**Health Economics: The Perspective of a Prosthetic Manufacturer**

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**ABSTRACT**

Health economic evaluations of pharmaceuticals and subsequently medical devices were introduced in the early 1990s and have since developed into a standard decision-making tool for payers to appraise the value of new health technologies. To the prosthetic and orthotic industry, health economics is still a new concept that may help overcome the limitations and restrictions of the current reimbursement system by driving the discussion with payers and their coverage decisions from a purely price-based to a value-based perspective. However, to move the industry in that direction, manufacturers would have to make substantial investments in qualified staff and research funding. This paper gives an overview on how iterative health economic modeling could be implemented and how it would transform current research and development processes of prosthetic manufacturers. It would add another aspect to decision making, allowing to identify the most cost-effective option among several potential development projects, or even to terminate development of devices that have no chance to ever be cost-effective. The adoption of health economic methods would probably also have a dramatic impact on the manufacturer community and the marketplace as a whole. Bigger companies that are able and willing to afford the cost to generate clinical evidence and health technology assessments would probably introduce fewer innovations that are supported by better evidence than today. Smaller companies that are unable to absorb the cost would likely have to cooperate or focus on products that fit in the limitations of the current reimbursement system. As a result, we would probably see fewer innovations and many more me-too products. However, that situation would underscore a challenge that innovative manufacturers are already facing today. Payers demand high-quality evidence for new devices but tend to extrapolate the benefits demonstrated for the predicate device to similar, yet-unstudied components. That puts innovative manufacturers that invest in clinical and health economic research at a business disadvantage against technology followers. Therefore, policy makers are advised to hold individual components to comparable standards of demonstrated performance when making decisions on coverage and reimbursement.

**INTRODUCTION**

Health technology assessments (HTAs) seek to synthesize information on the clinical, economic, social, and ethical value of health technologies with the aim of informing the formulation of safe and effective health policies, particularly in regards to coverage and reimbursement decisions. In many areas of health care, health economic and budget-impact analyses were introduced in the early 1990s and have since developed into a standard decision-making tool for the appraisal of pharmaceuticals. Subsequently, medical devices and clinical procedures have followed suit, adopting and modifying the methodology to their specific needs. As medical devices differ considerably from pharmaceuticals, there is still research to be conducted to find the optimal HTA approach to these technologies. A generic application of current international HTA pharmaceutical guidelines to medical devices is widely considered inappropriate, because these methods overlook important differences between drugs and devices.1, 2

To the prosthetic industry, however, health economics is a fairly new concept. Companies need to realize that a steep learning curve, similar to that which began about 15 years ago with the rather late adoption of clinical research, is necessary to keep or gain coverage and reimbursement of advanced prosthetic components.

Although health economics is not yet a widely recognized component of prosthetic and orthotic health care provision, the increasing need to allocate limited resources within health care budgets combined with the growing medical needs of aging populations and rapidly advancing medical and technological innovations will inevitably require informed coverage and transparent funding decisions. Thus, manufacturers and providers are well advised to prepare for this foreseeable new challenge in a timely manner. This paper aims to discuss strategies for and likely consequences of the adoption of health technology assessments on research and development (R&D) processes and the general market environment from the perspective of a prosthetic manufacturer.

**CURRENT REIMBURSEMENT SYSTEM CHALLENGES TO PROSTHETICS IN THE UNITED STATES**

Currently in the US health care system, health economic studies are not a standardized part of the decision-making process for prosthetic coverage, issuance of new L-codes or patients´ access to treatment.

In fact, the US reimbursement system for prosthetics does not encourage or facilitate the fast adoption of new prosthetic technologies. To a certain extent, this situation is due to the fact that clinical research and demonstrated patient-related outcomes associated with innovative prosthetic components have only recently been requested or required by payer communities and thus represent a relatively new challenge to many manufacturers.

Additionally, the vast majority of prosthetic components are class I medical devices that are not regulated by the FDA and thus do not require regulatory studies to access the market. Therefore, efficacy and effectiveness outcome parameters are generally evaluated only after market introduction. In this setting, patient-related outcomes often depend on the training and experience of the health care service provider, many of whom are frequently uninterested in or incapable of aggregating large outcomes databases.

Furthermore, many prosthetic manufacturers are rather small businesses that are unable to absorb the investments necessary for high-quality research with greater numbers of components or patients. Rather, they are in the precarious position of risking large investments that may not even guarantee reimbursement in a predictable time frame.

Additional confusion occurs when an entire class of prosthetic devices, such as microprocessor-controlled knees, is appraised by payers using the existing evidence that has just been created for a single device in that class, extrapolating the evidence to other, yet-unstudied devices.2 Such settings assume beneficial outcomes of some products in the same class that have not yet been demonstrated. Thus, there is actually no proven value to establish value-based payments for these components.

Ultimately, the field needs to determine whether manufacturers or payers will initiate health economic assessments. There are several examples of health care systems around the world that bear the cost of economic evaluations with study data provided by the manufacturer, such as Germany, Austria, France, and the UK. In some countries, such as the UK and France, it is even possible to grant limited coverage of devices for the purpose of systematic data collection for health economic appraisals of the technology.

**HEALTH ECONOMIC ANALYSES MAY HELP SUPPORT FUTURE COVERAGE OF TRUE INNOVATIONS**

Health economic analyses should primarily be performed for truly innovative products or those with high budget impact on the health care system in order to justify the efforts of the industry. This requires a well-developed research plan with scientific objectives that are relevant and beneficial to patients. As this is so important, it is desirable to have a transparent interaction process with payers to obtain their perspective on what information is needed and which advancements are seen as valuable. Several such evaluations may culminate in an accepted standard health economic model that can guide smaller companies and payers in the future.

The goal should be to move coverage and reimbursement discussions from purely price-based decisions to value-based health care considerations that overcome the current barriers of capped reimbursement that attempts to force innovative technologies into existing codes for established components, leaving little or even no room for the appropriate reimbursement of truly innovative components with proven clinical benefits. The adoption of health economic evaluations in the prosthetic market in the US may enable a transition from that current confusion, inconsistency, and discouragement to a future stimulation of true health care innovation.

Following the initial introduction of an advanced technology into the market place, most functional improvements are achieved by software improvements that require substantial research and development (R&D) investments by manufacturers. However, the CMS Healthcare Common Procedure Coding System (HCPCS) workgroup considers “software enhancements” an inherent part of the microprocessor feature of respective L-codes that do not warrant additional reimbursement or the establishment of new L-codes. Shifting from a price-based to a value-based discussion may help change this perspective. This will become increasingly important as patients are fit with greater numbers of microprocessor-controlled components.

In addition, the current coding system for prosthetics in the US mostly describes hardware components or functions in a very general way and verifies products following a Yes/No principle without acknowledging different levels of technology or function. For instance, L5845 [“stance flexion feature, adjustable”] does not distinguish between prosthetic knees that just allow for stance flexion for shock absorption during level walking and those knees that allow for enough stance flexion to descend slopes and stairs with reciprocal gait. Although the function provided by these knees is very different, their reimbursements are the same. Therefore, valid research should be incentivized by the opportunity to establish new codes that reflect differences in technology and function more appropriately.

Another positive effect of the adoption of health economic analyses based on more and better-quality research would be that marketing claims would become increasingly evidence-based rather than engineering-, marketing- and sales-driven as they are today.

**VALUE-BASED HEALTH CARE—THE NEXT LEVEL OF PAYING FOR OUTCOMES?**

Health technology assessments for medical devices evaluate the outcomes of the product in question. However, in the majority of the assessments, the device is only one part of the entire treatment regimen. For that reason, new approaches focusing on the full set of patients´ health outcomes in relation to the total costs of care for the patients´ condition are starting to become mainstream.3 It remains to be seen whether this may be a valid future concept for prosthetics.

**STRATEGIES TO IMPLEMENT HEALTH ECONOMIC ANALYSES IN THE R&D PROCESS OF MANUFACTURERS**

For most prosthetic manufacturers, development of new components has traditionally been driven by engineers who were intrigued by certain technologies that they wanted to utilize to create new and improved products. The same is true for further improvements of existing products. In contrast, relevant input from clinicians on specific patient conditions and patient needs and concerns have often been marginalized, if not ignored. While this approach has resulted in a number of fabulous and very successful components, it has also yielded complete development failures. Clinical research departments are usually confronted with more or less finished products and are tasked with demonstrating the clinical and health economic benefits rather than driving technology development. It is reasonable that the development process should start with patient needs, allowing research departments to generate those patient-relevant outcome parameters required for health economic studies to demonstrate cost-effectiveness.

In addition, there is a need for broad epidemiological data as well as cost data to be available for running a model on real-world direct and indirect cost assumptions from the payer’s perspective. For the societal perspective, these would include productivity data, control of disability, out-of-pocket payments, need for personal assistance, domestic services, assisted living or in-home nursing care, and disability benefits. These limitations notwithstanding, several studies in Sweden, Italy, the Netherlands, and the United States have demonstrated favorable cost-effectiveness of microprocessor-controlled knees.4-8

A new requirement to demonstrate cost-effectiveness of new prosthetic components would necessitate the adaptation of R&D processes and substantial investments in human resources as well as funding of health economic research projects. A comprehensive market access plan that includes economic analyses would be of paramount importance to approach market introduction and maintenance of a product in a valid manner.

There are several strategies to implement health technology assessments in a product´s life cycle. Currently, an HTA is performed if requested by payers in the process of appraising a product. Ideally, manufacturers would have to implement iterative approaches to generate health economic data on innovative products and use them in three ways:

First, to allow for the estimation of potential cost-effectiveness as part of the investment decision process to avoid investing in a technology that is unlikely to ever be cost-effective;

Second, to prioritize between competing possibly cost-effective concepts or technologies;

Third, to identify from early stages of development those parameters that have the largest impact on the likely cost-effectiveness of the product in order to direct limited research funds.5

Early HTA is used to inform manufacturers and investors about the design and management of a technology as well as the regulatory and reimbursement strategy. The suggestion is that an HTA process may also have an impact on the initial medical device design, specifications, and thus performance. This wider definition is the focus of most of the recent work on early HTA.9

In addition, many HTA agencies have developed specific organizational structures and processes for the handling of their evaluations of devices and developing guidance for the application of HTA methodologies to take into account the specific aspects of medical devices.1

**HEALTH ECONOMIC MODELING IN EARLY-STATE DEVELOPMENT**

Medical device manufacturers often start off their development process with a concept or prototype and try to make a “business case” for it. This includes costs of development, resource requirements, and justification for the project. The definition of the “ideal patient” is often not finalized even after market introduction. Because the route to commercialization of a device is impacted by regulatory and reimbursement requirements, most companies operate some variant of a staged decision-making process with regular reviews and decisions as to whether and how to proceed. At each stage, the decisions are based on a combination of objective information and subjective opinions regarding costs and potential future patient benefits of the product. Though attempts are made to remain as objective as possible, much early decision making is based on beliefs, and in the vast majority of cases, no formal economic evaluation takes place until a relatively late phase in the development process.10-14

In the early stage of the development process, there is usually very limited availability of clinical and economic data, which creates considerable challenges to the use of standard health economic methods to inform decisions. At this stage, the company may need to choose among a number of possible alternative directions to move the project forward. In the absence of data on the needs and value related to new technologies, the analysis can only be based on epidemiological data and the available evidence for the benefits and shortcomings of the current technology that the new device aims to substitute or will compete with. This may be supplemented by expert opinions and assumptions regarding the likely impact on cost and effectiveness of the new device.

As a result, the estimated increased incremental effectiveness of the new device can only be compared to a given or assumed willingness-to-pay threshold of health care payers. When the manufacturing company has determined the potential cost of the new product, this can be used to perform a so-called headroom analysis by comparing it to the acceptable reimbursement level based on the willingness-to-pay threshold for incremental effectiveness. The main limitation of this development stage is the challenge of obtaining realistic assessments about variables for which no evidence yet exists.

However, there is a growing body of research into how to elicit expert knowledge accurately and reliably.16 In the field of medical devices, there may also be relatively good information on the performance of previous device generations from earlier studies.17 With early data on health outcomes of value, a preliminary evaluation of cost-effectiveness at different pricing scenarios for varying patient populations with different indications may be carried out. Ideally, the pricing should match the clinical value to avoid an unfavorable reimbursement scenario in which a new product may end up in an underfunded niche market or be limited in its ultimate use by coverage restrictions.10-14 As health economic modeling is expensive, companies should consider setting up a model that informs decision making for all development stages as well as an after-market launch. It may also be advisable to publish the model prior to the market introduction of the product if there is no generally accepted model for the indication targeted.

**HEALTH ECONOMIC MODELING IN MID-STAGE DEVELOPMENT**

At the mid-stage of the development process, observational studies may provide some clinical evidence on the benefits of the product and some initial cost estimates may become available. This new but still limited data can be used to update the previous beliefs and assumptions derived from expert interviews. However, the process should be supplemented by expert opinion based on extensive experience to develop optimal clinical assumptions to establish a clinically meaningful model. This addition may help reduce rejection by HTA bodies when the new evidence is based on uncontrolled, small trials that may not be representative for the whole patient population.13

Early exchange with payers to formulate a valid economic research question and to incorporate clinically meaningful outcome parameters is highly recommended. A value-of -information analysis (VOI) could provide insights into the value of conducting further research and highlight the variables in the model for which additional information would be most valuable. Such VOI analysis can help reduce uncertainty and, thus, the probability of making a costly wrong decision.19 While the process of collecting further information to reduce uncertainty carries a cost, this must be weighed against the probability of making the wrong decision. This could include abandoning a device that payers would have eventually decided to reimburse, or proceeding with a device that payers would have ultimately decided not to reimburse.

Given the increasing complexity of HTA techniques, this mid-stage becomes more demanding in terms of model inputs as health economic models should be run with robust evidence only. A substantial effort may be required to elicit and apply plausible assumptions and distributions to parameters. The analyses in this stage usually apply an iterative process that is refined at several points in time and enables the aggregation of evidence from a wide range of sources. In each step, the last estimate of a parameter value that emerges from a refinement becomes the basis for the next step or round of refinement.10-13

**HEALTH ECONOMIC ANALYSES IN LATE-STATE DEVELOPMENT**

Currently, health economic analyses conducted in the late development stage are usually designed to inform health care payers about the cost-effectiveness of the technology to make the case for its reimbursement. Ideally, these coverage and reimbursement decisions should be based on a model regarding incremental effectiveness and corresponding costs supported by evidence derived from randomized controlled studies20 with reasonable patient numbers. It is necessary to have certain required outcome parameters, such as health-related quality of life, incorporated in the model. These should then be formally assessed in studies to make the most efficient use of research resources. Cohort databases can be valuable resource for disease-oriented modeling, service pathways, probabilities, and long-term outcomes. Applicable techniques should be used to combine randomized and observational evidence, taking into account the different nature of data sources and potential bias. Meta-analyses that simply pool data from all sources are likely not appropriate, but systematic reviews are a well-accepted resource. Health economic research guidelines provide very detailed tutorials on the data input requirements for modeling.

**LIMITATIONS TO HEALTH ECONOMIC MODELING AND ANALYSES IN THE DEVELOPMENT PROCESS**

Notwithstanding the appeal of health economic modeling, there are some potential caveats that need to be considered. First, because these techniques are not simple and require a substantial level of expertise, the cost and time involved in these analyses may act as a barrier to their implementation into the development process. Second, a critical element remains that, at any given stage, decisions are made based on analyses that contain the best knowledge available at the time. Third, it has to be acknowledged that there may be limitations to the interpretations that can be derived from early-stage evaluation due to both the learning curves and the fact that innovation in medical devices is often a process of continuous incremental improvement.21 Therefore, early interaction of all stakeholders in the development cycle is strongly recommended.18 Refining the health economic modeling across the entire development process could inform an early prediction of potential revenues and the optimum price based on the estimated likely cost-effectiveness in daily practice. The commercial analysis of the new product would thus build on the features of the cost-effectiveness analysis, but would also require additional information on production cost, scale, and so on.10-13

Finally, because health economic modeling and analyses are currently uncommon in R&D processes, prosthetic manufacturers are advised to benefit from the experience of pharmaceutical and implantable medical device companies to shorten the learning curve and minimize waste of investments.

However, an important limitation to health economic analyses is the ultimate determination of the “willingness to pay.” Thus, in times of restricted budgets, even a well-performed economic study does not automatically lead to coverage and reimbursement of a product.

**LIKELY CONSEQUENCES OF THE ADOPTION OF HEALTH ECONOMIC EVALUATIONS ON THE MARKET FOR PROSTHETIC COMPONENTS IN THE UNITED STATES**

As stated above, the adoption of health economic evaluations in prosthetics would require a substantial expansion of clinical research including development and adherence to quality standards and validated outcome parameters. Thus, manufacturers would have to invest considerably in qualified clinical and health economic research staff and funds. Given the current structure of the prosthetic manufacturer community with its many smaller businesses, this will present a substantial challenge. Therefore, the likely consequence of a requirement to conduct health economic analyses in prosthetics would be a further partition of the manufacturer community into a smaller group of bigger companies that are able to afford the research investments to support innovations. It is also conceivable that an increasing requirement for health economic evaluations drives collaboration and cooperation, and perhaps even concentration of manufacturers by mergers. Smaller companies that are unable to absorb the additional investments required would likely have to focus on the development of products that fit into the limitations and restrictions of the current reimbursement system. This may include the development of products within established reimbursement portfolios at lower cost than the established standard components. Although this would be a positive effect on the market, all manufacturers are aware of how difficult it is to pursue such a strategy, especially for companies based in developed countries with comparatively high wages and salaries.

However, even the group of manufacturers that are able and willing to support their innovations with health economic research will likely have to make some tough decisions. Clinical and health economic research is expensive and can therefore not be done for every new product. Thus, manufacturers will have to decide which of their products and R&D projects they want to support with this additional investment, leaving some of their products or even entire product categories vulnerable to unfavorable reimbursement decisions or even removal from the product portfolio.

Another challenge that may arise is that some products may deliver their biggest benefits with a good incremental cost-effectiveness ratio to a relatively small group of patients. While payers tend to grant coverage of a product preferably for these smaller patient groups, the smaller market size could possibly become unattractively small. Under such circumstances, it appears quite likely that most manufacturers would stop such projects at some point in the development phase. This phenomenon of disappearing innovation in small markets is well known from the pharmaceutical industry.

Thus, the likely consequence of a broader adoption of health economic evaluations in prosthetics would be the development of considerably fewer, yet better evidence-supported innovations and many more me-too products for bigger patient groups.

The “me-too” product development model could become an even bigger challenge to innovative manufacturers in the future. Initially, innovative companies invest heavily in clinical and health economic research with their products, paving the way to coverage and billing codes for new product categories. Other companies wait until this infrastructure has been established, and then launch me-too products that fit the billing codes and coverage criteria, claiming equivalence with the predicate device without comparable evidence. As these manufacturers save the substantial expenses for clinical and health economic research, they are usually able to offer their devices at a lower price than the predicate device. Given the comparable reimbursement of the predicate and subsequent devices, this creates a competitive advantage for me-too manufacturers and makes it more difficult for innovative companies to recoup their R&D investments.

Therefore, increasing requirements for demonstrating clinically meaningful patient outcomes and health economic evidence may be perceived as a short-term advantage but long-term disadvantage for manufacturers that are willing to make the necessary research investments. However, a positive development can be observed in the European Union that now regulates product entrance in the market by requiring clinical data generated for every individual product and continuous post-marketing patient safety monitoring. This precludes the manufacturers of me-too devices from simply claiming equivalence with predicate devices. A similar model would be required in the US to maintain the fiscal incentives of research-supported innovation. This would be in the best interest of patients, suppliers, providers, and health care payers, as the vast majority of prosthetic devices are currently not regulated by FDA research requirements for safety and effectiveness.

**SUMMARY**

Manufacturers of prosthetic components must recognize the increasing prevalence of HTAs in medical device manufacturing. The requirements for demonstrated evidence are only beginning to surface. Ultimately, considerable transparency between the payers and their willingness-to-pay threshold for valued clinical benefits will enhance the willingness of manufactures to pursue continued innovation at a sustainable cost model. As the emphasis on demonstrated clinical efficacy and value increases, policy makers are advised to hold individual components to comparable standards of demonstrated performance to ensure that the costs of development in this value-based model are born equally across all component developers and manufacturers.

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