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Market Access

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Addressing health equity disparities with patient services

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

Many pharmaceutical manufacturers offer Patient Services for their brands. These programs are designed to help patients navigate access and affordability challenges for getting on, and staying on, prescribed therapies. Left to their own ability to navigate a complex, and often confusing healthcare journey, many patients simply give up or avoid seeking treatment altogether. By comparison, patients who utilize Patient Service programs are more successfully able to get on physician-prescribed and payer-approved regimens, and have proven to be more adherent to those supported treatments over time.

While many patients benefit from manufacturer-sponsored Patient Service models, there are challenges with existing market dynamics that prevent these programs from being more widespread. The programs:

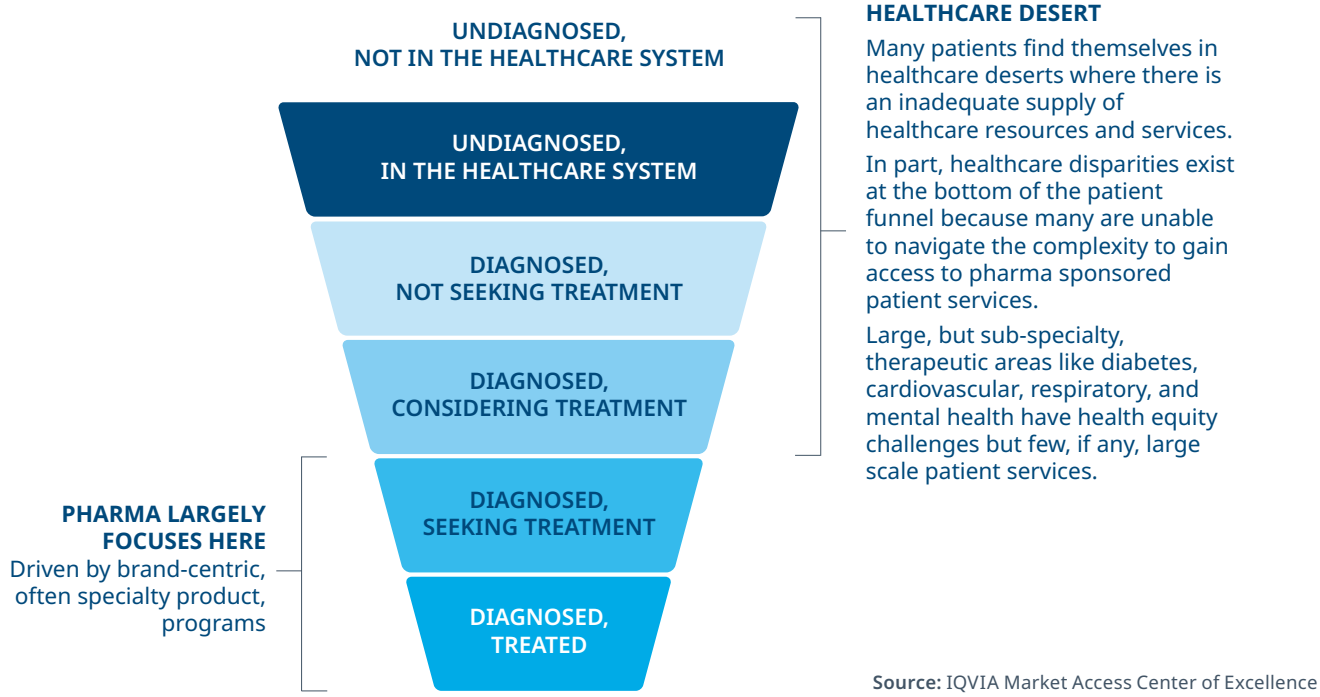
• Are costly and are used primarily to support specialty medicines (i.e., brands with list prices of +$750/month)

• Default to those patients who are successfully able to navigate the healthcare system to therapy

• Are not geographically focused into healthcare deserts, where resources are often most scarce

Certain populations in the U.S. face reduced access to healthcare providers, treatment, and health education. The COVID-19 pandemic has brought these inequities to the forefront, particularly among people of color. These complex market dynamics contribute to a Health Equity gap, as large therapeutic areas like diabetes, respiratory, cardiovascular, and mental health often lack the support mechanisms that Patient Service programs provide. As such, there are many patients who could benefit from Patient Services that are unable to do so.

Pharma's treatment paradigm focuses on patients who are able to successfully navigate healthcare, leaving many of the most vulnerable outside of, or lost in, a complex system



Source: IQVIA Market Access Center of Excellence

PATIENT SERVICE PROGRAMS ARE DESIGNED TO SUPPORT SPECIALTY PATIENTS

Administering Patient Service programs is a costly investment for manufacturers. Large programs can cost tens of millions of dollars annually to operate, as there are many support mechanisms needed. Access services often include large call center operations, nurse educators, case managers, digital enablement, marketing campaigns, and field reimbursement managers, amongst other strategies. The economics of building and maintaining operations for retail brands make it challenging for manufacturers to offer these services for many therapeutic areas at the scale needed for large populations. Manufacturers therefore typically focus these resources on high touch products, leaving many large, non-specialty, high-need disease states without such support.

PATIENT SERVICE PROGRAMS DEFAULT TO SUCCESSFUL PATIENTS

The entry point for most Patient Service programs begins with a patient receiving a prescription from a healthcare provider. That means that the patient was able to enter into the healthcare system, work through a referral network from a primary care provider, get a prescription that had Patient Service support, and successfully contact and enroll in the program. In many ways, Patient Services, while very beneficial to patients, lack the ability to interact upstream in the patient journey to address the scarcity of healthcare availability or provide needed disease state and therapy education. Once patients enter a program, there are many resources available, but they must first navigate to the program to gain access to them.

PATIENT SERVICE PROGRAMS ARE NOT GEOGRAPHICALLY FOCUSED

Challenges in Health Equity occur most frequently in urban and rural geographies.

"One of the most consistent findings in the health disparities literature is that place matters. Research shows that there are systematic disparities in morbidity, mortality, and other measures of well-being across different areas of the country, even across small areas that lie relatively close together."

- The State of Health Disparities in the United States

Access to the health system in these communities is, in general, more challenging than it is in suburban areas. Patient Service models, because of their focus on specialty medicines and their default to successful patients, often lack penetration into non-suburban markets. As such, patients in these geographies are under-represented in healthcare, which carries over into Patient Service programs.

INVESTMENT IS NEEDED

There are few mechanisms that so positively influence patient outcomes and allow patients to reach the full potential of available treatments as Patient Service models. The resources that get deployed, which are most often privately sponsored by pharmaceutical manufacturers, have proven effective across markets to address access and affordability challenges, treatment education, and necessary patient training. Going beyond the historical model, however, is going to require new focus on how Patient Service programs are financed, designed, and deployed.

Financial models that are brand agnostic with multiple sponsors could address the challenges of bringing services to broad, non-specialty but high-need disease areas, such as diabetes, cardiovascular disease, respiratory illnesses, and mental health. Partnering across the industry, government, payer, hospital, and non-governmental organizations will bring down the cost to any one stakeholder to introduce a new Health Equity Patient Service (HEPS) model designed to address disparities.

Broadening the aperture for Patient Service models to include community outreach through local media, partnering with community organizations, and encouraging the seeking of treatment will help bring Patient Services to those in need. Focusing on geographic areas with resource deployment and local representation can quickly supplement scarce healthcare resources by bringing new tools and capacity.

The industry is well positioned to support a new paradigm that encourages the appropriate utilization of prescription therapy. Supporting patients in their treatment journey, while focusing on addressing health equity disparities, is a meaningful mechanism to improve access to care.

CMS's battle against payer accumulator programs may have unintended adverse effects on patients and manufacturers

By Kevin Curran, *General Manager, Patient Access & Affordability Solutions*
Chris McKeil, *Director, Government Pricing Solutions*

Patients who join a copay program and leverage its financial benefits typically undergo a very simple journey. Pharmaceutical manufacturers go to great lengths to implement patient journeys that limit patient action to three things: attesting to their eligibility to participate, providing limited personal demographics, and providing their opt-in/consent to program terms and conditions. Once enrolled, a patient typically obtains their unique copay ID card in real time and then provides it to their pharmacy. This process is quite simple. However, Centers for Medicare & Medicaid Services' (CMS) policy change (CMS-2482-F) which was finalized in December of 2020 is likely to have significant impact on the simplicity of this experience, especially across programs that are subject to accumulator payer pressure. Let's review why this is likely to be the case.

At the heart of the issue is the topic of accumulator adjustor plans (AAP) and CMS' explicit expectation of manufacturer mitigation. Essentially, CMS has stated that despite the challenges that AAPs present to copay program effectiveness, it is the responsibility of the manufacturer to ensure that all funds spent on behalf of the patient count fully towards their insurance balances. Manufacturers with accumulator solutions already in place may still have a problem if receipt of a pharmacy copay claims are required, and/or if token payments (however small) are made directly to requesting pharmacies, as those payments run the risk of not being applied toward patient deductibles. While that may be acceptable now, once the CMS policy goes into effect on January 1, 2023, those token payments become de facto rebates impacting Medicaid Best Price, and in turn, Medicaid Unit Rebate Amounts (URAs). In fact, in certain scenarios, the scale of such rebates may approach the sales price of the drug itself.

The idea of a drug manufacturer having to pay out rebates equaling the sales price of its drugs (essentially providing free product) in certain cases may not seem that alarming, as that is the goal of their copay assistance programs. However, it only takes one such transaction involving a single patient to establish the URA for the entire Medicaid population in a given quarter. Since that URA also sets the price for the PHS 340B program, which for the first time in history exceeded Medicaid in rebate volume during 2020, it is possible that drug manufacturers may curtail or even cancel copay assistance programs altogether.

Pharmacy copay claims also contain valuable information regarding patient out-of-pocket balances, what is being dispensed, how much is being dispensed, etc. The expectation by a pharmacy that submits a copay claim is that there will be a resulting amount awarded to the patient and a net amount to collect. If a co-program consistently pays nothing (to address the de facto rebate issue), then we can expect these claims to trail off before disappearing altogether. If the value to the pharmacy of submitting a claim is not reciprocated with a payment, then the time is not well spent by the pharmacy and will eventually end. How will the knowledge in these copay claims be replaced? The answer lies with the patient.

Most accumulator solutions today require the patient to take an active role in ensuring that they receive the most benefit possible from the copay program. Patients may be given a reloadable debit account along with instructions for how and when to make payments to their dispensing pharmacy. As such, the patient typically will have provided additional contact information such as a mobile phone number for text messages or an email address. Establishing more robust channels of communication is an important step towards replacing the knowledge lost if pharmacy copay claims can no longer be leveraged.

Building a level of trust with the patient to use their communication channels for more robust engagement with the copay program may reflect a dramatic departure from the current way of thinking about patient 'burden' for most

manufacturers. Important stakeholders within various internal teams need to reach alignment on both the 'why' and the 'what' of patient messaging, and extra care needs to be applied to ensuring that messages are impactful, brief, and timely. As patients are coached through timely messaging to take a more active role in their receipt and use of program benefit funds, they will understand the need to help the copay program adapt to the changing landscape, and therefore, continue to receive much needed financial assistance.

In summary, CMS' policy change regarding accumulators will be in effect soon. Being prepared to adapt to an environment that lessens dependency on pharmacy claims will involve both a great deal of internal discussion among internal stakeholders, and a solution that supports timely and impactful engagement with patients. IQVIA's Benefit Guardian solution addresses all aspects of patient engagement, innovative payment delivery mechanisms, and efficient verification of accumulator mitigation.

For manufacturers planning to continue to offer programs subject to copay accumulators, this is the right time to be thinking about methods for acquiring copay data to allow it to be integrated into Medicaid pricing calculations. Contact us to find out how we are planning to leverage IQVIA Core data libraries to access and enrich copay data in order to fortify government program integrity.

Automation in revenue management and the Market Access system landscape

By Himanshu Mahajan, *Senior Consultant, Global Pricing & Contracting*
Heenal Patel, *Senior Principal, Global Pricing & Contracting*

Software testing is a vital part of Market Access applications due to its complex business processes and highly regulated landscape. It is important for IT and business teams to define "success" for their software testing efforts. While exiting application testing with a minimum number of bugs and defects is one measure, it is not the sole metric for success. Other measures for consideration include

- ✔ The scope and diversity of test coverage
- ✔ Test reusability
- ✔ The quality of the test execution
- ✔ Value of the data reported by software testing
- ✔ Completion of testing within project timeframes

Manual vs Automated Testing

Manual testing is prone to user errors	**ACCURACY**	Automation testing increases consistently in both test execution and documentation
Manual testing requires significant man hours and resources	**SCALABILITY**	Automation testing is scalable and can be used for many types of testing including Unit, Regression, System, Integration, and Performance testing across different systems
Manual testing is time consuming, requiring several resources to complete testing within project timeframes	**SPEED**	Automation testing can run many scripts in parallel reducing overall test cycle time with little to no user intervention and support
Manual testing requires added cost as it involves hiring domain experts to execute testing	**COST EFFICIENCY**	While Automated testing has initial set-up costs, automated testing can provide organizations significant cost savings
Manual testing is still a good candidate for test cases which are not routine or where the criteria is frequently changing	**AREAS OF SPECIALIZATION**	Automation testing can be used for almost every type of testing including complex types such as load, performance, and security testing.

CASE STUDY: PROOF OF CONCEPT – AUTOMATION OF SIT SCRIPTS

PROFILE	**Client:** Large Pharmaceutical Company **Engagement:** Proof of Concept automated several cross-functional manual System Integration Test (SIT) scripts using Tosca as the automation tool
CHALLENGE	• The six scripts spanned multiple functional areas of the Model N Revenue Management Application • Several scripts had more complex steps / actions including importing files from a desktop location via dataflow, moving fields on a drag and drop screen, exporting data from the Model N system and populating an Excel model to perform a comparison, and confirming calculated rebate amounts against a parallel rebate verification model
GOAL	• Fully automate the selected scripts including more complex steps such as parallel model verification • Ensure output reports met Client IT / Business compliance needs including results which can be reviewed by both compliance and business teams
RESULTS	• IQVIA was able to successfully automate scripts start to finish with a total of over 400 steps automated • IQVIA incorporated iterative feedback provided by client after script outputs were provided to address business comments / concerns • Test Script Automation significantly reduced execution time compared to manual execution • Client was satisfied with automated execution and results

Humans executing test scenarios and scripts has traditionally been the primary method of software testing and IT Quality Assurance. Due to the cost, manpower, and issues associated with manual testing, however, organizations are increasingly moving towards test automation. Automated testing tools can simulate users performing test execution, with a playback of pre-configured system actions, a comparison to expected results, and test execution results and screenshots. Scalability, repeatability, and quality testing are at the core of test automation.

While organizations may have some automation incorporated into their testing strategy today, a number of automation tools, such as those that are code-based, have limitations around which test cases they are able to support. Organizations may consider the option to automate their full suite of application testing by partnering with IQVIA and using its best-in-class tools to automate complex scenarios such as integration testing with multiple systems, reports, user role and security, and performance and load testing.

TEST AUTOMATION CASE STUDY

To prove the ability to automate complex scripts with functions both inside and outside of the system, in Excel and other Windows applications, IQVIA's Global Pricing & Contracting (GPC) team recently partnered with a top 20 pharmaceutical client to perform a proof of concept (POC) automating their System Integration Test (SIT) scripts. The team automated the testing of complex scenarios in varying functional process areas on their revenue management system. IQVIA used Tricentis' Tosca solution, which is a model-based, no-code tool to execute this type of POC.

The GPC team worked closely with the customer's compliance teams, business managers, and technical leads to iteratively incorporate feedback throughout the POC engagement. Additional details such as testing phase, operating system name, browser details, etc., were included in the test execution report output. The look and feel of the test report output was customized to meet the customer's audit and compliance needs. Ultimately, IQVIA was able to customize the test report output and successfully prove the scope of scripts could be fully automated to meet the customer's testing requirements.

CONCLUSION

IT projects that require system integrations, upgrades, and implementations can put a strain on an organization's resources and pocketbooks. With the use of automated testing tools, the organization will find test cycles can be greatly reduced, while introducing significant cost savings, and promoting confidence in the quality of testing. Through IQVIA's expertise in software testing and quality assurance, we are enabling organizations to make a shift towards

automating their testing activities. Our team would be happy to assist your organization in exploring automation. For information on test automation, please contact Heenal Patel, Senior Principal, Global Pricing, Contracting & Market Access, at heenal.patel@iqvia.com

Orchestrating Gross-to-Net: Do these challenges sound familiar?

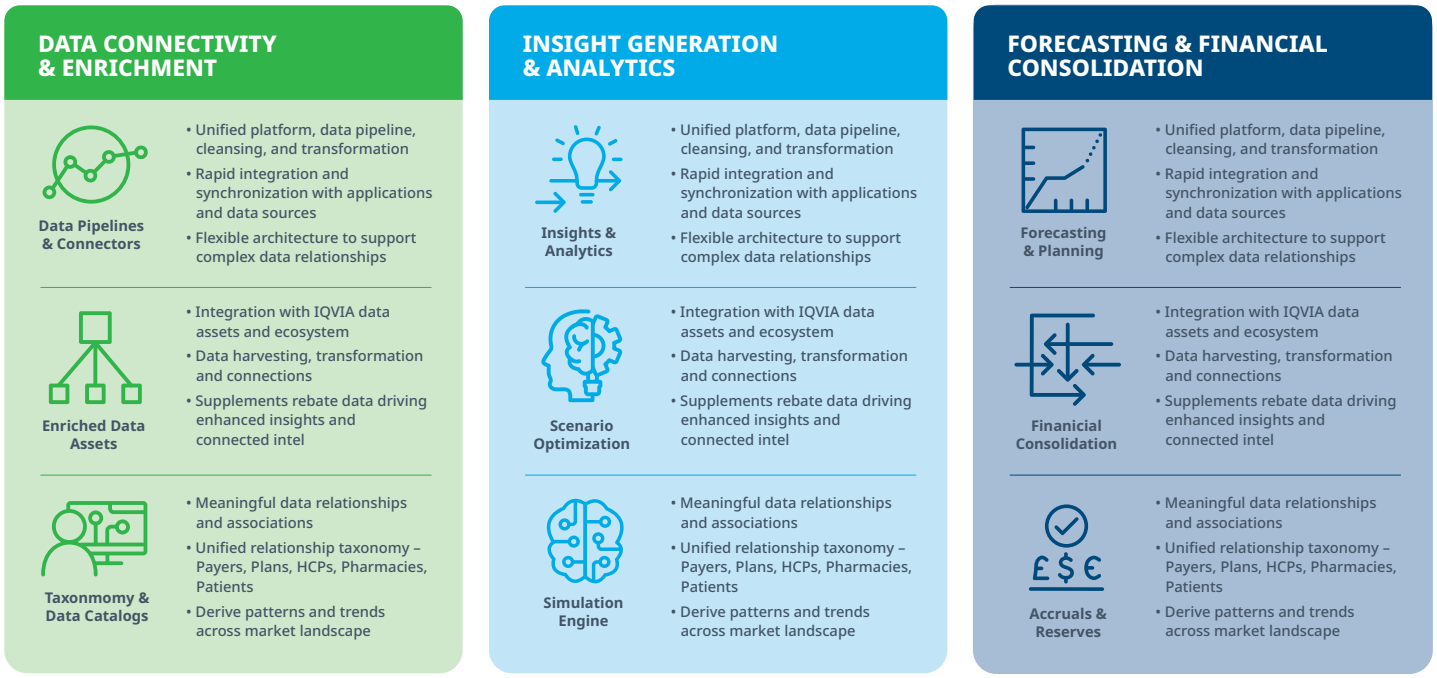
By John Lewis, *Product Strategy, IQVIA Market Access Center of Excellence*

Life sciences organizations increasingly face demand and margin pressures associated with market access challenges, regulatory changes, and program redesigns. Evaluating and understanding contracting strategies that remove access barriers while providing the most value to the organization is becoming extremely difficult to navigate. The need to improve competitive positioning while optimizing net revenue and profitability is at the forefront for market access and financial stakeholders. These compounding effects add to the complexity, attention, and scrutiny associated with managing the financial exposure related to extensive sales deductions and rebates across customer channels.

Unfortunately, inefficient processes and a lack of automated solutions that help address these challenges have long been the norm. Manual processes, spreadsheets, and antiquated point solutions that address only parts of the revenue management and gross-to-net lifecycle often leave key market access and financial stakeholders disconnected. These inefficiencies further increase departmental boundaries and add to the difficulties of accessing timely and accurate insights needed to manage a complex gross-to-net ecosystem.

IQVIA's Market Access Center of Excellence team recognizes the importance of addressing these challenges for the life

The connected gross-to-net intelligence ecosystem



sciences industry. Providing thought leadership to clients has long been our core focus. We have been engaged in helping clients understand, plan, and navigate challenges with our innovative, industry-leading solutions and services. By enabling connected intelligence across organizational personas, and making continuous advancements in data acquisition, enrichment, and business process automation, IQVIA can provide superior value to our clients through a single integrated platform driven by a connected intelligence ecosystem.

If market access, launch, patient service, revenue operations, preservation, or optimization challenges are pain points for your organization, you are not alone. IQVIA is well-positioned to support customers in navigating this journey through established data frameworks and connectivity across a suite of solutions and services. Consider IQVIA Orchestrated Gross-to-net – a suite of solutions and market insights focused on creating a data-based understanding of a product portfolio's financial ecosystem, driving superior value through a connected intelligence and business process automation.

To learn more, contact Scott Brzygot at IQVIA Market Access Center of Excellence.

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