MEDICAL DEVICES REIMBURSEMENT: AN INTRODUCTION

After reading this Fact Sheet you should:

- Understand the principles of reimbursement and why it is so crucial.
- Have links to related resources.

Refer also to Fact Sheet "Medical Device Reimbursement: US, EU and UK".

Medical device innovators should understand the importance of reimbursement and that it should be dealt with early. Also, become familiar with **'value-based' healthcare** and **health technology assessment** (HTA).

What is reimbursement?

Reimbursement, in the context of medical devices, is the payment by a public or private insurer or 'payer' to a health care provider for the costs the provider incurred in using a medical device or in performing a procedure. If a device is reimbursed it is said to be 'covered'. Reimbursement mechanisms constitute mainly three constituents.

- Coverage criteria: The payers' motivation or willingness to pay for a certain device or procedure.
- Device or procedure 'code': An alphanumeric symbol, used to identify the device and/or procedure in order to facilitate smooth communication between payers and healthcare providers.
- Payment rate: The amount that will be paid by payers following the use of the covered device.

A 'fourth' constituent is the 'care setting', as reimbursement mechanisms are setting-specific. For example, a device such as a blood pressure monitor could be used in a hospital inpatient setting, in an ambulatory setting (e.g. physician's office), or even in the patient's home. And depending on the setting where the device is used, different coverage criteria will apply, different codes will be reported, and different payment rates will be assigned.

HERE is a useful article entitled "What is Healthcare Reimbursement? Definition, Models and Resources".

Why should I think about reimbursement now?

A healthcare provider's ability to offer new technologies depends on whether the new medical device can be covered as reimbursable or not, and what that coverage amount is. This in turn affects a device manufacturer's ability or willingness to provide the device. There is an increasing burden for medical device innovators to provide insurers and healthcare providers with evidence of clinical and economic effectiveness to inform a coverage decision, and consequently innovators may be deterred from the sheer cost and effort of developing and bringing new technologies to market.

In today's world medical device companies need to start engagements with payers and providers early on in the product development process, and indeed often must lead the reimbursement process to increase the chance of product acceptance and coverage. To underline this point, investors have reimbursement at the top of their list when considering investment opportunities, therefore it should be one of the first things innovators think about when developing new products.

Where do I start?

The first step in planning for reimbursement is to identify the setting/s in which your device will be used. Then you can determine if your device fits within an existing reimbursement mechanism (code, coverage and payment rate), and if so, reimbursement is theoretically immediately possible. Alternatively, you will need to embark on the process of developing new reimbursement mechanisms (new code, new coverage criteria, and/or a new payment rate). This

requires presentation of specific clinical data to prove the clinical and economic benefits of your device, and you will need to establish an initial user base per country and harness the support of the local medical community. This process could take years and is costly. Alternatively, innovators may instead choose to modify their device features, functionality or specifications in order to instead fit under existing reimbursement mechanisms. In the latter category, it is easy to see why early reimbursement planning is critical: If a device company leaves reimbursement planning until after product design and/or clinical trials there is a risk either or both may have to be repeated if its product does not satisfy existing reimbursement codes, coverage and payment rates it was planning to use. This will lead to additional costs, delays to commercialisation and a reduced return on investment.

What are other important things to consider?

Code ≠ reimbursement: In order for a device to be reimbursed, the relevant decision-makers (typically payers) must first decide whether they will cover the device and if so, how much they will pay for it. To complicate matters, new devices seldom achieve national reimbursement from the start. Often the device company may have to start at the level of an individual hospital that may have a budget to acquire certain technologies or serve certain patient cohorts. Or certain payers or charity funds may allocate a portion of their budget to new technologies for the benefit of their members. It is most-times a long and arduous journey for manufacturers to establish their initial user base and gather real-life health economic and clinical evidence before convincing other providers and payers. The importance of early discussions with providers and payers cannot be overstated.

Decision makers: If your device can utilise existing reimbursement mechanisms payers do not have to be involved. Physicians and hospital management become your main decision makers, but you must be able to provide compelling evidence of the clinical and economic benefits of your device versus the currently available alternatives. Hospitals or physicians can then purchase your device and bill for it under existing reimbursement mechanisms. Conversely, if new reimbursement mechanisms need to be developed, payers will have to be convinced of the clinical and economic benefits of covering the use of your device before they agree to develop the required reimbursement mechanisms. It's important to realise that provider and payer decision makers will view clinical and economic benefits from their own organisational standpoint, therefore clinical studies and economic models should be designed with the main decision maker in mind.

Think global, act local: Developing new reimbursement mechanisms is almost impossible without harnessing the support of the local medical community and developing an initial user base. In addition to your KOLs, initiate a two-way engagement with local medical societies and advocacy groups as their support when applying for new codes will be helpful. In terms of an initial user base, some countries have formal national programs to encourage the introduction of innovative medical devices prior to reimbursement. In other countries regional hospital grants (e.g., Italy and Spain) or even support from charity funds (e.g., the UK) may be utilised to help with establishing this initial user base. Recently, a new "Innovation Fund", which provides funding for particular projects, was established in Germany, which may also be used to generate required evidence and help in establishing an initial user base.

The EU is diverse - are some EU countries more attractive than others?

Each EU country maintains its own reimbursement mechanisms, and so reimbursement in one EU country does not imply reimbursement in another. Criteria to consider when choosing the initial country markets might be **market size (health expenditure)** and **ease of the reimbursement process**. In this way, manufacturers might typically start with Germany and the UK as their first markets, followed by France, Italy and Spain as the second tier. Alternatively, you may be working with a healthcare provider or clinical collaborators in a particular EU country and may therefore choose this as your beachhead market based on relationships and traction you have already established.

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