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Evolving Reimbursement And Pricing Policies For Devices In Europe And The United States Should Encourage Greater Value

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ABSTRACT Rising health care costs are an international concern, particularly in the United States, where spending on health care outpaces that of other industrialized countries. Consequently, there is growing desire in the United States and Europe to take a more value-based approach to health care, particularly with respect to the adoption and use of new health technology. This article examines medical device reimbursement and pricing policies in the United States and Europe, with a particular focus on value. Compared to the United States, Europe more formally and consistently considers value to determine which technologies to cover and at what price, especially for complex, costly devices. Both the United States and Europe have introduced policies to provide temporary coverage and reimbursement for promising technologies while additional evidence of value is generated. But additional actions are needed in both the United States and Europe to ensure wise value-based reimbursement and pricing policies for all devices, including the generation of better pre- and postmarket evidence and the development of new methods to evaluate value and link evidence of value to reimbursement.

Given rising costs of health care and limited budgets, jurisdictions worldwide are increasingly concerned with getting better value from health care investments. This quest for value is especially evident in the case of health technologies, such as pharmaceuticals and medical devices, which account for a growing proportion of health care expenditures in almost all countries in the Organization for Economic Cooperation and Development.¹

The United States spends more on health technology per capita than does Europe, without evidence of commensurate gains in health outcomes.¹ A range of factors influence the higher US spending, including higher prices paid for technologies; a larger volume of certain procedures, such as hip and knee implants; a greater

supply or use of hospitals and doctors; and the possibility of more readily accessible technology.^{2,3} For example, in 2009 the rate of knee replacement in the United States was about 75 percent higher than the Organization for Economic Cooperation and Development median.¹

One way Europe has been able to maintain lower spending levels is through the use of national coverage, reimbursement, and pricing policies that place an emphasis on cost containment, efficiency, and affordability.^{4,5} Historically, European countries have employed various approaches, such as reference pricing, price-volume discounts, price cuts, and centralized purchasing, to meet these ends.

Over the past ten years, however, European decision makers have shifted their focus from

simple cost control to obtaining better value from investments made in new interventions.⁶ Consequently, most European countries have established some system of health technology assessment to apply in conjunction with the other policy tools. These value-based programs evaluate and weigh the available evidence on the clinical and cost-effectiveness of select interventions to determine their value for money. The evidence is then used to inform or guide national and regional coverage and reimbursement—and, in some cases, pricing—decisions.

Although the United States has traditionally failed to exercise a similar cost-conscious approach toward health technology, US policy makers and other stakeholders are increasingly focused on transforming the health system into one that seeks value, especially in light of current economic difficulties. For instance, the Affordable Care Act made substantial investments in comparative effectiveness research and in other reforms that promote value in Medicare payments and delivery systems.

To date, however, comparative policy analyses and the overall discourse about health technology reimbursement and pricing in the United States and elsewhere have focused on pharmaceuticals. Given the growing number and complexity of medical devices on the market, the time is ripe to examine reimbursement and pricing policies relating to those technologies.

This article compares such policies in Europe and the United States, with a particular focus on considerations of value. We also explore various policy initiatives, some of which have already been implemented in the United States and European countries, to better support value-based device reimbursement and pricing.

Device Reimbursement And Pricing

EUROPE In Europe coverage and reimbursement of devices typically occurs through publicly financed national health care systems. Such systems cover approximately four-fifths of the populations of the four largest device markets: Germany, France, the United Kingdom, and Italy.⁷ In principle, all member states are equal. Market approval of a device in one country should provide access to other markets through the Conformité Européenne marking process, which denotes that the device is safe and functions according to the intended purpose described by the manufacturer.

In practice, however, institutional arrangements for financing differ among countries, which can result in divergent coverage, reimbursement, and pricing decisions for a particular device.^{8,9} In France, for example, a centralized

body makes reimbursement decisions after assessing the safety and effectiveness of individual devices. Similar bodies in England and Germany conduct broader assessments of device types or procedures and include other considerations, such as cost and cost-effectiveness. In contrast, coverage and reimbursement decisions in Italy and Spain are delegated to the various regions, which apply their own methods and requirements.

Prior to making coverage decisions, European jurisdictions typically require that high-risk, innovative, or costly devices, such as implantable technologies, undergo a health technology assessment. An example of this process is the assessment of coronary stents by the UK National Institute for Health and Clinical Excellence.

In its appraisal, the institute considered clinical trial evidence and cost-effectiveness data submitted by several manufacturers and an independent assessment group. Based on the evidence, the institute recommended use of the device only in a subset of patients at high risk for restenosis (see the online Appendix).¹⁰

The health technology assessment processes required by each country differ with respect to the methods, evidence, and criteria used to determine coverage.⁶ However, all countries require that a device demonstrate therapeutic benefit, such as improved morbidity, mortality, or quality of life. In some countries, such as England and the Netherlands, evidence of cost-effectiveness is also required and measured against a value for money threshold.

In some cases, the available evidence for a particular device is insufficient or inconclusive to support a coverage determination. Consequently, some European countries, including England, France, and the Netherlands, have established policies that offer restricted coverage for patients enrolled in studies designed to collect better data on safety and effectiveness. Once enough evidence is generated, the coverage decision is revisited to determine whether coverage should be extended to a broader patient population, restricted to certain patients, or removed altogether. For example, the National Institute for Health and Clinical Excellence has applied its “only in research” policy to laparoscopic surgery for colorectal cancer and endovascular stent insertion for intracranial atherosclerotic disease.¹¹

Once coverage is determined, most European countries use prospective payment systems to determine reimbursement rates. In some cases, these payments reflect value, such as when a new diagnosis-related group or payment amount is calculated for a new device that is based on evidence or guidance from health technology

assessments or other sources. However, because payment systems in many countries are updated infrequently, they may not adequately reimburse new technologies, especially those that are particularly innovative or costly. The lack of sufficient payment may provide a disincentive for hospitals to adopt and use new devices that may be beneficial, because the payment amount is below actual costs.¹²

To address this issue, Germany, the United Kingdom, France, Italy, Spain, and Sweden have introduced separate or supplementary payments to provide partial or total reimbursements for potentially beneficial devices until they are fully captured by the payment system, either through a new diagnosis-related group or an increase in the reimbursement price.¹² Such payments are negotiated nationally or locally with manufacturers, hospitals, or other local authorities, and they are generally temporary, lasting two to three years. Most of the countries using this approach—particularly Germany, the United Kingdom, and France—consider evidence of therapeutic benefit and, in some cases, cost-effectiveness to determine whether a technology is eligible for the short-term payment.

Although hospitals are encouraged to collect evidence on the health outcomes and costs associated with a new medical device during the temporary payment period, there is limited evidence available to substantiate whether this is achieved. To date, these payments have been applied to drug-eluting stents, gastric bands (for weight loss), cochlear implants, and hip and knee prostheses, among other technologies.

For low-risk and typically low-cost devices, such as crutches and incontinence pads, coverage and reimbursement are generally determined at the hospital level or through centralized public purchasing arrangements. In many countries, including France, Germany, and England, hospitals are increasingly entering into collaborative purchasing partnerships to negotiate lower prices, and they are encouraged to do so by their respective departments or ministries of health. Either way, reimbursement prices are derived through reference pricing for similar existing devices or through a competitive public-tender process.¹² Unlike more complex, higher-cost devices, these types of devices do not normally undergo a health technology assessment to determine value.

UNITED STATES Similar to other areas of health care in the United States, coverage and reimbursement for devices are the responsibility of both public and private payers. The Centers for Medicare and Medicaid Services (CMS), the largest public payer, provides coverage for the vast majority of devices once they earn approval from

the Food and Drug Administration. After approval, most devices do not require a formal coverage determination, partly because of Medicare's prospective payment systems—diagnosis-related groups for inpatient care and ambulatory service categories for outpatient care. These payment mechanisms, which bundle items into an episode of care, allow payment for new technologies that offer incremental improvements over existing technologies or services. In effect, the provider simply determines coverage within the constraints of the fixed prospective payment.

For a limited number of devices each year, however, CMS conducts a national coverage determination. Although there is no coherent policy framework for activating national coverage determinations, this process is typically prompted by new technologies with major clinical or economic impacts—such as implantable cardioverter-defibrillators—and important new evidence, substantial variation in local coverage decisions, or concerns about inappropriate use. All other explicit coverage decisions are made locally by the private insurance carriers with which CMS contracts to administer Medicare coverage.

National coverage determinations are made through an evidence-based process, which besides CMS's own research is supported by evidence from manufacturers, physicians, and other entities, such as the Agency for Healthcare Research and Quality. In some cases, coverage determinations may also be made via consultation with the Medicare Evidence Development and Coverage Advisory Committee, which provides independent and expert advice to CMS on various clinical issues. Such evidence is used to determine the degree of benefit conferred by the devices compared to standard treatment alternatives. Unlike processes in some European countries, national coverage determinations do not explicitly require or consider evidence of cost-effectiveness, which has proved politically controversial.¹³

Despite these procedures, designed to improve CMS's ability to make informed decisions about the underlying value of a technology, existing evidence suggests that in the majority of cases, positive national coverage determinations are based on poor or limited evidence from clinical studies.¹⁴ However, in cases where technologies offer promise but have been inadequately studied to support a national coverage determination, CMS can approve coverage of a device under a clinical trial or another protocol, such as an observational study or patient registry, until the required evidence is amassed. This approach, called "coverage with evidence development," has been applied to a few devices

Private payers are increasingly considering evidence of value to support formulary and tier placement decisions.

to date, including implantable cardioverter-defibrillators, angioplasty of the carotid artery with stenting, cochlear implants, and left ventricular assist devices.

For local coverage determinations, depending on the technology or service considered, local administrative contractors make decisions relying on an evidence base that ranges from no evidence to peer-reviewed randomized controlled trials,¹⁵ which may be one reason why local contractor coverage often varies considerably.

The amount paid by Medicare is determined through a prospective payment for an episode of care or a retrospective fee-for-service payment for the actual service, or device, provided. With limited exceptions, CMS does not currently consider a device's comparative effectiveness or its cost relative to alternative treatment options in its pricing. Rather, payments are based on estimates of average cost for the provision of the particular device or bundle of care.

Similar to the situation in Europe, some beneficial yet costly new devices used in US inpatient care may be granted separate "add-on payments" to account for the high cost of new technology relative to the base diagnosis-related group payment and to encourage providers to adopt the technology.¹⁶ To receive these payments, devices must be new and high cost, and they must substantially improve the diagnosis or treatment of beneficiaries, compared to existing treatment alternatives. In such cases, the devices might offer a treatment option for patients unresponsive to current therapy, diagnose conditions that are currently undetectable, provide meaningful impacts to patient management, or substantially improve clinical outcomes. Similar payments, called "pass-through payments" and employing the same eligibility criteria, are used for devices provided in the outpatient setting.

For add-on payments, Medicare pays an amount equal to 50 percent of the additional

costs of treating a case using the new device, which is capped at 50 percent of the estimated cost of the new technology. Pass-through payments are made equal to 100 percent of the reported costs of the new device minus the device costs already built into the base payment rate. A device is eligible for an add-on or pass-through payment until data reflecting its costs are used to recalibrate the appropriate diagnosis-related group weights, generally two to three years after the new technology has entered the market.

Add-on payments have been extended less frequently than pass-through payments. Fewer than ten technologies have been approved for add-on payments, while pass-through payments have been made for more than a hundred different device categories. The majority of add-on payments made to date have been for implantable medical devices, while a wider range of devices have received pass-through payments.

Private payers cover about two-thirds of the US population. There is considerable diversity among insurance plans' coverage and reimbursement policies. Private payers sometimes look to CMS national coverage determinations to guide their decisions but largely develop independent policies based on the goals of the individual plan. Private insurers also tend to make coverage decisions more quickly after Food and Drug Administration approval than does Medicare, although the speed of decisions made by private payers depends on the amount and quality of evidence of clinical benefit.¹⁷

Private payers are increasingly considering evidence of value to support formulary and tier placement decisions and in applying preauthorization or utilization reviews. For example, WellPoint draws on comparative effectiveness evidence and on input from panels of medical experts to assign existing and new treatments to one of four value tiers.¹⁸ Both the Blue Cross Blue Shield Association and Kaiser Permanente have established institutional policies and dedicated funding for in-house or external programs that generate evidence to support coverage determinations and clinical practice guidelines. Other, smaller health insurers and health plans often rely on independent research organizations to provide evidence reports on new devices and other technologies. Similar to Medicare, when evidence is considered, private payers tend to consider effectiveness, not costs or cost-effectiveness.

Devices are rarely directly reimbursed by private insurers. Rather, insurers negotiate payment terms directly with physicians and hospitals, where each medical procedure or episode of care is reimbursed at a specified or negotiated amount that must cover the price of the device

along with other items—such as supplies, labor, and facility costs—that are part of the procedure or care episode. Negotiated reimbursement amounts are rarely based on whether a technology is more effective, or easier or more efficient to use, than existing treatment alternatives.

UNITED STATES VERSUS EUROPE As highlighted in the overview, there are distinct differences in the approaches that Europe and the United States take toward reimbursing and pricing medical devices. European countries have more centralized processes for making coverage determinations than the United States, which has a patchwork of public and private payers that may employ different processes and criteria to make decisions.

Moreover, compared to the United States, Europe more formally and consistently considers value to determine which technologies to cover, especially complex, costly ones. In the United States, a limited number of devices actually undergo a formal value assessment at the time of a coverage decision, especially within the public sector. Europe also places more emphasis on accounting for cost-effectiveness. In the United States, cost-effectiveness raises concerns about the formal rationing of care and whether such analyses can adequately capture the value of interventions for different population subgroups.

There are similarities, however. Both the United States and Europe tend to use evidence of value more frequently to support coverage decisions than to guide reimbursement or price decisions. However, the United States and many countries in Europe have introduced temporary payment mechanisms to provide increased reimbursement for beneficial but costly technologies. These approaches aim to allow payers to balance the goals of ensuring adequate payment for beneficial new technologies and being prudent purchasers. For the selected number of technologies that receive such payments in the United States and Europe, evidence of therapeutic benefit plays a central role in determining eligibility. Costs are also considered, with a number of European countries also accounting for cost-effectiveness.

Finally, where evidence is applied in coverage policies, both jurisdictions are often faced with having limited information to inform decisions. The lack of high-quality evidence for making informed coverage decisions means that coverage may be provided for a new device based on fair or poor evidence or that access to potentially beneficial technologies may be delayed or denied until better evidence is available. Conditional coverage with evidence generation has therefore gained some use in recent years.

One action that European and US regulators should consider is raising the premarket evidence requirements for new devices.

Policies To Improve Value-Based Reimbursement And Device Pricing

We outline and discuss potential initiatives to obtain better value in health care in Europe and the United States, highlighting their possible advantages and disadvantages.

FOSTERING PRE- AND POSTMARKET EVIDENCE

One of the main challenges in ensuring adequate evidence of effectiveness to make coverage and reimbursement decisions is that such data are not generally required for market approval. Following recalls of articular surface hip prostheses and Poly Implant Protheses breast implants, however, the Food and Drug Administration and European regulators are now considering an overhaul of the current regulatory frameworks for medical devices with a particular focus on strengthening premarket requirements for high-risk technologies.^{19,20}

One action that both European and US regulators should consider is raising the premarket evidence requirements for new devices. Current requirements allow clinical evaluations of most new devices to be based on similar existing (predicate) technologies rather than the actual device in question, and the clinical data submitted to be based on a literature review alone. Current systems therefore reward “fast followers” that can take advantage of existing evidence about similar products that are already on the market.

Instead of simply assuming that devices of a given type are equivalent, fast followers could be required to generate the same level of evidence as exists for other devices already on the market. Discussions could take place between regulators and the first manufacturer to determine the level of evidence required—for example, a registry or a randomized controlled trial. Imposing such a

Given the expense and time involved in collecting reliable data on new technologies, more public-private collaboration would be desirable.

requirement would not only give industry an incentive to undertake clinical studies on new devices and foster a better understanding of the comparative differences between devices, but it would also enhance public health protection.

Regulators should supplement efforts to strengthen premarket evidence with incentives and, where possible, requirements for postmarket evidence generation. Premarket evidence is often not ideal for “real-world” decision making because of uncertainty regarding long-term outcomes, effectiveness in different practice settings, and benefits and risks to populations that are not well represented in clinical trials.

The various approaches to coverage with evidence development for new technologies in Europe and the United States offer some opportunities to ensure that sufficient postmarket evidence is available to inform coverage determinations. Although the coverage with evidence development mechanism has been used on a limited basis, it has provided evidence that otherwise might not have been obtained. However, substantial improvements to this approach are needed. Because coverage with evidence development has been used on a limited basis, clear and predictable criteria for its application and methods are lacking. There are also challenges in delineating well-defined funding sources to cover the large research costs and an infrastructure to collect and share data.

Coverage with evidence development should be aligned with existing mechanisms to expand electronically available health data, including longitudinal patient registries; electronic health records; and, in the United States, claims data collection and analyses. Some European countries—including Germany, Italy, Sweden, and the United Kingdom—have introduced registries, particularly in orthopedics and cardiology,

to collect postmarket data. Typically, these registries are collaboratively supported by medical associations, academic centers, and national research organizations.

Similarly, the Patient-Centered Outcomes Research Institute and the National Institutes of Health in the United States could provide support for an ongoing infrastructure for registries or clinical trials in major clinical areas. The involvement of clinicians or medical associations may prove particularly helpful, given their early involvement in device development and acquired early knowledge of particular technologies.²¹ These efforts would help ensure that the necessary data are generated to support coverage with evidence development schemes and, ideally, that better evidence exists to make informed coverage decisions in the first place.

Given the substantial expense and time involved in collecting reliable data on new technologies, more public-private collaboration would be desirable. One approach would be for payers and regulators to provide scientific advice to manufacturers to ensure that clinical studies meet the evidence requirements for both market authorization and coverage and reimbursement. Concurrent review of devices by regulators and payers could help reduce evidence generation burdens and thereby allow beneficial technologies to reach patients more quickly. In the United States, for example, the Food and Drug Administration and CMS have initiated a voluntary, two-year “parallel review” program for devices, which entails a partial alignment of their respective review processes for regulatory approval and coverage, respectively.²²

EXPLORING NEW APPROACHES FOR ASSESSING VALUE Another possible initiative would be to establish new methods for assessing the value of devices. Devices have particular characteristics that introduce unique challenges to measuring their value.^{23,24} For instance, devices undergo frequent modifications following initial development, which means that they do not “stand still” long enough during the period of randomized controlled trials to allow for adequate data collection. Moreover, accurate or effective use of devices often depends on the skills and training of the health professionals who use them, especially for those devices used in surgery.²⁴ Practitioners may acquire more expertise with a device over time—or move along the “learning curve”—even over the period of a trial.²⁵

Some of these issues can be tackled through the use of tracker trials, which begin in the early stages of technology development and follow the evolution of a device,²⁶ but these are not commonly conducted. Although not officially required by a regulator, the trial of endovascular

aneurysm repair, a procedure using a stent, is an example of a trial using this approach.²⁷

Alternative study methods might also be better suited to medical devices. Although randomized controlled trials are considered the gold standard, there is increasing recognition that alternative study approaches may be suitable in some instances. For example, the comparative effectiveness research initiative in the United States has focused attention on pragmatic randomized controlled trials, which take place in real-world practices as well as observational studies and patient registries.^{28,29}

LINKING EVIDENCE OF VALUE TO REIMBURSEMENT Value-based reimbursement, an approach increasingly of interest to US private payers, may provide a viable option to better incorporate evidence into reimbursement decisions. In a survey of employer-sponsored health plans, Niteesh Choudhry and coauthors³⁰ estimated that 81 percent of large employers plan to offer this approach in the near future.

This approach sets different reimbursement rates for different levels of clinical effectiveness, based on available evidence. It may also entail differential copayments for treatments of demonstrated high value versus those of questionable or low value, and it aims to encourage the use of services when the clinical benefits exceed the cost. The approach may likewise discourage use when the benefits do not justify the expenditure. This may also help remove financial barriers to beneficial technologies and thereby increase patients' compliance with treatment,³¹ which in turn can improve health outcomes, reign in costs, and assist in controlling total spending by health plans or hospitals. Elements of this approach could also be employed in Europe, but given the absence of cost sharing, evidence of value could not be tied to copayments.

A related strategy that could be considered is the use of performance-based reimbursement and pricing strategies that link payments to patient outcomes. For example, a certain reimbursement price may be set—and later modified—according to whether the device is used in accordance with evidence-based clinical

guidelines or produces satisfactory clinical outcomes. Using such strategies, payers may face less financial risk from the treatment of demographically different patient groups that were not included in clinical trial testing or that did not demonstrate substantial improvement.³² This approach has been used on a limited basis in Europe and by private payers in the United States, but only with regard to pharmaceuticals, not devices.

These approaches need to be applied with care, however. The few performance-based schemes implemented for pharmaceuticals in Europe have been costly to administer and marked by difficulties regarding oversight, methodological requirements, and ethical considerations.³³ Such challenges may be more pronounced in the case of devices. In addition, even in cases where the available evidence demonstrates that a device provides low value, it may prove administratively and politically difficult for payers to disinvest from the technology once it has diffused into practice.³⁴

Conclusion

Policy makers and other stakeholders in Europe and the United States are increasingly concerned with getting better value from investments made in technological innovations. One potential solution is to rely more heavily on studies of the effectiveness and costs of new technologies to inform coverage, reimbursement, and pricing decisions. Historically, such efforts have largely focused on pharmaceuticals. But with the growth in the number and complexity of devices, the United States and Europe have shown interest in applying evidence of value in coverage and reimbursement decisions, albeit with varying degrees of implementation and success.

Although these strategies are still unfolding, we have outlined a number of them that could help support the timely generation of evidence to inform value-based decisions about reimbursement and pricing for devices. Further discussion and research are needed on the various options to substantiate their effectiveness, best practices, and areas for improvement. ■

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In this month's *Health Affairs*, Corinna Sorenson and coauthors discuss medical device reimbursement and pricing policies in the United States and Europe and the evolution of such policies to focus more on value. They note that compared to the United States, European countries more formally and consistently consider value in determining which technologies to cover and at what price. However, the authors also believe that additional actions are needed in both the United States and Europe, and they set forth several proposals, including the generation of better pre- and postmarket evidence and the development of new methods to evaluate value and link evidence of value to reimbursement.

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