executive insight
HEALTHCARE CONSULTANTS

Exploring the case for alternative access models

Public or governmental reimbursement of newly launched medicine is considered the traditional access model in several countries, and the primary focus for pharmaceutical market access efforts. Alternative access models are usually only considered when traditional access is delayed or not granted, or for specific assets and therapeutic areas, for example when it comes to rare and ultra-rare diseases.

While it is important to consider geographical differences with reimbursement (for example, what is perceived as alternative in one market may be traditional in another), there are a number of scenarios where alternative access models might provide the best pathway to market access. This is particularly true with innovative medicines – for example advanced therapy medicinal products (ATMPs) – where an alternative access option could provide:

1. Timely patient access by bridging the gap between marketing approval and reimbursement, especially if a decision with a health technology assessment (HTA) body or other payer is delayed

2. Broader access for uncovered patient populations subject to potential reimbursement restrictions that may arise due to affordability issues or clinical uncertainties. This can lead to payer unwillingness to reimburse for patients who don't meet specific criteria.
3. Limited patient access solution if traditional reimbursement is denied.

Some of the alternative access models can be identified as:

- Early access schemes that bridge the time between regulatory market authorisation and funding decisions. These solutions are variously referred to as "named patient access" and "special access schemes" with some differences in how they operate in each local market.
- Private health insurance, employer support, affordability or co-pay schemes to close funding gaps or coverage of otherwise excluded patient cohorts across a wider sociodemographic scope. These patients can slip through funding gaps for a variety of reasons, including income, age, education and other reasons that affect access to healthcare coverage.
- Conditional reimbursement with additional evidence creation (for example, real-world evidence generation initiatives) or adapted payment models to address clinical outcome or budget uncertainties, such as outcome-based agreements.

With ever-growing budget constraints and innovative medicines starting to target larger populations, payers often limit traditional access models or reimbursement to a narrower population than granted by regulatory bodies through a therapeutic indication (or label). In light of these constraints, alternative access models should be considered as an integral part of the access strategy to optimise access to innovative therapies, resulting in a win-win-win for patients, payers or healthcare systems, and pharmaceutical companies.

Why alternative models make sense

Public reimbursement of innovative products in a timely fashion and for the full population in the label is not a given anymore.

Even within the European Union and European Economic Area (EEA), where marketing authorisation of innovative products is managed through the centralised procedure,

there is wide discrepancy with regards to time to reimbursement, ranging from 128 days in Germany to over 918 days in Romania, as well as to the rate of available and reimbursed products in a country compared to the overall number of centralized approvals, which is as high as 88% for Germany or as low as 44% for Portugal, according to an EFPIA Patients W.A.I.T. Indicator 2022 Survey [1,2].

In some markets that have public reimbursement, but where coverage of innovative therapies can be significantly delayed, such as Saudi Arabia and Argentina, a segment of the patient population can afford to pay (partially) out of pocket, often getting quicker access through the alternative route than the public pathway.

In emerging markets, coverage from third party payers, whether public or private, is often limited, and as a result the patient is the primary payer[3] thus limiting access to a small number of patients who are willing and can afford to pay out of pocket.

All these market differences underscore the importance of building innovative strategies into any market access initiative to ensure a timely and broad launch success.

An asset-based access strategy

Alternative access models are especially relevant for high-cost therapies, or those assets in therapeutic areas with a perceived low unmet need or low public health relevance by payers – by way of example, diseases perceived as having more of a cosmetic impact, or for which several valid therapeutic options are already available.

For some high-cost products, reimbursement will lead to significant restrictions in use or challenges in use. This is perhaps best illustrated with advances in cell and gene products, such as CAR-T therapies. These products are highly personalised with the intent of curing as a one-and-done treatment. However, there is a high upfront cost for these therapies, which places a large financial burden on the healthcare system with unclear long-term clinical outcome.

A solution leveraged in several countries to this is outcome-based annuity payments[4] that limit the one-off cost burden by distributing payments over a longer time only if a-priori defined clinical outcomes are realised.

For products with a perceived low unmet need or low public health relevance by payers, alternative access models will need to be considered. Here we pose two examples of the types of products that present a challenge from a traditional reimbursement perspective.

The first example includes products such as the Janus kinase (JAK) inhibitor (JAKi) to treat alopecia areata, an autoimmune disorder leading to hair loss, as well as products such as glucagon-like peptide-1 (GLP-1) receptor agonists, a weight-loss medication. In some countries, such as Germany, the law prohibits reimbursement of cosmetic or "lifestyle" issues. The alternative access solution in these instances is either patients pay out of pocket to gain access to these products, or leverage private insurance that may offer cover beyond the public pharmaceutical formulary.

A second example might be a condition such as migraines, which, while not life-threatening, does have a high impact on occupational health and productivity. There are already therapies available to treat migraines and, as such, public reimbursement of more innovative therapies for prevention of migraines may be limited. For higher-cost products such as calcitonin gene-related peptide (CGRP) monoclonal antibodies or gepants, both novel migraine treatments, reimbursement criteria would take into account the severity of the patient's migraine, limiting access to patients with more severe forms of migraine, and where treatment with several generic oral preventive therapies has failed. The solution in this situation might include employer support, for example, including these novel therapies in their health insurance package to improve productivity.

A holistic approach

To ensure launch success, defined as providing fast and broad access to innovative medicines, modern pharmaceutical companies should explore, consider and incorporate innovative and alternative access models in the early development of their market access strategy in addition to pursuing the more traditional access route.

References

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