

The cost of medical device innovation: can we keep pace?



Overview

Innovation is the hallmark of U.S. health care. Over the last decade, advances in medical device technology have had an extraordinary positive impact on patient outcomes and quality of life. In 2017, the number of first-time premarket approvals by the U.S. Food and Drug Administration (FDA) increased 28 percent from the previous year, while the number of 510(k) clearances was up 9 percent.¹

Innovation in the cardiovascular space accounts for nearly 40 percent of the first-time FDA approvals, significantly outpacing other medical subspecialties. For example, within the past six years, the FDA approved a number of highly innovative medical devices that have revolutionized cardiovascular care, including transcatheter aortic valve replacement (TAVR), the MitraClip, leadless pacemaker, left atrial appendage occlusion and drug-coated balloons for treatment of peripheral vascular disease.

While these novel devices may provide advanced treatment options, improved quality of life and extended longevity for patients, the high costs associated with the devices and procedures create challenges for hospitals. Because of high research and development costs, the expense of clinical trials and market factors, an innovative medical device almost always carries a premium price. Additionally, manufacturers may set prices higher hoping that the Centers for Medicare & Medicaid Services (CMS) will also set reimbursement rates higher. As a result, for innovative medical devices such as those previously noted, these premium prices are often significantly higher than those of current therapy.

Consequently, providers often become caught in the middle of a reimbursement quagmire. New devices are rarely reimbursed adequately upon market introduction, so the reimbursement does not cover the hospital's costs. In addition, early adopters of innovative devices may be forced to rely on the use of temporary codes that may or may not cover procedure costs.

The conflict between high costs and low reimbursement for innovative devices creates a disconnect between the hospital's clinicians, supply chain and revenue cycle administrators. Physicians gravitate toward innovative new

medical technology that can improve patients' quality of life; supply chain leaders are focused on availability and cost; and revenue cycle executives are focused on getting appropriately reimbursed and ensuring the hospital's financial viability.

In the current environment of payer-mix erosion and lagging reimbursement, hospitals must develop a focus on innovation that enables the evaluation and adoption of emerging technology in a way that benefits all stakeholders (patients, providers, suppliers and payers) in a financially sustainable way.

Narrowing the gap between device cost and reimbursement

A review of several recent innovative cardiovascular medical device introductions reveals an average 273.3 percent increase in price (range, 163 percent to 565 percent; Table 1) over the predicate medical device.

For novel devices that have no predicate device, such as left atrial appendage occlusion, the premium over the surgical comparator can be much higher.

Table 1. Medical device price premiums over predicate devices^a

New technology	Predicate technology	Price increase vs. predicate
Drug-eluting stent	Bare-metal stent	181.5%
Transcatheter aortic valve replacement	Tissue aortic heart valve	565.2%
Leadless pacemaker	Pacemaker, single chamber	256.6%
Sutureless heart valve	Tissue aortic heart valve	200.0%
Transcatheter mitral valve repair	Surgical mitral valve repair	1,530.0%
Drug-coated dilatation balloons	Peripheral stent	163.0%
Coronary bioresorbable scaffold	Coronary drug-eluting stent	231.4%

^aVizient Savings Actualizer™, 2018 data.

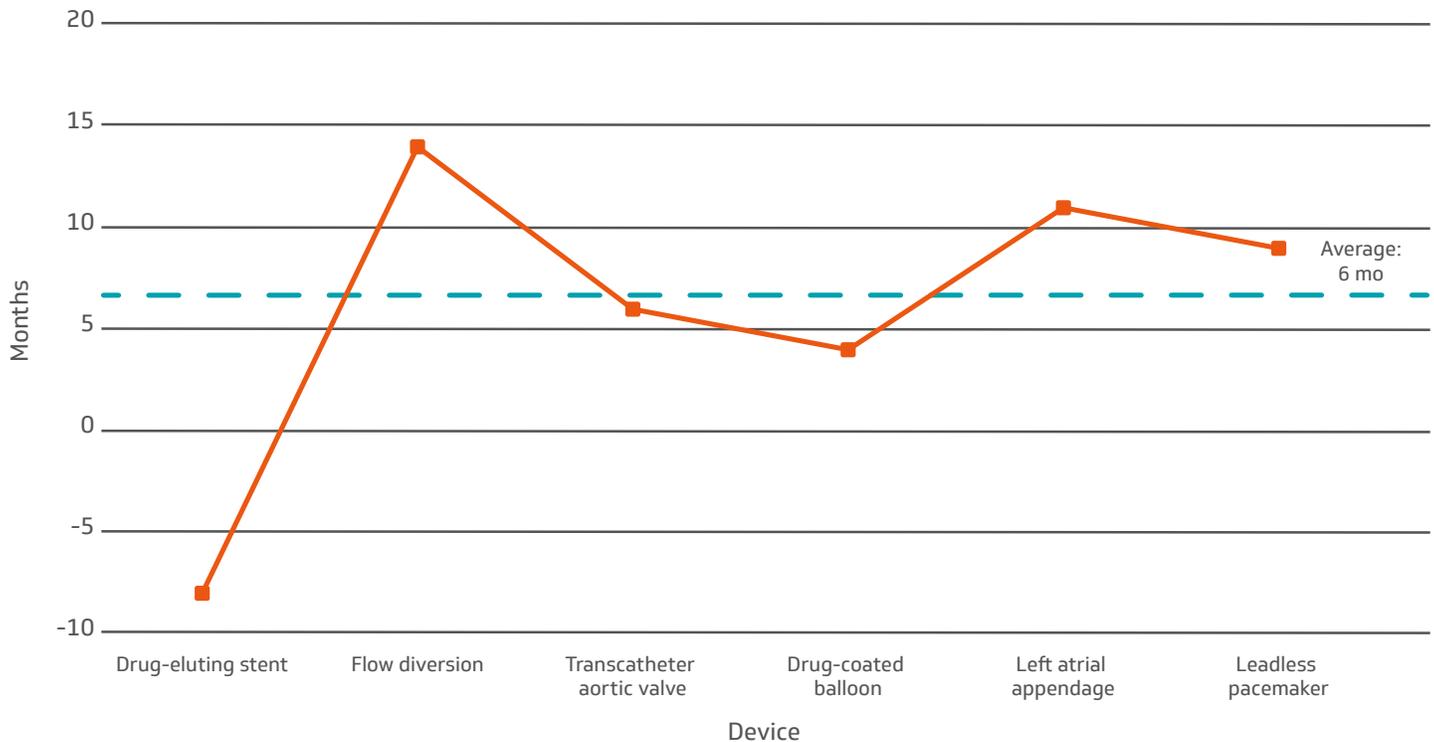
Reimbursement practices challenge early adopters and ongoing sustainability

As previously mentioned, innovative technologies are rarely reimbursed immediately upon market introduction. In fact, over the past two decades, relatively few products have been assigned diagnosis-related group (DRG) codes for reimbursement at the time of their introduction. The drug-eluting stent was the only cardiovascular device to receive reimbursement at the time of the FDA's premarket approval. For other medical devices, the time from market

introduction to reimbursement has averaged approximately six months (Figure 1).

In 2010, the FDA introduced the parallel approval pathway, which calls for the FDA and the CMS to work together to approve both the device and the reimbursement at the same time. However, to date this policy has had little effect as no innovative cardiovascular devices have been approved this way.

Figure 1. Time from device introduction to assignment of CMS reimbursement rate^a



^a Data derived from FDA PMA approvals and CMS National Coverage Analyses.^{2,3}

To ease the burden on providers, CMS implemented New Technology Add-on Payments (NTAPs) for select devices (§412.87(b)(3) of the Social Security Act) in 2001.⁴ New technology costs that are not adequately considered under the current DRG payments may be temporarily (i.e., for two or three years) eligible for reimbursement if they can demonstrate clinical benefit over existing technologies. Though the reimbursement is often still too low, hospitals receive up to an additional 50 percent of the product's list

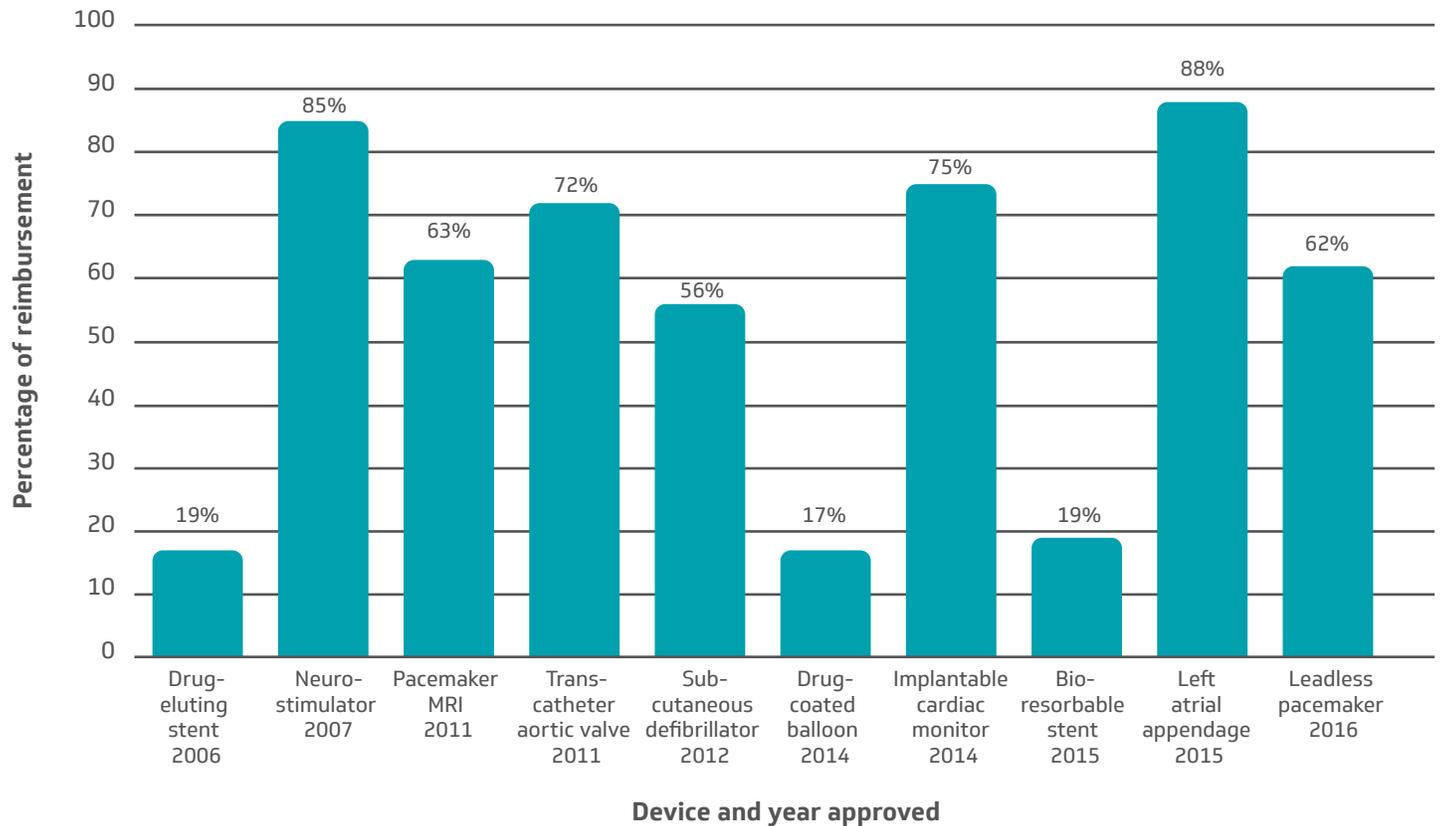
price under NTAP. Hospitals may use these incremental payments to bridge the reimbursement gap for innovative technologies.

Unfortunately, even after reimbursement approval, a gap between pricing and reimbursement often still exists, meaning that many early adopters of new technologies will lose money on each procedure performed, especially in Medicare cases.

A review of select cardiovascular medical devices demonstrates considerable variability in the ratio of device cost to reimbursement (Figure 2). In fact, for some of the recent innovations, the device cost alone consumes a

very high proportion of the overall reimbursement for the procedure, leaving minimal coverage for other expenses such as supplies, room costs and other miscellaneous resources required for the procedure.

Figure 2. Average medical device cost as a percentage of average CMS reimbursement^a



^a Data derived from Vizient Intellisource, Vizient Savings Actualyzer and CMS IPPS 2018.⁵
Abbreviation: MRI = magnetic resonance image.

Example: TAVR financials continue to challenge traditional metrics

Sg2[®] data shows that Medicare covers approximately 90 percent of TAVR procedures. When specific reimbursement was established under DRG codes 266 and 267, there was a significant increase in reimbursement compared with the traditional open surgical valve procedure (codes 216 through 221). Initially, the medical device cost accounted for 61.6 percent of the total DRG reimbursement.

However for fiscal 2019, CMS has reduced payment by nearly 17 percent while the device cost has remained stable. The result is that the device cost as a percentage of reimbursement has increased to 74.0 percent. With margins getting smaller, programs must focus on program efficiency, prevention of complications and continuing to partner with manufacturers in order to remain sustainable.

- Existing reimbursement models take into consideration that medical devices, unlike pharmaceuticals, represent a portion of the total cost of a procedure. However, in the past few years we have seen several new medical devices that are taking a much greater portion of that reimbursement, with some coming close to 100 percent based on an analysis from Vizient® of the average reimbursement received versus device cost paid by hospitals across the country. This leaves little to cover the extensive costs that come with device implantation, such as hospital stays, surgery and anesthesia.••

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Focus on strategic and value assessments when making technology decisions

While the ever-widening gap between device pricing and hospital episode of care reimbursement complicates financial considerations about the adoption of innovative technology, that doesn't mean these novel devices are not providing additional clinical value over predicate therapies. Providers may just need to redefine how they assess the value of an innovative technology. In short, hospitals need a systematic process for evaluating both clinical and financial outcomes associated with the technology—in this case, value is a product of weighing cost against outcomes.

To start the technology assessment process, it is important to rigorously evaluate the available clinical evidence. Emerging technologies that address an unmet need, provide improved outcomes, have relatively low clinical risk and incur favorable economics comprise a subset of innovation where a lower level of proof may be sufficient to justify adoption. Adoption of technologies that improve patient care and change quality of life is a win for patients and hospitals. On the other hand, high-risk, high-cost procedures like TAVR require a higher evidentiary standard before adoption. Well-designed, randomized controlled trials may be the appropriate level of proof needed before adopting these technologies.

- To use a value-based evaluation paradigm, the hospital's technology adoption committee must engage in a systematic review of the clinical literature to determine pertinent clinical outcomes and also conduct financial analyses to estimate the total cost of care.••

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Example: mitral valve repair therapy

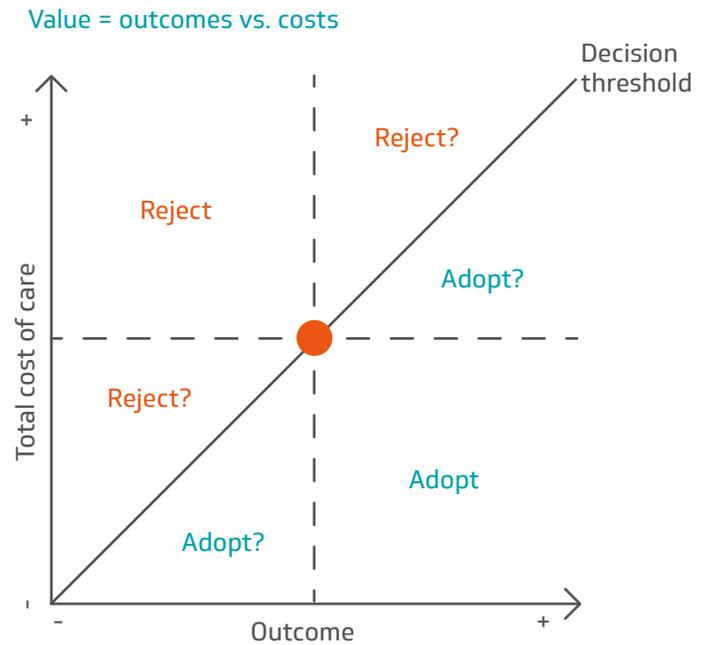
One of the largest studies of a heart valve technology, the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (COAPT) trial,⁶ demonstrated significant clinical benefits to using the device. MitraClip reduced the annualized rate of all hospitalizations for heart failure and death within 24 months compared with the control group. This suggests a high clinical value when used in the patient population defined in the study.

The procedure is reimbursed under DRG codes 228 and 229. For fiscal year 2019, base payment rates for these codes are \$40,176 and \$28,398, respectively. Yet the medical device's average purchase price alone is \$30,000 and often more than one clip must be used during a single procedure. Vizient Service Line Analytics shows that the benchmark total costs per procedure are \$54,638 and \$34,763, respectively. It is easy to see that for a hospital, this procedure is not profitable, resulting in respective average losses of \$14,462 (26.5 percent) and \$6,365 (18.3 percent) for each procedure.

In this case, traditional margin calculations make this procedure appear to be low value, but the positive clinical outcomes show that adoption of this technology can potentially reduce the total cost of care. These data, combined with increasing patient demand, may lead more providers to begin offering this therapy. However, sole-source market dynamics will result in little incentive for the supplier to reduce the price of the device.

Determining the value of a technology is key to the innovation adoption process. This is especially true in the era of alternative payment paradigms like value-based care and premium-priced novel therapies. Technology value can be plotted as the relationship between outcomes, determined from the published clinical evidence, and the total cost of care, determined through financial analysis (Figure 3). A high-impact innovative technology can fall anywhere to the right of the decision threshold line, but the innovation sweet spot is in the lower right quadrant: lower total cost and improved outcomes.

Figure 3. Value-based product adoption paradigm^a



^a Adapted from Black.⁷

Most innovative technologies, however, tend to fall in the upper right quadrant—those with a better outcome but also a higher cost. TAVR, drug-coated balloons and left atrial appendage occlusion reside in this quadrant. When they are above the decision threshold line, often defined by an incremental cost-effectiveness ratio of greater than \$50,000 to \$100,000 per quality-adjusted life year, the price of the technology may be too high and present a barrier to adoption.

Interestingly, this kind of analysis provides a snapshot in time that can change as the technology matures. Drug-eluting stents were above the decision threshold at introduction, but price decreases and newer-generation stents that improved outcomes even further have pushed them well below the decision threshold; they may even be dominant over (i.e., lower right quadrant) bare-metal stents in select cases.

Example: Inadequate reimbursement hinders adoption of TAVR

Hospitals performing TAVR procedures struggle to be profitable and, according to Vizient data, are more likely to operate in the red or just break even on this procedure. Reimbursements under DRG codes 266 and 267 for fiscal 2019 are \$44,253 and \$36,019, respectively, down 3.7 percent from the 2018 rates. Vizient Service Line Analytics shows that the benchmark total cost per procedure is significantly higher, \$64,508 and \$59,532, respectively, with a national average of \$61,716. The medical device's average purchase price alone is approximately \$25,685 after rebates.

This procedure puts a high burden on providers, which face average gross losses of \$22,082 (35.8 percent) on each procedure. Actual profit or loss varies by facility based on multiple factors such as length of stay, level of nursing care, other procedures and tests performed during hospitalization and potential complications associated with the procedure.

A critical question facing providers is when they should implement an innovative technology. Physicians often want to be early adopters and have access to the latest technology because their goal is to always provide the best care for patients. But many potentially innovative technologies are never widely adopted for various reasons. This is why the timing needs to be closely linked with the evidence development process through the evaluation of robust clinical data. Organizations can achieve this by leveraging the evaluation process noted above to ensure that all information and viewpoints are being captured. A further advantage to delayed implementation is that reimbursement also often improves as the evidence matures.

••I often recommend hospitals try to be in the early majority phase when considering technology adoption. Innovators (early adopters) usually don't have proof just yet that it does work as advertised, and that's where the risk comes in. In the early majority phase, you still get most of the benefit of early adoption, but mitigate the risk somewhat with the availability of more evidence. It's okay to be an early adopter to fulfill a research mission, but you should make the technology adoption decision knowing that the evidence is not yet mature. ••

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Hospitals also consider new technology adoption as a service differentiator to separate themselves from their competition. Strategic technology adoption decisions may also be based on physician recruitment, research and teaching missions and establishment of core clinical services.

••The analysis methodology noted herein demonstrates the imperative for hospitals to initiate a comprehensive approach for the review and adoption of new technology. What is often lost in the financial focus is the strategic implications of innovation adoption and the necessary programmatic components needed to support novel therapies. It is important to treat these as programs, not procedures, when determining what is right for your organization. ••

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Summary

Medical device innovation is pivotal to the continued advancement of health care, improving patient outcomes and enhancing quality of life. Innovation will continue to improve patient outcomes and enhance quality of life. Unfortunately, this innovation often comes with a higher price that forces providers to make tough decisions due to the financial constraints that hospitals face. Data compiled by Vizient indicate that price premiums for innovative devices range from two to 10 times those of predicate therapies.

Payers are slow to adjust their reimbursement models to accommodate these higher-cost procedures, creating a gap between device cost per episode of care and reimbursement. This gap will continue to challenge health care organizations as they consider adoption of new technologies, taking into account the financial impact, which may be looked at independently of improved outcomes and quality of life. Due to the increasing costs and risk to suppliers of bringing new technologies to market, the cost of these new products will continue to rise despite lagging reimbursement, leaving providers shouldering much of the burden and possibly requiring resources to be shifted from other areas of care.

Most hospitals should be highly selective about which new technologies must be adopted. Ensuring that they can provide the best care to the largest patient population will require taking a multifactorial approach that looks at clinical benefit, technology risk, financial implications and strategic differentiation. This will help create a more complete picture of whether to adopt a new therapy.

- Hospitals must consider the new therapy as part of a broader programmatic decision. Physicians will naturally gravitate toward innovative medical technologies that can improve patient quality of life; however, the financial viability of the hospital must also be factored into the decision.
- Hospitals, working collaboratively through multidisciplinary committees, must use a systematic, open and objective process focused on innovation assessments to determine which technologies provide better (optimal) patient care with improved value.
- Suppliers initially, then technology advocates, must provide better clinical data during the launch and early-adopter phases of a medical device introduction. The data must clearly demonstrate better outcomes to support informed decision-making by physicians and hospitals.
- Partnerships between providers and suppliers that allow for shared risk can help push both sides to improve quality and outcomes.
- Continued efforts to adopt best clinical practice models to enhance care protocols need to be investigated and implemented to optimize both outcomes and margins.

It is incumbent on decision-makers to ensure that the benefits of innovation are realized by patients without reducing the standard of care provided across the board. But can hospitals afford to keep pace with innovation? The answer is yes—if they implement strategies to invest in technologies that bring the greatest patient benefits, decrease the total cost of care across the continuum, improve quality of life and allow hospitals to adequately cover costs.

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Joe Cummings

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