Generic Drug Pricing: Understanding the Impact

Strategies for being prepared in a fluctuating, dynamic marketplace

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The evolution of the generic drug market in recent decades has introduced many benefits to the healthcare industry – lower pharmaceutical costs and greater consumer access to needed medicines. By offering the bioequivalent product of a brand name drug that is no longer protected by a patent, the generic market has carved out a significant niche within the U.S. healthcare landscape, representing approximately eight out of 10 prescriptions. [i]

According to the Congressional Budget Office, generic drugs save consumers between $8 billion and $10 billion a year at retail pharmacies alone. Billions more are saved when hospitals and healthcare providers use generic options. [ii] In today's healthcare climate, the generic drug market plays a critical role in making needed medicines affordable for consumers and helping pharmacies and healthcare organizations manage budgets in response to economic pressures.

While stakeholders within the healthcare community have come to depend on the low-cost advantage of generic drugs, pricing trends have become much more fluid and unpredictable in recent years. For example, the Average Wholesale Price (AWP) is based upon manufacturer-provided information. The AWPs for generic alternatives to Synthroid® (thyroid drug), Fiorinal with Codeine® (migraine drug), and prednisolone have doubled since last year, [iii] and digoxin (congestive heart failure drug), a medication found on the World Health Organizations list of essential medicines, went from an AWP of $0.12 a pill in July of 2013 to $1.06 in June 2014. [iv]

While the impact is being felt across the industry, small to mid-sized pharmacies can face notably greater challenges, as they do not have the resources, prescription volume, or affiliations with other purchasers that can empower them to bargain for discounts in a competitive marketplace. A survey conducted by the National Community Pharmacists Association (NCPA) revealed that pharmacy acquisition prices for many essential generic drugs have generally risen by between 600% and 1,000% in recent years. The same survey revealed that 84% of pharmacists at small or mid-sized pharmacies believed that increasing generic drug costs could result in unsustainable losses that would have a "very significant" impact on their ability to remain in business. [v]

A number of market factors are expected to continue to influence generic pricing trends. These include ongoing consolidation of manufacturers within the generic pharmaceutical industry, aggressive portfolio management by generic manufacturers, reduced competition between brand and generic manufacturers, foreign supply issues, and a backlog on approvals for new generics within the Federal Food and Drug Administration (FDA). This dynamic marketplace requires pharmaceutical industry professionals to strategically plan for their business by understanding the factors that influence the generic market and how to best anticipate changes and respond.

EVOLUTION OF GENERIC COSTING TRENDS

Because generics are copies of brand name drugs, the costs associated with introducing them to the market are lower because there are less research and development expenses that manufacturers must recover. For this reason, there have traditionally been many generic manufacturers supplying products, and the resulting product volume has tended to keep acquisition costs low.

Studies suggest that four to five generic suppliers need to be competing in the market at one time to keep costs from rising. In the case of digoxin, for example, the number of manufacturers dropped to only two by late 2013, leading to price increases.[vi] In recent years, when prices have unexpectedly increased, adjustments to payer reimbursements have, at times, been slow to catch up to the market.

Most drugs follow a typical product reimbursement lifecycle when they are introduced. When a branded product is protected by a patent, it is often reimbursed based on a discount of approximately 15% below a published AWP. Once the product comes off of patent and generics enter the market, the reimbursement is generally adjusted to a non-Maximum Allowable Cost (MAC) rate of an AWP discount (e.g., AWP minus 25% with two or less competitors) or a MAC price that is generally greater than the non-AWP discount (with three of more competitors).

As additional manufacturers enter the market, payers will set a maximum rate, but sometimes that maximum rate is not implemented as quickly as pharmacy acquisition costs decrease. In this scenario, some pharmacies have been able to take advantage of lower costs and higher reimbursements, with resulting increases in margins, until payers' reimbursement rates catch up to market prices. When the opposite scenario occurs and prices rise unexpectedly, pharmacies can experience acquisition costs that exceed reimbursement rates, resulting in lower margins.

Consider the drug Diovan for historical perspective of the typical product reimbursement lifecycle. Following expiration of the drug's patent in July 2014, the first generic – valsartan manufactured by Sandoz – entered the market in September 2014. At that time, the manufacturer-provided wholesale acquisition cost (WAC) for Diovan was $4.63 per tab, and the National Average Drug Acquisition Cost (NADAC), a government pricing benchmark, was $3.36 per tab. By the end of January 2015, 13 generic manufacturers had entered the market, and by the end of April, the NADAC price for valsartan had dropped to $0.49 per tab, while the WAC price of the brand Diovan had risen to $5.32 per tab. Because there is a lag in updating NADAC prices to reflect market conditions, this scenario could have presented an opportunity for pharmacies to temporarily reap the benefits of lower costs and static reimbursement rates, allowing them to enjoy increased margins until reimbursement rates were adjusted. It should be noted that the government's Centers for Medicare and Medicaid Services (CMS) has tried to reduce the lag time and has created a pharmacy hotline to report NADAC price discrepancies for review.

Depending on where a generic drug is in its lifecycle, pharmacies have come to expect an acquisition cost savings of anywhere from 30% to 70% when compared to the brand drug. Discounted generics have become a staple for many pharmacies in terms of attracting business over the past decade. Similarly, patients have come to expect nominal co-pays on generics and may seek out discounted generic alternatives to brands when filling prescriptions.

THE IMPACT OF A DYNAMIC MARKETPLACE

In a perfect world, drug price changes would not affect pharmacy gross profits if payer reimbursement rates moved in tandem with market changes. Unfortunately, the lag in payer response to sudden price increases in the market can cause pharmacies to realize reduced profits or to lose money on prescriptions.

While this lag creates difficulties for pharmacies, sudden increases and decreases in generic drug prices also make it difficult for payers to set an appropriate MAC. For example, if one generic manufacturer leaves the market, payers may want to wait to see if others follow suit before increasing MAC prices.

Chlorpromazine 50 milligram is a drug that has had generic equivalents for many years; it provides a good example of how sudden fluctuations in price impact pharmacy reimbursement. Over time, the generic market for the drug dropped to three suppliers, limiting competition and enabling some manufacturers to increase prices in late 2014. While pharmacy acquisition prices increased from approximately $1.50 to $4, NADAC lagged two months behind, and payers were slow to update MAC rates, which stood at $1.65 per tablet in late 2014.[vii] As a result, some pharmacies buying the drug at a price close to NADAC rates were losing money for up to six months.

In comparison, the brand Celebrex lost its exclusivity in December 2014, and six generic manufacturers immediately entered the marketplace with the generic celecoxib. According to NADAC reports, pharmacy acquisition costs, which were approximately $4.48 per capsule prior to the introduction of generics, dropped to roughly $1.56. Unlike the prior example, where there was a lag in reimbursement response, payer response in this case was not as protracted. An average MAC in January 2015 was $1.70, and within a month or two, that price fell to $1.30.

Following these kinds of disparities in response times by payers and outcry from the retail pharmacy community, legislation was introduced requiring greater transparency in generic drug payments. Introduced in 2015, the federal MAC Transparency Act (an amendment to the Medicare Voluntary Prescription Drug Benefit Program portion of the Social Security Act) is intended to ensure that federal health plan reimbursement to pharmacies keeps pace with generic drug prices and to ensure that pharmacy benefit managers (PBMs), who manage reimbursements, update their MAC benchmarks at least every seven days to better reflect market costs.[ix]

The Medicaid Generic Drug Price Fairness Act has also been introduced to create a penalty for generic manufacturers that increase generic prices at a faster rate than increases in the Consumer Price Index (CPI). If implemented, the law would require a generic manufacturer that increased prices by 20% when the CPI had increased 3% to pay a 17% rebate to CMS.[x]

POSITIONING FOR THE FUTURE

Going forward, pharmacies need to respond to the dynamic market situation by doing two things:

1. Drive top-line sales
2. Maintain gross and net margin objectives

To meet these goals, pharmacies should focus on both brand and generic sales. Current trends suggest that many retail pharmacies are increasingly pursuing specialty pharmacy offerings even though payers and manufacturers may want to limit network participation. While generics have traditionally offered a better gross margin, this is now realized on a smaller scale, and at the end of the day, the net profit margin can be similar for both brands and generics.

Inventory turns should be monitored in this volatile pricing environment and optimized against the NCPA's reported annual average rate of 12.6.[xi] If this rate is upheld and inventory turns over approximately every 29 days, there should be a month of inventory to protect pharmacies against a MAC adjustment lag. On-hand inventory at the former lower cost should enable pharmacies to be profitable for at least the period of time that the product is in stock.

CONCLUSION

Generics are no longer a dependable deflationary market, but opportunity still exists. While generic product availability has increased in some cases, in recent years the number of available generics has generally stayed the same or declined.

Pharmacies should expect prices to continue to fluctuate based on current market trends, and payers will need to adjust reimbursement more quickly to protect pharmacies from unsustainable losses.

i http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm

ii http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm

iii Medi-Span® Price Rx®

iv http://www.sanders.senate.gov/newsroom/recent-business/senate-hearing-on-generic-drug-prices

v http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say

vi http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html

vii Medi-Span® Price Rx®

viii www.ncpa.co/pdf/hr244-mac-transparency.pdf

ix http://www.ncpanet.org/newsroom/news-releases/2015/01/12/ncpa-backs-generic-drug-payment-legislation

x http://sanders.senate.gov/download/s-2948?inline=file

xi www.ncpanet.org/pdf/digest/2013/2013digest_financials.pdf

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