Q1, March 2022

Market Access

Quarterly Advisor

IQVIA

Market Access outlook: 2022 and beyond

By Luke Greenwalt, *Vice President, IQVIA Market Access Center of Excellence*

As we find ourselves well into 2022 and look ahead to the industry activities and trends anticipated going forward, we will see many of the same market dynamics remain in play — but with compounding complexities and accelerating speeds of change.

We can expect a continued increase in payer controls, rising strains in patient affordability, intensifying pressures due to policy impacts, and ever more difficult launches as products enter the market facing immediate headwinds.

Subsequently, these will culminate in continually increasing gross-to-net pressures, forcing manufacturers to do more with less. Given such challenges, the need for careful planning and detailed assumptions is greater now than ever.

IQVIA's Market Access Center of Excellence is here to help! Throughout the year, we will explore these and other critical industry issues, and identify approaches to help navigate through the challenges and trends that continue to pressure the industry.

Overcoming launch access barriers with patient support programs

By Ross Perak, *Senior Principal, Market Access Strategy Consulting, IQVIA*

The biopharmaceutical industry has evolved, and the market access landscape is especially difficult for launch brands. Previously, patient support programs were used primarily to address affordability issues, but they have since expanded into helping patients without coverage to ensure they can receive the therapy they need. The traditional copay card and free trial vouchers are now only two examples of programs in a complex ecosystem of patient support that also includes automatically distributed e-coupons and denial conversion programs, temporary bridge coverage, and debit cards.

PATIENT ACCESS CHALLENGES AT LAUNCH

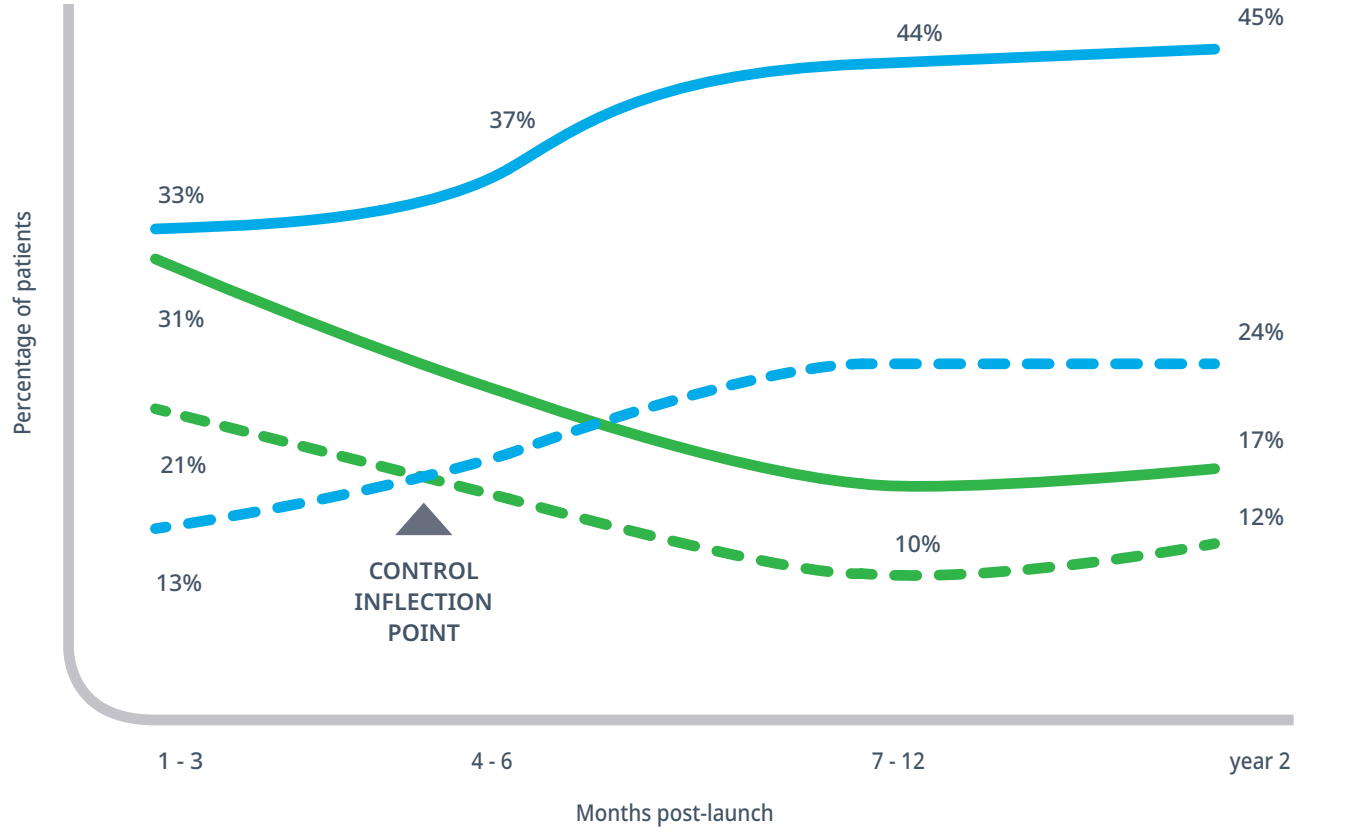
Across all pharmacy products that launched in 2019, only one-third of patients who attempted to initiate treatment were able to fill therapy; more than half faced a formulary restriction, and some abandoned due to cost. All too often, launch products must plan for initial formulary exclusion across payers with the expectation that eventually those exclusions will make way for coverage. For launch and mature brands alike, that access increasingly comes with higher patient cost-sharing and utilization restrictions such as prior authorization and step therapy. (Fig. 1.)

DIFFERENT STRATEGIES FOR LAUNCH BRANDS

Because the environment for launching a new pharmaceutical has changed, the definition of a successful launch is also evolving. Today, it is a question of volume versus value – the delicate tradeoff of margin for early volume gains, with the hope for long-term return. In the short term, a free trial voucher, bridge program, or a denial conversion program can help patients initiate treatment while payers are making coverage determinations. This early support brings assurance to providers that their patients will be able to start on therapy while also relying entirely on the manufacturer to subsidize patient costs outside of a healthcare benefit.

Long term, these programs can erode manufacturer margins in a way that is not sustainable. Recent launch brands have shown support programs investments as large as 60 percent of their gross-to-net in the first year[1]. So, as manufacturers make these early margin tradeoffs, they must also consider how all of the patient support offerings can work together in such a way that patients transition off of full manufacturer sponsorship and temporary coverage to their actual healthcare or pharmacy benefit.

Fig. 1. Example of New Patient Rejections by Months Post-Launch (Commercial Payers)



Source: IQVIA LAAD Pharmacy Claims Data; US Market Access Strategy Consulting

Since the margins for launch products are already thin, other challenges, such as accumulator and maximizer programs, can surprise many patient support budgets, where a more established brand may have a better sense of how to absorb and/or mitigate these effects. For these reasons, not having an exit strategy for what are supposed to be temporary fixes is dangerous for a launch.

ELEMENTS OF A SUCCESSFUL LAUNCH STRATEGY

Successful support program strategies have a level of agility – or adaptability – that is useful at any stage of a brand's lifecycle, but is especially useful at launch when patient needs are changing rapidly. For example, unexpected accumulator or maximizer use, poorer coverage than anticipated, and health policy curveballs can combine to upend a launch plan. Of course, evidence and scenario planning are also key characteristics of a good strategy because some of the challenges mentioned before can be anticipated (and modeled) with the right combination of data and analytics of analogue launches.

Lastly, patient support strategies are dependent on payer contracting strategies, and vice versa. Anticipating formulary wins and losses will help manufacturers prepare for access challenges that a support strategy will help overcome. Understanding the geographic footprint of access can even help to target certain support tactics where patients will rely on them most to access a therapy.

If a strategy is designed well, the launch brand will have agreed on a definition of success: What does good look like? Moreover, the strategy will have anticipated margin costs and volume gains based on the various market access strategies working in concert.

[1] IQVIA Market Access Copay Card Library

How to manage complex revenue workflows

By Heenal Patel, *Senior Principal, Global Pricing and Contracting, IQVIA Market Access Center of Excellence*
Emily Turturici, *Consultant, Global Pricing and Contracting, IQVIA Market Access Center of Excellence*

Ensuring access in today's healthcare market requires manufacturers to manage complex pricing quotes and contractual agreements with third parties in every major function in an organization. This can result in hundreds, if not thousands, of contracts for organizations to manage, all while new offers are continuously pursued and executed by sales teams. Contractual relationships with customers and suppliers are becoming increasingly more complex to implement and manage. To mitigate risk, overcome operational challenges, and improve customer/supplier relationships, many manufacturers are turning to cloud-based solutions to streamline their contracting process.

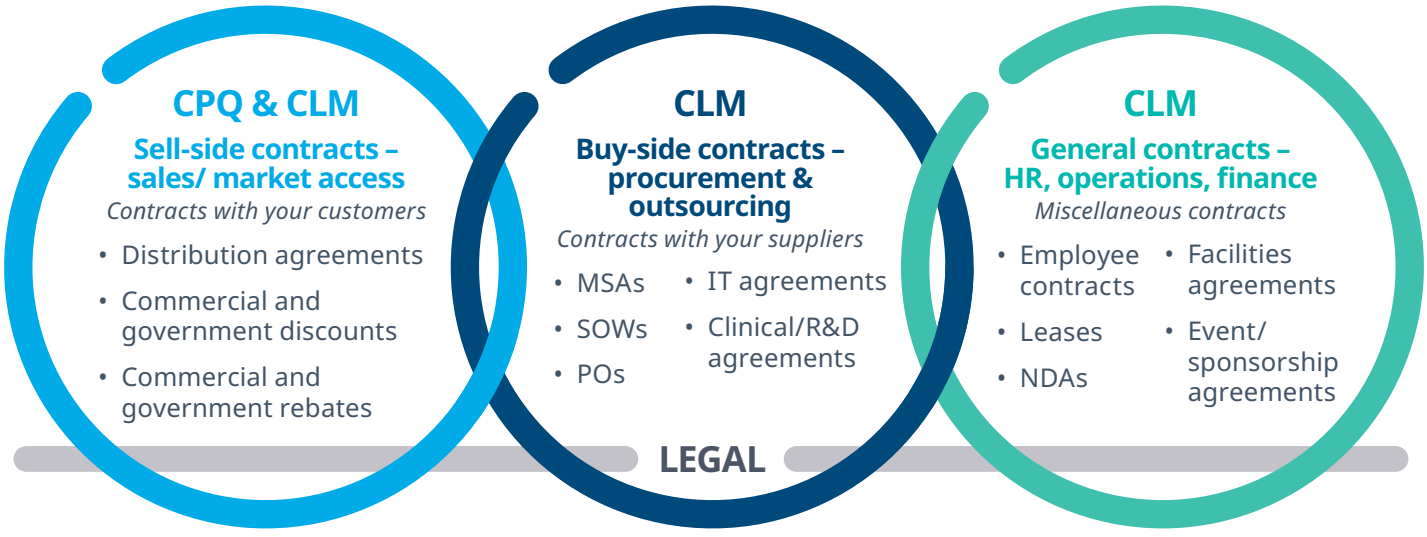
Specifically, an increasing number of life sciences organizations are working with trusted system integrators, including IQVIA, to implement Configure, Price, Quote (CPQ), and Contract Lifecycle Management (CLM) tools to achieve a highly efficient quote-to-cash process, particularly when the two are integrated together.

CLM CLM tools are a one-stop-shop for all contracting needs including contract creation, review and redlining, intelligent workflows to manage approvals, integration with e-signature tools, document storage, and robust search and reporting. Create and manage complex contractual agreements in a single system for a streamlined contract process.

CPQ For sell-side contracts, CLM can be coupled with a CPQ tool to automate price quoting and offer development. Implementing both a CPQ and CLM tool ensures seamless integration of the product and pricing configuration with the terms and conditions of an agreement. Seamlessly produce accurate, complete, and customized quotes using real-time pricing and discounting data.

As an organization, it is important to ask the following questions:

- Does your organization struggle to find executed agreements?
- Are there standardized templates and clauses to streamline your Legal review process?
- Is it overwhelming to keep track of the redlining process and management of document versions?
- Do you know when contract expirations or renewals are coming due?
- Are you managing price quoting in an offline process?
- Are your tools built to handle complex pricing strategies?
- Do you know how long it takes to close a deal from inception to execution?



- Do you have a workflow-based process to manage approvals at every step of your negotiations?

If any of these questions trigger a pain point for your organization, it may be time to start exploring CPQ/CLM solutions with IQVIA. To get started, you can reach out to John Wu, Global Pricing & Contracting GM/Practice Lead, at John.Wu@iqvia.com.

The impact of the Affordable Care Act's maximum out-of-pocket limit

By Kepler Illich, *UC Davis School of Economics*
Rory Martin, *IQVIA Market Access Center of Excellence*

INTRODUCTION AND FINDINGS

The Affordable Care Act (ACA) was a healthcare reform law enacted in March 2010 with the aim of making health insurance more affordable, expanding Medicaid, and supporting innovative models for care delivery. Although much has been written about the overall changes due to the ACA, little has been published about the impact of one of its key provisions: the requirement of compliant health plans to limit cost sharing for beneficiaries by setting an annual maximum for out-of-pocket (OOP) costs.

The current study analyzed the impact of the ACA's maximum OOP limit on privately insured patients and found it lowered patient OOP costs and increased patient drug utilization. Specifically, the percentage of patients who reached their OOP limit tripled from 5% before the ACA went into effect to 15% afterwards. Also, the proportion of branded prescriptions free to the patient (zero-dollar copays) increased by 59% relative to pre-ACA levels, an effect that was stronger in disease areas with high-priced products. Furthermore, once patients reached their OOP limit, their branded drug consumption increased 12% and generic consumption grew 7%. Finally, lower income patients benefited the most, with their drug utilization increasing four times as much as seen in higher income patients.

ORIGINS

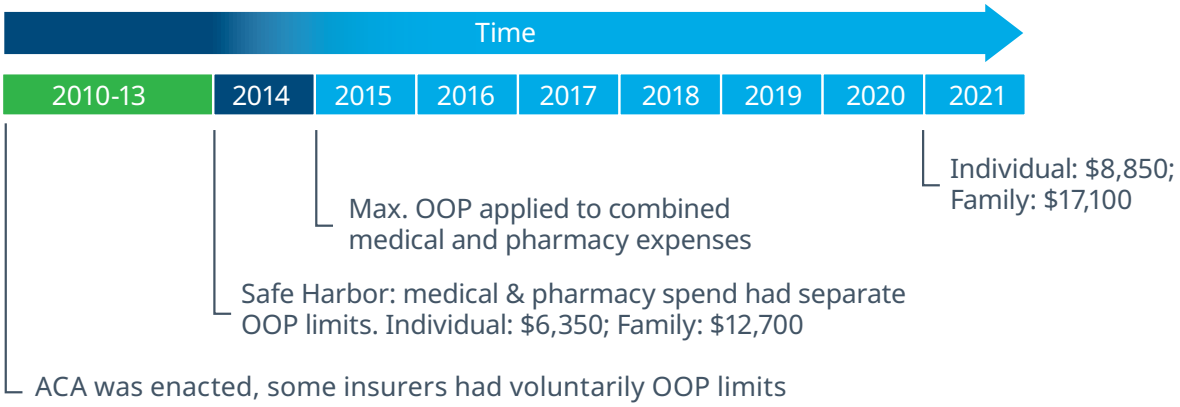
Starting in 2014, the ACA established a maximum for OOP limits for private insurance plans. When insured patients reach an OOP limit their treatment costs become zero, which helps protect patients with severe medical conditions from high costs. Although the ACA's maximum OOP limit applied to all private plans, at first glance it appears many beneficiaries would have been unlikely to be affected by it. For example, in 2013, 73% of covered workers were already enrolled in a plan with an OOP limit of $5,999 or less,[1] which was a lower, more stringent limit than the ACA's $6,350 limit. Furthermore, fewer than 1% of private group insurance beneficiaries had OOP costs higher than $6,350 in 2013.[2] Also, policymakers had previously implemented maximum OOP limit legislation for government sponsored plans: Medicaid has had an OOP limit of 5% of family income for decades, and in 2011 Medicare Advantage plans were required to have an OOP limit for services covered under Medicare Part A and B, but not for Part D.

Nonetheless, an additional component of the ACA provisions was that the OOP limit applied jointly to medical and pharmacy expenditure, and this part of the legislation was more likely to have a wider impact on patients. For example, in 2009, 85 percent of beneficiaries in PPOs with an OOP limit had plans that didn't count prescription drug spend towards meeting the OOP limit.[3] Note that regulators gave insurance companies a "safe-harbor" year in 2014, delaying this part of the regulation to give insurance companies time to combine their medical and pharmacy systems.

HOW THE ACA MAXIMUM OOP LIMIT WAS IMPLEMENTED

The ACA's maximum OOP limit was implemented in two phases for private insurance: separate maximums for pharmacy and medical benefits in 2014, and a single, combined maximum in January 2015, as illustrated in Figure 1. Each year, the maximum OOP limit is set by the Department of Health and Human Services to account for inflation in healthcare costs.

Fig. 1. How the ACA's maximum OOP limit was implemented



HOW MANY MORE PATIENTS REACHED THEIR OOP LIMIT?

To determine the impact of the maximum OOP limit, three time periods were studied: 2012-13, prior to the maximum OOP limit; the "safe-harbor" phase in 2014; and the second phase from 2015-18, when the combined pharmacy and medical maximum for OOP limits was implemented. For the current study, the impact of these changes on the pharmaceutical market was measured using the proportion of prescriptions paid for by private insurance that were purchased with a zero-dollar copay. This statistic is a salient outcome that affects insurers, manufacturers, and patients alike: "free to the patient" prescriptions. See Analysis Methods and Data for further details.

In 2012-13, only 15.9% of branded prescription volume corresponded to a zero-dollar copay, which rose to 19.5% in 2014 and to 25.3% in 2016, the second year of the combined maximum for OOP limits, as shown in Figure 2. From 2013 to 2016, the volume of branded scripts with a zero-dollar copay saw a relative increase of 59% and an absolute increase of almost 10 percentage points. Details of the analysis are provided in Analysis Methods and Data.

Fig. 2. Percent of branded prescriptions with a zero-dollar copay dispensed to privately insured patients

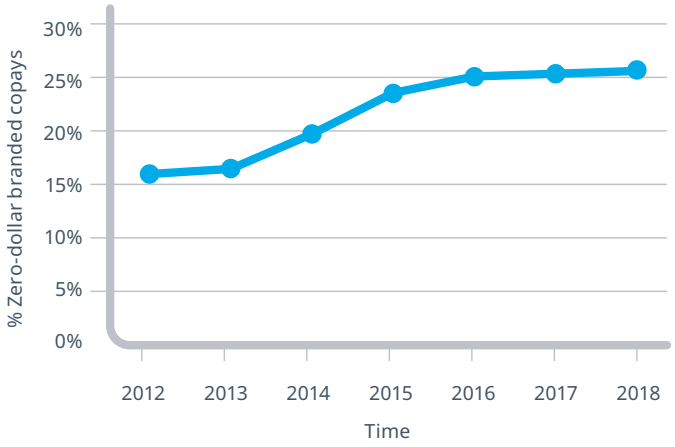
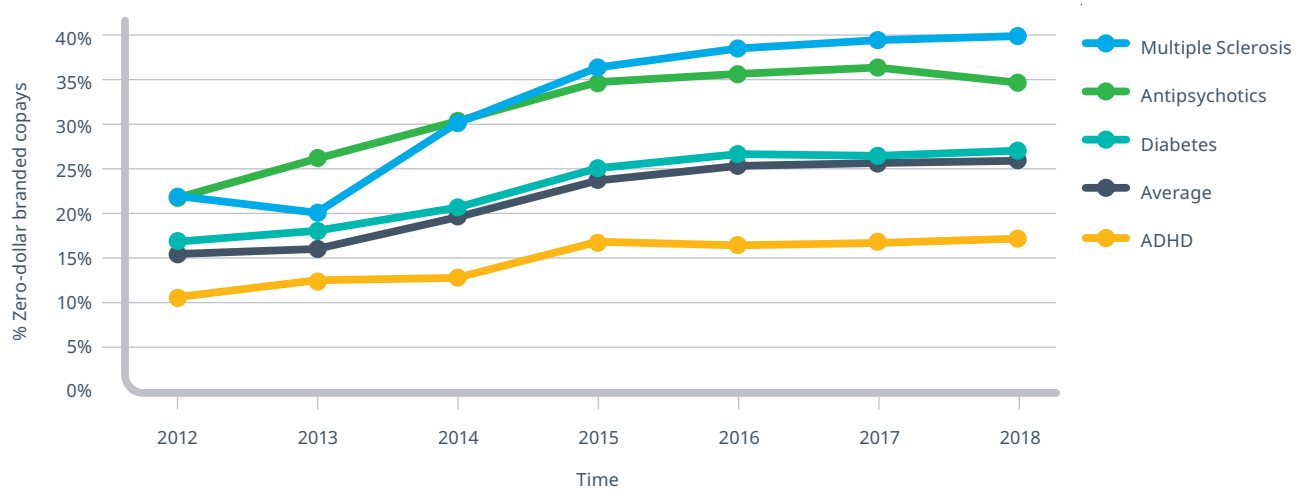


Fig. 3. Percent of branded prescriptions with a zero-dollar copay dispensed to privately insured patients

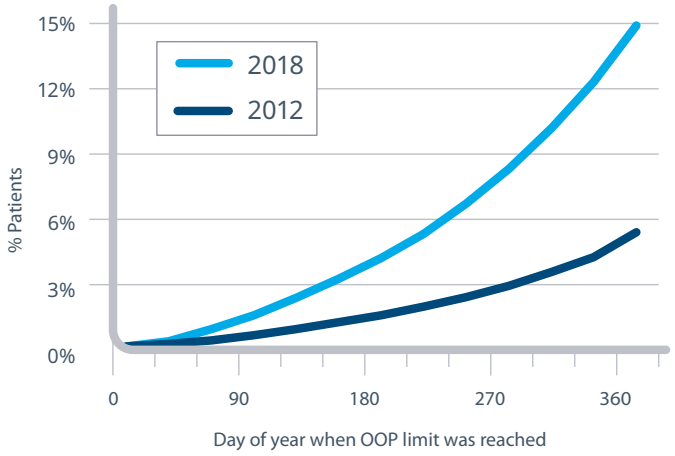


Given that prior to 2014, fewer than 1% of covered workers had more than $6,350 in OOP costs and 73% already had an OOP limit, it is surprising to see a 4-percentage point increase in zero-dollar scripts between 2013 and 2014. However, patients who are prescribed and fill branded medications face much higher healthcare costs than the average covered worker. Because of this, the direct effect of this portion of the ACA on the branded pharmaceutical market was larger than may have been expected.

The second phase beginning in 2015 also had a substantial impact: by 2016, when the rate appears to have stabilized, the proportion of scripts with no OOP costs had increased an additional 6 percentage points. Additional longitudinal patient analysis confirmed that almost all of this increase in zero-dollar branded prescriptions was due to patients reaching their OOP limit more often and earlier in the plan year (results not shown).

The impact of the maximum OOP limit varied substantially by therapeutic area, with largest impact in therapeutic areas where patients had high cost exposure. For instance, in the multiple sclerosis market, zero-dollar copay prescriptions increased 18 percentage points with most of the impact taking place between 2013 and 2014, as illustrated in Figure 3. This may be due to the high cost of multiple sclerosis pharmaceutical products. On the other hand, for the diabetes market, more of the impact occurred between 2014 and 2015 potentially due to high medical costs associated with diabetes and its comorbidities (the American Diabetes Association has estimated that almost half of the $16,752 in average medical expenditure per year for diabetes patients comes physician office visits and inpatient care[4]). Meanwhile some therapeutic areas, like ADHD, were not as heavily affected, possibly because ADHD patients are less likely to have high OOP costs in other disease areas.

Fig. 4. Percent of patients reacing their OOP limit



Another way of quantifying the impact of the maximum OOP limit is to study the proportion of patients hitting an OOP limit. Each year, this proportion starts at zero in January and increases until it reaches a peak at the end of December, as shown in Figure 4. In 2012, two years before the ACA came into effect, only about 5 % of patients reached an OOP limit (of course, some patients had no OOP limit at all). In 2018, several years after the ACA was implemented, this figure had tripled to almost 15% of patients hitting an OOP limit.

Each calendar year there is an increase in the percent of patients with $0 copays, followed by a drop in January when the vast majority of private plans reset. This became more pronounced after the ACA changes of 2014 and 2015 and is market wide. It has become an integral part of the healthcare landscape for patients, manufacturers, and insurers.

DID PATIENTS INCREASE DRUG UTILIZATION AFTER REACHING THEIR OOP LIMIT?

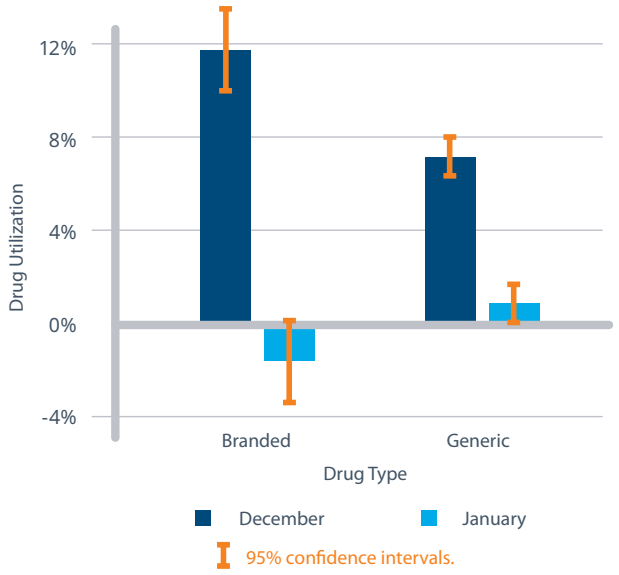
Almost three times as many patients now reach their OOP limit each plan-year as a result of the ACA's implementation, thus it is more important than ever to understand how these patients behave when they reach this limit. Although basic economic theory predicts patients will use more pharmaceutical products when prices decrease, this is a dynamic decision-making process for patients with doctors, pharmacies, and insurers acting as intermediaries, so the question is worth careful analysis.

The data showed that patients increased branded drug utilization by 11.8% in the last month of the year after reaching their OOP limit, controlling for how much utilization they had in the earlier part of the year (Figure 5). This raises the question of whether there was a corresponding decrease in the following January when prices return to standard insurance pricing. That is, were patients simply stockpiling? The data showed a much smaller decrease in the following January, indicating that overall utilization was increasing as a result of the OOP limit rather than patients stockpiling free product in December to use in January when their plan-year reset.

The data also showed patients increased their utilization of generic medications by 7.2% in December after reaching their OOP limit (Figure 5), an increase that was smaller than for branded products potentially due to generic medications being cheaper than branded drugs (at full price and in most benefit designs).

One thing that health industry insiders often forget is how complicated and obfuscated the American healthcare system is, and studies have shown that consumers do not make rational choices in healthcare.[5] An additional analysis was performed to test whether patients who reach their OOP limit in multiple years learned from the experience, but the data showed no statistically significant evidence of such behavior.

Fig. 5. Impact of reaching an OOP limit on therapy purchased in December and January



Since we have shown that the ACA increased the proportion of patients reaching their OOP limit and that once this happened patients increased utilization, we wanted to understand the impact of this provision on total pharmaceutical utilization. We estimate that the branded prescription utilization in December increased by 0.75% due to the ACA's maximum OOP limit. If we extrapolate the behavior of December patients to the entire year after accounting for the rate at which patients reach their OOP limit throughout the year, we calculate a 0.29% increase in total branded utilization as a result of this single provision in the ACA. In 2018, this would have represented an increase in pharmaceutical gross revenue of about $1.4 billion.[6]

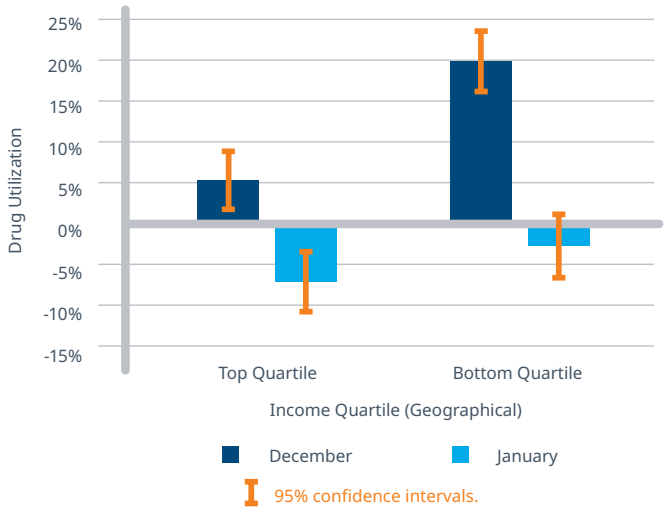
WHICH PATIENTS GAINED THE MOST FROM REDUCED COSTS AFTER REACHING THEIR OOP LIMIT?

The finding that patients increase utilization of both branded and generic products upon reaching their OOP limit raises the question of whether patient socioeconomic status, which may be associated with being better informed, plays a role. To explore this further, the impact of patient income on drug utilization was tested. No direct measure of patient income was available, so patients were segmented based on the income quartile of the Census Public Use of Microdata Area (PUMA) geography in which they lived.

Patients in the lowest income quartile geography increased their utilization four times as much as patients in the highest quartile geography once they reached their OOP limit, 20% versus 5%, respectively (see Figure 6). This is evidence that lower income patients benefit the most from a maximum OOP limit and that increased price sensitivity among lower income patients outweighs any information advantage that higher income patients may have. The analysis also found evidence that wealthier patients engage in product warehousing, advancing purchases from January into December. This is consistent with the notion that low-income patients struggle to pay for drugs and increase overall utilization when it is cheaper to do so, while wealthier patients are simply reducing OOP costs while maintaining their existing medication schedule.

Encouragingly, this analysis is evidence that the OOP limit has substantially helped low-income patients who have

Fig. 6. Impact of reaching an OOP limit on branded products purchased in December and January by census PUMA income quartile geography



experienced very high OOP costs in the calendar year to fill their prescriptions at the end of the year.

To learn more about the findings from this study, you can read the full white paper version by clicking here.

2022 Market Access conferences preview

IQVIA's Market Access Center of Excellence is pleased to announce that we will be participating in a variety of Informa-hosted industry conferences in 2022. While we're on the road to discuss the latest in Market Access innovation, we invite you to meet with us in-person to explore how the IQVIA Market Access Center of Excellence engages in helping clients understand, plan, and navigate current market challenges with our industry-leading solutions. We hope to see you at these upcoming events:

MAR

LIFE SCIENCES ACCOUNTING & REPORTING CONGRESS

In-Person: March 21-24 (Philadelphia, PA)
Virtual: March 29-30

At IQVIA Global Pricing & Contracting (GPC), we understand the continuous pressure you face to stay competitive in an ever-changing market. Visit our booth to learn more about our deep expertise in revenue management systems and existing relationships with leading RPA providers. Our experts have the framework to help. While on-site, learn more about the GPC difference as we address an array of modern-day industry challenges:

- Market access / Contract strategy
- Business case definition
- Tender assessments
- System and operational roadmaps
- 340B assessment / Audits
- PMO / Governance
- Outsourcing services
- Informatics solutions

To schedule a complimentary consultation at any of these conferences, contact Scott Brzygot at IQVIA's Market Access Center of Excellence.

TBD

PHARMA/BIOTECH GTN SUMMIT

2022 Date TBD

IQVIA's Orchestrated Gross-to-Net offers a holistic, connected intelligence platform that automates operational challenges while providing advanced insights. Together, the integration between our clients' complex data ecosystems and IQVIA's data enrichment processes provides the framework to understand revenue and the profitability drivers that maximize performance. This is the foundation of IQVIA's GTN value proposition. Join us to learn firsthand how our advanced insight engine automates KPI generation and isolates strategic decisions that drive performance outcomes, while providing detailed insights across all GTN taxonomies.

OCT

MEDICAID DRUG REBATE PROGRAM (MDRP) CONFERENCE

In-Person: October 11-13 (Chicago, IL)

Each Year, IQVIA brings new and innovative 340B rebate validation methodology to the industry designed to reduce revenue leakage as well as identify and resolve complex 340B issues. We welcome you to visit our booth to learn more about the latest in 340B validation strategy and technology.

OCT

COUPON & COPAY CONFERENCE

In-Person: October 18-20 (Philadelphia)
Virtual: October 25-26

Join IQVIA's Patient Access and Affordability and Strategic Consulting team to learn more about our best-in-class solutions. We will demonstrate how IQVIA's data rich resources provide insightful and actionable analytics, advanced technology, and extensive institutional knowledge. Learn how these resources provide IQVIA with visibility into many details beyond copay program utilization. Topics will highlight our ability to help clients design, deploy, manage, and analyze copay and voucher programs with a set of unique capabilities, expertise, and perspectives.

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