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At $1,650 per month, the first digital pill will soon roll out to certain Medicaid patients with mental illness

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The first digital pill will carry a price tag of $1,650 per month and soon be rolled out commercially to the first patients: people with mental illness covered by Medicaid, likely in regions including Florida and Virginia.

The pill, sold by the drug maker Otsuka as Abilify MyCite, is embedded with a sensor that can alert a patient's physician or caregiver after it's been swallowed. Approved last November by the Food and Drug Administration for patients with schizophrenia and bipolar disorder, it's a high-tech upgrade to the antipsychotic drug Abilify, which was first approved 16 years ago and has now gone generic.

The first patients to try out the product outside of clinical trials will be those on a handful of Medicaid plans administered by the managed care company Magellan Health, which operates across the U.S. Patients can opt in if they want to try it, and Magellan will not have access to patients' individual-level data on whether and at what time they ingested their pills.

The regions where the product will be initially rolled out haven't been finalized, but Magellan's chief innovation officer Dr. Seth Feuerstein said Florida and Virginia would be obvious candidates, because Magellan is the Medicaid provider for significant concentrations of patients in those markets.

"Historically, certain patient populations are sometimes the last to get new innovations," Feuerstein said. "We look hard for ways to bring interesting new tools to the clinicians and patients in our Medicaid businesses. Often, they get short shrift, honestly."

With Abilify MyCite, Feuerstein said he saw "a place where we could actually let Medicaid participants have the option of some new innovations before the general markets."

In addition to administering Medicaid plans, Magellan also contracts with private insurers and employers to control the care that covered patients receive, using its own medical guidelines and networks of hospitals and clinicians. As part of such contracts, companies like Magellan have the power to try new technologies and services with potential to keep patients healthier and costs down. Magellan does not immediately plan to offer Abilify MyCite to these commercially covered patients, but that may change down the line, Feuerstein said.

From Otsuka's vantage point, the limited initial rollout was a deliberate strategy, said Andrew Wright, a vice president leading the company's efforts to commercialize digital medicine.

"We believe having fewer people treated initially really allows us to listen hard and focus in on the patients, the prescribers, and the health plans," Wright said.

Among the questions Ostuka will be looking to answer: Does the system fit smoothly into the daily lives of patients and their families? Do physicians, already burdened with too much information, find that system offers actionable insights and fits into their workflow?

Those answers will inform the company's eventual full-scale push to get the product to commercially insured patients all over the country, Wright said.

Skipped pills are a problem across medicine; studies across a wide range of conditions show that patients with poor adherence to their medication have worse health outcomes and incur higher costs. But it's an especially vexing problem in mental illness, where too many skipped pills can lead to relapses, hospitalizations, and, in the most severe cases, homelessness or incarceration.

Research indicates that patients with mental illness don't take their medication as prescribed for a multitude of complex reasons: They might not think they're sick. They may distrust the health care system. Or they could be concerned about side effects or cost.

Abilify MyCite has not been shown to improve adherence, but Otsuka is betting that patients and their physicians will want a way to reliably track whether and when a dosage was taken.

After a patient swallows Abilify MyCite, the embedded sensor emits an electrical pulse, which sends the date and time to a Band-Aid-like adhesive patch worn on the torso. Like a Fitbit, the patch also tracks whether patients are sleeping or exercising. The patch relays all those data to a smartphone app, where patients can check to see how well they're following their medication schedule. Patients can allow their doctor as well as friends or family members to have access to the data, too.

Most patients will likely take Abilify MyCite for eight to 12 weeks, the period for which it was tested in clinical trials, before switching over to a regular form of the drug, which is known to scientists as aripiprazole. But some patients may take it for longer, depending on what they and their physician decide is right for them, Wright said.

Otsuka, which lost market share after normal Abilify went generic, now has a product that stands out — and comes at a markup over regular aripiprazole. A 30-day supply of Abilify MyCite pills and all the accompanying technology has a list price of $1,650. (Medicaid copays are defined on a state-by-state basis, but Otsuka said it expects the out-of-pocket cost to be "affordable" for patients.) By comparison, the average cash price for a month's supply of regular aripiprazole is around $700, according to the drug coupon provider GoodRx. That's for the same dosage range that's recommended for patients starting Abilify MyCite.

The approval of Abilify MyCite sparked concerns that a vulnerable population of patients could be coerced into taking the drug, perhaps through a court order or a deal offered in exchange for freedom, child custody, or a lighter sentence. Experts also saw a privacy risk, if a patient's insurer or other companies could peer in on a patient's daily medication intake patterns and other data.

Otsuka for the past several years has been turning to leading bioethicists as a sounding board to help make more informed decisions about consent and privacy with Abilify MyCite, Wright said. The bioethicists consulted include Harvard's Glenn Cohen, DePaul University's Craig Klugman, the University of Maryland's Jack Schwartz, and Stanford's Laura Dunn.

"We believe that we are custodians of the data, and we have a big responsibility, particularly to this underserved population, to really make sure that we earn their trust," Wright said. "What we are trying to prevent is any scenario where they could be coerced into taking medicine, although I think that's a very unlikely scenario, given the implications it would have on the health care system."

Abilify MyCite could be the first in a wave of smart pills aimed at helping patients take their medicines as prescribed. Proteus Digital Health, the Silicon Valley company behind the sensor technology that powers Abilify MyCite, said earlier this year that it has 31 digital medicines in its pipeline, including cancer drugs and opioid painkillers.

Another application may be in preventing HIV infection. At a scientific conference in July, researchers presented data on an experimental high-tech upgrade to Truvada, Gilead Sciences' HIV prevention pill known as pre-exposure prophylaxis, or PrEP. That technology, involving a tiny ingestible sensor attached to the pill, was also developed by Proteus Digital Health.