

# Ensuring Day 1 Readiness for Innovative Oncology Therapy



## BATTLING BREAST CANCER

In early 2018, an emerging pharmaceutical manufacturer found itself preparing for the launch of an innovative, infused therapy. While preparing for launch, the customer identified a number of challenges that would need to be addressed:

- The need for a comprehensive, low-maintenance contract and pricing solution to ensure all contracts were in place on Day 1. They needed coverage for all government price types including monthly Average Manufacturer Price (AMP) and quarterly AMP, Best Price (BP), Average Selling Price (ASP), Federal Supply Schedule (FSS), and Non-Federal Average Manufacturer Price (NFAMP).
- The ability to calculate net price for their new drug and ensure their Gross-to-Net calculations accurately accounted for all incentives, fees and discounts
- Data aggregation and visibility to all sales and inventories to manage its specialty distribution network and its customer base of infusion centers, oncology groups, and health systems
- Accurate sales rep incentive compensation and performance management tools. Due to increasing visibility challenges caused by data redaction and increasing 340B contract pharmacy white and brown bagging, the manufacturer needed a reliable data source that could be aligned with its Veeva CRM and Nitro data warehouse system.

After going through a formal proposal process, the manufacturer selected IntegriChain to handle its government pricing. With the help of outside legal counsel, pricing policies were developed in tandem with the rollout of the managed service, ensuring alignment between the two.

### 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.



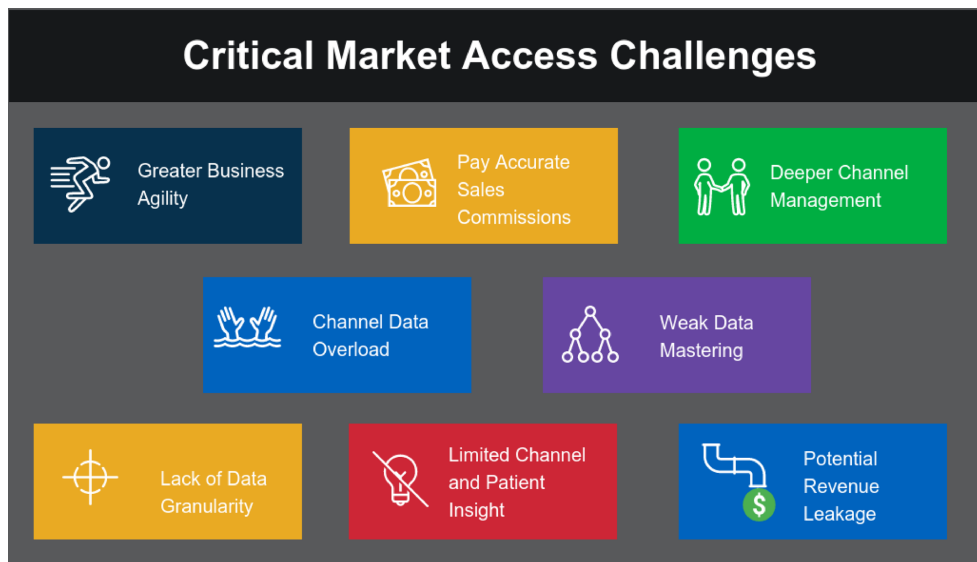
**Chargeback Managed Service.** Timely and accurate processing of chargeback claims against contract eligibility and discount levels to reduce revenue leakage, meet contractual commitments, and improve accuracy of GTN accruals.

The project and relationship took an unexpected turn at the end of 2018 when the customer suddenly received a Complete Response Letter (CRL) from the FDA, indicating that the agency would not approve the application for the therapy in its present form and for the specified indication. This turmoil ripped through the customer’s organization, causing executive-level turnover and effectively putting the project on hold.

## Pivot and Reset

In early 2019, however, the situation looked quite different. The manufacturer had new commercial leadership in place and was seeking accelerated approval of its treatment. Meanwhile, IntegriChain had expanded its portfolio, creating a best-in-class payer solution that incorporates gross-to-net and government pricing solutions. Based on some casual meetings during the 2019 ASEMBIA conference, IntegriChain followed up with meeting with the manufacturer’s new head of analytics, who was already aware of IntegriChain’s data management capabilities from a previous position. He wanted to become more knowledgeable about how to better leverage EDI 852 and 867 data to improve their channel and patient insight. Although they had recently signed a contract with a competitor, the customer became increasingly impressed with IntegriChain’s expertise around data enrichment and insights around leveraging 867 data, as well as the time IntegriChain invested in presentations and workshops.

During these discussions with the manufacturer’s executive leadership as well as commercial finance, market access and trade/channel management functions, several business challenges became evident:



1. **Criticality of Business Agility.** In a small manufacturer, it is imperative that the leadership team, including the board of directors, understand the health of the business as close to real-time as possible.
2. **Paying Accurate Sales Commissions.** The manufacturer's drug used a buy-and-bill model, as it was mostly purchased directly by oncology clinics and hospitals. Consequently without using channel data, there was no trusted, clean information which is required to calculate sales force performance and incentive compensation. In addition, distribution data (e.g., EDI 867 data) for oncology brands often contains 5-10% data redaction, making the data virtually unusable.
3. **Deeper Channel Management.** The leadership team was envisioned an integrated approach to managing the relationship of providers, points-of-care (POC), and patients. The customer shared that they were using Veeva for reference data and wished that Veeva and IntegriChain had some level of integration. More specifically, they were looking for integration around mastering POCs, hierarchical relationships of treatment centers, and the need to have Veeva's HCP affiliation data integrated into IntegriChain's POC data for a complete view.
4. **Channel Data Overload.** The manufacturer was engaged with a number of wholesalers, each of which provided the manufacturer with critical sales and inventory data. However, each of the six wholesalers transmitted data at different times of the day, resulting in the manufacturer receiving four or five different files every day, for each of the wholesalers. This created a huge amount of data to ingest, de-duplicate, cleanse and perform master data management prior to sending it on for downstream analytics. The combination of data volume and complexity made it difficult to accurately assess the performance of the business and rapidly respond to channel-related issues.
5. **Weak Data Mastering.** All of this sales, inventory, channel mix, patient status, and prescription dispense data was sourced from different systems and could not be mastered and aligned to generate information needed by market access, finance, and sales operations. Furthermore, data quality and integration challenges with the company's data warehouse and CRM system created disputes and inefficiency in the incentive compensation process.
6. **Level of Data Granularity.** The manufacturer routinely received specialty pharmacy or syndicated from 3rd-parties which tracks sales down to the physician level. However, their channel data reflects shipment to an address, not a specific physician. This inability to link physician-level call reporting and syndicated claims data with channel sales data made it difficult for the market access teams to evaluate sales performance and messaging effectiveness. It also hampered the ability for account management and

field reimbursement management (FRM) teams to quickly identify, triage, and remediate patient access issues.

7. **Limited Channel and Patient Insight.** IntegriChain learned that the manufacturer was lacking critical insights from their market access platform and channel data including:
  - Comprehensive patient status data that tracks all of the steps from in-take, benefits verification, prior authorization, financial assistance, shipment, refills, transfer, discontinuation, or closure.
  - Key drivers of the patient journey including Time to First Fill, First Fill Rates, Time on Therapy, and Proportion of Days Covered
  - Pharmacy-level insight into provider and payer level issues that are driving the pharmacy's performance
  - 100% visibility into dispensing and inventory positions as well as sales transactions across all of their partners
  - Insight into co-pay utilization
  - Identification of providers who are struggling to work with the brand's network and service model
  - Trends for purchasing patterns to discern changes in channel models, speculative purchases, and channel over- or under-allocation
8. **Potential Revenue Leakage.** The final priority involved potential revenue leakage around administration fees. The manufacturer contracted with several group purchasing organizations (GPOs). As part of the contract, the manufacturer needed to pay the GPO an admin fee that is based on the volume of business that flows through the GPO. The manufacturer uses the 867 data from the GPO along with chargeback data from the wholesalers to calculate the correct admin fee based on the amount of business that went through each GPO. Even though the admin fees are a small percentage, the absolute dollar amount for specialty drugs can be very high. Therefore, the accuracy of chargeback validation and rebate management becomes extremely critical.

## Full Speed Ahead

This time, the customer's major concern was speed and time to market. Since they were pushing for an accelerated approval, their launch date could come at any time. This meant that all of their Medicaid, Federal Supply Schedule (FSS), TriCare, and 340B contracts needed to be in place as soon as possible. The Medicaid contract was a particular area of concern. The quarterly nature of the contract meant that the contract needed to be in place by the end of April 2019 in order to achieve an effective date of July 1st. Any delay in contract finalization would cause the effective date to slip from July 1st to October 1st.



Ultimately, the combination of IntegriChain's expertise, comprehensive platform covering data, contracts and pricing and gross-to-net, Veeva integration, and passion for the customer's business convinced the customer to make IntegriChain their market access solutions partner. IntegriChain had even initiated discussions with Veeva regarding the integration of IntegriChain's Master Data Management (MDM) with Veeva's OpenData, with the focus primarily on Oncology POCs. Within a few weeks, IntegriChain was able to demonstrate seamless integration linking providers to POCs to channel data.

The leadership team was impressed with IntegriChain's initiative and commitment to success that they terminated their existing data management contract and selected the following IntegriChain solutions:

Advisory  
Services
**Channel Advisory**

Develop world-class channel data aggregation, refinement, data management and channel analytics strategies leveraging industry best practices and benchmarks.

 CHANNEL DATA  
SOLUTIONS
**Channel Data Aggregation**

Aggregate all channel data sets, including distributor sales, distributor inventory, specialty pharmacy inventory, and product returns.

**Inventory Analytics**

100% visibility to downstream inventory, from the retail pharmacy shelf to specialty, mail and institutional channels. Reduce risk of channel stock-outs, accrual risks while improving forecast accuracy with total pipeline inventory reporting.

## Outcomes

Thanks to IntegriChain, the customer's market access, finance, and contracting functions were in place to support the successful launch of their therapy.

- **Operational Readiness.** With IntegriChain, the field reps know the number of units that each physician, at each site in their geography, purchased in the past 12-24 hours. This signals the field teams that (1) a new patient has started therapy and (2) which
  - All government contracts were submitted one month ahead of the desired deadline. While the Department of Veterans Affairs has delayed the FSS contract, all other contracts are active. The potential one quarter delay in Medicaid contracting was avoided.
  - Gross-to-Net calculations are being efficiently managed with processes fully transparent to the customer.
  - Government pricing calculations began May 2020 and are fully managed by IntegriChain.
  - All Drug Data Reporting (DDR) reporting is in place and ahead of schedule. This ensures compliance with the Medicaid Drug Rebate Program (MDRP) and that State Medicaid agencies are aware of the newly-marketed therapy.
  - The customer was confident in their ability to accurately pay incentive sales compensation. Additionally, sales reps are spending more time selling and less time dealing with compensation related concerns.

- **Actionable Data for Field Teams.** With IntegriChain, the field reps know the number of units that each physician, at each site in their geography, purchased in the past 12-24 hours. This signals the field teams that (1) a new patient has started therapy and (2) which doctor ordered the therapy. From there, the field reps can proactively engage the doctor and learn about their experience as well as work with nursing teams to enable outreach to ensure a positive onboarding experience for the patient as well. All of this is made possible with IntegriChain's ability to both unblind data as well as refine and master data in near real-time.
- **Automated Data Management.** The manufacturer now has multiple files coming in every day which are aggregated, cleansed and mastered by IntegriChain. From there, the files go directly to their Veeva commercial data warehouse (CDW). Built-in rules in the CDW feeds the manufacturer's business intelligence (BI) tools which then communicates information down to the field teams. All of this happens without any manual interventions, minimal handoffs and close to real time.
- **Insight for Leadership Team.** The leadership team also receives multiple reports each data that ensure they have a constant view of inventory levels across their entire supply chain as well as how much demand has gone from wholesalers to clinics. This information enables the team to project current and future sales levels, adjust inventory levels, and proactively manage relationships with trading partners.
- **A Culture of Trust.** IntegriChain's transparency and close collaboration has created trust and confidence in IntegriChain's ability to deliver. There are no surprises of unanticipated market access hurdles. This ensures patients have no gaps or lags in coverage.

## Looking Ahead

The relationship has continued to grow, leading to several other related engagements:

- **GPO Management:** IntegriChain handles all of the GPO administrative fee calculations and payments and alerts the customer and provides detailed documentation when there are discrepancies.
- **Medicaid Rebate Management:** Delivering 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 ensure contractual commitment around rebate claims processing are met.

What began as a relationship to provide essential contract operations in preparation for launch has matured into a collaboration where the customer has realized the benefits and efficiencies



of a comprehensive market access platform supporting their cross-functional business. IntegriChain now provides a vast array of operational, data and analytical functions which are vital to the day-to-day operations of the customer's organization. As in the beginning, the customer continues to be impressed with IntegriChain's expertise, operational aptitude, responsiveness as well as the flexibility of our ICyte Platform

**About IntegriChain**

IntegriChain delivers Life Sciences' only comprehensive data and business process platform for market access. More than 220 life science manufacturers of all size and complexity rely on IntegriChain's analytics, applications, managed services and expert advisors to power their operations and harness the value of their channel, patient and payer data. IntegriChain has played a vital role in more than 70% of product launches over the past two years including 35 first launches. For more information, please visit [www.integrichain.com](http://www.integrichain.com) or [ic@integrichain.com](mailto:ic@integrichain.com)



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