Health Technology Assessment
for
Similar But Not Interchangeable Biologics

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Private Payer Perspective

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Agenda

• Impact of Biologics on Private Plans

• Clinical Evaluation Process

• Benefit Management Strategies
Biologics

- 14 - 16% of drug spend
- < 1% of claims
- Ave. cost per Rx $1,242
- 33% of drug spend in 2014
- 60% of catastrophic claims
- Growth 14% annually
## Top DINs by Eligible Amount – 2002 to 2012

<table>
<thead>
<tr>
<th>Rank</th>
<th>2002</th>
<th>2005</th>
<th>2007</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Losec 20mg</td>
<td>Lipitor 10mg</td>
<td>Lipitor 10mg</td>
<td>Remicade 100mg</td>
</tr>
<tr>
<td>2</td>
<td>Lipitor 10mg</td>
<td>Losec 20mg</td>
<td>Lipitor 20mg</td>
<td>Humira 40mg</td>
</tr>
<tr>
<td>3</td>
<td>Paxil 20mg</td>
<td>Lipitor 20mg</td>
<td>Nexium 40mg</td>
<td>Enbrel 50mg</td>
</tr>
<tr>
<td>4</td>
<td>Lipitor 20mg</td>
<td>Nexium 40mg</td>
<td>Remicade 100mg</td>
<td>Nexium 40mg</td>
</tr>
<tr>
<td>5</td>
<td>Celebrex 200mg</td>
<td>Altace 10mg</td>
<td>Pantoloc 40mg</td>
<td>Celebrex 200mg</td>
</tr>
<tr>
<td>6</td>
<td>Vioxx 25mg</td>
<td>Pantoloc 40mg</td>
<td>Crestor 10mg</td>
<td>Crestor 20mg</td>
</tr>
<tr>
<td>7</td>
<td>Zocor 20mg</td>
<td>Enbrel 25mg</td>
<td>Enbrel 50mg</td>
<td>Tecta</td>
</tr>
<tr>
<td>8</td>
<td>Pantoloc 40mg</td>
<td>Effexor XR 75mg</td>
<td>Prevacid 30mg</td>
<td>Ezetrol 10mg</td>
</tr>
<tr>
<td>9</td>
<td>Prevacid 30mg</td>
<td>Crestor 10mg</td>
<td>Lipitor 40mg</td>
<td>Symbicort</td>
</tr>
<tr>
<td>10</td>
<td>Altace 10mg</td>
<td>Remicade 100mg</td>
<td>Celebrex 200mg</td>
<td>Neulasta</td>
</tr>
<tr>
<td>11 – 20</td>
<td>#12 Remicade</td>
<td>#18 Humira</td>
<td>#44 Enbrel</td>
<td>#21 Enbrel 25mg</td>
</tr>
<tr>
<td>20 – 50</td>
<td>#44 Enbrel</td>
<td>#92 Humira</td>
<td>#90 Neulasta</td>
<td></td>
</tr>
<tr>
<td>51 - 100</td>
<td>#92 Humira</td>
<td>#90 Neulasta</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Medavie Blue Cross
Drug Trend in Private Pay Direct Drug Market, Traditional vs. Biologics, 2002 - 2012

Biologics grew by 40% in 2003 compared to 2002.

Traditional products dropped by 0.6% in 2012 compared to 2011.

Source: ims|brogan, PharmaStat®
Cost includes ingredient cost and applicable markup.
Subsequent Entry Biologics

- Similar and Subsequent to an innovator
- New Drug Submission pathway
- Not declared Bioequivalent by HC
- Reduced Cost
Medication Advisory Panel - 1994

- Established Drug Evaluation Process
- Interdisciplinary Panel
- Recognized for Comprehensiveness
- Evaluate All New Drug Molecules
- Evaluate New Indications
The same reference product should be used for all steps of comparative studies. The stepwise approach should start with extensive structural and functional characterization of both the SEB product and the reference product, which serves as the foundation of a biosimilar development program.
Clinical Evaluation

- Pharmacokinetic/Pharmacodynamic
- Comparative Efficacy - Clinical
- Length of Trial(s)
- Superiority or Non-Inferiority
- Safety and Harms Data
- Pharmacoeconomic modelling - Private
- Real World Data
The Integrated Benefits Database

- Short-term Disability
- Long-term Disability
- Extended Health Benefits
- Drug Therapy
# Subsequent Entry Biologics (SEBs)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Estimated Annual Cost*</th>
</tr>
</thead>
</table>
| Omnitrope | Children 0.025 – 0.035mg/kg daily  
            | Adults 0.15 – 1.33mg daily | $5,687 – $7,961  
            |                                             | $1,706 – $15,127 |
| Saizen  | Children 0.2 – 0.47mg/kg weekly  
            | Adults 0.005mg – 0.01mg/kg daily | $9,048 – $12,215  
            |                                             | $5,954 – $11,908 |
| Nutropin | Children 0.3 – 0.7mg/kg weekly  
            | Adults 0.042-0.175mg/kg weekly | Up to $12,149  
            |                                             | $6,378 – $13,288 |
| Humatrope | Children 0.18-0.3mg/kg weekly  
            | Adults 0.006-0.0125mg/kg daily | $8,737 – $14,561  
            |                                             | $7,666 – $15,970 |

*Based on average child weight of 20kg & adult weight of 75kg
Benefit Management

- Provincial
- Preferred Networks
- % of what price
- Targeted Therapies
- Patient Choice Cards
- Deductibles
- Adherence
- Special Authorization
- Duration and Response
- Tiered Formularies
- Physician Acceptance
- Indication Creep
- Step Therapy
Conclusion

• Steady increase in Utilization of Biologics
• Pharma Pipelines
• Benefit Management Strategies