

A Guide to US Reimbursement for Drugs, Medical Devices, and Diagnostics



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Boston Healthcare Associates

Boston Healthcare Associates is a life sciences consulting firm whose mission is to help emerging and established companies gain competitive advantage in an increasingly complex health care marketplace. Boston Healthcare provides reimbursement, market strategy, and business development services to biopharmaceutical, medical device, and diagnostics clients worldwide. Through its EXPERTech division, Boston Healthcare also offers companies complete FDA regulatory and quality systems services, helping clients to obtain regulatory approval and secure manufacturing and design control compliance. In addition to its Boston headquarters, the company has offices in Phoenix, Research Triangle Park, and London.

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CHAPTER 1: THE 2006 REIMBURSEMENT GUIDE

Reimbursement—The Key to New Medical Technology Commercialization Success

Many companies focus on Food and Drug Administration (FDA) regulatory approval to the exclusion of reimbursement, which is often relegated to an afterthought. However, reimbursement is a key ingredient in assessing value and is applicable at all stages of a product's development. Reimbursement issues can and should be addressed over the entire technical development continuum, yielding an innovative company a better understanding of market value, commercialization strategies, and the tactics necessary for success.

There are many ways to address reimbursement when a new medical technology is launched. Often there are similar technologies or procedures on the market that serve as predicates for determining the initial reimbursement environment for a new technology. Other times a technology represents a shift in the standard of care that will necessitate implementation of new coverage policies, codes, and payment rates. Ultimately, before product launch, it is the responsibility of the developer to understand whether it is developing a “next generation” versus a “truly new” or “novel” technology. It is the distinction between next generation and novelty products that eventually impacts how the new technology will be received and adopted by all stakeholders from payers to patients.

An innovative company can secure a competitive advantage prior to product launch when the company integrates reimbursement into its product development plan. Alternatively, if a product's commercialization plan fails to address any or all of the reimbursement components (coverage, coding, and payment) it will severely impact that technology's adoption and use. When hurdles do arise during the early stages of commercialization following product launch, they are most often a result of inadequate planning and are sometimes more difficult to overcome because of concomitant pressures such as the need to meet predetermined sales forecasts. Troubleshooting issues that directly impact the company's ability to achieve these forecasts prior to product launch and identifying any potential barriers to reimbursement can make the difference between the products that succeed in the market from those that fail.

Covered products with explicit reimbursement pathways are more likely to be used by providers than products with limited or no coverage. Once positive coverage is obtained, the marketer must also ensure the availability of identifying codes for the product and its corresponding procedures. If possible, the marketer should support the provider in the claims submission process—improper coding is often the cause of a payer's delayed or denied payments to providers. Finally, even when coverage and coding is secured, a poor associated payment can strike a blow to a product's utilization and uptake onto the market—making the valuation of a

product or service by the payer an area that must be supported through a strong body of clinical and cost utility literature.

The clinical utility of a product is always going to be of paramount concern, but even good products sometimes fail to overcome issues regarding reimbursement. The easier a manufacturer can make it for the physician to use and, finally, gain reimbursement for the product, the more likely the product will move to the top of the decision pathway. Repeated delays in payment and denials from payers are often easily rectifiable, but if not addressed, can result in a decrease in provider utilization and ultimately, manufacturer revenue.

Why an Update?

In 2003, when Boston Healthcare Associates (BHA) began the task of compiling a comprehensive, illustrative guide to aid pharmaceutical, medical device, and diagnostic innovators and other industry stakeholders through the complex quagmire of reimbursement—where business strategy and government regulation intersect to play equally important roles—there could be no way of predicting how rapidly the environment would change. While it is true that the regulatory landscape is seldom stagnant, it took a special confluence of events to create the political show of force, compromise and bipartisanship needed to pass the most widespread changes to the Medicare program since its inception. On December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 ushering in sweeping changes, the most monumental being the first ever Medicare outpatient prescription drug benefit. In the following chapters, this Guide retains all of the basic reimbursement concepts detailed in the original published in August 2003, but incorporates the principal changes the MMA has already wrought and documents the many changes to come.

Medicare's influence on the reimbursement arena is mammoth. Its policies and trends are important not only to the technologies intended for use in the Medicare population, but also for technologies funded almost entirely by private payers. For good or ill, Medicare decisions act as bellwether for other payers, causing all those interested in the United States (US) health care system as a purchaser, vendor, innovator, middleman, or user to sit up and take notice.

Like the original Guide, this version is not intended to be an all-inclusive examination of the US reimbursement system, but rather a general overview and handbook for the medical products and services industry representatives interested in reimbursement. We believe that the new updated Guide will provide readers with both a comprehensive introduction to the concepts of reimbursement, as well as practical tools and suggestions the reader can use at any stage of the reimbursement process.

Style and Organizational Changes

The Guide has been divided into nine chapters plus appendices. Each section can be used alone or in combination with the others, depending on the individual reader's needs. The Appendices, for example, are intended to be used as reference tools both for the experienced reimbursement professional and the unlucky individual, who out of necessity (in an organization with no prior reimbursement experience) is tasked with figuring out "reimbursement" for their company, simply because no one else volunteered.