Industry News

RECAPITULATING THE COMMERCIALIZATION PROCESS OF MEDICAL DEVICES FROM THE INDUSTRIAL PERSPECTIVE

By Subramanian Gunasekaran, PhD

With 40 years of experience in the Society For Biomaterials (SFB), coupled with expertise as a biomaterial device developer and active involvement in the commercialization process of developed medical devices, the author aims to share insights about our industry with the younger generation.

MARKET CLEARANCE OF A MEDICAL DEVICE BY FDA

Embarking on the journey of commercializing a medical device involves navigating through various intricate processes, with the first critical step being clearance through the U.S. Food and Drug Administration (FDA). This federal agency plays a pivotal role in approving and ensuring the safety and efficacy of medical devices.

CMS COMMERCIAL VALUATION

Following FDA clearance, the product's commercialization journey continues with the submission of detailed information to the Centers for Medicare and Medicaid Services (CMS). This submission includes comprehensive data on the product's description, indications, and clinical performance. CMS, in turn, assigns a commercial value and a Healthcare Common Procedure Coding System (HCPCS) Code to the product, setting the stage for reimbursement procedures.

CONCEPTS OF MEDICAL BILLING & CODING

The process of medical billing and coding is a nuanced yet indispensable aspect that manufacturers must master. Understanding how coding and billing are executed by healthcare providers is crucial. Notably, medical coding software companies like Codify, AAPC and Supercoder.com, may exhibit biases favoring major pharmaceutical products. Smaller companies often find their clinically superior products facing challenges in receiving fair reimbursement due to such biases.

ROLE OF BILLING AGENTS

Billing agents play a pivotal role in facilitating the proper submission of CMS-1500 forms by healthcare providers. Their responsibilities include ensuring accurate coding, submitting necessary documentation, and navigating the intricacies of reimbursement from insurance companies.

INFLUENCE OF THE AMERICAN MEDICAL ASSOCIATION (AMA)

The Relative Value Update Committee (RUC), consisting of 32 Clinicians affiliated with the American Medical Association (AMA), performs the triannual commercial valuation of medical devices. However, a notable gap exists as the RUC lacks representation from the field of biomaterial science, potentially impacting the accurate valuation of advanced medical devices.

PROVIDER PAYMENTS AND INSURANCE

Providers, upon utilizing a medical device, receive payments from various payors, including government insurance agencies like CMS & its MACs (Medicare Administrative Contractors) and private payors such as PPOs (Preferred Provider Organizations) or HMOs (Health Maintenance Organizations). The reimbursement process involves meticulous coordination and adherence to specific billing procedures.

ISSUES WITH HOSPITAL DISTRIBUTION

Selling a medical device through hospitals involves engaging with complex supply chain management systems operated by the hospital's Purchasing and Materials Management departments. Most hospitals will have their own confidential Group Purchase Organizations (GPOs) through which the manufacturer should strike a purchase deal after convincing their Value Analysis Committee (VAC). There is no systematic approach to organizing and monitoring this committee of every hospital system to value an advanced medical device. Mostly, it is orchestrated by nurse practitioners and purchasing managers who may not be qualified people to assess the value of advanced products, especially those biological products meant for tissue regenerative applications.

ANTICIPATED ROLE OF SFB

With all due respect to the AMA and their evaluation process for a medical device along with our respect to the hospital purchasing system, we Biomaterial Scientists should take precedence to influence the system to assess the biological efficacy and safety evaluation of a medical device especially that involves tissue repair and regenerative application. Recently even the rulings of CMS related to one of the LCDs (Local Coverage Determinations)

Industry News (Continued)

were overthrown by a special interest group. Similarly, our Biomaterials group should have a stronger hold and power to express our knowledge towards updating the current flaws in recognition of a biomaterial-based device. This is the reason the author of this article underscores the need to establish a Consortium comprising Clinical Associations and Basic Scientific Societies, such as our SFB, to aid the FDA in assessing Safety & Efficacy, and assist the Centers for Medicare & Medicaid Services (CMS) in delivering a more equitable Commercial Valuation for Tissue Regenerative Medical Devices. Otherwise, the public might miss the opportunity to choose an appropriate biomaterial device for their medical applications.

CONCLUSION

The path to medical device commercialization is loaded with complexities, confusing the providing doctors and nurse practitioners specifically from the reimbursement procedural points of view. Navigating these challenges requires a deep understanding of the regulatory landscape, billing intricacies, and the influence of key stakeholders in the healthcare ecosystem. SFB should be in a position to advocate the manufacturers of advanced medical devices and the relevant government regulators to strategically approach each step to ensure fair recognition and reimbursement of any innovative technology product.

CALLING ALL BOOKWORMS!

If you'd like to contribute a review of your recent favorite read to the ***Biomaterials Forum***, send it for consideration to the Editor at ***Roger_narayan@ncsu.edu***. If it's approved, it will be published in a future Forum Book Review column!