Drugs, Dollars and Dynamics: The Ups and Downs of Generic Pharmaceutical Pricing

Presented by: Pharmacy Healthcare Solutions, Inc.
Learning Objectives

1. Understand factors influencing generic pharmaceutical pricing dynamics
2. Examine the impact of generic price changes, both increases and decreases, across market segments
3. Increasing market share of the top pharmacy chains & effect on generic purchasing leverage
Generic Marketplace: Historic Perspective

Generics have generally been thought of as a deflationary market

As the number of generic manufacturers increase, the acquisition cost of the generic product decreases

Generic reimbursement set by payers follows costs and declines over time
Lifecycle of Product Reimbursement

(1) Brand Drug

Reimbursement:
1. Brand reimbursed at AWP discount
Example: AWP - 15%

(2) Generic Exclusivity
(Limited Suppliers)
(i.e., 1-2)

Reimbursement:
1. Same as brand AWP discount Example: AWP-15%
2. Greater generic AWP discount/ Non-MAC reimbursement rate
Example: AWP–25%

(3) Generics-No Exclusivity
(Multiple Suppliers)
(i.e., 4-6)

Reimbursement:
1. MAC:
Set to save plan money yet incent pharmacy to convert to generic – generally more profitable than the brand
2. Post-exclusivity:
MACs are lowered more slowly than generic acquisition costs

(4) Generic Commodity Model
(i.e., 8-12 suppliers)

Reimbursement:
1. MAC is more aggressive, pharmacy profit is lower and similar to the brand profit
Generic Marketplace: Diovan 160mg Historic Perspective Example

4/22/2015: Generic NADAC: $0.49 per tab

5/8/2015: Total of 13 generics

1/21/2015: Generic NADAC: $3.17 per tab

1/20/2015: Qualitest launches generic (13 total generics)

1/5/2015: Eleven other generic mfgs enter market (12 total generics)

7/18/2001: Diovan 160mg tablets approved

7/6/2014: Diovan 160mg WAC on 7/6/2014: $4.63 per tab

7/7/2014: First valsartan generic (Sandoz) launches

9/17/2014: Sandoz generic NADAC: $3.36 per tab

1/4/2015: Generic NADAC: $3.21 per tab

1/6/2015: Diovan 160mg WAC change on 1/6/2015: $5.32 per tab
Stakeholder Reactions to Traditional Generic Marketplace

**Wholesalers**
- Made little profit on brand drugs
- Generics were profit center
- Bank on high generic profitability (generic dollars supports larger discounts for brand purchases)

**Payers**
- Established nominal copays to drive generic utilization
- Savings for generic vs. brand drugs significant (Often 50% to 90%)
- Only MAC A-rated generics
- If patients want brand, they have to pay the difference

**Generic Manufacturers**
- Compete on price for a piece of the business
- Unless at capacity, price is somewhat elastic
# Stakeholder Reactions to Traditional Generic Marketplace

<table>
<thead>
<tr>
<th>Prescribers</th>
<th>Pharmacies</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Educated and conditioned to prescribe generics</td>
<td>• Generics often priced as a savings off of brand (Save 30-70%)</td>
<td>• Expectation of a nominal copay for generics</td>
</tr>
<tr>
<td>• Extra effort to dispense brand product when AB rated generic available</td>
<td>• Established discount generic lists (i.e. $4 lists)</td>
<td>• “Is there anything on the discount generic list that I can take?”</td>
</tr>
</tbody>
</table>

State laws support and drive lower cost generic utilization. Prescribers need to take extra “out of the ordinary” step to mandate brand.
Factors Influencing Generic Pricing

• Generic manufacturer mergers and market consolidations
• Generic manufacturer diversification
• Portfolio optimization
• Foreign supply issues regarding API
• FDA backlog
IMPACT OF GENERIC PRICE CHANGES ACROSS MARKET SEGMENTS
Impact of Sudden Price Changes

- Existing inventory and lags in stakeholder reactions create winners and losers
- Price changes only affect pharmacy gross dollars as long as payer reimbursement moves in tandem to price changes
- Sudden price increases and decreases make it difficult for payer’s to adjust MAC pricing accordingly
  - Many manufacturers’ products vary in pricing
- Pharmacies do not carry much inventory of new generics during 180 day exclusivity periods without price protection
  - Rare scenario when all stakeholders can anticipate falling prices
New World Order for Generics

“Two members of Congress have launched an investigation and asked 14 generic drug makers to provide data about what the lawmakers called the ‘escalating prices they have been charging’ for generic medicines.”
~The Wall Street Journal

“The Need for Legislation Regarding Maximum Allowable Cost (MAC) Reimbursement”
~National Community Pharmacists Association

“8281% increase in the average market price of doxycycline hyclate 100 mg tablets”
~Pharmacy Times

“Teva Bid for Mylan Sparks Worries of Rising Generic Drug Prices”
~Bloomberg
NADAC Pricing

• NADAC updates from voluntary pharmacy surveys
• NADAC pricing is published monthly
  – Usually published around the 20th of each month
  – Data lags by approximately 2 months (i.e. Data published in April is from February)
  – Does not include back-end discounts/rebates
• Market moving towards more of a transparent model with need for accurate dispensing fees
  – Opposite of “historical” generic pricing where profit created from higher ingredient cost reimbursement
AMP Pricing

• Manufacturer reported pricing
• Average price paid by wholesalers to manufacturers for drugs distributed to retail pharmacies
• Calculation is based on actual sales transactions
• Eventual plan to use for Medicaid reimbursement with established Federal Upper Limits (FULs)
• AMP data for January 2015 made available April 1, 2015
AMP Pricing Concerns

- Not able to serve as a concurrent pricing metric to address sudden pricing changes
- No one likes to be average!
- AMPs may trend to a narrowing of the discounts between large and small pharmacies
- Need a much higher dispensing fee
Example 1: Chlorpromazine 50mg

- Generics launched in 1980’s
- Currently, few suppliers with limited competition
- Payer increased MAC on 3/2/2015
  - $1.65 → $4.78 per tablet
  - Acquisition cost at time near $3.66, based on NADAC
- With two months lag, acquisition cost increased approximately 10/2014
- With a MAC of $1.65, those buying at NADAC were losing money for 6 months
- Payer slow to update MAC

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<tr>
<th>NADAC Unit Price</th>
<th>Effective Date</th>
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## Example 2: Duloxetine

- Many suppliers slowly entering the market since mid 2014
  - 16 suppliers as of April 2015

### Pricing for Duloxetine HCl Oral Capsule Delayed Release Particles 20mg

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<tr>
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Example 2: Duloxetine

- WAC pricing varied from $1.31 to $5.60 per capsule
- Payer decreased MAC on 1/29/15
  - $4.25 → $1.50 per capsule
  - Based on two month lag of NADAC updates, average acquisition cost roughly $1.10 in January
- Pharmacy averages a profit of $0.40 ($1.50 - $1.10) per capsules
  - RX: 30 caps x $0.40/capsule = $12 + disp fee
- Several months before MAC update, pharmacy buying at approximately $1.11 to $1.28 and being reimbursed $4.25
  - Large profit during that time frame

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<td>6/18/2014</td>
<td>$4.83</td>
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</tbody>
</table>
Example 3: Celebrex 100mg

- Upon brand LOE on 12/10/14, six manufacturers launched generic celecoxib products
  - Brand WAC = $4.28/cap
- Generic competition caused acquisition costs to fall
  - NADAC declined approximately 26% in the first two months

<table>
<thead>
<tr>
<th>Manufacturer</th>
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<td>AG</td>
</tr>
<tr>
<td>Teva</td>
<td>ANDA</td>
</tr>
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</table>

- Reimbursement declines rapidly since price decreases fell quickly post LOE
  - January MAC: $1.70 → February/March MAC: $1.30

Reminder: NADAC data is on a 2-month lag
Payer Challenges in Dynamic Generic Marketplace

- Legislative changes require creating continual price monitoring for compliance
  - Increased time and costs to monitor generic market
  - Buy and sell side
- Payer-client expectations more difficult to meet
- Increased attention to MAC pricing

- Rapidly changing generic prices impact pharmacy profitability
- Retailers pursuing MAC adjustments more frequently to avoid profit losses
- More frequent attention to MAC lists lead to quicker declines as prices erode
- Creation of additional copay tiers
  → Two generic tiers
Wholesalers Implications

• Top 3 wholesalers generated about 85% of all revenues from drug distribution in 2012\(^1\)
  – Aligned with larger chains
• As pricing transparency is increasing, wholesaler margins being squeezed
  – Force wholesalers to reevaluate business model
  – Negotiate better service agreements with manufacturers
  – Look for alternative profit centers besides generic drugs
• Monitoring AMP, NADAC and AAC will drive continual wholesaler negotiations
• Appropriate cost allocation for brands and generics
• Direct purchasing strategies force competition

Sources: 1. Modern Distribution Management; http://www.mdm.com/2013_pharmaceuticals_mdm-market-leaders
Pharmacies

• Need to drive top-line sales and gross margin
  – Need to drive top-line sales has increased desire of retail pharmacies to pursue specialty pharmacy business

• Generics traditionally offered better gross margin, but this is now seen on a smaller scale

• Market dynamics may drive frequent supplier changes

• Discount generic lists
  – Lack of expansion
  – Reduced items as generic costs increase
Pharmacies: Inventory Turns

• NCPA reports that the average annual rate of prescription inventory turnover is 12.6\(^1\)
  – Inventory turns approximately every 29 days
• Expect to be slightly higher at chain pharmacies
• Most top selling generics are stocked continuously in retail pharmacies

Takeaway

Even though MAC prices may not adjust immediately, one month of inventory purchased at the previous price before the increase → Approximately 29 day lag

Pharmacies

• Large pharmacies are better insulated from rapid price changes
  – At least for some period of time
  – Small chains and independents face more difficulty
• Wholesaler alignment for large chains leads to better purchasing
• Increased conflicts with payers to adjust pricing in a timely manner
  – Led to MAC price laws
New Legislation on the Horizon: Implementation Scheduled 1/1/2016

• CMS’s “Prescription Drug Pricing Standards and Maximum Allowable Cost”
  – MAC prices must “accurately reflect the market price of acquiring the drug”
  – Prices to be updated “not less frequently than once every 7 days”
  – Part D sponsor required to “disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publically available”
    • Pharmacies will know the MAC prices before changes are implemented

• Legislation will increase speed for both MAC increases and decreases
INCREASING MARKET SHARE OF PHARMACY CHAINS & EFFECT ON PURCHASING LEVERAGE
Prescription Sales of Largest Retail Chains

- Top 50 pharmacy chains had $224 billion in sales in 2014
  - Top 4 chains account for over 50% of these sales
  - Considerable purchasing leverage → Negotiate lower purchasing prices
    1. Affects NADAC and AMP pricing
    OR
    2. Forces wholesalers to be more transparent with pricing for smaller pharmacies

Sources: 1. Drug Store News Powerx Top Pharmacy Retailers; April 27, 2015.
Conclusions

• Generics are no longer the traditional deflationary market

• Some generics have increased large percentages, but most have stayed the same or declined
  – Some generics have high percentage increases with relatively small dollar increases compared to brand

• Payers need to adjust reimbursement to protect pharmacy from financial loss

• Generally, generic manufacturers more selective in product portfolio – React to market changes as suppliers exit market, API shortages, etc.
Questions?

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