Q2, June 2021

Market Access

Quarterly Advisor

IQVIA

Is it time for value-based contracting to go mainstream?

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

As the contract environment keeps evolving, let's pause and focus in on defining value-based contracting (VBC). There are multiple examples of innovative contracting in the market, such as the "Netflix Model" being utilized with Hep-C manufacturers in the states of Louisiana and Washington. Or, consider the amortized payment models being used by some rare/orphan drugs to spread payment out over four or five years. While both examples are innovative, are they really value-based contracts?

True VBCs would represent a manufacturer's guarantee of efficacy to hit pre-determined endpoints that are agreed to by the contracting parties in advance. Historically, there have been many obstacles to seeing these implemented. Common questions such as who holds the risk, who does the measuring, and what is the availability of data, have made such contracting challenging. Another very real challenge is the impact on a manufacturer's best price calculations.

A simple example of the best-price implications demonstrates how challenging contract non-performance could be. Let's assume that the manufacturer and contracting parties agree to a simple "Our drug works or it's free" endpoint. This may sound like a great way for the manufacturer to put their money where their mouth is as they may feel exceptionally confident that they will hit their efficacy endpoint based upon clinical trial results.

However, relative to best price rules, a single failure to meet the stated endpoint would set a new best price of free! Thus, the one claim that a manufacturer may be willing to give away now has set a new best price benchmark for the entire Medicaid channel for the next reporting period. A very expensive prescription, indeed.

The Centers for Medicare and Medicaid Services (CMS or the "Agency") recognized the best price challenge in recent guidance issued at the end of 2020[1].

"Rules on prescription drug rebates and related reporting requirements have not been updated in 30 years, and are thwarting innovative payment models in the private sector," said CMS Administrator Seema Verma. "Medicaid's outdated rules have consistently stymied the ability of payers and manufacturers to negotiate drug reimbursement methods based on the actual outcome of the treatment. A new generation of approaches to payment methods is needed to allow the market the room to adapt to these types of curative treatments while ensuring that public programs like Medicaid remain sustainable and continue to receive their statutorily required discounts."

The new approach that Administrator Verma references, however, has yet to be articulated. Opening up a second VBC rebate that would be excluded from best price calculations would make entering into such arrangements more palatable for manufacturers. While technical and operational challenges may still exist, a change in the regulatory environment would be meaningful as incentives for figuring out these other challenges are no longer off the table.

On Wednesday, May 26, 2021, CMS released a Proposed Rule that delays certain provisions of the Medicaid Value-Based Purchasing Final Rule, published on December 31, 2020.

Specifically, CMS proposes to delay for six months the January 1, 2022 effective date of the measure that permits drug manufacturers to report multiple best prices for each drug when those prices are tied to value-based payment (VBP) arrangements. CMS also proposes to delay the inclusion (inclusion date) of prices of drugs sold in U.S. territories in the calculation of Average Manufacturer Price (AMP) and the Best Price in Medicaid to April 1, 2024.

In the alternative, the Agency is proposing to finalize an inclusion date that may be sooner than April 1, 2024, but not before January 1, 2023, based on public comments received. CMS is requesting public comments on the proposals. Comments are due 30 days after date of publication in the Federal Register.

IQVIA is well positioned to help clients navigate through VBC challenges by way of established frameworks.

Understanding what to contract for, who to contract with, how to measure, how to pay, and how to measure contract compliance are only a few of the tactics we help clients navigate. If you are asking yourself whether value-based contracting is right for you, or otherwise considering such an agreement, please reach out to your IQVIA Market Access specialists.

[1] https://www.cms.gov/newsroom/press-releases/cms-issues-final-rule-empower-states-manufacturers-and-private-payers-create-new-payment-methods

How to manage complex revenue workflows

By Heenal Patel, Principal, Global Pricing and Contracting, and Emily Turturici, Pricing Contracting Delivery Resources, 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.

Case Study

IQVIA assists many clients seeking to improve, unify, and automate their quote-to-cash process through CPQ and/or CLM implementations. Most recently, IQVIA's Global Pricing & Contracting (GPC) team implemented a combined CPQ/CLM system for a large biopharmaceutical manufacturer that was relying on manual tools to execute and store offers and agreements (e.g., SharePoint, Excel spreadsheets). The case study below details the engagement.

Case Study - Apttus CPQ & CLM Implementation

Profile

Client: Large Biopharmaceutical Company

Project: Managed Markets & Strategy Operations Apttus CPQ & CLM Implementation

Challenge

- No single repository for all Managed Markets proposals, agreements, and amendments
- Lack of standardized workflows or templates for the Pre-Deal or Contracting processes
- Inability to report on negotiation cycle times
- Difficulty searching for agreements with special or customized terms
- Loose tracking of approvals on new contracting strategies and/or customer proposals

Goal

- Increased efficiency with automated standardized workflows and self-service capabilities built to scale
- Governance. Structured and auditable review and approval process for Proposals and Contracts
- Single Source of Truth. One system to request, manage, and store all Pre-Deal and Contracting related documents and approvals

Results

- Implemented Apttus CPQ & CLM modules for all departments within the Managed Markets team. 4 new record types, 14 workflows, 20 templates, 200+ fields, and 10 reports configured
- Moving forward all Managed Markets proposals will be entered and approved in CPQ and used as the basis for future agreement creation, negotiation, and execution
- Migrated Legacy contract records for active Agreements

GPC worked closely with the impacted teams to design a fully connected CPQ CLM solution that addressed current challenges, achieved future goals, and met all compliance/audit standards. A successful implementation improved the overall pre-deal through contract execution processes, and ultimately, the manufacturer gained process optimization, transparency, and increased compliance.

Conclusion

Through its expertise in the CPQ/CLM space and top-notch consulting services, IQVIA is helping manufacturers take the first step in implementing a CLM/CPQ solution.

Patient Services: Clinical trial reimbursement optimization

By Amy Hathaway, Director Operational Support, Patient Access and Affordability Solutions, and Kevin Curran, General Manager, Patient Access and Affordability Solutions, IQVIA Market Access Center of Excellence

The IQVIA Patient Access and Affordability Solutions (PAAS) team recognizes that, now more than ever, the challenges manufacturers face related to patient recruitment and patient retention are increasing at a steady rate. Providing patients with access to therapy and the tools to remain adherent is a primary focus of Patient Access and Affordability Solutions.

When a manufacturer presents these types of challenges to the PAAS team, part of our recommended solution is the use of web-based tools which provide easy access to program participation for patients and their support system consisting of HUBs, prescribers, and pharmacies. These web-based tools are used for activities such as enrollment, eligibility and attestation capture, producing real-time copay card information, tracking claims and payment history, escalation resolution, and much more. Here, we focus on one tool that has been implemented in clinical trial space — StudyScripts.

The StudyScripts solution provides a method for study participants to obtain study medications at no cost by presenting a prescription for the study medication, or concomitant medications that are pre-defined, along with a uniquely identified card or voucher, activated for a uniquely identified study participant, at a retail pharmacy of the participant's choice. Utilizing a program such as StudyScripts assists a trial sponsor with reducing logistical costs and challenges associated with shipping medications directly to sites by leveraging pharmacy inventories. Patient retention and active participation in the study is more likely when patients are empowered to continue to visit their preferred pharmacy to fill prescriptions throughout the study period.

Tracking of study participants and their utilization of a copay or voucher solution can be difficult through standard reporting or data feeds. To address this challenge, IQVIA developed a portal for the StudyScripts solution designed to provide secure access for authorized parties to

- Actively manage participant enrollment for the medications, and monitor participant adherence by identifying missed refills, which may be an early indication of a potential participant's discontinuation in the program
- Review program metrics
- Re-order cards to be shipped to the study sites
- Reprint cards, in real-time, in the event a patient has misplaced the information
- Activate/deactivate cards
- Maintain study site information
- Maintain study participant information (de-identified)
- Maintain appropriate user access

IQVIA has successfully supported 46 clinical trials with this solution over the past eight years. These clinical trials span Phase II to Phase IV, and across multiple therapeutic areas, including, but not limited to Cardiology, Endocrinology, Pulmonology, and Rheumatology.

To obtain more information about the StudyScripts solution or any other copay-related solutions offered by IQVIA, please contact your Account Executive.

IQVIA Value & Access 2021 Thought Leadership Webinar

By Rob Glik, Vice President, Global Head of Value & Access, Consulting Services, and Jen Karweit, Managing Principal, US Head of Value and Access, Consulting Services, IQVIA Market Access Center of Excellence

IQVIA is taking its annual V&A conference virtual this year by hosting a series of live webinars on hot topics. Our first presentation, IQVIA Value & Access 2021 Thought Leadership Webinar, held in April, focused on the influence and impacts of COVID-19.

As an industry, we have been challenged to adjust to a 'new normal' since COVID-19 interrupted the status quo. But what will be the 'next normal' once the pandemic resides? IQVIA developed a variety of post-COVID-19 recovery scenarios to guide thought leaders' strategic thinking going forward. The webinar explored those scenarios and addressed payer-specific questions to help market access teams prepare for the 'next normal'. If you missed the live presentation, click here to request the on-demand webinar.

Precommercial companies: Want an achievable forecast? Start at the bottom.

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

Did you know that more than half of brands miss their first-year forecast and that of those that miss, only 20% are able to get back on track? Or that compared to historical launches, brands launching into a COVID-19-impacted market experienced as much as 75% more negative impacts on uptake?

No one can fully predict or control the dynamic market conditions that will affect your brand. But you can take a much more granular, sophisticated approach to understanding – and adapting to – complex variables that can make or break your commercial performance.

Leaders in precommercial companies manage multiple functions and responsibilities, including creating a forecast, and then organizing and operating against those assumptions. As your company advances toward launch, how confident are you that your forecast accurately reflects evolving market realities, especially when it comes to increasingly restrictive payers?

A top-down forecast has an important role to play in studying metrics like market volume, share performance, price, gross sales, and expected net sales; yet, those variables can lack the specificity and precision required to succeed today. Many organizations struggle to align on key market, payer, patient, and gross to net assumptions, causing internal strife that compounds stress levels and makes post-launch performance hard to tie back to pre-launch assumptions. It is also common to hear frustration expressed over the inability to describe launch performance in a high-pressure board room meeting when targets are being missed.

For help, consider Dynamic Brand Planning – a bottom-up, payer-by-payer approach to forecasting. It uses data and analytics to model challenging market dynamics that influence your brand performance. It also empowers you to "pressure test" your forecast over time, so you can adjust your commercial strategy and expectations to reflect the latest market conditions.

Dynamic Brand Planning

Explore this topic further and uncover the approaches that can make or break your commercial performance.

Download White Paper

CONTACT US
One IMS Drive,
Plymouth Meeting
PA 19462 USA
+1 513 404 1313
scott.brzygot@iqvia.com
iqvia.com