization. Fortunately, Highmark has been able to build an analytics team to support these types of contracts. Other companies have had success in using a third party, but we have not had to enter into any third-party arrangements to support these contracts yet.

The process should not be slowed down too much if the organization is able to find the right trustworthy partner; however, it is another place to send the data, which may increase concern about data flow. Based on discussions with our data governance team, having a direct contract without a need for a third-party vendor is ideal for data tracking. However, I do know that some other organizations have had success using third-party analytic groups to assist in doing these types of analyses.

AJMC®: In terms of internal stakeholders, which department presented the biggest challenge to get on board in this partnership?

Reitmeyer: Privacy and data governance are definitely the stakeholders that demand the most time and attention when working through the

contracting process. There are always major concerns regarding [a] member's privacy, and organizations entering into these partnerships need to be aware of that, for good reason. For example, they want to make sure that what we are sharing is in compliance with the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act. As a covered entity, it is our duty to make sure that any data set that is shared is what is minimally necessary to accomplish the basic need for that purpose.

Privacy and data governance definitely asked a fair amount of questions when we were reviewing this contract with Boehringer Ingelheim. These contracts regularly require different data than standard contracts. Building relationships with internal teams and scheduling meetings to discuss the contract, requirements, and what data we were sharing undoubtedly made a difference in getting through the contract review process more quickly. It also helps to keep track of your organization's internal changes and processes, because privacy and data governance can change frequently depending on government and privacy policies.

AJMC®: What were the clinical and organizational goals or expected benefits from this collaboration, and have they evolved as the partnership matured?

Reitmeyer: One major goal was to grow our portfolio of value-based contracts and to be looked at as a pioneer in value-based contracting. This was also in line with our clinical and organizational goals. There are other departments at Highmark involved in other types of value-based work focusing on tracking quality and not quantity. This is the right thing to do, and actions to accomplish this will only increase at Highmark and industry wide.

The specific goal of this partnership was around total cost of care. A positive outcome would mean that Jardiance® (empagliflozin) tablets cost the same or less than the other antidiabetic therapies, tracked through a per-member-per-month or per-member-per-year kind of threshold.

We have not come to the term date of the contract yet, and so we have not run the full analysis for the contract. Our first measurement period is near the middle of this year, and so we expect to have some results by next year. Obviously, it will take some time to gather all the data, analyze, and review with Boehringer Ingelheim.

IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)

Genital Mycotic Infections: Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

Hypersensitivity Reactions: Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

Increased Low-Density Lipoprotein Cholesterol (LDL-C): Monitor and treat as appropriate.

MOST COMMON ADVERSE REACTIONS (≥5%): Urinary tract infections and female genital mycotic infections.

DRUG INTERACTIONS: Coadministration with diuretics may enhance the potential for volume depletion.

AJMC®: When you have results, with whom does Highmark plan to share these results?

Reitmeyer: That is another point of negotiation and will depend on what both organizations are comfortable with sharing publicly. Highmark has always promoted sharing the outcomes of these contracts; however, it is a decision that the plan and the pharmaceutical manufacturer have to make together before publicly disclosing the final results.

AJMC®: Presuming that the contract was successful, what would a next-level VDP look like?

Reitmeyer: Right now, we typically see 3 types of contracts: a clinical outcomes contract, tracking a product's clinical outcomes; a persistency contract, which tracks adherence or discontinuation of a product; and then the total cost-of-care contract. We will see more innovative contracting opportunities come forward as more organizations are able to successfully enter into these contracts and are willing to share their experiences and outcomes. In sharing our outcomes-based

contract publicly, Highmark and Boehringer Ingelheim have been approached by many healthcare organizations to have conversations around successfully implementing these opportunities.

AJMC®: Would you suggest this model to other managed care organizations that are looking to partner, and if so, what kind of advice would you give to them?

Reitmeyer: From a plan perspective, a total cost-of-care partnership makes perfect sense. We want to ensure that our members are receiving the most clinically-effective and cost-effective products. Although these partnerships require time, attention, and resources from a data perspective, they align perfectly with where our focus should be on value, not volume. •

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**IMPORTANT SAFETY INFORMATION (CONTINUED)
USE IN SPECIAL POPULATIONS**

Pregnancy: JARDIANCE is not recommended, especially during the second and third trimesters.

Lactation: JARDIANCE is not recommended while breastfeeding.

Geriatric Use: JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with empagliflozin.

