Drug Disinvestment–Is It Needed and How Could It Work?

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Despite being conceptually appealing from an HTA perspective, disinvestment schemes have proven to be challenging for local payers to implement and realize savings. An alternative disinvestment model may be more appealing: temporarily reimbursing new treatments where evidence is available, following by funding, discounting, or disinvesting

As public healthcare budgets face increasing constraints, new health technologies face increasing evidentiary hurdles to justify investment of limited public economic resources. Several emerging classes of therapies, including chimeric antigen receptor-T cell (CAR-T cell) and gene therapies, offer transformational, potentially curative patient benefits in areas of significant unmet need and often in rare patient populations. As such, they can demonstrate positive benefit-risk ratios to regulators at earlier stages of their clinical development, when supported by less mature and comprehensive data packages. However, reflective of their transformational patient benefits, these therapies can be cost-effective at very high per patient prices.

The Institute for Clinical and Economic Review recently issued reporting, pricing Zolgensma (onasemnogene abeparvovec-xioi), a gene therapy for spinal muscular atrophy, at nearly $1.5 million per treatment using a cost per QALY gained threshold.[1] Affordability of these newer, higher-value potentially curative therapies could be better supported with disinvestment schemes that remove funding for certain low-value healthcare interventions with poor evidence of clinical effectiveness, and/or replace high-cost medicines with lower-cost alternatives with comparable efficacy, such as generics and biosimilars. However, despite being conceptually appealing, previous disinvestment attempts have faced significant challenges in their implementation. This article discusses why this is the case, whether there is a need for disinvestment, and how this could potentially work.

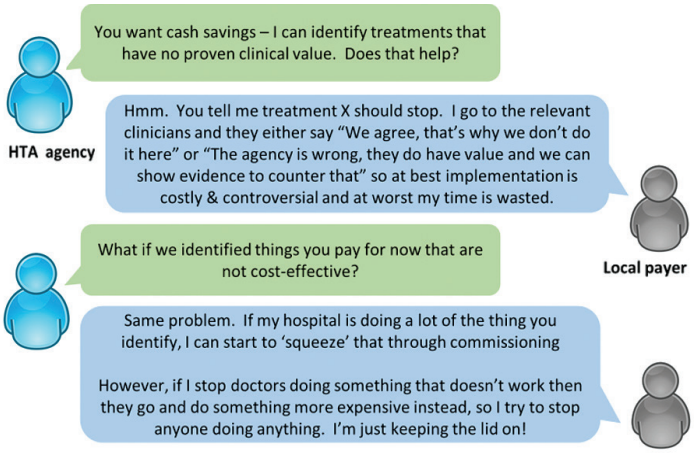
KEY CHALLENGE #1: DEFINING VALUE

Health technology agency (HTA) bodies such as the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium issue recommendations for public reimbursement of new healthcare technologies based on their incremental clinical- and cost-effectiveness. However, they do not directly influence local services, nor do they have budgetary responsibilities. Thus, implementing this guidance can be very challenging for local payers who are frequently facing significant financial constraints and for whom modelled future cost savings (especially considering when these will occur and with what degree of certainty) may not be a priority given their current budget situation. As a result, the value of investing or disinvesting in certain therapeutics may look very different to a local payer than to an HTA body.

In cases where a new lower-cost medicine replaces an existing medicine with a similar clinical profile, disinvestment is of high value to a local payer. An example of this is, disinvesting in branded products with generic or biosimilar alternatives. However, while a new medicine may appear to be cost saving from an HTA perspective by reducing future hospitalizations and other costly interventions, they are often not perceived as such from the view of a local payer. For example, new hepatitis C virus therapies have curative potential and may avert the need for liver transplants and drastically reduce liver cancer rates, but payers however may not realize these cost savings to their budget for many years after initial treatment and such therapies demand a large upfront investment. Similarly, novel oral anticoagulants may be deemed cost-effective from an HTA point of view, including facilitating disinvestment in warfarin monitoring clinics. But for a local payer, this reduction in monitoring services may have little impact on their overall budgetary spend if costs such as how much staff capacity can be reduced are not considered (most staff are on long-term employment contracts and are considered a fixed cost). Further, HTA bodies do not consider the true value of resources freed; local payers may not value releasing dermatology time but strongly value gaining intensive care time.

It is apparent that while HTA bodies may provide value as gatekeepers to help manage the costs of healthcare technologies, their investment

Figure 1. Discrepancy between HTA body and local payer viewpoints



recommendations may not be aligned to local budget holders' priorities at the frontline of healthcare delivery. Similarly, disinvestment decisions issued by HTA bodies also may not always consider the costs of redeploying resources that might otherwise bring meaningful value to a local payer and the true value of resources freed.

KEY CHALLENGE #2: IMPLEMENTATION CHALLENGES

Even when local payers and HTA bodies agree on what is considered a low-value treatment, there may be substantial challenges implementing disinvestment recommendations. If clinicians agree with such a recommendation, then they will likely not be prescribing that therapy. However, clinicians may oppose moves to preclude access for therapies for which they have direct experience of their benefits for certain patients. Even if they concurred, they may use higher-cost alternatives in its place. We illustrate this situation in an imaginary dialogue between an HTA body and a local payer (Figure 1).

While the actual dialogue may differ in the real world, in reality, cost savings from disinvestment efforts that may seem clear and evidence-based to an HTA body may in fact be nebulous and difficult to implement to a local payer. Examples of disinvestment where funding is removed for older healthcare interventions with a lack of strong evidence supporting their effectiveness tend to be less controversial. For instance, in November 2018, the NHS England announced that they will no longer fund a variety of low-value interventions, including silk garments and bath oils on which they currently spend £17 million a year.[2] However, many other previous disinvestment attempts have faced some major challenges in their implementation, particularly those reversing prior reimbursement decisions.

Conditional financing in the Netherlands was designed to be a scheme whereby orphan medicines undergo economic re-evaluation 4 years post-launch. After the first few medicines were found not to be cost-effective under this process, the draft reports resulted in public and clinician outcry.[3] Consequently, the medicines were never de-listed nor were their prices reduced. In another example, NICE attempted to revisit the recommendation of erlotinib in 2014, having initially approved the therapy in an all-comers population for pretreated lung cancer in 2008. This followed a phase 3 trial in patients who were EGFR mutation-negative that showed the generic drug docetaxel was more effective at prolonging survival than erlotinib. However, after the first appraisal consultation document restricted reimbursement of erlotinib in EGFR mutation negative patients in February 2014, there was substantial physician and patient pushback,[4] including concerns that the toxicities of docetaxel precluded it as an option for many patients. Two further committee meetings were held before final guidance reinstated restrictions in August 2014.

OR MAYBE WE NEED TO LOOK AT DISINVESTMENT IN A DIFFERENT WAY?

Disinvestment is clearly conceptually appealing but faces major challenges in its implementation that may outweigh any potential benefits. Alternatively, we may consider another disinvestment model: temporarily reimbursing innovative new technologies until more evidence is generated and then funding, demanding discounts, or disinvesting when we have a clearer idea of their clinical benefits. The newly reformed Cancer Drugs Fund (CDF) in England has enabled such a model since 2016, within which the CAR-T cell therapy Kymriah (tisagenlecleucel) was recommended for funding 10 days after European market authorization. But even this may face major challenges. If therapies are disinvested because their price is not justified by the subsequent evidence, there may be equity issues, such as introducing a time lottery whereby patients diagnosed after a certain date will not be able to access potential groundbreaking therapies. However, as of September 2019, no therapy has entered the new CDF and not subsequently been recommended by NICE. This will be the true test of this model—until then the jury is out!

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ADDITIONAL INFORMATION

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