

Surveying the Reimbursement 'Landscape'

Address coding, coverage policies, payment methods, and other reimbursement questions early in a device's life cycle.

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The purpose of this article is to demystify the reimbursement process by providing the eight critical steps required for the reimbursement of any medical device.

Step 1: Reimbursement Landscape Report

This step always reminds me of my 10th grade math teacher, who repeatedly asked us to organize the mathematical data in the problem we received before aiming to solve it. The same applies here. First, it is essential to clarify the reimbursement data that are relevant for your product.

It is essential to determine where your product will be used. The setting in which your product is used will affect the reimbursement mechanisms that apply. For example, the same treatment, provided to the same patient, may be subject to different coding systems, coverage policies, and payment methods when it is furnished at the hospital than when it is furnished at the physician's office.

Here are the questions you need to answer about relevant reimbursement mechanisms:

- What types of coding systems may be used to identify your product? From the various types of coding systems (e.g., ICD, CPT or HCPCS in the United States, or OPS, EBM or GOÄ in Germany), it is important to verify the one that applies to your product.
- What are the relevant coverage policies, limitations, and guidelines? Will the use of your product be limited to a certain age group, to a certain facility, or to a specific indication, for example?
- What are the relevant payment methods that may be used for your product? You need to verify which of the various types of payment methods (e.g., MS-DRG, physician fee schedule or DMEPOS fee schedule in the United States, or G-DRG, EBM, or GOÄ in Germany), will be relevant for your product.



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Figure 1. The eight critical steps to reimbursement. (click image to enlarge)

You also need to examine the applicable reimbursement mechanisms. Are there any existing codes, coverage policies, and payment methods that could be utilized by your product? After identifying the relevant information, search for the specific codes, coverage policies and payment methods that may be used for the reimbursement.

The completion of the above steps allows for the development of an initial reimbursement strategy. In a nutshell, in case all the required reimbursement mechanisms (codes, coverage policies, payment methods) are available, there is no need to contact the reimbursement decision makers, or RDMs. The relevant decision makers are the healthcare providers and the patients.

Once your company has established the reimbursement landscape, then comes Step 2.

Step 2: Sales Tools

In theory, since all the relevant reimbursement mechanisms for your product exist, immediately after receipt of FDA clearance or the CE mark, healthcare providers may bill for your product and obtain reimbursement. In order to convince them to do so, we typically develop the following documents:

- Value story. This document demonstrates the clinical and economic benefits of using your new product, compared with existing alternatives.
- Economic model. This document empirically supports the value story.
- Billing guide. This document helps your customers' bill payers when using your device.

Naturally, some "evidence" in the form of clinical trials and published articles should be used to convince healthcare providers of your product's clinical and economic benefits. However, the level of evidence required is much lower than the level needed to convince the RDMs.

In case all, or some, of the required reimbursement mechanisms are not available, RDMs must be persuaded, in addition to healthcare providers and the patients.

In this case, we turn to Step 3.

Step 3: Evidence Planning

If the reimbursement landscape report conducted in Step 1 shows that your company needs to develop specific codes, coverage policies, or payment methods for the new product, the company should prepare the following supporting evidence tools for the relevant decision makers, or RDMs.

- Value story. This is similar to the value story described under Step 2 above. However, this value story would be written from the perspective of the reimbursement decision makers, such as coding entities, payers, and payment committees.
- Economic model. This tool is similar to the economic model described under Step 2 above, but again, this economic model would be written from the perspective of the reimbursement decision makers. In addition, if required, this economic model will also identify specific additional outcome data that should be added to the clinical study protocol.
- Clinical study protocol. In order to verify that the planned clinical study could be used to derive the required “evidence” for the reimbursement process, we typically review and add reimbursement-related points to the clinical study protocol.

Steps 4–6: Evidence Development

Now you are ready to start developing the evidence to convince the RDMs. This will require:

- Conducting the clinical study.
- Publishing articles that substantiate the claims in the value story.
- Achieving an adequate user base (centers/procedures.)

Steps 7–8: Application for Reimbursement

Once you have the relevant stakeholders’ support from medical societies, key opinion leaders, and the like—and assuming CE mark/FDA clearance has been granted—you are ready to formally apply for new and specific reimbursement mechanisms for your product.

Securing a new code, obtaining new coverage, or being assigned to new payment level may take a couple of years. There are, however, some methods that allow for interim reimbursement of your product even before your company formally completes this step. This is done typically on a case-by-case basis.

Recommended Time Frames

As can be seen from the eight steps above, addressing reimbursement questions should start relatively early in the product’s life cycle. Starting with Steps 1 and 2 or 3 only after the product development has ended, or after finalizing clinical trial protocols, may result in the following real-life examples from our customers:

- Problematic FDA/CE applications. It should be noted that the shortest regulatory path does not necessarily lead to optimal reimbursement. One of our customers had to reapply for a 510(k) FDA clearance because the one the company applied for prevented the product from being reimbursed.
- Wrong features. Incorrect product features impede reimbursement, making the device expensive and delaying market introduction. Minor modifications to a product’s features (e.g., the number of sensors installed) at the early development phase may make the difference between fitting into existing reimbursement mechanisms and having to develop specific reimbursement mechanisms for the new product.
- Unnecessary trials. Some of our clients that have already completed a clinical trial that was used to obtain the FDA or CE regulatory approvals did not gather data that should have been provided to payers. These clients sometimes have to repeat clinical trials just to add information that could have been included in the initial trial at no extra cost.
- Wrong applications. Some products can address different applications. Selecting the appropriate application at an early stage can make the difference between fitting into existing reimbursement mechanisms and having to develop new and specific ones.

By taking the described step-by-step approach for handling reimbursement issues, device companies may be able to:

1. Shorten the time to generating substantial sales with their product.
2. Reduce the costs associated with overcoming reimbursement hurdles by making the right strategic decisions early on and by combining clinical studies to serve regulatory as well as reimbursement purposes.

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