

>>David Filmore



WHAT TO DO ABOUT MEDICAID?

Challenges and Tips for Medtech Innovators

At-home sleep apnea test firm Itamar Medical is making progress with payors, but has hit a barrier with Medicaid for its technology. It's not an uncommon challenge, say experts, who discuss the challenges and offer advice for medical device innovators dealing with state Medicaid programs.

Israel-based **Itamar Medical Ltd.** is making market, and payor, inroads with a novel home-based approach to diagnosing sleep apnea, a condition that is increasingly recognized as a major public health threat. Sleep apnea impacts nearly a billion people worldwide, and tens of millions in the US, recent data suggests. The condition, in which breathing repeatedly stops and starts during sleep, is linked to a range of health conditions, including atrial fibrillation, diabetes, and liver problems. But it goes widely undiagnosed. The conventional approach to diagnosis and assessment is sending someone with suspected sleep apnea to a lab where they spend the night hooked up to multiple instruments, undergoing a sleep study (polysomnography). However, this diagnostic method can be expensive and a burden to the patient. In particular, it's not an ideal approach to address what the medical community is increasingly recognizing as a very sizeable population of people with potential sleep apnea. This large and growing challenge has put more focus on finding a way to evaluate suspected sleep apnea while patients sleep in their own beds.

Home-based systems that measure airflow, among other parameters, using respiratory equipment, are available. Itamar's *WatchPAT* technology relies on peripheral arterial tone technology allowing someone to be tested for sleep apnea at home with only a chest sensor, wristwatch device, and finger probe, which the company argues is a simpler and more comfortable approach. The firm has had some success with its *WatchPAT 300* system, launched in the US earlier this year. That device is worn overnight, and patients return it to their healthcare provider for analysis the next day. More recently, in June, Itamar gained 510(k) clearance in for the *WatchPAT One*, which the company says is the first-ever disposable home sleep apnea test. Results are sent to clinicians via a secured server using an app on the patient's smartphone.

"Before you brush your teeth in the morning, the doctor knows how severe your sleep apnea is, and you don't even

have to go back to the doctor's office," Itamar President and CEO Gilad Glick said in an interview with *Market Pathways*.

The company, which is primarily targeting cardiology patients, has data validating the approach compared to gold-standard lab-based sleep studies. This has helped it gain a reimbursement foothold for the *WatchPAT 300* and now the *WatchPAT One*, which will rely on the same billing codes. The Centers for Medicare & Medicaid Services has provided more openings for home testing in recent years, and private payors have started to pick up support. There are challenges, for sure. Clinical guidelines previously stipulated airflow measurement as a necessary component of home sleep apnea tests, which limited some payor pickup, but those guidelines have been updated to remove that condition. In addition, some state Medicare contractors have been less supportive of the move to home-based testing—in particular, Florida, which pays about half of the national Medicare rate for home testing, making the state virtually off-limits for the technology.

But there is one particularly noticeable hole in the reimbursement patchwork for *WatchPAT*, and home sleep apnea testing in general. It's with Medicaid, which has extremely limited coverage of home sleep apnea testing throughout the US, even as Itamar and others in the space argue that the Medicaid population might actually benefit most from the technology.

Medicaid beneficiaries, on average, "have higher BMI," Glick says. "On average, they have a higher prevalence of sleep apnea." Meanwhile, Medicaid covers lab-based sleep testing, but, because Medicaid payments are low, Glick points out, Medicaid beneficiaries often are put in the back of the line in terms of scheduling for limited bed space.

Medtech Medicaid Barriers

This is not just a sleep apnea challenge. Medicaid, which is run at the state rather than national level, is generally standoffish to new health monitoring technology, according to David Vorchheimer, a cardiologist at Mount Sinai Hospital in New York. "Device monitoring in general,

of which the *WatchPAT* is one particular example, is one of the gravest shortcomings of Medicaid coverage," Vorchheimer told *Market Pathways*.

"If you look at cardiology as a field, it has had some, obviously, major interventional innovations, which are procedures and stuff like that, all which are covered by Medicaid and Medicare." But when it comes to equally important advances in monitoring tools, including home sleep apnea testing, ambulatory blood pressure monitoring, and new modes of arrhythmia monitoring, "all of those, generally, are adversely covered in a way that they pose an obstacle to care for patients covered by Medicaid," Vorchheimer says.

Beyond particular barriers with monitoring devices, Itamar executives also see a fundamental process challenge with Medicaid, particularly for small medtech firms with more limited resources and less political connections.

"Medicaid is fragmented," Itamar's Glick says. "You can't find a medical director to write, or to submit a dossier, or to ask for a meeting to educate. There are no published policies that you can ask to amend." The company has found it challenging to find a platform from which to make its case to Medicaid policymakers, the CEO lamented.

"It's traditionally always been a challenge for any medical device company, unfortunately," agrees Skip Ashmore, Itamar's VP of Marketing.

Just Have to Ask?

Reimbursement experts who spoke to *Market Pathways* agree that medtech firms tend to be on less sure footing when it comes to dealing with Medicaid compared to other payors. "Truly, I hear it all the time," says Kip Piper, an independent consultant who used to run Wisconsin's Medicaid office.

On one hand, it's understandable, Piper says, considering that "Medicaid is the most complicated social program ever created," he says.

On the other hand, the US healthcare payment system is, by nature, diverse, and

Medicaid Facts

- About 75 million low-income Americans covered
- 56 Medicaid programs (states, territories and the District of Columbia)
- Many states contract with private or non-profit managed care organizations, which can offer some additional services
- There are mandatory and optional benefit categories, as well as state-by-state "Home and Community Based Services Waivers" used to cover durable medical equipment/supportive services for home care
- All states must have the "Early and Periodic Screening, Diagnostic, and Treatment" (EPSDT) benefit for children under 21, requiring access to any Medicaid-coverable service that is medically necessary, even if not covered by the state plan

Sources: CMS; Kaiser Family Foundation; Kip Piper



“THE RIGHT TOOLKIT, PER MEDICAID STATE, HAS TO BE A FACT PATTERN BASED ON THAT STATE’S LEGACY, AND HOW THEY GOT TO WHERE THEY ARE’.”

—Kuo Tong

there is no reason why Medicaid is necessarily *more* challenging than the varied array of other commercial and public payors. It’s just different, experts say, and it is natural for each type of payor to have its own needs and priorities.

Short of a single-payor system, “there will always be a disparate playing field,” says Kuo Tong, a managing director at Navigant, a Guidehouse company. “From Medicaid, from a managed care plan, from a Kaiser HMO to Medicare fee-for-service and Medicare MAC contractors, they’re all different,” Tong says, “but they all have their own behaviors, and what people need to do is just analyze those behaviors and historical fact patterns to figure out what the message is.”

When it comes to Medicaid, it can often simply be a matter of asking. “There’s always a Medicaid medical director somewhere,” one expert notes.

Although the process of reaching out to each Medicaid director is, in itself, a potentially significant organizational challenge for a smaller medtech company. There are 56 different Medicaid programs—covering states, territories, and the District of Columbia. In addition, there are the Medicaid managed care organizations (MCOs), which are contracted by states to deliver Medicaid services in some areas. The MCOs generally have to follow state coverage policies, but they have some discretion. Many of these individual MCOs “might may not be on a company’s radar,” Piper notes.

There is no published protocol in Medicaid for submitting coverage requests, as there is with Medicare. But companies can send a written request to Medicaid directors and relevant

MCOs. The requests should straightforwardly document the device’s targeted population, clinical data, FDA regulatory status, and other supplemental information, Piper says. Companies should also detail other insurers’ coverage policies and reimbursement rates—in particular, from Medicare contractors and private insurers established in the same state as the respective Medicaid agencies, he advised. In addition, firms should make it very clear if the technology can be used to help patients who are younger than 21 years old, because Medicaid has special rules for children. “They are entitled to any medically necessary service that Medicaid could theoretically cover, even if the state chose not to cover that,” the consultant explains. Overall, as a company, you should “do the work for them as much as you possibly can.”

Once you send the requests, it is also helpful to set up a “war room” to track responses from each state agency and, since there are no established timelines, follow up as needed, Piper says. When an updated coverage policy is confirmed, it’s important for a company to ensure that the precise approach to submitting claims for the new technology is clear to healthcare providers. He cautions: “Sometimes, where something is covered, there is something either unclear or missing or unspecified in the provider manual.” Or sometimes the relevant information is “just buried somewhere in the manuals.”

Medicaid Math and Politics

Medicaid is most distinguished from Medicare and commercial insurers by its very high level of budget sensitivity. That reality means innovators might face a steeper, and more political, challenge in seeking Medicaid reimbursement, particularly in cases when a state already covers an established service that a new technology is seeking to displace.

It will not always be as simple as sending in a request to the Medicaid agency and making clinical arguments. “This is a political effort,” explains Tong. “You’re not talking clinician to clinician, peer-to-peer.”

So in the case of sleep apnea testing, for instance, Medicaid agencies have negotiated and locked in very low rates with a select group of providers for lab-based sleep testing. Extending coverage to home testing would involve a new contracting process, establishing a new budget line-item, and likely adding more short-term costs to the bottom line, if it is likely to increase overall testing volume, Tong says.

“Home testing has to be specifically opted in by the bureaucrats and the legislators who pay for this stuff,” he notes. A Medicaid agency is not going to add it “unless the state legislature decides to do it.”

The standard medtech argument that adoption of a new technology will lead to downstream returns on investment, and

health savings, is not likely to do the job in these cases where short-term vote-getting needs are driving decisions.

Making a case in that environment means understanding the political dynamics in each state, which may include policymakers who are inclined to support new healthcare spending as well as their more fiscally conservative colleagues, and the political horse trading that happens between them.

"The right toolkit, per Medicaid state, has to be a fact pattern based on that state's legacy, and how they got to where they are," Tong explains.

In general, state government officials under such tight budget restraints tend to view return-on-investment a lot of differently from private companies, and device firms must be mindful of that, Piper, the former Medicaid official, affirms.

In the device industry, "if somebody put together a business plan with a reasonable, thoughtful way of generating \$10 billion in revenue, but needed a \$1 million investment, you'd get a lot of takers on that, right? In the government, you wouldn't necessarily get a taker on that," Piper says.

"What you need, to kind of bridge these things, is a certain matter of tolerance, acceptance, if you will, or sympathy and understanding," Piper says. "And it helps when a company is not BSing. That's important. When a company actually goes to them, and says, 'look, we're going to make this as easy as possible.'"

Harder for Some?

Of course, in addition to sympathy, it's clear that engaging Medicaid about a new technology can take organizational resources and a political ground presence in individual states. These are things that larger companies will tend to have in greater reserves.

Itamar, headquartered in Caesarea, Israel, might face steeper barriers than some in accessing key decisionmakers for Medicaid, CEO Glick acknowledges.

"Remember, we're foreigners in a way, right?" he says. "We have advisors to help us. But we did not find a way to organize, like in Medicare or Blue Cross Blue Shield. We have not found anywhere a process we can follow that will help us for the patient."



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