

The Future of Market Access in US

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Abstracts

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When it comes to the affordability challenge, have payers and drugmakers reached a stalemate in the US? Pricing wars continue to rage, pharma initiatives are having lacklustre impact, and payers are still not happy. At the same time, the US President is waxing lyrical about sweeping change which most of the industry expect will likely never come to fruition. In this highly-charged environment, what steps can be taken to actually move market access forward? This report steps away from the rhetoric and delves into the practicalities of how progress can really be made.

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1. Executive Summary

This report examines the critical issues facing the US public and private health insurance payer market and how the actions of drugmakers, the government, and other stakeholders are expected to shape future market access. FirstWord's research and analysis for this report identified the following key findings:

Without a regulatory body to oversee drug prices in the US, spending on medicines continues to skyrocket. With prescription drug budgets growing increasingly constrained, now more than ever drugmakers need to take steps to demonstrate value. Strategies to accomplish this goal include comparative effectiveness research, real world data studies and setting drugs at a price point that meets the needs of all stakeholders.

Value-added services are generally not considered by payers to be significantly influential in the formulary decision making process. In most cases, these

programmes are viewed simply as a marketing tactic to help build brand loyalty with patients. However, companion diagnostics – which are typically approved in connection with a new prescription drug offering – hold significant potential to influence market access decisions as they can help better identify which patients are most likely to respond to a therapy, particularly if it is an expensive treatment option.

Payers suggest that the drugmaker response to the challenges facing payers has been largely lacking. However, in recent months, several pharma companies have started to price therapies at a rate that is more reflective of other relevant treatments, as opposed to setting the highest price that they believe that the market can bear. This, paired with an increase in companies performing comparative effectiveness and real-world studies, suggests that drugmakers are attuned to payer requests for greater demonstrations of value.

The current US political climate, while fraught with uncertainty, has put a sharp focus on efforts to reduce healthcare spending. Prescription drug spending is at the eye of the storm, with President Donald Trump discussing a multitude of ideas that could significantly impact market access, including efforts to speed up drug approvals, shorten the patent life for original therapies, and even shift global pricing to align more closely with prices paid in the US.

Although regulatory approval ensures access to medicines in the US, payers are able to impose restrictions on certain drugs. In particular, the payers suggested that they could eventually impose additional restrictions in the form of lower formulary tiers, restricting availability to qualified patients, or requiring proof that the therapy in question is effective for individual patients. This could hold particularly true for therapies in expensive indications – such as oncology – as well as those where multiple treatments are already available.

Pay-for-performance tie ups between payers and drugmakers are emerging and represent an interesting strategy that could potentially curb spending. However, the relative newness of these strategies means that they are currently underutilised and more research needs to be done to ensure that they do in fact deliver cost savings as promised and to a degree that it will offset the administrative burden associated with operating such a programme.

2. Research Methodology and Objectives

The ongoing price war between payers and drug companies is not sustainable, and without a clear path forward, effective change is proving problematic. This report reveals what payers think can realistically be achieved to improve the situation for all stakeholders.

The insights presented are based on detailed interviews carried out between 5-11 September 2017 with 8 expert payers. All interviewees are based in the US.

Vice President at Molina Healthcare

Senior Director at Tenet Healthcare Systems

Vice President at Change Healthcare (Formerly Emdeon)

C-suite Executive at Healthfirst

Medical Director at Humana

Chief Medical Officer at a Pharmacy Benefits Manager

Pharmacy Director at an anonymous health insurance provider

Pharmacist and Drug Use Management Leader at a managed care organisation (MCO)

Key questions explored in this report include

What do US payers think about traditional market access tools such as price controls, reference pricing, restrictions and off-label prescribing?

How has the FDA's accelerated approval process for specialist drugs made a difference to market access?

Which elements of clinical evidence are most important for payer decision-making?

How do companion diagnostics and real-world studies influence market access

decisions?

How serious is US pharma about flexible outcomes based contracts and pricing according to payers?

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4. More reasons to buy this report

In the US, payers are looking squarely at pharma to help relieve the current drug pricing stalemate. With no formal industry plan for seismic change, the only alternative is to find smaller ways to improve market access – and that means both sides meeting halfway and working together in a positive spirit of fairness and collaboration. This isn't starting with a 'blank sheet' as there are already some strong and workable ideas on the table. But before any progress can be made, what's needed is a positive change in mood and approach and an atmosphere that is more conciliatory. Only time will tell if that is possible.

This report will enable you to

Take stock of the current market access climate in the US including the latest views on value-added services, comparative effectiveness research and fair price points.

Review the role of regulatory oversight, including accelerated approval for select drugs, and the impact this has from a payer perspective.

Determine what payers think about various pharma initiatives designed to boost market access including real-world data, companion diagnostics and patient groups.

Understand more about payer responses to non-traditional pricing models including value-based contracts and pay-for-performance initiatives.

Hear payer views on proposed political moves that will impact market access such as a repeal of Obamacare, importing drugs, slashing FDA regulations and trade agreements.

Gain insight into the future of market access in the US, including payer ideas on practical improvements and key focus areas for action.

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