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Dana Regan,
*Senior Vice President,
Client Strategy*



Brian Davis,
*Vice President,
Payer Strategy*

THE IMPACT OF TECHNOLOGY ON ADVANCING DIABETES CARE

Statistics from the World Health Organization report that over the past 25+ years, the number of people around the world diagnosed with diabetes has almost quadrupled to 422 million. According to the Centers for Disease Control, diabetes is the 7th leading cause of death in the United States with an annual financial impact of \$327 billion (this includes both direct medical/pharmaceutical costs and indirect costs such as lost work and wages).

Diabetes is a chronic condition that payers, providers, and even the Centers for Medicare & Medicaid Services (CMS) have been trying to actively manage. Over the past few years, a number of treatment options have been approved that offer better control while reducing the burden on the patients. These new treatment options have had a direct correlation to the increase in patient adherence and better health outcomes experienced. Over the past 2 years, a 2% increase in proportion of day covered rate (PDC) in Medicare Advantage Prescription Drug (MAPD) patients and a 1% increase in prescription drug plan (PDP) patients have been observed (Solutions, 2019).

Innovations in diabetes care go beyond new therapeutic classes. Pharmaceutical companies are continuing to invest in new technology to help improve diabetes treatment and patient adherence with progress ranging from artificial pancreases to smart insulin pens and pumps. Companies such as Fitbit, Apple, and Cecelia Health have introduced digital solutions (e.g., wearables, real-time glucose monitoring, health diaries, patient counseling apps) to help improve health outcomes.

Patient adherence has been an elusive goal due to complications in dosing regimens and patient engagement. However, as technology has advanced, adherence has been on a steady incline. Since 2012, diabetes medication adherence has increased from the middle 70% range to over 80% (Solutions, Medicare 2019 Star Rating Threshold Update, 2019). These advances have left the health care industry looking for more innovative ways to continue to increase patient adherence as well as measure outcomes to demonstrate improved patient health. The market has seen continued growth in diabetic testing standards, gene therapies, continuous glucose monitoring devices, and the development of delayed release treatment options that deliver a controlled dose of drug over a period of time. All of these options have made controlling the disease more predictable.

Diabetes has long been considered a retail channel disease, but with the growth of technology in this space, specialty pharmacies have begun offering more services geared towards managing patients. Diabetes is now considered a pipeline target for specialty pharmacies due to the expansion in technology and treatment options (Service, 2019). This means that specialty pharmacies and payers will be working towards developing clinical programs designed to track the health of patients and collect patient reported outcomes (PRO) in an effort to consolidate data and report outcomes.

Growth in technology has been welcome from a patient and management perspective; however reimbursement guidelines have been slow to change to accommodate the influx of options. Reimbursement codes and claims

systems need to be updated. In many cases, slow adoption of reimbursement for new technology delays the time to improve patient care. To overcome these challenges, CMS has revised its J code application process and payers are starting to see the short- and long-term value in new technology as they are working through the process of getting these new therapeutic options paid for.

New technology is also changing how the industry thinks about value propositions in the market. With the advance of evidence collection and higher payer expectations of the patient experience of care, pharmaceutical companies must rethink how they approach a payer when asking for coverage. The idea of better managing patients is the key to new technology, but we also have to think about how to quantify that management over a period of time and how these data can supplement a product's traditional clinical efficacy and safety data to establish a more compelling value proposition.

As the technology continues to grow and evolve, the market must always determine the proper endpoint or outcome and be able to measure against that metric on a predictable basis. Different types of technology will necessitate the need for different endpoints. For example, continuous glucose monitors and smart pens can put more emphasis on patient adherence and better HBA1C levels, making this metric more valuable in the overall value proposition. Other technology like gene therapy and artificial pancreases can reverse or stop the disease, which can have a strong impact on downstream comorbidities such as cardiovascular endpoints, turning the value proposition into a cost-offset model for total metabolic health. Thinking about

the technology and its direct impact will allow the market to establish the value for each stakeholder involved, resulting in more efficient coverage and reimbursement policies and proper patient access to the technology.

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While evaluating these new technologies, payers and manufacturers must consider the insurance benefit dynamic, as well. An understanding of how claims are processed is vital for determining the best path for coverage and reimbursement. Value propositions support why a product should be covered, but not how. Many of the new technologies sit in a space that is not categorized under traditional medical or pharmacy benefits. Payers are faced with the questions of how to cover a product, and on what benefit. They are not yet experienced in providing coverage determinations for digital therapeutics. Pharmacy benefits are usually the path of least resistance for covering products, but when the product requires medical intervention, patients can end up with both pharmacy and medical bills that create confusion on what the actual cost of the product is for them. Evaluation of alternative payment models must be considered to ensure all parties understand the total costs and the coverage of these new technologies.

Overall, technology is growing at a fast pace in the treatment of diabetes, allowing patients to be managed in a better, easier, and more reliable framework. As technology advances, the market will continue to face reimbursement and coverage challenges that must be addressed to allow patients and healthcare providers to benefit from these innovations.

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About EVERSANA™

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