Value-Based Payment for Medical Devices: It’s Here to Stay

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The U.S. is facing unsustainable increases in the cost of healthcare. Despite recent efforts to curtail this growth, there remains a great deal of concern about the escalating costs, with the political atmosphere contributing to the uncertainty. As a result, there is unparalleled pressure on manufacturers from payers, employers, hospitals, physicians, and group purchasing organizations to reduce prices or prove that new technologies deliver substantial value to all stakeholders. A recent Robert Wood Johnson Foundation report labeled medical technology the “dominant driver” of long-term costs.¹

Medical device companies historically have operated under the assumption that if they built it, physicians would buy it. With increasing focus on cost containment, even some legacy products have been met with a demand for compelling economic data. Understanding and incorporating the payer perspective and data requirements early in product development is essential in this increasingly cost-conscious market. The payer perspective must be regarded as just as crucial to success as regulatory agency input and approval. It is essential to proactively seek payer input, listen closely, and incorporate expectations. Adding early payer input will likely require a fundamental shift in how organizations think about market strategy and product development.

Expensive new technology that cannot clearly demonstrate better outcomes and/or lower costs will continue to face reimbursement challenges. Payers have been quoted as saying that they “don't want to squelch innovation,”² but they want to know exactly what they are getting for their healthcare dollars. The Centers for Medicare and Medicaid Services (CMS) is prohibited from considering cost data to determine coverage and reimbursement decisions. Realistically, CMS likely reviews publicly available global economic data to inform coverage and reimbursement decisions.

Healthcare Delivery Feels the Pain

There is growing interest among payers in value-based payment models, including bundled payments, population health management, and capitated payments that have the impact of shifting risk for quality of care to healthcare delivery organizations. CMS has committed to disbursing half of its total payments through value-based payment agreements by 2018, and private payers appear to be following the government’s lead. CMS has demonstrated its commitment with the implementation of mandatory value-based payments through its Comprehensive Care for Joint Replacement initiative and is proposing similar initiatives for other therapeutic areas. Entire healthcare systems increasingly consider cost and value as much as individual payers in deciding whether to adopt new medical technologies.

As these changes reshape the landscape of U.S. healthcare, medical device manufacturers can no longer assume their new technologies are a “sure bet” and will be paid for and widely adopted.
Demonstrating Value – Where to Start

The cost of not proactively developing economic data can be high. Payer decisions have a significant impact on clinical adoption rates and profitability. In spite of this, many medical device companies continue to think about evidence generation strategies for payment as an afterthought.

Development of economic and clinical outcome evidence that takes into account prevailing market forces must start early in product development and be updated at regular intervals. Manufacturers need to demonstrate value to a new and broader set of stakeholders, including hospital administrators, payers, employers, and even patients as consumers.

Success in today’s dynamic and increasingly cost-conscious healthcare environment requires manufacturers to fundamentally rethink evidence requirements for their products. They must understand how their products impact clinical outcomes against existing and alternative therapies and what data they will need to prove it. Public and private payers are increasingly resistant to providing reimbursement at premium levels—and sometimes even at par levels—without convincing economic data demonstrating significantly improved outcomes or cost reduction.
Even if product performance meets regulatory requirements, if it fails to demonstrate critical economic and clinical impact against existing technologies, reimbursement decisions can be significantly less favorable.

Device manufacturers are operating in an increasingly cost-conscious environment where risk shifting is common. Companies that are able to adapt to a value-based marketplace will be positioned to succeed in this changing environment.

How Exponent Can Help

Exponent’s consultants provide a range and depth of expertise in epidemiology, regulation, statistics, and health economics and outcomes research to assist our clients in the identification, design, and development of materials that help them achieve a competitive market edge, including:

- Health economic and outcomes research
- Economic and clinical value analyses
- Risk-based pricing models for new products and services
- Data analytics, including payer database and electronic health record analytics
- Scientific white paper development and peer-reviewed publication
- Evidence generation and value demonstration
- Market access and reimbursement strategies
- Portable modeling tools for one-on-one discussions with stakeholders
- Medical device review assessment.

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2 Dr. Scott Josephs, national medical officer for the health insurance provider Cigna Corp. in an interview. Modern Health Care “Health officials tell medical technology group to ‘prove it’” By Sabriya Rice | October 8, 2014. [Link](#).