Quickstart guide: Reimbursement in the US

How does reimbursement currently work in the US?

The system which determines what drugs are available to who, and at what price, is very complicated in the United States. There is a very complex **supply chain**, which includes a range of stakeholders including the people who manufacture the drug, deliver it to patients, the patients themselves, as well as insurers and representatives of insurers, government and large employers called "**Pharmacy Benefit Managers**", or PBMs, who act as intermediaries between the other stakeholders to adjust availability and pricing.

In a simplified system, for every **prescription drug**, the maker of that drug, the **pharmaceutical company** sets a **list price**, which is paid by **distributors**, who bring that drug to patients. Patients pay a "**co-pay**", and a **claim** is sent to the patient's **insurer**, who in turn reimburses the distributor for supplying the drug to one of their insured patients.

In reality, the system is more complex, with much of that complexity introduced by PBMs. Representing a given employer (for example an insurer, large company or a government agency), PBMs negotiate with pharmaceutical companies for a **rebate** on a given drug for their employer. The PBM passes some or all of this rebate on to their employer. The pharmaceutical company gives this rebate in exchange for having their drug favorably positioned on a **formulary**. A formulary is the list of drugs that a given employer covers, grouped into tiers. The higher the tier that a drug is placed in, the more of the list price the employer covers. This means that patients covered by that employer will preferentially be prescribed that drug. Thus in an ideal scenario, the PBM negotiates a large rebate, which means that the drug is available more cheaply to a large number of patients, while also creating more revenue for the pharmaceutical company due to the larger volume of sales. This is often not the case, however, and has been the subject of a lot of media attention.

How is the list price of a drug currently set in the US?

There are no formal rules in the US for determining the price of a drug. However, **list price** for a drug is primarily influenced by three factors:

1. The **costs incurred** to bring a drug to market
   - This includes estimates of investment for research and development, running trials to generate evidence, scaling up manufacturing and other factors
   - As not every drug successfully makes it to market, the pricing of successful drugs also considers the investment across a given company's portfolio, including those drugs that did not make it to the market

2. The **level of competition** from other companies, usually divided into three groups:
   - Medicines currently without competition, which occurs when an innovator has both market exclusivity and there are no therapeutic alternatives.
   - Medicines where multiple products compete by providing therapeutic alternatives for treating a condition (notwithstanding market exclusivity for each innovator).
   - Generic drugs with robust competition.

3. The **effectiveness** of the drug
   - This is based on estimates of the benefits it provides over the **standard of care**, and cost savings afforded by the product by preventing complications and hospitalization, which reduce the overall burden on the healthcare system.
   - A new idea is the concept of "value based agreements" or VBAs, where payment is tied to predetermined, mutually agreed upon terms that are based on clinical circumstances, patient outcomes, and other specified measures of the appropriateness and effectiveness, i.e. only where an intervention "works", on an individual basis, is it reimbursed

The basis for valuing a drug when HHS Sets its price

Although list prices are not regulated by the government in the United States, the US Department for Health and Human Services (HHS) can influence drug prices through policy and through negotiating prices for people covered by Medicare. A recent report outlines how HHS is seeking to address high drug prices in the US.

When HHS negotiates drug prices, there are two key considerations:

1. Scope
   - Does the price apply to all patients on Medicare or just a specific sub-group?

2. Value
   - At best, effectiveness research is capable of estimating the value on average for all of the units of a service or a drug combined. Under a system determining price on the basis of value, confusion about the average patient versus the patient who gains the smallest improvement in outcomes could lead to inadvertent but substantial overpayments to manufacturers. A further complication arises because of concerns about limitations associated with the most widely-used metric of value, quality-adjusted life-years (QALYs)
   - It has been proposed that personalized definitions of value, i.e. only reimbursing the supplier in cases where the individual patient can be shown to have benefited, could be a better way to approach this problem. This system, or "VBAs", has a lot of potential but is still limited by discussions over how to assess individual benefit, and how to define value

Read more about how HHS sets prices here.