As today’s sales and marketing channels becoming increasingly complex, so do the structure of contract terms with customers. Enter gross-to-net management, a regulatory obligation for manufacturers to accrue for discounts and other financial elements and properly state these liabilities on income statements. Excellence in gross-to-net management, however, can have much broader implications, as companies that can more accurately forecast discount liabilities can also apply these principles to understand the potential impact of contract decisions on their business.

For example, a company that can predict with more certainty that paying a greater rebate for “preferred” status on a formulation that has little impact on its sales volume and market share will be in an advantageous position to minimize rebates and thus improve its net selling price. Through improved gross-to-net management, a company that can achieve merely a 1% percent change in net price can often have a 5-10% impact on its profit. Industry studies have also found over and over again that operational revenue leakage within Pricing & Contracting can be 4% of total revenues. Well-defined and -implemented gross-to-net analytics including benchmarking analyses, identification of outliers, and executive dashboards can identify over-payments of customer obligations that significantly improve bottom lines.

To understand and best address this complex area, we first define the scope and complexities for understanding gross-to-net management which extends well beyond the forecasting of rebates, chargebacks, and administrative fees within managed markets. From an accounting perspective, any deduction to gross sales needs to be accounted for and reported and thus is a part of gross-to-net management. With this understanding, we take a much more detailed look at the gross-to-net components within managed markets to understand forecasting of related transactions that impact gross-to-net. It is this understanding that’s the key to transforming gross-to-net management from merely a back-office accounting function to a strategic management tool that improves contract decision-making across a company’s product portfolio.

Scope and methodology
Accurate forecasting and management of gross-to-net encompasses much more than purely creating a trend line or benchmarking deductions against historical averages. Specifically, gross-to-net involves expertise in a number of areas for any product you’re managing:

1. The product and therapeutic class: Key differences in the type and amount of deductions required by a company will be driven by whether or not the product is brand or generic, the degree of competitiveness within the therapeutic class, stage of the product lifecycle, whether or not the product is retail- or hospital-based, and finally the type of distribution model the company will utilize for the product (e.g. direct, indirect, specialty).

2. The potential types of discounts/credits that are going to be offered: Some of these discounts/credits will be applicable to almost every product while others will be more specific to different types of products. These discounts/credits fall into one of three categories:
   - Supply Chain Discounts: Discounts that are paid to customers related to the physical distribution of a company’s products. These discounts include wholesaler discounts and pharmacy discounts along with related returns, prompt pay discounts, and promotional allowances.
   - Commercial Managed Markets Discounts: Rebates, administrative fees, upfront off-invoice pricing, and chargebacks to commercial customers including PBMs, managed care organizations, GPOs, private hospitals, and Medicare Part D plans.
   - Government Discounts: Those same discounts as described above but to government entities such as DOD, PHS, Medicaid and state supplemental plans.
3. Forecasting Methodologies: The tools and techniques used to forecast the actual liabilities for the above discounts described. Some of the simpler forecasting tools include extrapolation of historical averages such as a percentage of sales (in the case of estimating chargeback liabilities), rolling averages, and weighted rolling averages. Some of the more complex techniques include leveraging analog models and advanced quantitative models including multiple regression models. Many times, simpler models will suffice; however, in the managed markets area forecasting of contract utilization under “contract” or “no contract” scenarios has been challenging. In these cases, more sophisticated forecasting of the maximum utilization that can be achieved as well as how fast it will be achieved (e.g. adoption) should be undertaken. This maximum not only drives more accurate gross-to-net calculations but forms the foundation for optimal pricing and contracting decisions. Given that commercial managed markets typically represent one of the largest gross-to-net discounts, greater forecasting precision in this area will drive less variance in overall gross-to-net.

Integrating gross-to-net with contracting strategies

While gross-to-net from an Accounting perspective has historically been more focused on broadly forecast product liabilities, Pricing & Contracting organizations are increasingly conducting more sophisticated analyses to increase the accuracy of their forecasts for individual contracts. In essence, Accounting looks “top-down” to ensure liabilities are accurately forecast, while Pricing & Contracting looks “bottom up” to assess the profitability of individual deals and ensure that pricing floors are not violated. Therein lies the opportunity: harmonization between different internal forecasting and management approaches to have one forecasting “standard” that serves the needs of both groups.

To be successful, managed-markets pre-deal analyses and forecasting efforts need to be much more quantitatively based, with well defined methodologies in place for objectively assessing individual deal potential. For example, it’s simply not enough in today’s increasingly cost constrained environment for an Account Manager to aggressively forecast increases in market share and/or revenue if a favorable formulary positioning is achieved through a contract, or alternatively, dramatic losses if the product is left off the formulary. The question becomes, what is the quantitative basis for such predictions? One relatively straightforward method is to use analog models for the potential contracted customer being analyzed to understand historical abilities to drive market share and/ or revenue for products on formulary. Just as important, in situations with mature therapeutic areas and well defined competition, is to have a forecasting model that takes into consideration existing national market shares when forecasting changes of all products under new contract scenarios.

For example, a contract could be negotiated that creates “preferred” status on formulary as a “1 of 2”, “1 of 3”, or “1 of 4”. How will market shares shift to formulary products in each of these scenarios? Quantitative, objective methodologies that

<table>
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<tr>
<th>Contract Lifecycle Stage</th>
<th>Analytic Category</th>
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<tr>
<td>Contract Strategy</td>
<td>Forecast Models</td>
<td>Forecast models built to gain objective insight into utilization of products under different contracting scenarios.</td>
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<tr>
<td>Offer Development</td>
<td>Pre-Deal Analytics</td>
<td>Leveraging the models above, these analytics forecast the utilization of a specific deal with typical metrics being incremental revenue and gross profit.</td>
</tr>
<tr>
<td>Contract Administration</td>
<td>Compliance Analytics</td>
<td>These analytics provide the first insights into over- or underperformance of a contract as well as whether or not contractual terms are being adhered to as a prerequisite for payment.</td>
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<tr>
<td>Payment Processing</td>
<td>Post-Deal Analytics</td>
<td>Post-deal analytics provide the final analyses of over- or underperformance based on the metrics established during contracting strategy or offer development.</td>
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can reallocate market share to formulary products based on existing national market share and a customer's ability to convert non-formulary products to formulary products are keys to accurate forecasting.

One such methodology, called a Conversion Effectiveness Index methodology (CEI), assigns a value of between 0 and 100% based on a customer's historical ability to drive formulary utilization. When combined with a Conversion Efficiency Model which forecasts the rate of conversion to formulary products, the CEI provides an overall forecast against the life of the contract for incremental revenue and/or market share. Other methodologies that have been used for different product situations include multiple regression models based on utilization controls of plans as well as elasticity models based on differential co-pays, just to name a few.

The other challenges in bringing harmonization to the process are organizational and technological. From an organizational perspective, those responsible for gross-to-net management have not been typically involved in working with Account Managers and others to set Pricing & Contracting strategies other than as a control to ensure that pricing floors have not been violated or a new Medicaid Best Price has not been set. A gross-to-net analytical model requires these individuals have much more in-depth knowledge of the dynamics of managed care and therapeutic areas in which the company participates.

Finally, from a technological perspective, such a process can become overwhelming if the right IT infrastructure is not in place, especially for companies that have high numbers of contracts or sophisticated contract structures. New package software systems as well as custom solutions have greatly enhanced the capabilities of companies to implement this type of model.

Forecasting is just the start

Whether someone is forecasting contract utilization or more broadly gross-to-net, it should be viewed as the first step of a continuous quality improvement process. For contract management, there are four distinct categories of analytics that link to each stage of the contract lifecycle (see also Fig. 2)

Within this closed-loop process, post-deal analytics should provide insights into the reasons why there was over- or under-performance. To the extent the original forecast models did not include relevant variables (e.g. sale force share of voice, early introduction of a competitor) or did not accurately assess their impact on utilization, these analytics can be leveraged to enhance upcoming forecast models from a continuous quality improvement perspective for both contract forecasting and ultimately gross-to-net forecasting. In addition, by capturing pre-deal forecasts on a systematic basis, incentive compensation programs can be developed based on actuals vs. forecasts.

However, despite these challenges, there is a great opportunity to integrate gross-to-net management with Pricing & Contracting strategies for competitive advantage. This integration will enable manufacturers to better forecast their financial exposure for reporting purposes, more quantitatively assess the amount of discounts to contractually offer individual customers, and evaluate customer contract performance based on more objective benchmarks that compare other similar contracts and customers. It is this movement from more subjective-based decision making to more fact-based decision making that will ultimately drive more efficient discounting and also create competitive advantage for those that can achieve it.

Summary

The management of gross-to-net continues to be challenging given the diverse array of line items and individual transactions that impact it. In addition, industry dynamics such as the introduction of new legislation, new channels of distribution, and more complex contract structures will continue to present ongoing operational challenges. Because of these dynamics, one of the most challenging areas for accurate gross-to-net management is commercial managed care forecasting and accruals.

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