

The Impact of Medical Device Reimbursement on Cost, Innovation and Health Outcomes



Reimbursement, broadly defined, is repayment of a person or organization, which has expended money and in which the amount reimbursed reflects perceived value. In the medical device segment of healthcare, reimbursement refers to the payment to a healthcare provider by a third party public or private insurer for payments or costs the provider incurred while using a medical device or performing a procedure. In some countries, this process is called something other than reimbursement, such as payment by result. The amount a medical device or procedure is reimbursed, and, moreover, whether a device or procedure is covered as reimbursable can have an important impact on a healthcare provider's ability to purchase a manufacturer's medical technology.

Medical device reimbursement policy can have a significant impact on a healthcare provider's ability to access innovative medical technologies. GE is committed to delivering these technologies to address key clinical gaps. However, the clinical community's access to advanced technologies and solutions is limited by a variety of policy challenges associated with medical device reimbursement. While these challenges vary by country, common challenges include a misalignment between the value of a technology and reimbursement levels, cuts in government healthcare spending, higher requirements for evidence of clinical effectiveness for coverage, and opaque and complex reimbursement processes. These policy challenges limit or delay the ability of healthcare providers to access medical technologies that peer-reviewed studies have shown can help deliver better clinical and economic value. In addition, these challenges create disincentives for medical devices companies' innovation because uncertainties about coverage for reimbursement make it difficult to predict whether investments in new technologies will provide sufficient returns. GE supports the adoption of flexible reimbursement policies to address these policy challenges which will help lower costs, encourage innovation and improve health outcomes. Such policies should match reimbursement with the value of technology, be developed transparently and with predictable processes, encourage investment in advanced technologies, help drive a shift in healthcare emphasis from treatment to early diagnosis, and leverage global best practices.

Overview of Reimbursement Policy Challenges

Misalignment between the value of a technology and reimbursement levels

Among the major reimbursement policy challenges is the fact that in many countries reimbursement rates are cost-based but not value-based. In most countries, reimbursement rates are set or recommended by a governmental body consisting of clinicians or government officials that determines what the reimbursement should be for the use of a certain medical device or procedure. These decisions often rely on standing formulas that are applied to device or procedure types, rather than individual manufacturer's technology or features. If a medical device is recognized by the reviewing body as having a sufficient health benefit in its own right there will be reimbursement for the use of that specific medical device. In other cases, if the use of the device is seen as being a resource in part of a procedure, then there may be reimbursement or payment by result for the entire medical procedure. In many countries reimbursement amounts are the same regardless of the age or level of the technology, which means reimbursement reflects the cost of using a device or performing a procedure but not value of the technology used, even where there are more advanced offerings within a specific technology type. Instead these boards determine average rates at which these procedures or devices will be reimbursed. Often this average reimbursement amount will be too low for healthcare providers to purchase advanced medical technologies. Yet, as will be discussed in greater detail below, having access to these technologies can lower costs and improve health outcomes over time. In addition, inadequate reimbursement rates

mean that companies cannot earn the revenue needed to invest in developing new more advanced technologies, which could lead to better health outcomes in the future. Matching reimbursement levels with the value of medical technology, or vice versa, is essential to ensuring access to advanced medical technologies and future medical innovation.

Cuts in government healthcare spending

Another challenge is cuts in government healthcare spending. With rapidly aging populations in the U.S., EU, Japan, and China, governments around the world are looking for ways to prevent healthcare costs from growing too high. Among the ways governments believe they can control healthcare costs is by cutting healthcare spending and reimbursement amounts. Some governments have cut back on reimbursement for medical devices, which typically account for 6-7 percent of overall healthcare spending, according to the Global Medical Technology Alliance (GMTA). For example, in the United States, Congress cut medical imaging reimbursement by 12 percent in 2005. Since that time Congress has cut medical imaging reimbursement a further 12 times during which time the medical imaging industry has seen its revenues decline by 35%, according to the National Electrical Manufacturers Association.

Even while some governments have been cutting medical device reimbursement, evidence suggests that investing in medical device technology is clinically and cost-effectively sound. For example, a 2005 study in the journal *Radiology* found that every \$1 spent on inpatient imaging leads to \$3 in total savings and every \$385 spent on imaging decreases hospital stays by one day, contributing to a cost savings of \$1,172 a day.¹ Other studies that show the economic and clinical value of medical imaging include:

- Ultrasonography has yielded savings of more than \$4,000 per patient by reducing the occurrence of unnecessary, invasive breast cancer procedures.²
- Computed tomography (CT) angiography can save an estimated \$1,455 per patient by reducing unnecessary cardiac catheterizations.³
- CT and integrated positron emission tomography PET/CT have led to a 6.7% reduction in all cancer mortalities, including a 20% reduction in lung cancer alone.⁴

These statistics are but a small portion of peer-reviewed literature, which shows the benefits of access to medical imaging technologies. More evidence from peer-reviewed studies is included in the Medical Imaging Technology Association (MITA) report, "The Economic and Clinical Value of Medical Imaging," which is attached to this white paper. Sufficient investment is needed to ensure patients and healthcare providers can access medical technologies, which can contribute to costs savings and improved health outcomes.

Increased evidence requirements for reimbursement coverage

An additional reimbursement policy challenge is increased requirements for evidence of the clinical and economic effectiveness in the coverage decision process. This relatively new phenomenon means that governments are paying more attention to the cost- and

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1. Beinfeld et al. "Diagnostic Imaging Costs: Are They Driving Up the Costs of Hospital Care?" *Radiology*. 2005 June; 235(3):934-9
 2. Lee MC, Eatrises J, Chau A et al. "Consequences of Axillary Ultrasound in Patients with T2 or Greater Invasive Breast Cancers" *Annals of Surgical Oncology*; 18 (1): 72-77.
 3. Goldstein JA, Chinnaiyan KM, Abidov A et al. "The CT-STAT (Coronary Computed Tomographic Angiography for Systematic Triage of Acute Chest Pain Patients to Treatment) Trial." *Journal of the American College of Cardiology* 2011; 58 (14):1414-1422
 4. Aberle DR, Adams AM, Berg CD, et al. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening." *New England Journal of Medicine* 2011; 365(5):395-409.

clinical effectiveness before granting reimbursement coverage to new medical technologies. This development is understandable given concerns about containing rising healthcare costs while improving patient outcomes. Therefore, companies increasingly recognize the need to be able to provide evidence of the value of new technologies for which they are seeking coverage. While such requirements may be rational given concerns about controlling costs, they should be implemented in such a way that does not place significant costs on medical technology companies. When developing such requirements governments should avoid creating too high of a burden for medical device companies such as requiring a full health technology assessment. Such a burden would divert company resources from investing in developing new innovative technologies which can contribute to better health outcomes in the future.

Opacity and complexity of reimbursement process

The opacity and complexity of the reimbursement process can be another challenge which limits access to advanced technologies. In many countries, the reimbursement process involves many stakeholders with which companies need to interact. Further, there are not always formal channels to work with government bodies that set reimbursement policy, or these bodies may not be accustomed to working with industry. In some countries, decisions regarding reimbursement amounts and coverage can be opaque, lengthy, and unpredictable. When companies invest in new innovative technology without knowing how much reimbursement will be for a technology, it is difficult to decide on the level of investment for a certain market.

To address these issues we support transparent reimbursement policies, which allow for input of various stakeholders. In addition, we encourage timely decisions on reimbursement amounts on coverage. Governments should provide some mechanism to enable companies to predict adequate level of investment aligned with the future reimbursement trend. Such steps would ensure that governments can have a full range of perspectives when making reimbursement decisions and that healthcare providers can access advanced technologies in a timely manner that may in turn improve health outcomes and reduce healthcare costs.

Potential Reimbursement Policy Models

While in many countries there are a variety of reimbursement policy challenges, Australia and Japan have adopted policies which help address these issues and could serve as models for other countries. Reimbursement in these countries is based on a differential payment system, which reimburses different amounts based on either technology (Japan) or age (Australia). These reimbursement systems have been adopted because the Japanese and Australian governments saw that their existing reimbursement policies were pushing up rather than driving down costs and limiting access to new technologies rather than increasing it. In addition, they understood that increasing access to the most advanced health technologies would contribute to better health outcomes in their countries. Finally, they took the view that innovation was not being sufficiently rewarded in a system where no distinction was made between new, advanced technologies and old, lower-end equipment. The reimbursement policies Australia and Japan have adopted offer models of the kind of differentiated reimbursement system that lowers costs, improves health outcomes, and encourages innovation.

Reimbursement Policy Principles

Given the reimbursement policy challenges that have been identified above, in order to lower costs, improve health outcomes, and encourage innovation, governments should be encouraged to adopt the following principles in regards to reimbursement policy:

1. Align reimbursement amounts with the value of medical technologies

In many countries there is a misalignment between reimbursement rates and the value of medical technologies. This fact means that healthcare providers and patients are often limited in their access to gaining the most advanced medical devices. In order to address this issue, we encourage governments to adopt reimbursement policies which are value-based rather than cost-based. By doing so, providers will have better access to medical technology, which can improve health outcomes and lower costs while rewarding innovation.

2. Maintain or increase reimbursement for medical devices

Governments across the world are understandably trying to contain healthcare costs from growing too high. In particular, governments should avoid cuts to reimbursement for medical imaging devices, which can limit access to medical devices which can save money and lives.

3. Implement value evidence requirements in the least burdensome manner

In order to contain costs, governments are paying closer scrutiny to evidence of clinical and cost effectiveness as part of the reimbursement coverage decision. This development is understandable because of governments' goal of reducing costs while improving health. However, when developing such requirements, governments should avoid creating too high of a burden for medical device companies. Such a burden may inadvertently divert company resources from investing in new technologies which could contribute to better health outcomes in the future.

4. Establish transparent reimbursement processes that allow for stakeholder input

At present, the reimbursement process in many countries can be opaque, difficult for various stakeholders to have a voice, and unpredictable. The complexity of this process puts additional costs on companies and makes it difficult to anticipate the outcome of reimbursement decisions. We support more transparent reimbursement processes which allow for greater stakeholder involvement. In this way, we believe that reimbursement processes can be better understood by all stakeholders involved.

5. Move from treatment to early diagnosis and preventive care

With increased health spending in aging societies, governments should consider a fundamental paradigm shift towards incentivizing early diagnosis through reimbursement, such as by screening for breast cancer.

6. Learn and share global best practices

While each country's healthcare system differs and healthcare is seen primarily as a domestic policy issue, countries should look to learn from each other about best practices. As has been discussed, there are several reimbursement policy challenges which are shared by many countries. Learning from other countries, especially countries with effective reimbursement systems, should be a consideration for health policymakers. Governments should consider supporting technical and industry exchanges on reimbursement so global best practices can be better shared and understood.

While policies may vary by country, we think the principles set out here may serve as a basis for reimbursement policy discussions around the world. By following these principles, countries may be able to reduce costs for their healthcare systems while helping their citizens live healthier lives.

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