EXECUTIVE INSIGHTS

Inverting the Medtech Value Pyramid: Business Models for Engaged Healthcare Consumers

Medtech companies operate as well-oiled product development and commercialization machines, bringing a range of devices and diagnostics to market through repetition and experience. While the product may be different, from a new ultrasound device to a continuous glucose monitor, the business model and process remain largely unchanged. A lengthy design and regulatory process accumulates significant cost, which in turn dictates a high price point and limited patient ability to pay out of pocket for the device.

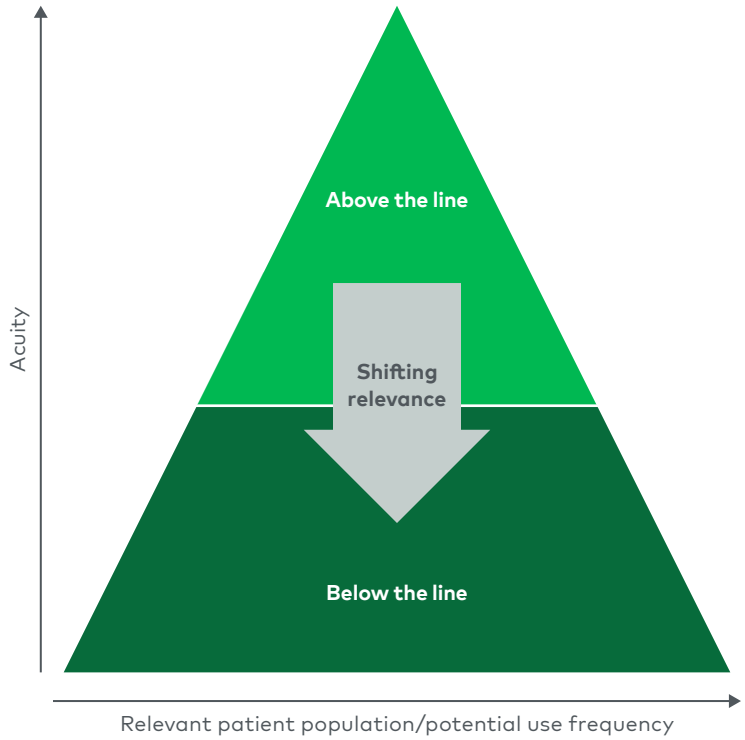
Medtechs must seek out reimbursement coverage through insurance to facilitate adoption. While this business model enables medtechs to recoup significant investment costs, it limits the reach and impact of devices and diagnostics as payers set eligibility guidelines for qualifying patients to ensure they are not paying unnecessary costs; some patients who could have had some benefit (albeit possibly less than an insurance-qualified patient) will not have access.

Patients could potentially be ineligible for the device if they are not sick enough or are unable to meet prior authorization requirements (e.g., physician visits) or simply because of improperly completed paperwork. Given the nature of this system and the high value per patient, medtechs deploy large physician outreach teams to help ensure qualified patients who could benefit from the device are informed of its availability, adding further to the underlying cost of the devices (i.e., in selling general and administrative). It's just the way things are done — but should it be?

Product acuity (i.e., the level of patient care needed) and relevant patient population/potential use frequency (e.g., how often is the device needed coupled with how broad is the group of patients addressed) are two critical considerations in bringing a product to market. The status

quo medtech strategy described above can be referred to as an above-the-line business model (see Figure 1). The nature of this model (e.g., high costs and reimbursement coverage) inherently limits the reachable patient population and focuses on higher-acuity care. A new model, however, is gaining traction as the medtech ecosystem evolves — a below-the-line model.

Figure 1
The medtech pyramid model



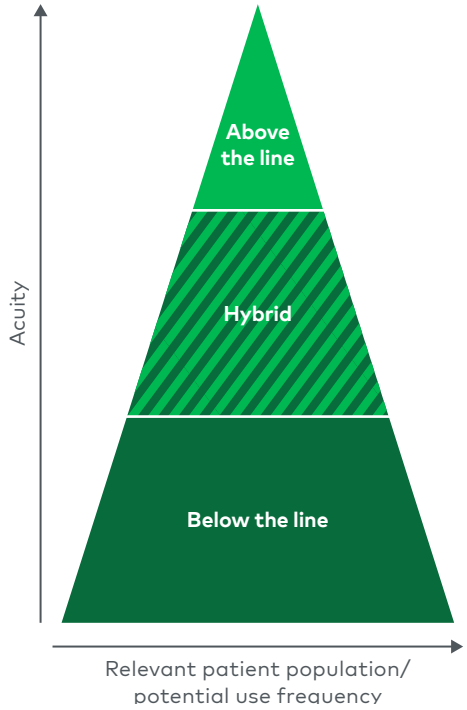
Source: L.E.K. research and analysis

This model directly caters to lower-acuity devices that are used with higher frequency and diagnostics as they directly target patients themselves. By bringing products to market in a lower-cost, more affordable way, medtechs can facilitate patients self-paying for their product. While this model has historically been reserved for less complex healthcare-adjacent products, the paradigm is beginning to shift. Greater patient involvement, driven by growing patient frustration and an emerging willingness to seek care alternatives — as well as advancing technology — is facilitating a change in where the line between these models is drawn. Over time, a larger percentage of medtech market value will shift below the line, potentially inverting the medtech value pyramid. In this L.E.K. Consulting *Executive Insights*, we assess this shift, the factors accelerating the shift and the implications, including which devices might be more impacted by these changing dynamics.

What products are ripe to move to below-the-line/hybrid models?

While a below-the-line business model has the potential to shift the paradigm of the medtech industry as we know it, certain products are likely to continue to be successful (and more appropriate for) leveraging the more traditional above-the-line model. Three correlated factors can help assess whether an offering is ideal for a below-the-line model: payment, medical oversight needed and regulatory pathway (see Figure 2). For devices that straddle factors, a hybrid business model pursuing reimbursement, while leveraging a self-pay approach in the interim or for noncovered patients, could potentially optimize profitability.

Figure 2
Market indicators for below-the-line vs. above-the-line business strategy



Payment	Medical oversight	Regulatory	Product examples
Typically **purchased directly by the hospital** and/or reimbursed by a health payer via hospital billing	Generally, **requires a clinician to be present** for use (in case a reimbursement form has already been submitted for professional component)	Class II or III devices typically	Surgical robots Orthopedic implants Heart valves Pacemakers
Paid for out of pocket but is often partially or fully reimbursed by a payer if eligibility conditions are met	**May require a medical professional** (e.g., nurse or home aide) to train in use or setup	Class I, II or III devices	IOL implants Hearing aids CPAP machines CGM devices
Consumer fully self-pays for below-the-line medical device, without payer reimbursement	**No medical professional involved**	Class I or II devices typically	Smartwatches Percussion massagers Aesthetic dental products

Note: IOL=intraocular lens; CPAP=continuous positive airway pressure; CGM=continuous glucose monitoring
Source: L.E.K. research and analysis

Medical devices that are a better fit for the above-the-line model are typically more complex, are well covered by insurance and require in-person clinician involvement (due to potential for major adverse events or complications). Examples of such devices are pacemakers and orthopedic implants. For these types of products, shifting to a below-the-line model is obviously a nonstarter; physicians are highly involved in product selection, as they are responsible for making sure a procedure is successful. A patient's influence on a provider's choice of pacemaker or knee implant is therefore more limited (and appropriately so).

However, there is a broad spectrum of medical devices that are ripe for a below-the-line strategy. They are typically used primarily outside the hospital, require less clinical know-how, involve patient preferences (e.g., comfort and aesthetics) and do not carry major risks of adverse events or complications. In these instances, clinicians shift from key purchasers and decision-makers to influencers helping patients find the best device fit. For instance, patient monitoring and telehealth-enabled products can often be used outside clinical settings and can be incorporated into a patient's daily life (e.g., smartwatch to capture electrocardiograms and monitor blood oxygen levels) to help them better manage their own health.

Clinicians can help patients understand the benefits and trade-offs of these devices, rather than making the decision and device selection for the patient. Another example of a product that has found success with a below-the-line strategy is Softwave Tissue Regeneration Technologies' shock wave device, which is used to reduce pain and accelerate healing of musculoskeletal and wound injuries. After years of payer negotiations and clinical evidence generation efforts, the company found more rapid, greater commercial success in bypassing reimbursement altogether and selling directly to self-pay-driven care settings (e.g., chiropractors).

The hybrid model also provides intriguing possibilities and can be approached in a variety of different ways. Medtechs can design the reimbursement strategy so that payers either cover a subset of the market (e.g., hearing aids, sleep apnea equipment) or partially reimburse devices (e.g., intraocular lens implants (IOLs)).

The hearing aid market provides an example of a patient being able to buy a medical device directly if not reimbursed. The market can be segmented into two distinct categories based on severity of the need. Patients with severe hearing loss will require a prescription device and need to work with a hearing specialist or audiologist to prove the device's necessity and properly fit the device. Some insurers cover or partially cover these devices if proper documentation illustrating the need for the device is shown. Alternatively, a patient with mild-to-moderate hearing loss is unlikely to have the device covered by insurance but can purchase more affordable over-the-counter hearing aids and also avoid the cost of clinician visits (e.g., prescription generation, equipment fitting).

Sleep apnea and continuous positive airway pressure (CPAP) equipment provides another example of a hybrid strategy. While payers typically cover the CPAP machine itself as well as base equipment (mask, tubes, etc.) if a need is proven, a patient who prefers a higher-quality mask or prefers to change the associated tubes more frequently can pay out of pocket. In addition, many patients do not want to jump over the hurdles of proving they need a CPAP machine and, as a result, purchase one directly without reimbursement.

Medtechs can also pursue a partial reimbursement strategy with payers to achieve a hybrid business model. Premium IOLs used to treat cataracts provide an example of this strategy. While a base IOL is typically covered by payers, premium IOLs that not only correct cataracts but also improve vision for near- or farsighted patients, replacing the need for glasses or contacts, typically are not covered as they are vision improving rather than correcting. However, payers will cover the cost of the base IOL, allowing a patient who elects to use a premium IOL to pay only the difference in price rather than the full amount. This reduces the burden on the patient when selecting a premium lens and grows the overall market size.

As the hybrid model continues to gain traction, new ways of pursuing a hybrid business model are likely to continue to arise.

Why are below-the-line and hybrid business models becoming more relevant?

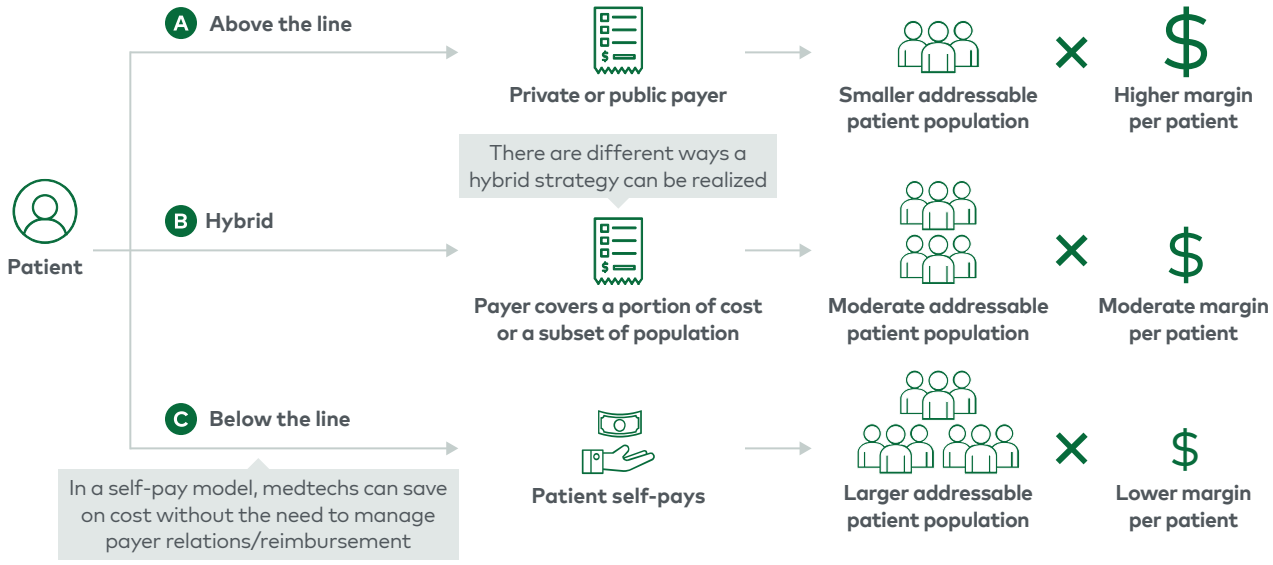
Five critical healthcare macrotrends are helping drive the increasing relevance of below-the-line business models in medtech:

1. **Higher patient engagement** in healthcare is leading to a greater likelihood of patients being involved in key care decisions, and as a result, patients are now more involved in choosing and paying for their own medical products that they believe best facilitate their health.
2. **Increasing prevalence of high-deductible plans** is shifting the cost of care to patients, increasing the amount of self-payment, and encouraging more proactive decision-making to reduce downstream costs.
3. **A generational shift in patient demographics** is increasing the share of patients who are more willing to use alternative payment models and are decreasing their reliance on healthcare plan recommendations and payment models. Patients are also increasingly frustrated with the limitations of the current healthcare system and the difficulty of qualifying for reimbursement, which is leading to increased willingness to search out self-funded care alternatives.
4. **Key technology advances** in device miniaturization, the democratization of digital and the proliferation of smartphones are creating the requisite infrastructure to bring affordable yet relatively complex devices to market.
5. **Growing availability of and access to information** online coupled with increasing healthcare transparency better enable patients to shop around for treatment and medical product alternatives, giving them agency over their own healthcare like never before.

How do below-the-line/hybrid business models impact profitability?

In contrast to the traditional above-the-line business model where medtechs target a smaller addressable patient population with a high profit margin, below-the-line models can potentially lead to higher profit if the volume gain can offset the smaller margin per patient (see Figure 3).

Figure 3
Business model profitability calculation



Note: DTC=direct to consumer
Source: Company websites; National Library of Medicine – "Prevalence of Hearing Loss by Severity in the United States"; L.E.K.'s DTC Hearing Aid Market Primer (2019)

Though patients pay for their medical devices directly, the lower prices allow patients who have insufficient insurance coverage or who are unwilling to jump over the hurdles of insurance to access the product. Moreover, medtechs may also generate potential savings and earlier revenue in a below-the-line model. The process of securing and lobbying for reimbursement coverage with payers is not only lengthy but costly as well. By forgoing the need to navigate reimbursement coverage, medtechs can reach commercial launch sooner, adding revenue while reducing the investment required. The cost equation can be further improved using this approach as it can require a less-costly sales model.

For a hybrid approach, the different strategies to establish the hybrid model can lead to different profitability outcomes. For some devices, it may be feasible to pursue either a scenario where payers partially reimburse devices (e.g., IOLs) or one where payers cover a subset of the market (e.g., hearing aids, CPAP machines). Pursuing these different options can lead to varied profitability based on how it impacts the cost of the device and the relevant patient population/potential use frequency.

As the hybrid model gains more prominence, a critical factor in go-to-market strategy will be evaluating these various scenarios to determine the right reimbursement pathway to optimize patient benefit and profitability. Medtechs will need to consider and understand factors such as the size and segmentation of the patient population, payer and patient willingness to pay, and the costs (e.g., fixed, variable) associated with the device to determine the best path forward.

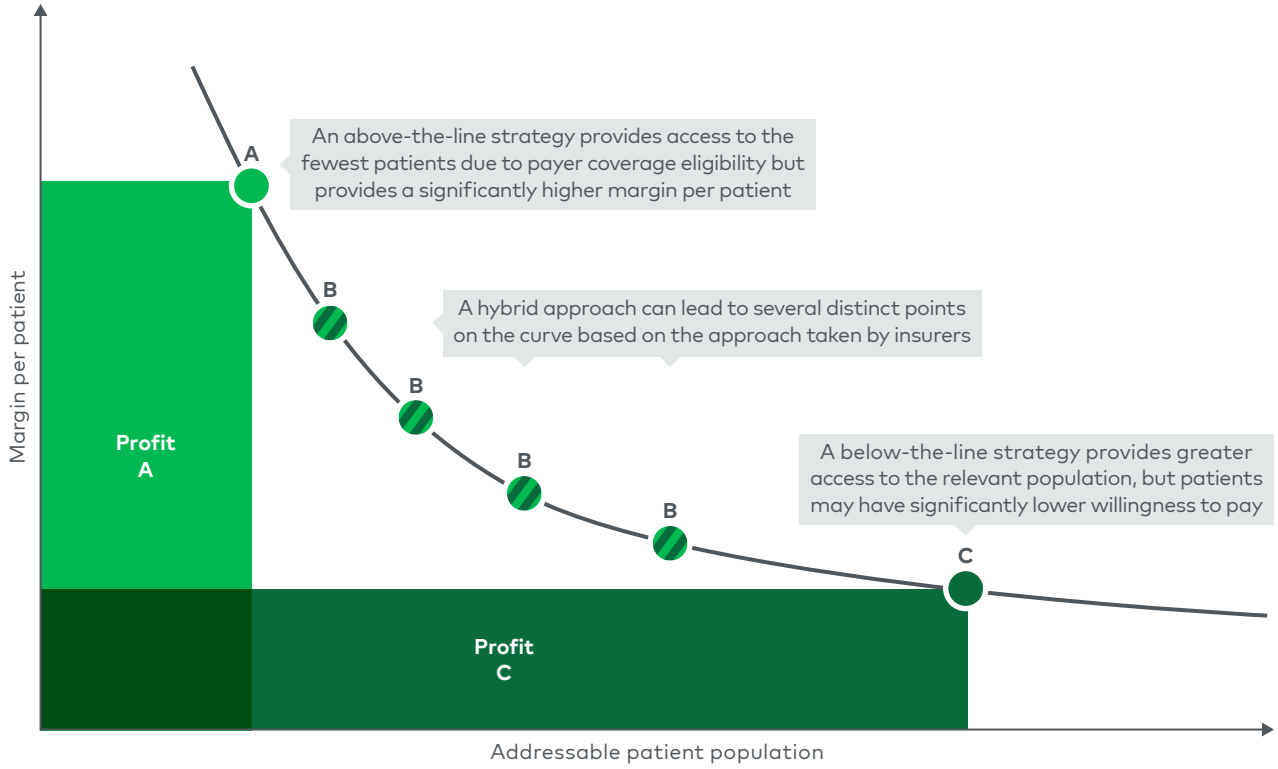
One additional critical factor to understand for a hybrid strategy will be the trade-offs in terms of earlier sales and eventual reimbursement magnitude. The Centers for Medicare & Medicaid Services and the American Medical Association leverage the cost of devices in determining reimbursement magnitude.

The process of collecting data to determine eligibility for reimbursement as well as magnitude can span years. As such, pursuing direct-to-patient sales at an affordable price while reimbursement is in process could increase short-term revenue (and profitability) but could impact the long-term magnitude of future reimbursement payments. As more medtechs leverage a hybrid model, the implications for reimbursement will likely become less opaque and better illustrate the potential trade-offs.

To determine which model is most viable and attractive for a given product, medtechs should weigh a variety of considerations. Regulatory requirements and complexity may make some products ineligible — or poor candidates for anything other than an above-the-line model. For those that are potentially attractive candidates, medtechs should evaluate go-to-market considerations such as the size and segmentation of the patient population, payer willingness to cover and health economic data requirements, patient education level on a disease state, patient training required on use of a product, patient willingness to pay, difficulty and expense of identifying and acquiring patients, and availability of viable channels to reach and support patients. And critically, of course, medtechs need to evaluate the potential profitability trade-offs of different model options.

A profitability curve can be developed as a function of expected margin per patient and addressable patient population (see Figure 4). An above-the-line strategy may limit patient access due to payer coverage eligibility, but it tends to drive a significantly higher margin per patient (see point A in Figure 4). Alternatively, a below-the-line strategy allows medtechs to expand access to the entire relevant patient population, but profitability is limited based on patient willingness to pay (see point C in Figure 4). A hybrid of both business models can lead to several distinct points on the profitability curve based on the approach taken with insurers/coverage eligibility (see points B in Figure 4).

Figure 4
Device profitability analysis



Source: L.E.K. research and analysis

Ultimately, more-complex devices with stringent regulatory requirements may not be eligible for a below-the-line approach, while less-complex devices that have a high customer willingness to pay and greater levels of patient education on the disease state are likely good candidates.

What impact can this business model shift have on the medtech industry?

The acceleration of below-the-line business models can impact medical device players in several ways. Medtech companies may experience a reduction in product development and go-to-market costs as products are designed to be more affordable and functional rather than to achieve engineered perfection.

Medtechs can strategically reinvest these cost savings to best position themselves in this new era of increased competition. In addition, below-the-line products are likely to mandate higher production volumes as devices become more affordable and accessible. As a result, medtechs may need to expand their current capabilities to meet higher volume demands and build additional competencies around direct-to-patient sales and support. Finally, for the right products, profits could increase through a much larger addressable population, lower development costs and earlier realized revenue, despite lower margin per patient.

As a larger percentage of market value shifts below the line, medtechs will face multiple challenges and risk falling behind on a rapidly evolving portion of the market.

- Medtechs will likely face an increase in competition from tech companies and nontraditional players entering the medical device industry. This rise in competition is already occurring in areas such as wearables and patient monitoring.
- The velocity of product development will increase (e.g., more products and faster development time) as more products are designed specifically for the below-the-line business model (rather than shifting existing products from above the line). Though in the near term, medtechs will be reevaluating their portfolios to see which devices are ready for this type of business model shift (e.g., hearing aid market is currently undergoing this shift).
- Medtechs will increasingly need to stand up additional capabilities to address the needs of below-the-line products. This includes setting up direct-to-patient marketing functions, increasing manufacturing capacity and flexibility, and creating consumer-facing payment models.
- Clinicians will increasingly shift from being primarily customers to being broader partners for medtechs, both in influencing patient product selection and helping medtechs select which products best fit to support a below-the-line model. This shift will likely lead to more clinician involvement in the commercialization process.

While these challenges are substantial, the potential rewards for medtech players that adapt are also considerable. Those that can evolve to support below-the-line business models could generate significant growth, ward off the risks of increasing encroachment from non-medtech competitors and, most importantly, expand patient access to many valuable medical innovations. While changes from the traditional medtech business model will be gradual, they will likely continue, and, ultimately, the medtech value pyramid may even become inverted.

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