

The 10 Biggest Mistakes Manufacturers Make When Seeking Reimbursement for Their Medical Device

L. Neal Freeman, MD, MBA, FACS, CCS-P

Medical device manufacturers find it is worth the effort to dedicate significant resources to reimbursement issues. The path to successful reimbursement will be considerably eased if you avoid the mistakes described below.

Mistake #1

Not understanding the rules of the game.

The rules and regulations surrounding Medicare reimbursement for a new device are complicated, but are available for review. Much of the information is available on the Medicare website, www.cms.hhs.gov. Private payers follow their own protocols. Access to this material from private payers varies significantly depending on the payer.

Mistake #2

Failure to generate a coherent reimbursement strategy.

In the reimbursement arena, planning is everything. A carefully-conceived reimbursement strategic plan is required to establish all preparatory steps and to optimally time the stages in the process. It is best to ensure that the entire strategy is in place first and to temper the urge to immediately submit inquiries and applications.

Mistake #3

Failure to distinguish between coding, coverage, and payment.

The three prongs of reimbursement are coding, coverage, and payment. All three must be satisfactorily addressed. If one or more components are missing, reimbursement will be slow, inadequate, and/or burdensome to obtain. Pursuit of these areas must be coordinated. Often, progress on one or more of the components is limited by lack of progress along one or both of the other two components.

Mistake #4

Not having a reimbursement team/payer access team.

A device manufacturer should establish a reimbursement team that will be responsible for creating, modifying, and implementing the reimbursement strategic plan. The team need not be large, but designating individuals to carry out this task highlights the importance of this function. Payers appreciate, and frequently respond favorably to, a well-defined group within the company that deals with reimbursement.

Mistake #5

Lack of communication between the reimbursement team and the rest of your company.

Frequently, departments and/or key individuals within a company are essentially unaware of the efforts being made in the reimbursement arena. Poor internal coordination between the team and the rest of your company will hamper all external reimbursement efforts. Regular updates between the reimbursement team and sales representatives, marketing personnel, and financial staff must be maintained.

Mistake #6

Going into battle without clinical ammunition.

Payers are looking for evidence that a new device will improve the condition of patients and compares favorably with existing treatment options. Approval from the final governmental body can be considered a requirement. A complete list of peer-reviewed articles should be assembled. A clinical trial is typically considered as the ideal, but will not be required in many circumstances. Supporting information may include previously-conducted technology assessments. Experiences outside of the United States will be interpreted variably by payers, but will not replace American literature.

Mistake #7

Not confirming support from key sources before moving forward.

Payers will look to expert sources when making reimbursement decisions. Identification of these sources is important to success. A typical source is the medical specialty society or societies with the greatest familiarity with the device or condition in question. Physician thought leaders are another source, as are representatives to the Medicare Carrier Advisory Committee. Knowing where your device stands with these and other sources is invaluable in the approach to the process, especially with regard to timing.

Mistake #8

Failure to provide necessary education to payers.

A continuous educational effort needs to be undertaken. Regular educational contact with payers can result in an initially favorable coverage response, or reversal of a negative policy. Cost savings (immediate and/or long-term) that would accrue to the payer as a result of the device should be highlighted. The goal is to establish trust between the payer and the manufacturer based on active exchange of accurate and useful information.

Mistake #9

Not knowing how to respond to a negative initial decision.

Not all initial reimbursement decisions will be favorable. Although playing catch-up is to be avoided, an initial negative decision often should be followed by a repeat attempt or attempts by the manufacturer incorporating appropriate modifications.

Mistake #10

Not getting help to navigate the process.

Today's economic environment has created especially daunting reimbursement challenges. The situation is frequently complex and the stakes are high. Consequently, engaging the help of an expert is usually well-advised. Confirm that those helping you through this process are knowledgeable, practical, and able to grasp the nuances of coding, coverage, and payment related to your device.

L. Neal Freeman, MD, MBA, FACS, CCS-P is a practicing ophthalmic surgeon who provides expert services in reimbursement for medical devices including coding, coverage, and payment. He is the President of Coding and Physician Reimbursement Analysts, Inc. and serves as a consultant and expert witness in medical reimbursement and compliance, with an emphasis on eye care. Contact Dr. Freeman at www.CPRAnalysts.com, or call (321) 253-2166.