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Sharing Risk between Payer and Provider by Leasing Health Technologies: An Affordable and Effective Reimbursement Strategy for Innovative Technologies?

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ABSTRACT

The challenge of implementing high-cost innovative technologies in health care systems operating under significant budgetary pressure has led to a radical shift in the health technology reimbursement landscape. New reimbursement strategies attempt to reduce the risk of making the wrong decision, that is, paying for a technology that is not good value for the health care system, while promoting the adoption of innovative technologies into clinical practice. The remaining risk, however, is not shared between the manufacturer and the health care payer at the individual purchase level; it continues to be passed from the manufacturer to the payer at the time of purchase. In this article, we propose a health technology payment strategy—technology leasing reimbursement scheme—that allows the sharing of risk between the manufacturer and the payer: the replacing of up-front payments with a stream of payments spread over the

expected duration of benefit from the technology, subject to the technology delivering the claimed health benefit. Using trastuzumab (Herceptin) in early breast cancer as an exemplar technology, we show how a technology leasing reimbursement scheme not only reduces the total budgetary impact of the innovative technology but also truly shares risk between the manufacturer and the health care system, while reducing the value of further research and thus promoting the rapid adoption of innovative technologies into clinical practice.

Keywords: cost effectiveness, decision uncertainty, risk, value-based pricing.

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Introduction

The challenge of implementing high-cost innovative technologies in health care systems operating under significant budgetary pressure has led to a radical shift in the health technology reimbursement landscape. Where 10 years ago, the majority of reimbursement decisions were either yes or no, with the occasional special scheme for politically high-profile technologies, now decision makers are increasingly choosing from a menu of reimbursement strategies, as illustrated in Figure 1 [1]. The procedural justice considerations and efficient operation of health care systems mitigate against one-off reimbursement schemes. A characteristic of all these reimbursement schemes is that the risk associated with the uncertainty about the true value of the technology is transferred from the manufacturer to the health care payer at the time of purchase. Thus, the new reimbursement strategies attempt to reduce the scale of the risk of making the wrong decision, that is, paying for a technology that is not good value for the health care system, primarily by reducing the total budget impact or by creating an opportunity for the development of additional information to inform future reviews of the funding decision. A positive reimbursement decision, however, still entails significant risk and that risk is not shared between the manufacturer and the health care payer at the individual purchase level; it continues to be passed from the manufacturer to the payer at the time of purchase.

In this article, we propose a health technology payment strategy that allows the sharing of risk between the manufacturer and the payer: the replacing of up-front payments with a stream of payments spread over the expected duration of benefit from the technology, subject to the technology delivering the claimed health benefit. The article is structured as follows: The second section briefly reviews the history of innovative reimbursement schemes—the so-called access with evidence development (AED) and the move toward value-based pricing (VBP)—and discusses the extent to which these address the problem of asymmetric allocation of risk between the health care payer and the manufacturer. The third section describes the technology leasing reimbursement strategy (TLRS) and the method used for calculating the lease payment. The fourth section applies the TLRS to an exemplar cancer treatment, showing how the risk borne by the payer is significantly reduced and how this can facilitate

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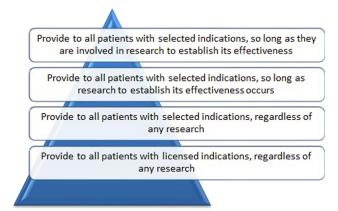


Fig. 1 – Selected reimbursement strategies ordered according to restrictiveness.

more rapid and broader patient access to new technologies by changing the expected net present value of further research. The fifth section discusses the potential value of the TLRS in the context of VBP [2].

AED, VBP, and Uncertainty in the Evidence Base

Stafinski et al. [3] recently reviewed AED schemes. They observed that although the problem that AEDs attempt to address has been around for a long time, and that most developed health care systems have been involved in at least one such scheme, there is very little evidence to suggest that they are successful from the health care payer perspective. As well as being of limited value from the payer perspective [3,4], patient advocates and manufacturers complain that AEDs restrict access to effective therapies and reduce the return on investment in developing new technologies, thus threatening future research and development.

VBP has been proposed as an alternative mechanism for promoting the uptake of new technologies [5] that avoids the delays associated with AED schemes. VBP, however, works by identifying the price at which a technology is expected to be cost-effective and although upward and downward price adjustments based on observed effectiveness allow some longer term mitigation of the costs of uncertainty, the risk of nonreturn on investment in the technology is transferred in its entirety to the health care payer at the time of payment. Hence, VBP is at best a weak policy instrument for addressing the uncertainty in the evidence base for interventions requiring up-front investment.

Because the high levels of uncertainty in the evidence for cost-effectiveness are typical for innovative technologies, a policy response is required. "Only in Research" and "Only with Research" AED schemes are the primary choices currently available to decision makers concerned about uncertainty. Hall et al. [6] have shown that Only with Research schemes are extremely inefficient mechanisms for addressing uncertainty in the evidence base because the value of the information produced will typically be much less than the cost of the scheme unless the degree of decision uncertainty or the budget impact of the technology is small. Only in Research schemes in contrast are more efficient but are politically less acceptable because of their effect on patient access to the technology. The current portfolio of policy options for allowing access to potentially valuable but highly uncertain technologies is likely to be either highly inefficient or highly unpopular. An alternative strategy that shared the risk that is inherent in funding such technologies while allowing prompt patient access would be useful.

Technology Leasing Reimbursement Strategy

Industries in which reliability of delivery is highly important, such as civil aviation, have developed payment mechanisms in which the suppliers receive payment only for delivered outputs rather than delivered technology [7]. For example, airlines buy flying time from aero engine manufacturers rather than engines per se [8]. When engines need maintenance or repair, a replacement engine is provided to maximize the time that the airline is in the air and minimize the risk that the airline fails to deliver scheduled flights. By leasing a working engine rather than merely paying for an engine, the airline pays only for what it receives. Just as importantly, the manufacturer has a strong incentive to provide surety of service because it is this service that is paid for rather than the technology itself. Although airlines enjoy other benefits from leasing engines, the ability to link payment to delivered benefits commends the consideration of leasing as a payment strategy for health care.

Although leasing is not unknown in health care, its use is limited to the provision of technologies with very high up-front costs that are used in the treatment of a large numbers of patients, such as Di Vinci surgical robots and magnetic resonance imaging scanners. The standard model in health care sees payers purchasing health care rather than health. Although treatments are not engines—we cannot return or reclaim a treatment already provided—it is feasible for payers to reimburse manufacturers for delivered healthy time rather than for the delivered technology. To a degree this happens with chronic therapies such as statins and beta blockers, where failure of the treatment (death) results in stoppage of the payment stream. For many expensive technologies such as surgical implants and cancer drug treatments, however, the link between health delivered and payment does not exist at the individual patient level.

In the context of a value-based reimbursement decision using a cost-effectiveness rubric, the question of cost-effectiveness would be established in the same manner as now. Here, costs and benefits over time are assessed, and a judgment made. Having established the price at which the technology is expected to be cost-effective, the "lease" payment due for each period of health delivered could be established by calculating a stream of payments over the expected lifetime of the technology that has the same expected net present value as the agreed price. Many such streams are possible, and there are many dimensions in which they might differ. These include whether the streams allow the price paid to increase for inflation or not; whether they limit payment to a fixed period after the delivery; and, of course, which measure of effectiveness is used to judge whether a technology has delivered the promised effectiveness. This article does not make specific recommendations about which types of stream are relevant, but chooses a case in which the price paid increases in line with discounting; that is, we assume that the price paid is adjusted for inflation and the net present value of each payment is equal. No time limit is set on the length of

The TLRS would work by paying the company for each period of health delivered at the individual patient level. If the observed mean effectiveness was equal to the expected effectiveness, then the manufacturer would receive the full value of the technology. When an individual's health experience from the technology was less than predicted, the payment would stop and thus the health care system would be to some degree protected from the risk of paying for a technology that was not in fact good value for it. Equally, if the observed effectiveness exceeded that expected in a person, the company would continue to receive additional payments for them. To this extent, the TLRS at least partially automates the VBP proposal that the price paid for a technology

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