Pharmacy Benefit Management in Oncology

October 28th, 2015

Business Health Care Group
Protecting the Future of Oncology Care:
A Community Conversation

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General Manager, Luminera Health Services
AGENDA

• Setting the Stage
• Formulary and Utilization Management Strategies
• Plan and Benefit Design
• Role of the Specialty Pharmacy
Navitus is a national, full-service pharmacy benefit manager (PBM) committed to providing superior customer service, ensuring regulatory compliance, improving member health and lowering drug costs in a manner that instills trust and confidence.

- Founded in 2003
- Owned by SSM Health
- Commitment to service excellence and evidence-based care
- Over 4.5 million members and growing
- 100% Pass-Through, Transparent Model
- Lowest-Net-Cost Strategy
- Managed Care Roots
- Madison & Appleton, WI; Austin, TX; Phoenix, AZ
NAVITUS PBM PASS-THROUGH BUSINESS MODEL

Plan Sponsor

Pharma Manufacturers

Retail/Mail Pharmacies

 Truly Transparent PBM

OTHER FEES
REBATES
BRAND DISCOUNTS
GENERIC DISCOUNTS

PMPM
LUMICERA HEALTH SERVICES

- Fully-owned subsidiary of Navitus located in Madison, WI
- Offers innovative specialty pharmacy solutions
- Functions as a stand-alone specialty pharmacy
- Adheres to Navitus’ core principals of transparency and stewardship
- Employs the same high-touch, high-quality patient care currently experienced with Navitus
- Cost-Plus Business Model
Injectable or oral, self-administered or administered by a healthcare provider

Complex to manufacture, requiring special handling and administration; limited distribution channels

Method of Administration

Nature of the Disease

Drug Cost

Biological / Biotechnology

Significantly higher cost than traditional medications

Taken by a relatively small share of the population who have complex conditions

Requires ongoing clinical support
SMALL MOLECULE VS. BIOLOGIC

Figure 1. Comparison between a biologic monoclonal antibody and an aspirin molecule
An approximately 800-fold difference in size necessitates magnifying the boxed area to clearly identify the aspirin molecule on the lower left. The antibody structure was taken from the RCSB Protein Data Bank and has the identifier 1HZH.
Current state – specialty products represent¹:

- Significant shift from traditional brand to specialty products
- Utilization and costs have continued to increase

¹Navitus Internal Data
INDUSTRY PERSPECTIVE ON SPECIALTY DRUG SPEND

US specialty drug spending will quadruple by 2020

Projected specialty drug spending from 2012 to 2020

Spending amounts in US$ billions

$87.1
2012

$192.2
2016

$401.7
2020

121% increase from 2012

109% increase from 2016

Adapted from 2014 PricewaterhouseCoopers LLP.
FDA NEW DRUG APPROVALS

U.S. Food and Drug Administration
THEN AND NOW
The Rising Cost of Specialty Drugs

- Price increased 2.7 times over last 7 years
- Average Annual price increase of 24%
- Generic expected 1Q 2016

Navitus Internal Data: 2015.
Formulary and Utilization Management
Utilization Management Toolkit

- Formulary and Rebate Management
- Reporting
- Plan Design Modeling and Support
- Pharmacy Network Management
- Clinical Utilization Management e.g., Step Therapy & Prior Authorization
- Drug Therapy Management
UM TOOLS

• Formulary and Rebate Management
  - Identification of products that provide the best value
  - Manufacturer rebates used to offset costs
  - Tiering of products based on value and plan / benefit design

• Prior Authorization / Step Therapy / Quantity Limits
  - Used to ensure use is consistent with FDA approved labeling and recognized national treatment guidelines
  - Encourages the use of lower cost agents when appropriate
  - Limits quantities to optimize dosing regimen

• Reports
  - First Fill Trigger Reports
  - Outlier claims
  - Fraud / Waste and Abuse
UM TOOLS CONT.

- **Drug Therapy Management**
  - Use of Clinical Pathways (PA Process / Specialty Pharmacy)
    - Patient Education
    - Side Effect Management
  - Partial Fill Programs
  - Retrospective Drug Utilization Review
  - Adherence Reporting

- **Pharmacy Network Management**
  - Preferred Specialty Pharmacies

- **Plan / Benefit Design**
  - Copays / Max Out of Pocket / Deductibles / etc.
  - Closed / Limited Pharmacy Networks
  - ACA and other regulatory limitations
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were study results published?</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Were study results peer reviewed?</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Was comparison to placebo when other treatments are possible?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Was it compared to active comparator?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>If yes, was the comparator appropriate (i.e. standard of care)?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Was QOL assessed?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Was an appropriate tool used to assess QOL?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Were OS available?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Were PFS data available?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>If OS data were not available did PFS correlate with an improvement in OS?</td>
<td>NA</td>
<td></td>
</tr>
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</table>
## ONCOLOGY DRUG A

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Y</th>
<th>N</th>
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<tbody>
<tr>
<td><strong>Was the drug statistically significantly better than:</strong></td>
<td></td>
<td></td>
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<tr>
<td>placebo?</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>active comparator in primary endpoint?</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>active comparator in secondary endpoint?</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td><strong>Was there a clinically meaningful benefit to the patient?</strong></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td><strong>If non-inferior to the comparator are there benefits in:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cost of drug?</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>reduced medical costs?</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>reduction of AEs?</td>
<td>x</td>
<td></td>
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<tr>
<td>improved QOL?</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Are clinically acceptable formulary options available?</td>
<td>x</td>
<td></td>
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<tr>
<td>Is there a therapeutic advantage of the new drug over available standard of care?</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Does Pharma adequately justify the increase in cost of the new drug?</td>
<td></td>
<td>?</td>
</tr>
<tr>
<td>Other metrics</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Complete hematological response</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Major cytogenic response</td>
<td>NA</td>
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Benefit and Plan Design
Drug Utilization Review
Average Script Cost vs. Script Volume

Observations:
- In 2015-Q1/Q2, 67.1% of the claims volume had a Plan Paid amount of <$25.
- Only 1.3% of claims (15,144 claims) have a Plan Paid amount of >$1000, which accounted for 40.7% of Total Plan Paid.
PLAN DESIGN TRENDS

• Increasing Member Out-of-Pocket costs
  - Multiple Formulary Tiers
  - Specialty Tiers
  - Co-insurance and Max-Out-of-Pocket
  - Growth in High Deductible Health Plans
  - WI Oral Chemotherapy Parity Legislation

• Narrow or Limited Specialty Pharmacy Networks
  - Mandating use of a preferred specialty pharmacy
  - Limited Distribution Drugs (LDD)

• Key Statistics from EMD Serono Specialty Digest
  - 84% of surveyed plans have high-deductible benefits
  - 59% of surveyed plans have dedicated tiers for specialty products
  - Dollar Copay for Specialty Ranged from $45-$250 (mean $102)
**Oncology Drug A**
Cost: $5,000 / month
Benefit: HDHP - $5,000
$100 per Rx after deductible

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**Pharmacy Sends Claim to Patients PBM**

1st Claim
- Patient Pay: $5,000
- Plan Pay: $0

2nd Claim
- Patient Pay: $100
- Plan Pay: $4,900

3rd Claim
- Patient Pay: $100
- Plan Pay: $4,900

**Pharmacy Sends Claim to Manufacturer Program**

1st Claim
- Patient Pay: $25
- Manf. Pay: $4,975
- Plan Pay: $0

2nd Claim
- Patient Pay: $25
- Manf. Pay: $75

3rd Claim
- Patient Pay: $25
- Plan Pay: $75

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**Summary (3 Claims)**
- PBM Patient Pay: $5,200
- Actual Patient Pay: $75
- Manf. Pay: $5,125
- Plan Pay: $9,800
DIFFERENT TYPES OF MANUFACTURER PROGRAMS

• Direct Manufacturer Program
  - Eligibility Varies
  - Copays Varies
  - Maximum Benefit Varies

• Other Copay Programs
  - Non-Profit Foundations

• Pre-paid debt cards
Specialty Pharmacy Management
# RETAIL VS. SPECIALTY

<table>
<thead>
<tr>
<th></th>
<th>RETAIL</th>
<th>SPECIALTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to Product</td>
<td>Trend is moving specialty products AWAY from Retail to a more controlled environment with better services, patient care, and ROI</td>
<td>Must have “SP” service capabilities before access to product is granted</td>
</tr>
<tr>
<td>Clinical Program Benefits</td>
<td>Standard Adjudication, modest medical billing</td>
<td>Full Benefits Review including, pharmacy, medical, nursing, mail, specialty</td>
</tr>
<tr>
<td>Clinical Reporting</td>
<td>Rx dispensing systems typically do not allow electronic data capture in a reportable fashion</td>
<td>Rx Dispensing systems designed to capture data by product, by Payor, by Physician, by national guideline</td>
</tr>
<tr>
<td>CoPay Assistance</td>
<td>Utilizes copay cards</td>
<td>Uses cards, but often is connected electronically to 501c3 organizations/ foundations and manufacturer programs</td>
</tr>
<tr>
<td>Geographic Footprint</td>
<td>Usually Local/Regional</td>
<td>National: Licensure in all States Required</td>
</tr>
<tr>
<td>National Delivery</td>
<td>Local pick up, occasional courier</td>
<td>95%+ are via mail/FedEx/Courier to all Licensed States</td>
</tr>
<tr>
<td>Manufacturer Service Fees / Rebates / Discounts</td>
<td>Limited, if any availability</td>
<td>These fees are approaching 60% of gross margin for Specialty Pharmacies</td>
</tr>
</tbody>
</table>
WHAT IS A SPECIALTY PHARMACY?

- Any pharmacy can claim to be a specialty pharmacy
- URAC accreditation
  - Payers are increasing demand for accredited specialty pharmacies

Companies & Locations with URAC Specialty Pharmacy Accreditation, 2008-2014

*for 2014, total companies includes all companies classified as “In Process.” Pembroke Consulting estimate for total locations in 2014.
Note: This chart data appears as Exhibit 92 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
SPECIALTY FULFILLMENT PROCESS

- **Rx arrives @ Specialty Pharmacy**
- **Pharmacist performs PV1**
- **Pharmacist performs PV2**
- **Tech packages and ships**
- **Team member calls patient to confirm shipping information & need-by date and discusses any specific clinical and financial issues or concerns**
- **Tech reviews & enters Rx into system; benefits team conducts investigation**
CUSTOMIZABLE CLINICAL PATHWAY PROCESS

Set up at category and drug level

Pathway can be set up by fill date, number of fills, at enrollment, etc.

With program triggers, team member contacts patient with specified questions

Patient information is stored in system for future communications
SPECIALTY CLINICAL MANAGEMENT

- Increase adherence to therapy, monitor adverse events and side effects, and improve outcomes
  - Examples: Oral Oncology
- Ensure medications are being used in accordance with P&T recommendations
  - Facilitate formulary changes and use of biogenerics/biosimilars as available
- P&T determines PA criteria and formulary placement
- PBM makes PA determinations
- Support split-fill and dose optimization programs
- Identify and discontinue therapy that is duplicative or non-effective
QUESTIONS?

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Share a Clear View

High-Touch Service

Lowest Net Drug Costs

Improved Member Health