Dissecting the Temporal Impact of U.S. Managed Care Decisions on Newly Launched Drugs and Therapies

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Abstract: *The global disease burden patients are increasingly experiencing spans many different conditions, including oncology, non-oncology, immunology, and rare diseases. In a complex healthcare ecosystem, ensuring patients have reliable and timely access to vital medications to address these conditions is a top priority. In the United States, new drugs and therapies are approved year over year, prompting various market entities to employ diverse mechanisms to regulate the accessibility of these novel agents. Among the strategies managed care organizations use to control access to medications, such as prior authorizations and step therapy restrictions, a management approach known as new drug launch policies has emerged over the last decade and has continued to evolve. Pharmacy and therapeutics committee members may not immediately authorize newly launched medications for patient access, as managed care stakeholders require time to project the potential impact on their internal budgets. This research explores the time taken by decision makers in the world of managed care to establish final coverage and reimbursement policies for newly launched drugs and therapies in the United States, and also investigates potential variations in this process for life-saving oncology treatments compared to other critical indications.*

Keywords: managed care, pharmacy benefit, medical benefit, oncology, non-oncology

1. Introduction

In the world of managed care in the United States, multiple stakeholder groups exist in providing pharmaceutical and medical access to patients. These key stakeholders tend to include groups such as patient and physician groups, pharmacy benefit managers (PBMs), specialty pharmacies, etc. [1]. One of the most influential groups are managed care organizations, commonly referred to as payers, which are the financiers of pharmacy and medical benefits. Pharmacy benefits are differentiated from medical benefits typically by site of care and the types of services they cover. The pharmacy benefit covers prescription drugs that are taken orally or self-administered subcutaneously, and can be purchased through a pharmacy [2]. The medical benefit covers a wider range of medical services and therapies that are mainly administered intravenously by a medical professional in a healthcare setting (inpatient or outpatient facilities) [2]. Payers are derived from public (Medicare and Medicaid) and non-public (private health insurance) sources that provide access to the majority of insurable patients in the United States [3]. Perhaps unsurprisingly, these payers are the most important influencers in providing access to patients.

In the United States, the Food and Drug Administration (FDA) routinely approves numerous drugs and therapies every year. In 2022, the FDA approved 37 novel agents which were generally covered under either the pharmacy benefit or medical benefit [4]. Of the 37 novel agents, 22 were specialty drugs expected to be covered under pharmacy benefit, generally taken orally or self-administered subcutaneously. The other 15 agents were therapies expected to be covered under medical benefit [4]. In the context of drug and therapy classifications, these novel agents can be grouped into various categories related to oncology diseases and non-oncology diseases, and further into subclasses related to immunology and rare diseases. Within the oncology market landscape, 12 new agents were approved by the FDA; the most notable were Carvykti, Elahere, Kimmtrak, Opdivo, Pluvicto, and Tecvayli [5], [6]. Carvykti is a new type of CAR T-cell therapy that targets the BCMA protein in adult patients with relapsed multiple myeloma following four or more lines of therapy [5]. Similarly, Tecvayli, a bispecific monoclonal antibody, was approved as a fifth or greater line of therapy for adults with relapsed/refractory multiple myeloma [6]. Elahere was approved for ovarian cancer, Kimmtrak for uveal melanoma, Opdivo for melanoma, and Pluvicto for prostate cancer [6]. Of the new agents approved in the non-oncology market, the most notable were Mounjaro, Quviviq, Cibinqo, Relyvrio, Daxxify, and Vivjoa [7]. Mounjaro was the first glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 dual therapy approved by the FDA for adults with Type 2 diabetes [7]. Quviviq was approved for adults with insomnia, Cibinqo for atopic dermatitis, Relyvrio for amyotrophic lateral sclerosis, Daxxify for frown lines and neck spasms, and Vivjoa for chronic yeast infections [7]. In the rare disease subclass, 20 of the 37 novel agents were approved for the treatment of rare diseases including the approval of Dupixent the first treatment for adults with prurigo nodularis, a rare form of skin disease [8]. Treatments for rare diseases made up more than 50% of all the novel agents approved in 2022. The categorization of new oncology and non-oncology agents is necessary considering the growing diversity of subclasses and indications, along with the emergence of new cancer treatments.

The FDA will routinely grant label expansions to agents with prior approvals, but by definition, a new drug or therapy will not have a previously approved label for any indication. Hence, newly launched drugs or therapies are completely new to the market, and this creates a need for payers to evaluate coverage policy dynamics.

There are considerable different ways payers restrict and limit access to drugs and therapies in order to employ cost-saving methods. Payers can influence access to drugs and therapies by implementing prior authorization policies, step edit requirements, dosing limitations, quantity limits, duration and renewal restrictions, line of therapy restrictions, cancer-type restrictions, diagnosis requirements, lab testing requirements, specialist requirements, and more [1], [3]. As more complex novel treatments are introduced to the market, the number of different restrictive measures employed by payers will likely continue to increase. As such, pharmaceutical manufacturers regularly enter into contracting agreements with payers to enhance access to their drugs and therapies. This can involve offering discounts or rebates based on need, thereby countering payers' restrictive measures and improving the likelihood that payers approve access to their drugs and therapies [3]. The cooperation between pharmaceutical manufacturers and payers significantly influences the initial coverage determinations for newly launched agents and the sustained accessibility to current drugs and therapies.

In addition to the restrictions and cost-saving measures applied by payers to existing drugs and therapies, newly launched drugs and therapies face an additional barrier to access called new drug launch policies. New drug launch policies are introduced by payers temporarily until a pharmacy and therapeutics (P&T) committee fully reviews and decides on coverage for a newly launched agent [9]. The P&T committee's decisions could severely limit or broadly provide access to different drugs and therapies. This decision to remove a new-to-market policy and implement a finalized coverage policy can take a considerable amount of time and varies from payer to payer. As more expensive and complex treatments like cell and gene therapies are introduced to the market, some payers are relying on an alternative to P&T committees by establishing emerging therapies committees to help navigate the complexities of these novel and expensive treatments [10]. Evidently, there is a great deal of effort and planning around newly launched treatments for payers to protect their interests while providing adequate access to often lifesaving treatments.

The purpose of this study is to conduct an analysis of the time taken by payers to review and approve coverage for newly introduced drugs and therapies in 2022. The evaluation of the data spans a period of 12 months, beginning from the launch date in 2022 and extending into 2023. Extending the evaluation period into 2023 allows for a more comprehensive analysis of the data, regardless of the initial launch date. The assessment will encompass both pharmacy and medical benefits, with specific differentiation between oncology and non-oncology treatments to ensure comparability of results across all therapeutic domains. Payers will be categorized according to the speed (fast, moderate, and slow) at which they make their review determinations. This study's

significance is rooted in the examination of the temporal impact of payer review and coverage determinations for new drugs and therapies during their first-year post-launch. The findings are essential for gaining an understanding of the evolving patterns in payer behavior, specifically related to the review process of newly launched drug and therapies.

2. Methodology

A sample of pharmacy benefit drugs and a sample of medical benefit therapies that first launched in 2022 were selected for the purpose of conducting this study. In 2022, the FDA approved 37 novel agents across a diverse range of indications [4]. The data was normalized over a duration of twelve months for each sample regardless of the launch date in 2022. Drugs that are covered under pharmacy benefit are typically administered orally or self-administered subcutaneously, while therapies that are covered under medical benefit are generally administered intravenously by a medical professional [2]. To understand payer review and coverage trends, a mix of oncology and non-oncology agents was included in the sample. This was done to ensure that the sample is applicable across all therapeutic areas for both pharmacy benefit drugs and medical benefit therapies. The sample of drugs and therapies was evaluated based on the review process and coverage determinations of managed care organizations, generally referred to as payers. These payers represent more than 90% of overall insured lives represented by commercial, Medicare, Medicaid, State Medicaid, and health exchange lines of business. The 'average payer lives reviewed' is defined by the average percentage of lives controlled by payers that have undergone a review process to determine the coverage for new drugs and therapies. Average payer lives covered denotes the average percentage of lives represented by payers that ultimately decided to provide coverage for the sample of new drugs and therapies. The distinction between these two metrics is crucial when evaluating newly launched drugs and therapies, as it helps in understanding payer behavior since some payers opt to exclude coverage for certain therapies or simply exclude them from their formularies.

In the next phase of the study, payers were categorized based on how long it took for the organizations to review coverage (fast, moderate, slow, and varies by drug). This was determined by the percentage of lives represented by payers to review within three, six, and seven or more months across the sample of pharmacy benefit drugs or medical benefit therapies. Any payer that took between zero and three months to review the sample of newly launched drugs and therapies was classified as a fast review decision maker, while any payer that took between four to six months was considered a moderate review decision maker. Any payer that took seven months or more to review the sample was categorized as a slow review decision maker. When payers' review pace showed no clear correlation between the timing sequences and sample of drugs and therapies, they were classified separately, as 'varies by drug.' The analysis was split by payers representing lives under pharmacy and medical benefit including a breakout by oncology and non-oncology drugs and therapies from the sample. The review timing segments correspond to the percentage of payer lives to review the

sample of drugs and therapies by each quarter within the first-year post-launch.

The data was collected through a combination of primary and secondary research techniques to ensure the reliability and accuracy of the findings. The data was analyzed using Microsoft Excel to identify trends in payer review decisions and coverage uptake over the first-year post-launch for each sample agent. This methodology was adopted for both pharmacy benefit drugs and medical benefit therapies to ensure consistency in approach and comparability of the findings.
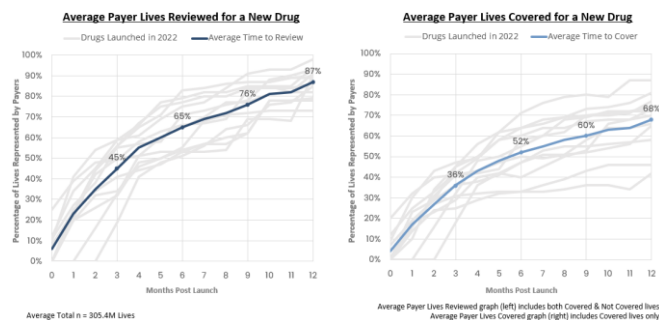
3. Results and Discussion

Figure 1: Average payer lives reviewed (left) and average payer lives covered (right) for new pharmacy benefit drugs in 2022 by percentage of overall lives.

Pharmacy Benefit
On average, payers representing 87% of lives made a review decision, which can include a degree of coverage or formulary exclusion, within the 12-month post-launch mark for the sample of newly launched pharmacy benefit drugs in 2022. Payers representing 45% of lives made a review decision within three months post-launch, followed by an average of 65% and 76% at six- and nine-months post-launch, respectively. Compared to the average payer lives reviewed, average payer lives covered include only covered lives–payers that decided to not cover the sample of new drugs were excluded. At the 12-month mark, 68% of lives represented by payers were covered indicating that the difference from the 87% of reviewed payer lives were lives where payers decided to exclude coverage for the sample of new drugs. At the three-month mark, 36% of lives represented by payers were covered, followed by 52% and 60% at the six- and nine-month mark, respectively. The average percentage of lives represented by payers excluded from pharmacy benefit coverage is usually not covered or not listed by payers in their formularies. Even if a payer excludes coverage at the formulary level, these lives may qualify for coverage through special exception processes at a later time [11]. Patients normally require the assistance of a doctor to submit requests for these special exceptions. Understanding the timeline and process of payer review decisions is crucial to traversing the evolving coverage landscape of novel drugs and therapies. This knowledge is essential for healthcare organizations and patients to navigate the complexities of accessing and affording innovative treatments.
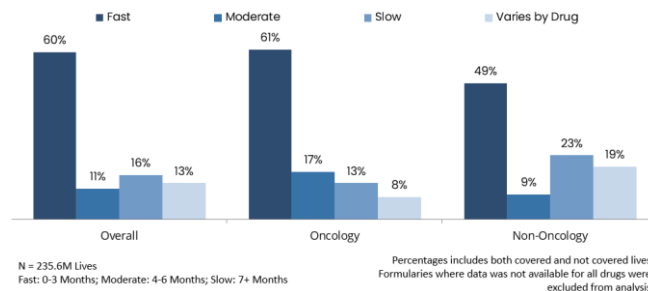

Figure 2: Overall, oncology, and non-oncology review time for new pharmacy benefit drugs by percentage of lives represented by payers

From the sample of newly launched pharmacy benefit drugs, the percentages of lives represented by payers to review the sample were grouped into different review timing segments (fast, moderate, slow, and varies by drug). Under the pharmacy benefit, 60% of overall lives were represented by payers that made fast review decisions (within three months post-launch). When analyzing the subset of newly launched oncology drugs under pharmacy benefit, 61% of lives were represented by payers that were fast review decision makers compared to 49% for the sample of new non-oncology drugs. This significant difference is expected given that oncology drugs tend to have strong positive reputations due to their potential to extend life, and the coverage uptake could also be traced to the rapid growth in cancer expenditures among both private and publicly funded markets [12], [13]. Payers accounting for 11% of overall lives were moderate decision makers, as they made review decisions within four to six months. Within the oncology subset, 17% of lives represented by payers were moderate review decision makers compared to 9% for the non-oncology subset. Payers accounting for 16% of overall lives were placed in the slow segment, as they took seven or months to review the sample of newly launched pharmacy benefit drugs. Within the oncology subset, 13% of lives represented by payers made slow coverage decisions compared to 23% for the non-oncology subset. Particularly in the slow segments, payers were quicker to review oncology drugs considering the lower percentage of payer lives for slow decision makers compared to non-oncology drugs. The fast review timing segment typically includes large national payers along with some regional organizations. Mid-size payers are generally classified under the moderate coverage segment, while smaller independent payers, lacking the infrastructure to establish P&T committees, fall into the slow coverage segment, where coverage determinations are made on a case-by-case basis.
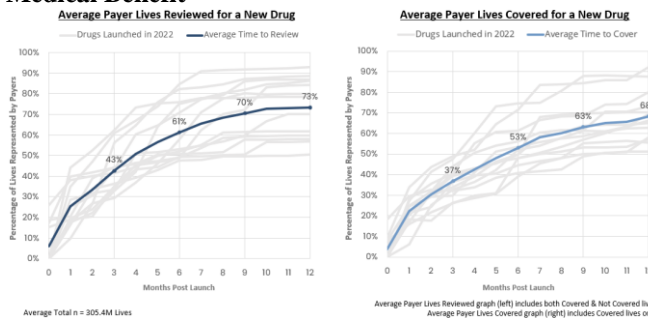
Medical Benefit

Figure 3: Average payer lives reviewed (left) and average payer lives covered (right) for new pharmacy benefit drugs in 2022 by percentage of overall lives.

From the sample of newly launched medical benefit therapies in 2022, 73% of lives represented by payers made a review decision within 12 months post-launch mark. Payers representing 43% of lives made a review decision within three months post-launch, followed by an average of 61% and 70% at six- and nine-months post-launch, respectively. Of the payers that made positive coverage determinations for the sample of medical benefit therapies, 68% of lives represented by payers were covered by the 12-month mark. Among sampled medical benefit therapies, the difference between the average percentage of lives reviewed (73%) and covered (68%) by the 12-month mark can be interpreted as the percentage of lives represented by payers that excluded coverage by the first year. At the 12-month mark, there was a significantly lower percentage of lives represented by payers that decided to exclude coverage for the medical benefit therapies compared to the pharmacy benefit drugs. At the 3-month mark, 37% of lives represented by payers were covered on average, followed by 53% and 63% at the six- and nine-month mark, respectively. Overall, it seems there may not be a significant difference in terms of the percentage of lives that are covered for the sample of pharmacy benefit drugs and medical benefit therapies by the 12-month mark. However, the real difference lies in how quickly pharmacy benefit drugs are reviewed compared to medical benefit therapies starting at the 3-month mark. Based on these findings, payers demonstrate a tendency to expedite the review process for pharmacy benefit drugs in comparison to medical benefit therapies during the initial year following their launch. Notably, this review trend becomes apparent as pharmacy benefit drugs begin to surpass medical benefit therapies by the end of the third-month post-launch.
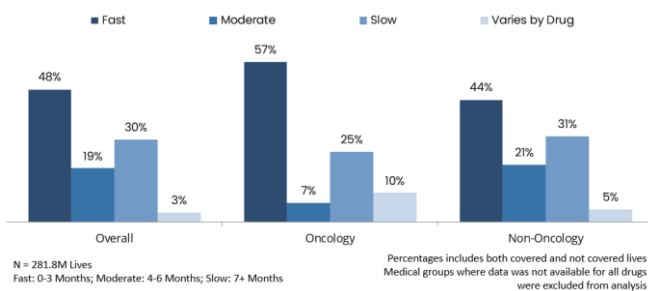

N = 281.8M Lives
Fast: 0-3 Months; Moderate: 4-6 Months; Slow: 7+ Months

Percentages includes both covered and not covered lives
Medical groups where data was not available for all drugs were excluded from analysis

Figure 4: Overall, oncology, and non-oncology review time for new medical benefit therapies by percentage of lives represented by payers.

Under the medical benefit, 48% of overall lives represented by payers made fast review decisions within the first three months from launch across the sample of medical benefit therapies. Newly launched oncology therapies had 57% of lives represented by payers that typically make fast coverage decisions under medical benefit compared to 44% for non-oncology therapies. The overall percentage of lives represented by payers that are categorized under the fast segment was lower for medical benefit therapies compared to pharmacy benefit drugs which is in alignment with the aforementioned review trend. Payers accounting for 19% of overall lives were classified as moderate review decision-makers, as they made review decisions within four to six months post-launch. Within the oncology subset, 7% of lives

represented by payers made moderate review decisions compared to 21% for non-oncology. Payers representing 30% of overall lives were slow to make review decisions, as they took seven months or more to review the sample of medical benefit therapies. Within oncology specifically, 25% of lives represented by payers made slow review decisions compared to 31% for the sample of non-oncology therapies. Similar to the slow coverage segments in the pharmacy benefit analysis, medical benefit review decisions for oncology therapies were faster with a lower percentage of slow decision makers compared to non-oncology therapies. In the context of both pharmacy and medical benefits, oncology drugs and therapies typically undergo faster review processes compared to non-oncology drugs. In a broader sense, pharmacy benefit drugs tend to receive review decisions at a swifter pace than medical benefit therapies.

4. Future Scope

Across the spectrum of payers in the United States, there is a trend of oncology treatments receiving faster review decisions compared to non-oncology treatments within both pharmacy and medical benefits. Major national payers and some regional payers predominantly decide on access to novel agents within three months from launch, while midsize payers including regional payers typically take three to six months. Smaller independent payers, on the other hand, often require seven months or longer since they commonly lack the infrastructure to establish P&T committees, and therefore coverage determinations are made on an ad hoc basis. Overall, payers generally are quicker to review pharmacy benefit drugs compared to medical benefit therapies and more specifically those for the treatment of oncology-related diseases.

Given these results, payers planning for 2025 should observe the continuing evolution of new drug launch policies. It will be pertinent to determine whether non-oncology agents will also undergo faster decision-making to match the pace of oncology approvals and if oncology agents will continue to experience the current pace of decision-making. Furthermore, with the escalating pressures concerning patient access to these new lifesaving treatments, it is crucial to investigate whether smaller regional and independent payers will speed up their pace of review decision-making to align with larger regional payers and their national counterparts.

As additional new drugs and therapies are approved throughout every year, payers will need to frequently adjust their management strategies to accommodate the increasing complexity of treatments. While payers, especially PBMs, continue to employ more restrictive and complicated management strategies under pharmacy benefit, it will be important to predict whether this restrictive trend extends into medical benefit [14], [15]. Ultimately, anticipating how payers will respond to the evolving landscape of new launches, particularly regarding the efficiency of managed care decision-making of oncology, non-oncology, immunology, and rare diseases, will be vital to secure patient access to new life-saving treatments amidst the growing challenges faced by the healthcare industry.

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