IntegriChain®

Using Market Analogs for FP&A During Product Launch

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Introduction

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Commercialization success and product profitability are traditionally evaluated on a product's gross sales, however companies are increasingly considering net sales and the value of investments in access rebates, co-pay cards, price protection, stocking programs, returns, and discounts like 340B and FSS. However, estimating the value of net sales adjustments from a Finance perspective can be very difficult due to a lack of available internal data and market information. The problem is especially acute before launch and in the first few quarters the product is on the market.

Factors Contributing to Net Sales Forecasting Challenge

- **Complex distribution networks across multiple channels**
- **More complicated contracts and price strategies including value and outcomes-based agreements**
- **Lengthy lag time between product sale, rebate claims, co-pay redemptions and returns**

At the same time, Financial Planning & Analysis (FP&A) teams are under increasing pressure from their CFOs and external auditors to adopt data-centric forecasting models, as opposed to assumptions-driven approaches. Excessive quarterly true-ups and year-end adjustments are increasingly scrutinized and large variances are not acceptable. Changes in revenue recognition rules, as well as profitability concerns, are driving the increased level of attention. As a data and analytics provider to over 130 bio/pharma manufacturers, IntegriChain often provides market-level benchmarks and analogs (i.e., metadata) that could be used in a data-enabled approach to gross-to-net. Market analogs are especially valuable when manufacturers are confronted by other product lifecycle events beyond launch including loss of exclusivity (LOE), or market entry of a competing brand.

Market Benchmarks

IntegriChain's Market Benchmarks are cross-manufacturer, blinded metadata derived from a basket of similar products in a therapeutic area or class. We use direct and indirect sales, returns, chargeback and rebate data collected across our 130+ customers and then apply rigorous privacy rules and data science to create a variety of analogs such as launch uptake curves, channel mix, payer mix, returns, and decay curves.

See **Appendix: Market Benchmarks** for more information on the datasets IntegriChain cultivates to create Market Benchmarks.

IntegriChain Market Benchmarks can serve as the foundation of a data-driven approach to financial planning & analysis for product launch. Manufacturers adopting this methodology would then have a credible source as the basis for estimating sales adjustments and a methodology that's been readily accepted by external audit firms.

This paper analyzes the potential benefit of using Market Benchmarks to produce estimates for managed care rebate allocations, product returns, and wholesaler chargebacks in support of product launch.

Rebates Allocation and Estimation

Most manufacturers contract with a variety of commercial, Part D and government payers, Federal and state Medicaid programs, health systems and distributors, many of which result in an after-sale rebate or fee payment. Consequently, estimating the impact of contracts on future rebate allocation is often the first or second budget item in any P&L.

At product launch, Finance teams are required to develop reasonable estimates of utilization and rebate rates across contracts and rebates. Rebate estimates are typically accrued at the time of product sale. For launch brands lacking sales data, access to competitive market analog product utilization trends at the payer channel level enables a defendable and data-driven approach to the estimation process.

The analysis conducted for this paper leveraged cross-manufacturer payer/plan level data across a selection of four key therapeutics classes, all of which are leading specialty drug categories, to demonstrate the current payer channel distributions:

- Oral Oncology
- Multiples Sclerosis
- Immunology
- Hepatitis C

Our analysis highlights the differences in product utilization across the categories. Observations from the meta-data analysis suggest a great degree of variability in the payer channel distribution model. From a launch perspective, it becomes increasing important to make reasonable estimates leveraging analog datasets, which provide transparency into payer channel level utilization trends during the first year post launch.

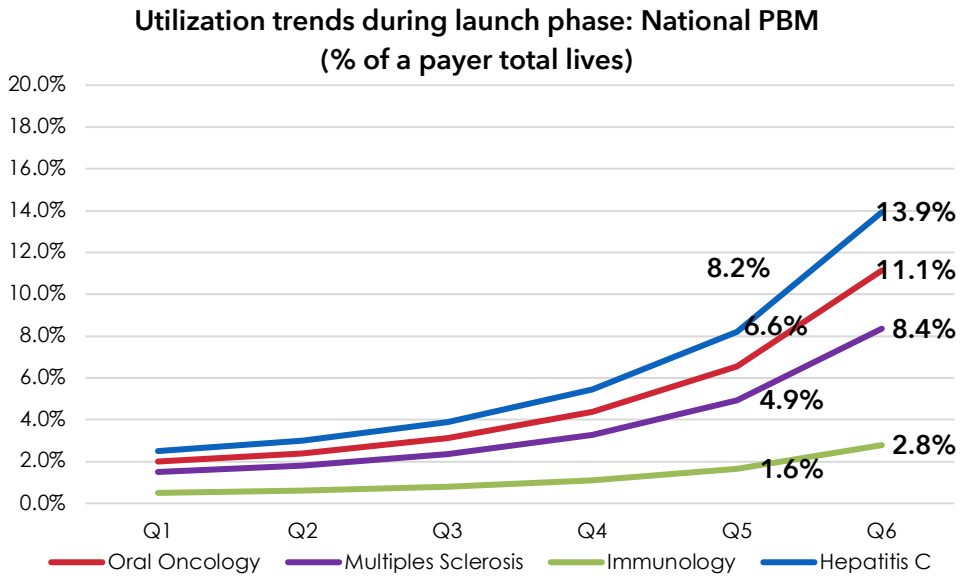

Figure 1: Utilization trends for six quarters post launch. Data analysis shows uptake for major therapeutic categories including Oral Oncology, Multiple Sclerosis, Immunology, and Hepatitis C. *Source: IntegriChain, 2018*

Additionally, the rate of utilization uptake post launch has tremendous variability by payer over time, which creates complexities when trying to assess the net profit of aproduct and reduce excessive variability in gross-to-net reconciliation. Through the use of rich analog data at the payer channel level, Finance teams can apply Marketing's unit forecast to the corresponding utilization rates by payer channel in order to create a reasonable estimate of managed care rebate liabilities. Moreover, by paying close attention to channel inventories, Finanace can conduct more accurate quarterly true-ups.

Estimating Product Returns Accruals

The significant lag between sales and returns makes estimating returns risk liabilities a formidable challenge for Finance. Estimating the returns risk liability is particularly challenging when robust in-house analog data is not readily available, which is typical for launch products. To address the need for a data-driven model in support of estimates, IntegriChain leverages cross-manufacturer sales and returns data across several therapeutic classes. The analyses allows a Finance team to assess both current (steady state) returns rates as well as those associated with launch sales to identify if there are any variances within the product lifecycle by therapeutic class and across classes.

From this perspective, the current (steady state) returns rate is defined as the average of H2 2017 basal returns rate. The returns rate from launch is defined as the total returns actualized post launch from month 12, and is expressed as a percent of the first 12 months gross sales volume. This two-pronged approach gives Finance the ability to:

1. Estimate a reasonable, returns accrual based on the internal forecast of anticipated gross revenue year 1 post launch
2. Generate a robust *returns accrual range*, which can then be refined based on their channel design and expected commercial contracting strategies.

Table 1 (below) demonstrates the variability of returns across various classifications of specialty products. More importantly, the table shows the difference between returns related to in-line products versus returns resulting from product launch. The broader pharmaceutical finance community is increasingly adopting this type of data-driven analysis to meet the changing business rule requirements pertaining to revenue recognition set forth by external audit teams.

Analog Group	Current State	Launch
Cold Chain (Injectable)	0.34% (n=9)	0.35% (n=3)
Combined Retail (Infusible)	0.18% (n=9)	2.88% (n=6)
Non Retail (Infusible)	0.24% (n=8)	0.73% (n=7)
Combined Retail (Tablets)	0.14% (n=10)	1.33% (n=10)

Table 1: Cross manufacturer gross factory sales and returns data (2015-2017); Launch returns rate assumes average product dating of 18 months and returns good window of 6 months pre-expiry and 12 months post-expiry.

Wholesaler Chargeback Accrual Estimates

A portion of the overall volume for most products is distributed through the non-retail institutional platform. The non-retail channel typically covers government programs and other contracted customer groups. The pricing model for these entities differs from the model applied to commercial payers, and within this group there tends to be a differential price concession structure by covered entity. Customer entities that purchase product indirectly from a wholesaler do so at their specific, lowered contracted price.

Class of Trade	Share of Chargeback Volume of Total Sales
Inpatient Pharmacy at Hospital	30%
Dialysis Clinic – Chain	14%
Military Facility	8%
Misc. Outpatient Clinic /Practice	8%
VA Hospital	8%
Misc. Federal Hospital	4%
Chain Drug Store Pharmacy	4%
Dialysis Clinic	2%
DSH/PHS Outpatient Pharmacy	2%
VA Clinic/Pharmacy	2%
Mass Merchant Pharmacy	2%
DSH/PHS Hosptial	2%
TOTAL	85%

Table 2: Cross manufacturer enriched EDI 867 and EDI 844 models. *Source: 2017 Vaccines; EAs volume; Class of Trade level.*

Since the wholesaler initially acquired the product at wholesaler acquisition cost (WAC), they then "charge back" the difference to the manufacturer. Since wholesaler chargebacks are estimated and accrued at the time of product sale, leveraging cross manufacturer EDI 844 data allows Finance teams to estimate the chargeback rate as a percent of overall sales by class of trade. A data-driven approach, grounded in non-projected data and visibility by therapeutic class, is a much more robust methodology for estimating wholesaler chargeback liabilities.

Junior Parent (IDN/GPO)	Account Count	Share of Total Volume as Chargebacks
Mother Frances Hospital (Tyler, TX)	2	0.18%
Holy Cross Hospital (Silver Spring, MD)	2	0.17%
Inova Fairfax Hospital (Falls Church, VA)	2	0.16%
North Central Baptist (San Antonio, TX)	1	0.16%
Parkview Hospital (Fort Wayne, IN)	1	0.16%
Abbott Northwestern Hospital (Minneapolis, MN)	1	0.15%
Swedish Medical Center – First Hill Campus (Seattle, WA)	1	0.13%
Sharp Mary Birtch Hospital (San Diego, CA)	1	0.13%
Virtua West Jersey Hospital (Voorhees, NJ)	2	0.12%
Elmhurst Hospital Center (Elmhurst, NY)	2	0.12%
Woman's Hospital (Baton Rouge, LA)	1	0.11%
Pomona Valley Hospital Medical Center (Pomona, CA)	1	0.11%
TOTAL	**4,908**	**30%**

Table 3: Cross manufacturer enriched EDI 867 and EDI 844 models.

The data in Table 2 (above) provides an example of chargeback liabilities associated with injectable vaccines. By leveraging these types of market analogs, Finance teams are able to apply the launch product's own estimate of yearly gross sales to the class of trade level distribution, as well as corresponding product discount rates.

Additionally, increased visibility into account level chargeback share and market level pricing concession structures provide Government Contracting & Pricing teams benchmark data to support pre-launch pricing at the broader group purchasing level (See Table 3 above). This level of data analysis can provide further accuracy when determining chargeback liabilities as estimates can be based on individual contracts while taking into account volume and pricing.

Summary

In conclusion, market benchmarks can be leveraged to increase accuracy when determining key sales adjustments that are integral to any product's top line profitability. Distribution model visibility at various levels, including channel, class of trade, and account, enable a data-driven approach to financial planning & analysis for product launch.

Additionally, manufacturers are able to ground their estimates in the product's own gross revenue forecast, which coupled with distribution trends from the market analysis, supports increasingly accurate financial modeling. The methodology laid out in this body of work has been readily accepted by external auditor firms as it relies on observed data to estimate sales adjustment liabilities in support of new product launches.

Appendix: Market Benchmarks

Through unified master data management and data enrichment processes, IntegriChain creates and maintains a number of datasets that serve as the foundation for our Market Benchmarks and analogs.

Enriched 867 Data

The enriched 867 data model allows finance teams to readily leverage cross-manufacturer insights to view the current distribution of product volume by channel across therapeutic classes. This type of longitudinal visibility into product distribution trends at a downstream customer and class of trade level allows manufacturers to assess the likely impact of rebate allocations at an aggregate channel level, and determine changes over time.

Ex-Factory Data

Starting with pre-defined analog selection criteria, the Ex-Factory dataset provides product returns rates across various therapeutic classes over time. The cross-manufacturer insights capture changes in returns behavior as a result of continuous changes in the pharmaceutical supply chain landscape.

Rebate Data

Rebate contracts, detailed claims and payment information from Medicaid, Managed Medicaid, Commercial and Medicare Part D payers is a helpful resource for understanding the payer channel mix by therapeutic class.

Enriched 844 Data

The enriched 844 data model provides a robust market view of product distribution trends through the lens of eligible downstream contracted entities as a percent of overall gross sales. These insights provide government pricing, contracting, and finance teams with the ability to understand, from a market perspective, liabilities associated with wholesaler chargeback volumes. This approach makes it possible to create reasonable and defendable sales adjustments.

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