Case Study



### Improving Access to Rare Disease Therapy through a Unified Data Platform



#### **The Passion for Patient Insight**

IntegriChain first developed a business relationship with this specialty pharmaceutical manufacturer in late 2019 as they were approaching the launch of a new orphan disease drug and were exploring different partners to assist them with launch readiness.

"We don't currently have a product in the pipeline commercialized yet, although we've filed our NDA and we're anxiously awaiting to get our product approval," said the Director of Government Pricing and Gross-to-Net.

The market access team had already made several important decisions regarding their commercialization strategy including:

**Network Design.** The very small population necessitated a closed, specialty pharmacy network design with an intense focus on closely tracking every patient's journey.

**Patient Services.** The rare nature of this disease and therapy meant a high cost of therapy. The access team was concerned about significant out-of-pocket costs as well as potential delays in payer approval.

**Patient Journey Insights.** The team wanted a best-in-class approach monitoring and optimizing the patient journey. They wanted insight into every step of the journey to rapidly identify potential patient access obstacles.

"With price predictability, we really had to reassess some of our programs that we were planning, like the co-pay program, for example. It can affect your best price, and it can affect how things are going to impact your financial bottom line. IntegriChain's Professional Services team have been instrumental in helping us navigate things like government programs. For instance, we were already going down a path of how we thought we were going to lay out a program, and then with the new CMS final rule, we had to reassess it."

- Director of Government Pricing and Gross-to-Net

**Net-Price Predictability.** Given all of the costs required to launch and support this expensive treatment, the manufacturer was concerned about their ability to accurately forecast and accrue for all of the related fees, discounts, and costs.

#### **Getting Gross-to-Net Off the Ground**

With a PDUFA date of mid-2020, the manufacturer engaged with IntegriChain around a Launch Readiness advisory project for a framework for preparing for market introduction. This early advisory work included the development of an initial gross-to-net estimate as well as strategic support on a number of complex pricing and contracting issues.

From there, discussions shifted to design and execution of a gross-to-net process. Pleased with the outcome of the launch readiness project, the manufacturer asked IntegriChain to help with the design of a basic analog gross-to-net process. However, the manufacturer decided that their finance department, numbering only two or three, would benefit greatly from IntegriChain's Gross-to-Net Advisory services:

**Gross-to-Net Advisory.** Leverage IntegriChain's GTN expertise, best practices, and industry benchmarks to ensure an accurate, efficient, and audit-ready GTN process.

With GTN Advisory services in place, the manufacturer could rely on IntegriChain to provide benchmarking and insights on contracting practices for both medical and pharmacy benefits.

While the manufacturer's market access team was small at the time, they anticipated a rapid growth after launch. The manufacturer knew that having an end-to-end revenue solution in place on day one would set them up for success in the future and began implementation of:

Gross-to-Net Solutions

**GTN Forecasts.** Achieve consistent, audit-ready GTN forecasts leveraging IntegriChain's industry-proven GTN methodology library, improve forecast accuracy, and create "what-if" scenario models.

**GTN Accruals.** Increase speed and accuracy of GTN close and improve product related decisioning with trusted, aligned, and consistent data.

As the gross-to-net project got underway, the manufacturer began to rely on IntegriChain's deep market perspective on recent launches to help them work through several strategic issues relating to free goods programs, bundled arrangements, and launch timing.

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#### **One Platform, One Approach**

Simultaneously, the manufacturer and IntegriChain held more strategic discussions during which it became evident that the market access team wanted to take an integrated, platform-based approach to managing their commercialization. They believed that the only way to effectively run their business and ensure patient success was to manage their payer, channel, and patient data in a single platform. They also decided that they could gain better focus on the patient journey by outsourcing several operational aspects of their business to IntegriChain.

Based on the discussions – and anticipating a challenging coverage landscape at launch – both IntegriChain and the manufacturer agreed on a roadmap to achieve their collective market access platform vision. To this end, the manufacturer chose to implement the following solutions from IntegriChain:

"In the co-pay space that's the biggest issue to help the patient, so we had to make sure the gross-to-net was aligned on our end as well. Also, with state pricing transparency, this was all new territory for us and there are so many different caveats and protocols per state. I can remember when it was pre-sunshine act and you had just six states you had to report on. Now it's not as easy as just reporting your expenses, there's a lot more you have to do and each state is different in what they want. IntegriChain provided the guidance, guidelines, and the templates and really helped us prepare to get ourselves ready for when we do launch."

Warket Access Solutions **State Pricing Transparency.** Proactively monitor pricing transparency legislation, mitigate compliance risk, and anticipate potential reporting and disclosure requirements as well as draft, review, and submit pricing transparency reports on behalf of the manufacturer.

**Government Pricing (GP) Managed Service.** Expert management of complexities and compliance requirements of GP, including comprehensive and auditable control reports covering all price calculation details to ensure contractual commitments around regulated pricing submissions are met.

**Rebate Managed Service.** Timely, reliable, and secure contract management, formulary validation, and processing of the full range of claims including Medicaid, Managed Care, Tricare, and Coverage Gap to meet contractual commitments around rebate claims processing.

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Finally, the longer-term view includes expanding State Pricing Transparency program, adding Claim-level Detail (CLD) validation to the existing Rebate Management managed service and expanding the gross-to-net program to a full managed service.

"We wanted to make sure that the patient is getting the best that they need," said the Director of Government Pricing and Gross-to-Net.

#### **Putting the Patient Front and Center**

By May 2020, the situation had changed. The launch date was now a few months away and several things were obvious to the market access team.

- The manufacturer's finance team was not capable of making gross-to-net operational by launch.
- They still lacked a solution for getting accurate, timely insights into the patient journey.

The manufacturer's Senior Vice President of Commercial reached out to IntegriChain for Patient Access solutions and the following solutions were deployed.

**Patient Data Aggregation.** Longitudinal de-identification, patient data mastering, and foundational data quality management of patient data enabling timely, accurate provider and patient insights.

**Refined Patient Data.** Advanced data quality stewardship, data cleansing and master data management (MDM) to enable more timely visibility to providers that are struggling with payer restrictions and more accurately measure the impact of patient service programs on patient initiation and adherence.

**Specialty Pharmacy Analytics.** Patient status data enrichment, patient journey KPIs, and diagnostic scorecarding to accelerate identification of operational challenges with specialty pharmacy (SP) patient enrollment, payer restriction navigation, and therapy on-boarding as well as help identify friction points between network SPs and patient service platform.

With these patient data solutions in place, the manufacturer began seeing the value of their ICyte Platform investment for market access and commercialization.

**Patient Access** 

Solutions

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Typical Benefits	Description
Elimination of missing patient status updates	IntegriChain frequently sees manufacturers in which 80% of new patients have gaps in status updates of at least seven days. Additionally, more than 40% had gaps of two weeks or more.
Clear, concise patient status reports	Manufacturers frequently discovered unexpected utilization of sub statuses that did not correspond to the brand team's expectations of the patient journey (e,.g, excessive use of "Other" as a sub status).
Elimination of missing payer data	Patient data routinely comes into the manufacturer with key payer fields blinded, null, or noted as "not applicable" (N/A). This prevents the manufacturer from gaining a clear line-of-sight into patient access issues.
Longitudinal tracking of the patient throughout their journey	It is quite common for a patient, during the initiation phase, to be transferred from one specialty pharmacy to another. However, those patients often disappear from the transferring pharmacy's data without showing up in the new (receiving) pharmacy's data due to patient mastering issues.
Correct patient status visibility	Resolve foundational issues with the usability of the patient status data, such as problems with status code mapping, delays in updates to individual patient statuses, or potential issues that stemmed back to the aggregation process.
Improved support for pharmacies and providers	The ability to have consistent, data-driven, and proactive discussion about hand offs with provider offices or patient service platforms.
Higher-impact operational reviews and QBRs	Many QBR meetings never get into enough detail to identify actionable operational issues or spend endless cycles debating about how certain KPIs will be calculated and reported.

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#### **Moving Forward**

Simultaneously, the manufacturer and IntegriChain held more strategic discussions where it became evident that the market access team wanted to take an integrated, platform-based approach to managing their business. They believed that the only way to effectively run their business and ensure patient success was to manage their payer, channel, and patient data in a single platform. They also decided that they could gain better focus on the patient journey by outsourcing several operational aspects of their business to IntegriChain.

Based on the discussions, both IntegriChain and the manufacturer agreed on a roadmap to achieve their collective market access platform vision. To this end, the following solutions will be implemented next:

Advisory Services **Gross-to-Net Advisory.** Leverage IntegriChain's GTN expertise, best practices and industry benchmarks to ensure an accurate, efficient and audit-ready GTN process.

**State Pricing Transparency.** Proactively monitor pricing transparency legislation, mitigate compliance risk and anticipate potential reporting and disclosure requirements, as well as draft, review and submit pricing transparency reports on behalf of the manufacturer.

Contract & Pricing Solutions **Government Pricing (GP) Managed Service.** Expert management of complexities and compliance requirements of GP, including comprehensive and auditable control reports covering all price calculation details to ensure contractual commitments around regulated pricing submissions are met.

**Rebate Managed Service.** Timely, reliable and secure contract management, formulary validation and processing of the full range of claims including Medicaid, Managed Care, Tricare, and Coverage Gap to meet contractual commitments around rebate claims processing.



Finally, the longer-term view includes expanding State Pricing Transparency work, adding Claim-level Detail (CLD) validation to the existing Rebate Management managed service and expanding gross-to-net to a full managed service.

## Gross-To-Net Solutions

**GTN Forecasts.** Achieve consistent, audit-ready GTN forecasts leveraging IntegriChain's industry-proven GTN methodology library, improve forecast accuracy and create "what-if" scenario models.

**GTN Accruals.** Increase speed and accuracy of GTN close and improve productrelated decisioning with trusted, aligned and consistent data.

#### Conclusion

Despite being a small manufacturer targeting a rare disease, the market access team had a vision that they wanted to run their business on a unified platform. "One of the things that sold us on going all in on the one platform with ICyte was that we wanted the one-stop-shop with all the services bundled," the Senior Vice President of Commercial said.

"Everythingseamlessly integrates. And with launch readiness, there's a lot that is going hand in hand so it "IntegriChain's expertise in patient data, their vision around a true market access platform, and their vision of helping patients initiate and adhere to critical therapies was a perfect fit for us."

**Chain**<sup>®</sup> IntegriChain<sup>®</sup>

- Senior Vice President, Commercial

just made sense. I like that while we work on the policies, procedures, and methodologies, all of our government contracts, pricing, and data ready data is all in one spot so we can go to launch as soon as we get our FDAapproval."

Like IntegriChain, this manufacturer put the patient at the center of what they do. Throughout the engagements, the market access team maintained a laser-like focus on being able to quickly identify, assess, and mitigate any obstacles that could impact patient initiation and adherence to therapy. At the same time, they understood all of the issues around their high cost of therapy, network design choices, and patient services investments as well as how all of this would impact their gross-to-net processes.

The combination of IntegriChain's unsurpassed depth of expertise in patient data aggregation, mastering, refinement, and analytics together with the unified ICyte Platform for market access makes IntegriChain the natural partner for this manufacturer.

#### About IntegriChain

IntegriChain is Life Sciences' data and application backbone for patient access and therapy commercialization. More than 250 manufacturers rely on IntegriChain's ICyte Platform to orchestrate commercial and government payer contracting, patient services, and distribution channels. ICyte is the first and only platform that unites the financial, operational, and commercial data sets required to support therapy access in the era of specialty and precision medicine. With ICyte, Life Sciences innovators are digitalizing labor-intensive processes – freeing up their best talent to identify and resolve coverage and availability hurdles and to manage pricing and forecasting complexity. IntegriChain is backed by Accel-KKR, a leading Silicon Valley technology private equity firm. The company is headquartered in Philadelphia, PA, with offices in Ambler, PA; Somerset, NJ, Raleigh, NC, and Pune, India.



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