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Mobile Prescription Therapy Offers Novel Approach to Diabetes Treatment

Reprinted from [DRUG BENEFIT NEWS](#), biweekly news, proven cost management strategies and unique data for health plans, PBMs, pharma companies and employers.

By [Angela Maas](#), Managing Editor

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People with diabetes now have another arrow in their treatment quiver. But it's not a drug, although it does require a prescription. WellDoc, Inc. is rolling out its mobile prescription therapy BlueStar, which will be adjudicated through the pharmacy benefit the same as other prescription drugs. Companies such as Ford Motor Co. and Rite Aid Corp. have said that they will cover the product for employees and covered dependents.

BlueStar received FDA clearance as a therapy for diabetes type 2, which is notoriously hard to manage.

Almost 26 million people in the U.S. have diabetes, which represents 8.3% of the population, says the American Diabetes Association. About 95% of that total is diagnosed with type 2 diabetes. According to the CDC, about 1.9 million diabetes diagnoses were made in 2010 among the population of people at least 20 years old. And more than 1 million of those cases were in the 45-to-64 age group.

The total cost of diagnosed diabetes in the U.S. last year was \$245 billion, up from \$174 billion in 2007 — a 41% increase over five years, notes the association. The largest components of that total are costs for hospital outpatient care, drugs to treat complications of diabetes, diabetic medications and supplies, physician office visits and stays in nursing/residential facilities. Additional drivers include indirect costs such as absenteeism and reduced productivity. Government insurers provide 62.4% of the care, with commercial insurers responsible for 34.4%.

FDA OKs Novel Diabetes Therapy

While many people with the condition take insulin and/or an oral medication, "Self-management education or training is a key step in improving health outcomes and quality of life. It focuses on self-care behaviors, such as healthy eating, being active, and monitoring blood sugar. It is a collaborative process in which diabetes educators help people with or at risk for diabetes gain the knowledge and problem-solving and coping skills needed to successfully self-manage the disease and its related conditions," says the CDC.

BlueStar is aimed at helping people with their self-management, as well as health care providers.

WellDoc offers face-to-face training for physicians and their staff. After a physician has prescribed the product, "the pharmacy adjudicates the claim, and we simultaneously enter a registration profile that allows the pharmacy to dispense a BlueStar customized to each patient's medication regimen, medical history and physician orders," explains Chris Bergstrom, chief strategy and commercial officer at WellDoc. This is followed by face-to-face training for the patient by a WellDoc Certified Diabetes Educator. The patient sets up a user account, and BlueStar's software is downloaded onto all of his electronic devices, such as computers, mobile phones and tablets. Providers can access it by fax and soon by electronic medical records as well.

Diabetes-related data about the patient are entered into the account so each patient's care can be

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personalized. In addition to medications, the patient tracks information about his blood glucose readings, diet and exercise. BlueStar captures and stores those data and then provides motivational, behavioral and educational coaching based on the information.

And when the patient goes in for a doctor's visit, the physician will have a clinical decision support report that is "based on the patient's life and provides actual evidence-based recommendations," explains Bergstrom. WellDoc's customer care is available to any patient using BlueStar or any physician prescribing it.

"The product learns and adapts to a physician's orders and to a patient's evolving needs as they progress through the terrible and complex disease of diabetes," says Bergstrom.

WellDoc has had experience with a somewhat similar product known as DiabetesManager. However, the two products are not the same, maintains Bergstrom. "The DiabetesManager was a call center-based product sold in the B2B market to disease management companies, and one of its primary features was enterprise tools that made nurse case managers more efficient. BlueStar is significantly different in that it is designed for the much larger provider market. It requires a prescription, has clinical decision support for HCPs [i.e., health care professionals], enhanced algorithms, increased levels of personalization, and incorporates standards of care and co-morbidities," he says.

In addition, he clarifies, although an app is included in this product, BlueStar is a mobile integrated therapy, which is not the same thing as an app. "The mobile revolution has been a blessing and a curse. A blessing in that everyone understands how connectivity can unlock value in any industry — even health care. A curse in that everything is thought of as just an app, which generally implies a thin piece of software that performs a specific function," says Bergstrom. "We designed BlueStar before there was an iPhone or an app store. The essence of the product is built using artificial intelligence called an expert system that is a powerful clinical and behavioral algorithmic self-management platform. An app happens to then be one element of the product, but the full product is an end-to-end solution that can scale a physician's care to his or her diabetes population in real-time, 24/7."

He tells *DBN* that BlueStar "is not tied to a device"; a person's account is in the cloud, and each device has a native copy. "By residing natively on each device, the full performance of BlueStar can be realized even when there is sporadic connectivity (e.g., in an airplane, basement or rural area). Then, when the device returns to coverage, BlueStar reconnects with the cloud for seamless updates and syncing," explains Bergstrom. "Further, BlueStar maintains military grade security and encryption, is HIPAA compliant and has safety measures allowing for lost devices." WellDoc also has "controls in place to mitigate fraud, waste, and abuse of our product."

DiabetesManager has three FDA clearances, and WellDoc has gotten clearance for BlueStar as well. The company worked with the National Council for Prescription Drug Programs (NCPDP), which creates consensus-based standards on various issues impacting the pharmacy industry, to demonstrate that BlueStar should be viewed the same way as a prescription drug, including indications for use specified on its clearance.

According to Bergstrom, "The FDA does not require clinical outcomes for 510k clearance, only human factors and safety testing. However, WellDoc chose to conduct multiple randomized controlled trials to demonstrate to the market effectiveness to ensure meaningful value can be realized by patients and providers." He notes that the company was founded by physicians, so "demonstrating this evidence was part of WellDoc's DNA. From the trials we know that the two main features of BlueStar each show unique value in driving outcomes, specifically (1) the contextually relevant, automated, real-time and longitudinal patient coaching drove about a 1.4 point A1C reduction and (2) the automated patient level clinical decision support added another 0.5 point A1C improvement. These features changed patient and provider behavior respectively while working in constant synergy."

Initial Focus Is on Private Insurers

WellDoc has focused on getting reimbursement from private payers first and then likely will target government insurers. Asked why that is, Bergstrom says that although he's taken this approach, as well as the reverse sequence, in past experiences, "Generally, there isn't a right or wrong approach as they feed off each other, so once you start one, the other gets pulled in anyhow."

Still, he says, various factors led to the company's approach with BlueStar:

- **There was "strong demand from the commercial market** as payers knew they would soon need products that went beyond the pill to address quality, engagement, care coordination, [and] satisfaction, as well as cost and outcomes."

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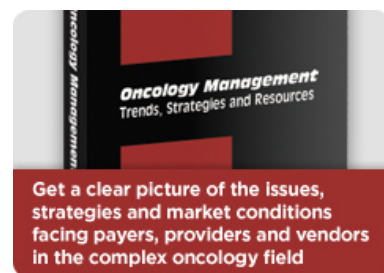
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- **“A significant portion of Medicare lives are managed by the private payers** anyhow via Medicare Advantage.”
- **“The product works well with seniors but is not ideal** for the elderly generation,” described as older than 80.
- **“Over the past few years public policy has been dynamic** — the general trend was clear, but the details not well known,” Bergstrom says. “Separately, several states are now approaching us for their Medicaid lives as we have successfully shown significant improvement in hospital and ER visits in Medicaid demonstrations, and they value the fact that BlueStar is the great social equalizer...allowing rich and poor to get the exact same quality coaching and support for the same standards of care.”

He tells *DBN* that private payers have had a “positive” response to BlueStar and that many are asking WellDoc for follow-up visits so they can really understand the therapy and how it works. “They recognize BlueStar fills a void in diabetes self-care and strengthens the patient-physician relationship in a way that other prescription products can’t,” says Bergstrom. “They also value how BlueStar can fit into their normal business model since it is FDA cleared, has an FDA granted unique NDC [i.e., National Drug Code] product code and can be recognized by pharmacies; thus, it is treated just like all other prescription products.” The company, he says, spent seven years “and \$10s of millions of dollars” on getting the product to where it is now.

Price Is Negotiated With PBMs, Payers

Asked about the cost for a prescription, Bergstrom says that BlueStar’s Wholesale Acquisition Cost “is listed in the compendia and approved by NCPDP, but pricing is negotiated uniquely with individual PBMs and payers. In certain situations rebates and modest discounts apply. However, we have publicly stated that even though BlueStar is a first-in-class, best-in-class product, our pricing is significantly less than most branded diabetes prescription products.” In other publications, the company has cited \$300 per month as the price tag for those therapies.

Bergstrom adds that “similar to all prescription products, a patient’s doctor must continue to refill the product based on their assessment of the patient’s medical necessity for BlueStar and their state laws governing how often they can prescribe.”

OptumRx has one external commercial client that had a July 1 implementation date, spokesperson David Himmel tells *DBN*. The PBM, he says, “feel[s] it’s premature to compare/contrast or discuss challenges with such limited data.”

And according to David Lassen, chief clinical officer for Prime Therapeutics LLC, the PBM has a few plans assessing the technology, but it has no true experience to speak of at this time.

BlueStar “officially launches in a few months in a yet-to-be announced regional roll-out followed by a national deployment in 2014,” says Bergstrom.

He adds that “we don’t expect to be an overnight success” because in the health care industry, “anything new...goes through a journey before it is widely covered and adopted. Fortunately, our trail was blazed by prior diabetes self-management products, such as blood glucose meters, insulin pens and insulin pumps, which were all new-to-the-world categories at one time, yet they became part of the standard of care for managing diabetes.”

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