

Utilization Management Techniques in the United States Managed Care Ecosystem

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Abstract: *The United States healthcare system tends to be complex often dominated by multiple stakeholders including payers, providers, specialty pharmacies, pharmacy benefit managers, integrated delivery providers, group purchasing organizations, apart from just the patient and the pharma manufacturers. Millions of dollars are pumped into the healthcare system to develop new therapies that treat patients with life threatening conditions such as oncology and specific rare diseases. Given the focus on dollars spent, payers and other stakeholders in the healthcare systems are involved in controlling costs for their business and they achieve this through a variety of utilization management techniques which optimize or in some cases limit access to life saving therapies. This study reviews the utilization management techniques developed and imposed the managed care organizations through formulary designs, prior authorization policies, step therapy, and other such limitations. Ultimately, it is important that the patient is the final beneficiary and therefore it is critical that all stakeholders work towards a system that is mechanized to work towards patients being able to access high-cost therapies for oncology and rare diseases.*

Keywords: managed care, formulary design, life sciences, tiering structures, prior authorization

1. Introduction

The United States healthcare system is one of the most complex systems in the entire world. Multiple stakeholders operate in this system, and it's not just limited to the patient and the treating physician. Patients, providers, payers, and pharmacy benefit managers form the core of the US healthcare ecosystem. Additionally, there are other stakeholders such as specialty pharmacies, group purchasing organizations, integrated delivery networks that all contribute to the incremental complexity in the healthcare ecosystem. [1]

The role of the payer also known as managed care organization of healthcare insurer is not to be underrated in the healthcare ecosystem. Payers are responsible for reimbursing the healthcare provider whether it is the treating physician or the healthcare institution which could be a hospital, outpatient clinic, ambulatory surgery center that are within the network of the payer. Payers reimburse their in-network providers differently from their out of network providers. Typically, in-network providers stand to gain from the payer reimbursement rates as they tend to be reimbursed higher than the out-of-network providers.

As a payer, it is important for the managed care organization to primarily control costs while ensuring that patients are receiving the treatments that they deserve in the setting that they expect. Payers are always looking to ensure that these treatments are not only effective but importantly cost-effective so that they can run their organizations successfully and meet their key performance indicators. The United States healthcare ecosystem spends millions of dollars year over year in research and development while churning out drugs that are approved for oncology, non-oncology, and immunology treatments. Several therapies are launched in the country where the treatments tend to range from a few thousands of dollars to hundreds of thousands of dollars. These specialty therapies can be orally administered, sub-cutaneous administered or intravenously administered. Depending upon the route of administration, the payer decides to cover the drug

in the pharmacy benefit or the medical benefit. [2] Pharmacy benefit drugs are predominantly orally administered and sub cutaneous administered while medical benefit drugs are intravenously administered. This distinction is important because the utilization management and reimbursement patterns will vary based on the pharmacy and medical benefit type.

When it comes to controlling costs, payers have a variety of tools at their disposal to control costs. The purpose of this study is to delve deeper into some of the utilization management techniques imposed by payers to control costs and how these restrictions may or may not serve as access barriers to patients while accessing these therapies. Most of these measures right from formulary design and tiering structures to prior authorization reviews, step edit and step therapy, quantity limits, have been in place for over several years now and their relevance and influence in controlling access to medications have only increased over time. As the importance of these utilization management techniques continue to grow with time, it becomes increasingly important for the community of life sciences professionals to understand these terminologies, techniques, and strategies in a great level of detail to effectively build holistic plans to counter these restrictions and ease access to medications for patients suffering from chronic and life-threatening diseases. [3]

2. Review and Results

Payers exists across different lines of business. Commercial payers are private insurers and represent at least sixty percent of the insured population. Managed Medicare payers are government payers that serve lives more than 65 years of age. Managed Medicaid and State Medicaid payers serve lives that may not have economical gains. In addition, health exchanges are a recent segment of payers that have emerged in the last decade in the marketplace. It is important to understand these different segments in order to truly analyze the utilization management techniques imposed by payers across these different lines of business or channels.

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Formularies are a list of drugs that are created by payers to communicate on whether these drugs will be reimbursed and if so at what level and extent to which the drugs will be reimbursed. A key part of formulary design is the number of tiers in the formulary. Each tier will typically indicate the level of copay or cost-sharing from a patient perspective. For example, commercial payers mostly have 3-tier formularies. In the commercial segment, generally tier 1 is allocated towards generic drugs where patients are required to pay zero-dollar copay or rather there is no responsibility on the patient to pay dollars out of pocket. Tier 2 is considered as a preferred tier whereas Tier 3 would be considered as a non-preferred tier. The difference between the preferred tier and the non-preferred tier is that drugs listed on the preferred tier would typically have a lower cost share than drugs listed on the non-preferred tier. Therefore, manufacturers might in some therapeutic areas and often in competitive therapeutic areas contract for positions on the preferred tiers through offering discounts and rebates because of which they would hope to increase their script volume against competition. In addition to the preferred and non-preferred tiers, there are specialty tiers where the cost share is non longer a copay but rather a coinsurance in which case the patient is required to pay a percentage of the drug's cost and carry that as their cost burden. [4]

Formulary designs obviously extends to other lines of business as well including Medicare and Medicaid lines of business. Within the Medicare system, typically, there are 5 tiers within a formulary unlike the commercial segment offering 3 tier formularies. Tier 1 within Medicare more often than not would host generic drugs. Tier 2 and Tier 3 would list preferred and non-preferred drugs while Tiers 4 and 5 would enlist preferred specialty and non-preferred specialty drugs with varying percentages of coinsurance. In the Medicaid line of business, across both Managed Medicaid and State Medicaid, the number of tiers would not cross more than 2. Formulary designs are not complicated, and it would simply be a case of whether a drug falls under the preferred tier or the non-preferred tier within the Medicaid line of business. Overall, formulary designs are an effective method employed by payers to control costs within the pharmacy benefit segment for orally administered and subcutaneous administered therapies.

Formulary design is only a part of how payers control costs. Within formularies, there are certain limitations that are imposed by the managed care organizations to limit access to therapies. For example, a common limitation required by payers is what is called a prior authorization requirement or simply PA requirement. A prior authorization requirement is essentially a set of criteria that are required by the payers for patients to satisfy prior to them receiving treatment for their diagnosis. A formulary would indicate whether a drug would be subject to a prior authorization or not. A patient would then have to indicate whether they fulfill the prior authorization criteria in a form that is required for them or the medical/office staff at a patient's office to complete. These prior authorization restrictions imposed by payers vary from therapeutic class to therapeutic class and are designed specifically for the drugs and the therapies themselves. Prior authorization criteria could indicate a variety of different

restrictions and can turn out to be especially burdensome for high-cost therapies. Prior authorization criteria can include but are not limited to dosing limitations, quantity limitations, line of therapy restrictions, diagnosis requirements, lab testing requirements, specialist requirements and are curated based on the drug's prescribing information or approved label usage. Prior authorization criteria alternatively called as utilization management criteria can sometimes be aligned with the drug's label or in other occasions be more restrictive than the label themselves. Typically, if a manufacturer competitively contracts against competition, then the payer would tend to ease out access restrictions from a prior authorization standpoint for the contracted drug and in other cases it can just turn out to be more restrictive. Prior authorization restrictions are observed across all lines of business including commercial and government payers. Sometimes Medicare policies could default to the approved guidelines or clinically applicable indications, but it is not always the case. The prevalence of these policies is also lower in the Medicaid channels. Additionally, while larger national plans have their own policies developed internally through pharmacy and therapeutics committee, smaller independent plans may not always have the infrastructure to make these coverage decisions and may default to making decisions on a case-by-case basis. Within the oncology class, one could expect these prior authorization policies to be relatively less restrictive than non-oncology or immunology classes. Especially within the immunology segment, where the competition is high, so is the degree of management imposed by managed care organizations. Rare diseases have expensive therapies that launch and therefore subject to a greater degree of restrictions with an intent to control costs. Another key utilization management technique employed within prior authorization policies is the step therapy or step edit requirement which are also sometimes indicated in the formularies. [5]

Step therapy or step edit while it may be indicated in the formularies, often are found in the prior authorization policies. A step edit would mean that the patient is required to step through another therapy prior to accessing the drug in question. A step therapy would mean that the patient would access the brand that they require only after failing another brand preferred by the payer. Payers indicate in step therapy policies that a trial, failure or documented intolerance to a payer preferred therapy (specified in the policy either as a drug or a class of drugs) would be mandatory prior to accessing the desired therapy. This is enforced by payers with the intent to control costs as sometimes a cheaper alternative in the form of a generic drug or a biosimilar might be available for usage which would drive total cost reduction for the payer if a large population of patients were required to use the preferred brands. Sometimes, there may be instances where a payer may require the patient to fail on more than one brand either due to the label or even outside label limitations from a step therapy standpoint. The prevalence of step therapy requirements tends to be a lot higher in immunology classes than in oncology class just given the increasing competition in these categories. While undesired by the patient as it may stop them from accessing therapies prescribed by the physician, ultimately it helps control costs from a managed care standpoint. From a provider's perspective, it is important to not always prescribe the cheaper alternative but the more efficacious drug which providers always tend to be inclined towards when writing

scripts. Therefore, these step therapy requirements may cause some delays when it comes to accessing desired therapies. While the payer may deny reimbursement for a drug requested by the patient, the patient always has the option to appeal against the denial to receive the desired therapy. Provider offices also include communication around medical necessity to help through these exception processes for the requested medications. [1]

In addition to step therapy requirements and prior authorization requirements, there are quantity limits that are listed on formularies which ensure that only the right quantity of drugs are being dispensed to the patient. Formularies may also indicate whether the patient is required to receive the medication at a designated specialty pharmacy. Drugs that are not listed on the formulary may end up not being covered by the managed care organization. While there may be exception processes in place, this could sometimes be a tedious process when it comes to accessing medications and could vary based on the payer and the organization in play. It is important to note that prior authorization requirements, step therapy requirements through formulary designs are not the only way to enforce utilization management but one of the many ways by which payers control costs. Quantity limitations, dosing limitations, and other restrictions such as lab testing requirements, proof of diagnosis are creative methods included in policies to ensure optimal usage of the therapies in question. [4]

Additionally, medical benefit drugs may not be listed on formularies but are subject to medical policies which have a set of criteria established based on payer organization that indicate how a drug needs to be utilized under the medical benefit. Prevalence of medical policies may vary based on channel type. While commercial channels may tend to have more medical benefit policies, the prevalence is sparse in managed medicaid and state medicaid channels, the administrative burden of these policies remains. [5]

3. Future Scope

Utilization management techniques are only expected to evolve even further. This review discusses only a dominant sample of the utilization management techniques. Payers are always finding creative ways to control costs. Contracting through discounts and rebates, value-based contracting, outcomes-based contracts encourage payers to prefer drugs based on different methodologies. Moreover, as the complexity of the healthcare ecosystem arises and more emerging stakeholders grow, it will be important to study in detail the relevance of provider organizations, integrated delivery networks, growing importance of group purchasing organizations, etc.

Ultimately, it is important for every member in the healthcare industry to ensure that patients get access to therapies despite existing barriers.

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