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Getting Medtech Covered: Payer Strategy Best Practices

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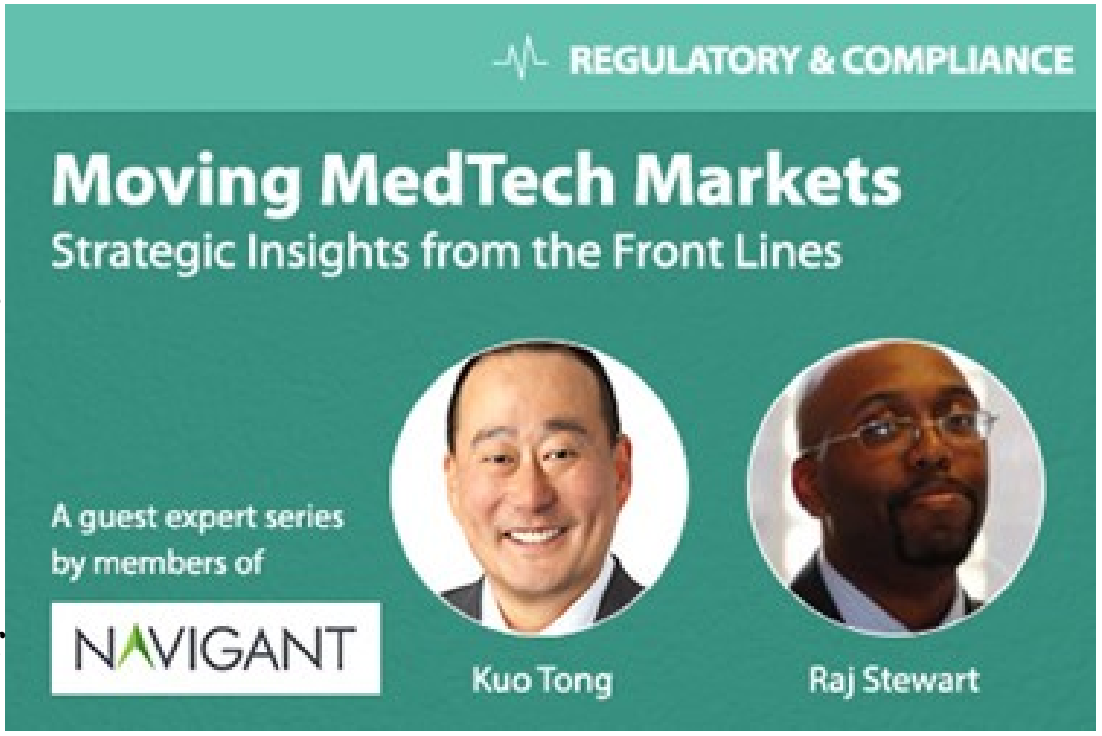

Many medical technology companies rely on securing payer coverage as a critical component toward achieving their revenue goals and realizing a return on investment on new products. Yet, few medtechs fully understand how to navigate the payer-coverage process, or how to fulfill its mercurial demands.

In the past 30 years, the only constant for medtechs seeking payer coverage has been the need for strong clinical evidence that a product does what the company says it will do, and provides a clinical benefit to the intended patient population. As a result, the only real control a medtech has rests in its own ability to articulate and prove the technology's market value, while anticipating the myriad variations in coverage requirements.

In this no-guarantees payer-coverage industry, virtually everything — from stakeholders to priorities to standards for evidence — is subject to change. Medtechs must plan to be proactive and deploy layered strategies to shift the coverage odds in their favor.

Objectively Assess Coverage Potential

Unlike one-payer system countries, such as Germany and Japan, the United States' system is fragmented, which adds significant complexity to seeking and attaining coverage. In the U.S., each payer has individual and differential policies, processes, and personnel to evaluate products; and, each payer can opt to grant full, intermediate, or no coverage for the same or similar therapy options across different systems and regions. Even "me-too" and improved versions of existing products might not be awarded the same coverage as their predecessors. Insurance corporations might make different territory-by-territory decisions — for example, for the same treatment option, residents in one state might have different coverage than residents in another state.

Furthermore, with mergers, consolidations, contractors, and staff turnovers, the conversations medtech companies had with payer representatives as little as a year ago may no longer be relevant. Case in point: the Medicare administrative contractor for parts of the southeastern United States changed from Cahaba GBA to Palmetto GBA in early 2018, so medtech companies seeking coverage in that area now must work with a completely different stakeholder.

Considering all these factors, companies that conduct an objective assessment — especially one performed by a detached third party — tend to be best -positioned to seek and attain payer coverage.

The assessment should include a comprehensive evaluation of the product profile, provable market value, and potential barriers to gaining payer coverage, so strategies can be put in place to resolve any issues and seek appropriate coverage. The most common coverage barriers tend to be information gaps that also hinder market adoption, including:

- **Patient segmentation** — The medtech company has not thoroughly evaluated or scientifically validated the ideal patient segment that will receive the best clinical benefits from the therapy option, and/or has not prepared guidelines for clinicians to help them understand best-use scenarios, and/or has not presented evidence specific to a targeted payer's beneficiaries. For example, in simplest coverage terms, Medicare will be looking for clinical evidence specific to its beneficiaries (i.e., patients aged 65 years or older, or

who qualify through Social Security Disability Insurance). So, either a substantial piece of a study or a whole study will need to prove and validate results for patient segments within these populations.

- **Patient journey** — Understanding where in the patient journey the treatment option will be utilized informs the size of the patient pool, which clinicians to target as customers (surgeons vs. primary care physicians, for example), and how to position the product in the commercial space, among other key variables. These insights are critical in sizing the potential need for the technology, as well as understanding the market dynamics for adoption, including the inclusion/exclusion criteria that help payers properly frame medical necessity criteria.
- **Hard evidence** — Local and national payers have high standards for evidence proving a technology's positive outcomes; it must be able to withstand scientific scrutiny. The evidence also should validate clinical and economic outcomes specific to a given payer's pool of beneficiaries, as well as weigh those outcomes against in-use technologies.

Several other critical factors — all of which revolve around proving the safety, efficacy, and economic justification for a therapy option — can inhibit a technology's market value and payer coverage opportunities. An objective assessment will provide insight into the probable outcomes of each potential strategy against commercial goals, including projected payer coverage profiles, opportunities to strengthen the product offering and its positioning, and secondary strategies (should an unexpected need to shift course arise).

Determine Coverage Desired, And Strategy

First, it is important to note that several scenarios exist in which a medtech company might be best served to stay its course without coverage. For example, when:

- A lack of comprehensive evidence exists to demonstrate the therapy's value
- Informal reimbursement channels exist, or passive coverage occurs organically
- An existing policy or benefit determination already covers the technology
- The investment required to seek coverage outweighs the financial benefit of gaining it
- The therapy already meets revenue generation goals

Assuming none of these apply, then a company must choose whether to forge a new path or rely on an existing one, as well as whether to pursue a national, local, or hybrid coverage strategy.

A product that effectively will create a new care category presents the opportunity for the company to define its coding and reimbursement value, based on the technology's intrinsic benefit to the healthcare industry holistically, and providers and patients specifically. Getting the value proposition right helps make sure these novel technologies and breakthroughs are accessible and economically sustainable. In contrast, with a "me-too" or predicate product, it generally is best to work within a current structure, unless a company wants to make that additional investment to differentiate its offering.

From there, while it might seem intuitively best to pursue a national strategy, local coverage strategies sometimes are more prudent, depending on the technology and competitive market landscape.

National Payer Strategy

A national coverage strategy is essentially a "winner takes all" approach that, when successful, provides broad access and reimbursement from a single engagement and coverage decision. This approach tends to be best for game-changing technologies with strong evidence proving significantly improved clinical outcomes. However, it is a high-stakes strategy, with rejection often sending a company into additional clinical trials and research in hopes of later appealing the decision with new, stronger evidence supporting efficacy within targeted patient segments. For interventions heavily weighted toward Medicare patients, this is a "one shot on goal" strategy, meaning, while the decision is being evaluated, no coverage is available, and a negative decision impacts all Medicare patients nationwide.

Local Payer Strategy

In contrast, local coverage strategies take an iterative, "win small battles" approach that allows for aggregation of positive outcomes to build a larger favorable coverage profile. This approach enables medtech companies to potentially leverage variations in evidence thresholds or soft factors among payers to establish coverage that would not be available through a single national engagement. It also

aids in generating pockets of revenue, while expanding coverage over time, potentially in parallel with additional evidence development.

Local payers tend to have more leeway in the types of technologies they approve for coverage, and tend to be less risk averse than national payers. This is in part because local payers can engage in customized risk-sharing and contracting agreements. This allows insurers to provide access to new products while mitigating the financial impact through manufacturer rebates or discounts anchored to clinical outcomes.

Local strategies tend to be preferred in cases where:

- A national coverage route does not align with the company's commercial timeline. For the most part, the national level requires more rigorous clinical evidence, and an intensive application and approval process, so it usually takes more resources and time to apply and get a decision. However, the local payer coverage strategy process often requires multiple payer engagements and protracted timelines to secure equivalent coverage to a national decision.
- The gap analysis results from the objective assessment indicate that a national payer is highly unlikely to offer coverage. A local strategy enables companies to request individual coverage decisions, target payers by patient segmentation demographics, and focus tight resources to gain revenue-generating initial wins as a base from which to expand.

Choosing The Right Strategy

With an objective assessment, a company can determine an achievable coverage plan, shift course as needed, and inform future strategy.

In a recent example, a medtech company relied on objective assessment results and recommendations to implement a four-tiered strategy in pursuit of local coverage that included:

- Developing a global value dossier to reflect the clinical and economic benefits of the product
- Establishing a dedicated customer program to assist providers with prior authorizations, appeals, and reimbursement rate issues
- Building a payer engagement team to facilitate new or revised favorable coverage policies for its products
- Securing a Category I code to support streamlined coverage and claims processing

The strategy worked — the company successfully increased payment for its therapy for treatment of an ophthalmologic condition, and overturned several local noncoverage policies, paving the way to garner more revenue and market penetration.

In another recent case, a medtech company with a novel implantable treatment secured national Medicare coverage by deploying a multi-tiered strategy to attain a series of local coverage policy wins. The strategy encompassed hard evidence demonstrating the technology's value, as well as several soft factors,

including nurturing stakeholder relationships to gain support. Additionally, the device became explicitly covered by a multi-state government benefits administrator and was removed from the non-covered service list of another, allowing expedited case-by-case coverage and reimbursement. The therapy also was assigned two new Category III CPT codes and a CMS outpatient payment rate exceeding $150,000 (i.e., the highest approved device payment rate on record).

Factors For Success

In this age of focal therapies and targeted medicine, medtech companies need to properly customize their products to meet the needs of identified patient populations, and to clinically validate and test these technologies in clinical trials to demonstrate their value. Payers expect medical technology companies to complete this comprehensive work in advance of engagements, and to be prepared to share their clinical value story. Otherwise, both national and local payers will be reluctant to offer coverage.

Again, every company's situation is different, and the landscape is dynamic. So choosing the right coverage strategy will depend on a variety of factors specific to a company's commercial goals, and a technology's position and value. Maximizing payer coverage requires objective, scientific assessment and evaluation, tailored and informed positioning, and a defensible strategic plan. It also requires the patience to endure a rigorous, complex process being carried out in a complicated market.

About The Authors

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