Emergence of New Drug Launch Policies in the United States Managed Care System

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Abstract: *As several new drugs get approved in the market by regulatory authorities, managed care organizations used to approve them with a prior authorization requirement for immediate coverage while an internal committee makes a final recommendation. However, this landscape has significantly shifted due to dynamics in high cost and highly managed therapeutic areas which have caused impacts to budgets at these organizations. Payers now feel that they would need more time to make a final decision on the newly launched therapy. As a result, there is a greater percentage of organizations that have developed interim policies or new to market policies that place restrictions on these therapies before a final decision is made by the internal committee. From a manufacturer's perspective, it becomes important to understand and embrace these changes and shifts so that they can proactively begin planning on how they would want to ensure that their patients get access to therapies. Ultimately, manufacturers would want to start well with their launches and meet their access and coverage metrics at the 3-month, 6-month, 9-month timestamps and therefore these shifts become critical for payer marketing teams to monitor, report and take action.*

Keywords: managed care, new drug launches, life sciences, commercialization, new to market

1. Introduction

Every year, several new drugs get approved in the United States. Drugs are approved across a wide range of therapeutic classes – oncology, non-oncology, immunology, rare diseases, etc. In a healthcare system as complex as the United States, there are several stakeholders who determine access to these therapies. Providers, physicians, payers, pharmacies, pharmacy benefit managers are some of the stakeholders that are involved in the process of ensuring or limiting patient access to therapies.

Typically, once a drug is approved by the regulatory authority, and a physician prescribes the drug for the patient, the patient should be able to access the therapy. Given the role of managed care, there is added complexity to patients receiving these medications and being eligible for reimbursement to therapies.

Ideally, if a drug has been in the market for an extended period or duration in terms of months and years, the managed care organization would ensure that these drugs are placed on formularies and are subject to prior authorizations policies which would in turn dictate coverage and reimbursement to the patient. The committee that makes these decisions is commonly referred to as the pharmacy and therapeutics committee and the group which is unique to every organization may also decide not to cover or reimburse for the therapy.

However, this situation gets complicated when a drug has just been introduced into the market as the committee may not have had enough time to make decisions around coverage and reimbursement for the therapy. Prior to 2016-'17, most of these drugs were defaulted to coverage through a prior authorization requirement indicating that these therapies can be approved for reimbursement through a defined set of clinical coverage criteria. [1] Due to learnings from launches in key therapeutic areas such as Hepatitis-C, this landscape has shifted considerably, and this research review aims to explore this further. [2] This exploration is important as the recent changes and dynamics to this landscape can significantly alter patient access to new therapies and calls for planning and implementation from a manufacturer's perspective to tackle these issues.

2. Review and Results:

Due to severe budget impacts to internal payer organizations from the launches of Hepatitis-C brands where payers, or most of them covered for the drugs, they started a process of implementing new drug launch policies. New drug launch policies, also known as interim policies, or sometimes new to market policies stay true to their name in the sense that they function as interim policies. These interim policies are pre-determined agnostic of clinical indications or brands and are unanimously applied consistently across all drug launches. P&T or pharmacy and therapeutics committees thereby gain time in developing a final policy or a coverage decision.

Interim policies can either be less restrictive or more restrictive. Some examples of interim policies that are restrictive are when a drug is covered with no prior authorization requirement. In this case, the interim policy would be that the drug would be reimbursed for coverage until a final coverage policy is determined. In other scenarios, the drug may be approved by a prior authorization requirement in which scenario a drug gets reimbursed on a case-by-case basis. Although uncommon, the drug may also be approved based on a varying new drug launch policy at a payer where sometimes it may be reimbursed without a prior authorization requirement versus other scenarios at the payer where it would require a prior authorization.

However, it is important to pay attention to the restrictive interim policies. These are policies that would explicitly state that drugs are not covered at launch. While this policy may be

interim, the impact of these policies are significant as this could mean that patients may not get access to the required therapies. In addition, some of these policies may have additional restrictions in terms of a definitive period for which the therapies may not be reimbursed. Payer organizations may have exception policies that ultimately grant coverage and this may cause a delay in coverage rather than an absolute denial which allows payers the benefit of time to make final coverage decisions on the drug. [3]

3. Future Scope

In conclusion, the landscape of drug approval and patient access in the United States is multifaceted, involving numerous stakeholders such as providers, physicians, payers, pharmacies, and pharmacy benefit managers. The introduction of new drugs often brings complexities, especially regarding coverage and reimbursement decisions made by pharmacy and therapeutics committees. Interim policies, which have been implemented to manage the impact of new drug launches, can vary in restrictiveness and significantly influence patient access to necessary therapies. These policies provide payers time to develop final coverage decisions but can also delay or restrict access to new treatments. Moving forward, it is crucial for drug manufacturers to closely monitor the effects of new drug launch policies on patient access and adjust their strategies accordingly. This includes proactive planning, resource allocation, and effective communication of the drugs value. The dynamic nature of payer policies will continue to evolve, potentially influenced by advocacy groups and competitive pressures. Ultimately, ensuring patients have timely access to therapies remains a key objective in this ever-changing landscape.

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