BIOSIMILARS LAUNCH WORKSHOP
Presented by Covance Market Access Services

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Agenda

Background
The Value Story for Biosimilars
US Market Access for Biosimilars
Implications for Launch Planning
Background

U.S. Biosimilar Headlines – 2015

- **Sandoz Makes First Biosimilar Review Looks Easy, Will Future Sponsors Be As Lucky?**
  Oncologic Drugs Advisory Committee’s unanimous endorsement of Neupogen biosimilar amounted to a slam dunk, but other sponsors with more complex biologics and less foreign marketing experience may face greater skepticism from FDA and its experts.


- **The Leading U.S. Biosimilars Company Is – Apotex?!?**
  Mid-weight private firm leverages partnership with Intas to become first company to announce multiple applications under FDA review.

  Source: The Pink Sheet. February 16, 2015

- **US FDA Postpones Celltrion’s Remicade Biosimilar Review Meeting**


- **FDA Approves Zarxio, Its First Biosimilar Drug**


- **PBM Wants Filgrastim in Pharmacy Benefit To Push Biosimilar Use**

U.S. Biosimilar Headlines – 2015 (cont’d)

CMS Releases New Reimbursement Guidance for Biosimilars

Amen Aims To Add A New Title: Biosimilar Star Player
Source: The Pink Sheet. April 20, 2015

As More Pieces Fall Into Place, Biosimilars Picture Becomes Clearer
Source: AIS Health. April 2015

Biosimilar On Hold: Sandoz’s Zarxio Launch Delayed Indefinitely
Source: The Pink Sheet. May 6, 2015

Every Biosimilar Should Have Its Own Medicare Pay Code, CMS Told
Source: The Pink Sheet. May 7, 2015

U.S. Biosimilar Headlines – 2015 (cont’d)

Patient Advocates, AbbVie Protest FDA’s Move To Scrap Biosimilar Labeling Reds
Source: InsideHealthPolicy. June 15, 2015

FDA’s Inaugural Biosimilar Review Bumpier Than First Appeared

Medicare Will Pay For Biosimilars Referencing Same Drug Equally, CMS Proposes

Drug Makers: CMS’ Biosimilars Part B Proposal Could Ruin Market For Biosimilars
Source: InsideHealthPolicy. July 10, 2015

Sandoz, Amgen: CMS Part B Pay Proposal Makes It Hard To Track Biosimilars
Source: InsideHealthPolicy. July 10, 2015

Novartis Can Sell Copycat of Amgen’s Neupogen in September, Court Rules
What are Biosimilars?

**STRUCTURAL IMITATIONS OF APPROVED BIOLOGICS, BUT NOT EXACT REPLICAS**

- **What are biosimilars?**
  - Structurally and functionally/clinically "highly similar" to the reference biologic product (innovator)
  - No clinically meaningful differences

- **How similar is "highly similar"?**
  - Even small differences may have significant effects; which ones matter?

- **Are biosimilars the same as generics?**
  - No. Like other biologicals, biosimilars are produced by living organisms, and thus are more complex in nature.

Biosimilars ≠ biogenerics!

Current FDA Approval Pathways for Biosimilars

**A MANUFACTURER MAY APPLY FOR APPROVAL OF A BIOSIMILAR PRODUCT THROUGH ONE OF THREE PATHWAYS**

- **Full Biologics License Application (BLA)**
  - Follow-on biologics that essentially are biosimilars to an innovator product, but do not have to demonstrate biosimilarity
  - Technically not biosimilars

  - **Teva's Granix (bio-filgrastim)** – a "biosimilar" of Amgen's Neupogen (filgrastim)

- **Abbreviated Biosimilar Pathway**
  - Biosimilars approved under new FDA pathway created by the ACA

  - **Sandoz's Zarxio (filgrastim-sndz)** – a true biosimilar of Neupogen

- **Abbreviated Biosimilar Pathway with Interchangeability**
  - Biosimilars approved under new FDA pathway that also have been deemed interchangeable by the FDA
  - May be subject to automatic substitution at the pharmacy

  - **TBD**
In 2014, Several Manufacturers Filed with FDA under the New Biosimilar Pathway

**MARCH 6 – SANDOZ 1ST TO RECEIVE APPROVAL**

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Product, Innovator, Therapeutic Area</th>
<th>Date of Filing</th>
<th>Estimated User Fee Date</th>
<th>FDA Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sandoz</strong></td>
<td>Filgrastim (approved as Zarxio) Amgen’s Neupogen Oncology</td>
<td>May 2014</td>
<td>March 8 (approved March 6; launch delayed until 09/02/2015 due to Amgen litigation)</td>
<td>Panel recommended unanimously on 01/07/2015; FDA approval granted on 03/06/2015</td>
</tr>
<tr>
<td><strong>Celltrion/ Hospira</strong></td>
<td>Infliximab J&amp;A’s Remicade Rheumatology</td>
<td>August 2014</td>
<td>June 2015</td>
<td>Panel meeting postponed indefinitely due to pending data requests (originally scheduled for March 17)</td>
</tr>
<tr>
<td><strong>Apotex</strong></td>
<td>Pegfilgrastim Amgen’s Neulasta Oncology</td>
<td>October or November 2014</td>
<td>August or September 2015</td>
<td>TBD</td>
</tr>
<tr>
<td><strong>Hospira</strong></td>
<td>Epoetin alfa Amgen’s Epogen and Janssen’s Procrit Nephrology and Oncology</td>
<td>December 2014</td>
<td>October 2015</td>
<td>TBD</td>
</tr>
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<td><strong>Apotex</strong></td>
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<td>October 2015</td>
<td>TBD</td>
</tr>
</tbody>
</table>


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US: Likely Cornerstone of Biosimilar Market by 2020

![US Biosimilar Market Growth Chart](chart.png)

**US share of biologics market - 2020**

- **Upper bound**: 11 - 25 Bil US$
- **Base case**: 20
- **Lower bound**: 11

**Not a large short-term market, but upside potential of $25B by 2020**

U.S. Biosimilar Market Key Drivers of Success

Biosimilar companies must overcome several barriers to entry:

► **Regulatory** – FDA has yet to clearly define naming conventions and clinical pathway; still awaiting guidance on interchangeability

► **Statutory/Legal** – State laws restricting biosimilar substitution: impacting uptake/market share; litigation from innovators

► **Market Access** – Insurance coverage/reimbursement decisions; perception among physicians/patients


Discussion: Biosimilars Background

► In your opinion, what has been the most significant development in the biosimilars space in 2015?

► Do you expect that the first biosimilars launched in the US will achieve market penetration comparable to biosimilars in other countries?

► What do you believe will be the most significant challenge facing biosimilar manufacturers in the US?

► Additional questions?
THE VALUE STORY
The Value Proposition
Strategic Communication Plan

Value Story In Support of Product Launch

Source: Adapted from Gadd, C. How to develop a compelling proposition in current European healthcare market. Otsuka Pharmaceuticals. Evidence EU 2014.
Standard Value Story Development

- Disease background
  - Establishes unmet need
- Current treatment options
- New product
  - Establishes value of new product
- Clinical efficacy and safety data
- Economic data

Evidence-based statements that provide information about the disease or product, and in doing so demonstrate and support the value of the product.

Different Stakeholders for Different Types of Products

- **Oral drug** (e.g., Lipitor®)
  - Reg Authority
  - Payers
  - Physicians
  - Patients
- **Injected biologic** (e.g., Epogen®)
  - Reg Authority
  - Physicians
  - Payers
  - Patients
- **Injected biosimilar** (e.g., Zarxio®)
  - Reg Authority
  - Payers
  - Physicians
  - Patients
Key Considerations For Stakeholders

PRIORITIES DIFFER AMONG TARGET AUDIENCES FOR VALUE STORY DEVELOPMENT

- **Physicians**
  - Noninferiority/equivalence/superiority versus reference product
  - Reimbursement
  - Switching between reference product and biosimilar
  - Shifting of standard of care
  - Real-world evidence of biosimilar performance post-approval
  - Patient out-of-pocket costs

- **Payers**
  - Acceptable data for regulatory approval
  - Pricing dynamics
  - Interchangeability and automatic substitution

- **Patients**
  - Out-of-pocket costs
  - Manufacturer's capabilities
  - Long-term efficacy and safety outcomes
  - Lack of easy-to-understand resource materials


Biosimilars are not Generics – Understanding Complexities of the Science

**BIOLOGIC MONOCLONAL ANTIBODY VS ASPIRIN MOLECULE**

*The enormous complexity of biologic molecules makes them impossible to replicate perfectly.*

Value Proposition for Generics

Cost savings

Efficacy

Value Proposition for Biosimilars

Knowledge and Understanding
- Terminology
- Name recognition
- Understanding of product complexities

Manufacturing and Cost Savings
- 25% to 30% cost savings vs innovator products
- Manufacturing process not “exactly” the same as innovator products
- Requires more extensive clinical testing

Safety, Safety, Safety
- Immunogenicity
- Short-term vs long-term use

Geography
- Availability of branded biologics
- US, Europe, Japan
- BRIC, Asia-Pacific, Latin America

Source:
Summary – Key Considerations for a Biosimilars Value Proposition

► New stakeholder paradigm
► Understanding the complexities of the science
► Comparative characteristics with innovator product
► Cost savings alone is NOT enough
► Safety issues

A value proposition focused on:
► Reducing health care costs
► Maintaining clinical efficacy and safety outcomes
► Significantly taking into account the perspectives of regulators, physicians, and patients

Value Proposition to Supported Value Proposition

- Supported value proposition
- Dissemination
- Translation
- Evidence generation
- Aspirational value message development
- Market landscape assessment
- Value proposition
Value Proposition – What to Communicate?

Datasets:
- Pre-clinical and clinical
- Reimbursement
- Health economic and PRO
- Real-world evidence

Key Value Messages:
- Efficacy and safety comparability with innovator products
- Cost savings
- Differentiation from other biosimilar competitors

Components of a Strategic Communication Program:
- KOL and patient engagement plans
- Regulatory, reimbursement, and HTA submission plan
- Comprehensive peer-reviewed publication plan
- Lay press/public audience publication plan

How to Communicate – Leveraging the Brand and the Experience

Amgen was one of the first companies to recognize the potential of modern biotechnology in developing valuable medicines for patients – and to assemble the diverse set of skills necessary to advance from hard to applied science. A leader in biotechnology since 1980, Amgen is focused on serving patients by discovering, developing and manufacturing innovative human therapeutics. By pioneering the development of novel products based on advances in cellular and molecular biology, Amgen’s therapeutics have changed the practice of medicine and helped millions of people around the world to fight cancer, kidney disease, rheumatoid arthritis and other serious diseases.

Source:
How to Communicate – Internet Websites

3. www.sandoz-biosimilars.com

Summary – Key Considerations for a Strategic Communication Program for Biosimilars

- Robust datasets to support the value proposition
- Different tactics in a communication plan to reach key stakeholders
- Multiple outlets and venues to communicate data and key messages
- New, non-traditional communication avenues
Discussion: Value Story

1. What is the percentage of biosimilar recognition among physicians in:
   - Europe
   - US

2. Are clinical data necessary for market authorization approval in:
   - Europe
   - US

3. Which of the following is NOT a term that has been used in place of “biosimilar”?
   - Biogeneric
   - Biobetter
   - Follow-on biologics
   - None of the above

4. Who is the original singer of RESPECT?
   - Aretha Franklin
   - Otis Redding
   - Diana Ross


US MARKET ACCESS FOR BIOSIMILARS

Medicare Reimbursement
Private Payer Reimbursement
US MARKET ACCESS FOR BIOSIMILARS

Medicare Reimbursement
Private Payer Reimbursement

Medicare Reimbursement Will Depend on the Regulatory Pathway

<table>
<thead>
<tr>
<th>Full Biologics License Application (BLA)</th>
<th>Abbreviated Biosimilar Pathway</th>
<th>Abbreviated Biosimilar Pathway with Interchangeability</th>
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<tbody>
<tr>
<td>Follow-on biologics that essentially are biosimilars to an innovator product, but do not have to demonstrate biosimilarity</td>
<td>Biosimilars approved under new FDA pathway created by the ACA</td>
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</tr>
<tr>
<td>Technically not biosimilars</td>
<td>Medicare payment equal to biosimilar’s ASP + 6% of the ASP of the reference product</td>
<td>May be subject to automatic substitution at the pharmacy</td>
</tr>
<tr>
<td>Eligible to receive distinct HCPCS code and ASP payment rate</td>
<td></td>
<td>Medicare payment equal to biosimilar’s ASP + 6% of the ASP of the reference product</td>
</tr>
</tbody>
</table>

- Teva’s Granix (tbo-filgrastim) – a “biosimilar” of Amgen’s Neupogen (filgrastim)
- Sandoz’s Zarxio (filgrastim-sndz) – a true biosimilar of Neupogen
- TBD
Part B Reimbursement for Biosimilars Approved Under the Abbreviated Pathway

► According to the ACA, Medicare payment for biosimilars approved under the abbreviated pathway will be based on the ASP of the biosimilar, plus 6% of the ASP of the reference product.*

► The intent of this provision is to remove the financial incentive to choose an innovator product over a biosimilar (or vice versa), since providers would receive the same “margin” for either product.

Biosimilar Payment Example

<table>
<thead>
<tr>
<th>Dollars ($)</th>
<th>Biosimilar</th>
<th>Brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td></td>
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<tr>
<td>60</td>
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<tr>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>110</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• ASP
• 6% of Brand ASP

Same incentive payment = 6% of brand ASP for both products


Recent CMS Developments – Part B

► On March 30, CMS released an MLN Matters article titled “Food and Drug Administration Approval of First Biosimilar Product”

► The MLN Matters article confirms the Part B biosimilar payment methodology mandated by the ACA (i.e., biosimilar ASP + 6% of brand ASP) and also includes the following new information:
  • During the initial post-launch period before ASP data are available, new biosimilars will be paid at WAC+6% (like other new drugs and biologicals).

► On April 1, CMS released the Q3 2015 quarterly HCPCS file, which includes the following HCPCS code for Sandoz’s newly approved biosimilar:
  • Q5101 – Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram

Sources:
Recent CMS Developments – Part B (Cont’d)

► On July 15, CMS published the Medicare Physician Fee Schedule (MPFS) 2016 proposed rule, in which the agency indicates that it plans to reimburse for different biosimilar versions of the same reference product at the same ASP-based rate, and under a single HCPCS code

“We would also like to take this opportunity to discuss and clarify some other details of Part B biosimilar payment policy. First, we plan to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. In general, this means that products that rely on a common reference product’s biologics license application will be grouped into the same payment calculation. This approach... is similar to the ASP calculation for multiple source drugs.” -CY 2016 MPFS Proposed Rule (emphasis added)

► At this point, it is unclear whether CMS is simply proposing this approach, or whether the decision has already been made

• The language in the proposed rule that discusses CMS’s planned approach to biosimilar reimbursement is not framed as a proposal, and does not invite comments


Recent CMS Developments – OPPS

► On July 8, CMS published the 2016 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule, in which the agency makes several proposals concerning biosimilar reimbursement under OPPS

► Specifically, CMS has proposed to:

• Extend the ACA-mandated biosimilar payment methodology to OPPS (i.e., the ASP of the biosimilar, plus 6% of the ASP of the reference product)
• Allow biosimilars to be eligible for transitional pass-through payment status under OPPS
• Apply the standard OPPS packaging threshold to biosimilar products (i.e., pay separately for biosimilars that have a per-day cost that meets or exceeds an annually determined per-day cost threshold [proposed to be $100 in 2016], and package payment for biosimilars that do not meet this threshold)

► In the proposed rule, CMS explicitly states that it is seeking comment on these proposals

Recent CMS Developments – Part D

► On March 30, CMS issued a biosimilar guidance memorandum for Part D plans
  • This is the only Part D guidance on biosimilars that CMS has issued to date
► In general, the Part D memorandum states that in most respects, new biosimilars should be treated like new branded drugs (i.e., not generics) from a formulary review and patient cost-sharing standpoint
► However, there are two important exceptions:
  • Reference and biosimilar products will not be considered as different drugs for the purposes of satisfying the two distinct drugs per category/class requirement for Part D formularies
  • Biosimilars are not eligible for the 50% coverage gap discount


US MARKET ACCESS FOR BIOSIMILARS

Medicare Reimbursement
Private Payer Reimbursement
Covance Primary Research with Commercial Payers

- Covance conducted a two-phased survey of commercial payer decision makers from plans covering a combined total of over 100 million covered lives.
- The first phase of the survey addressed payer insights regarding coverage of biosimilars and examined the impact of factors such as:
  - therapeutic area (specifically, oncology and rheumatoid arthritis [RA]),
  - type of FDA approval (BLA vs. abbreviated pathway),
  - interchangeability, and
  - pricing.
- The second phase of the survey focused more on reimbursement methodologies, coding, and clinical trial data requirements.

Overall, the survey results indicate that commercial payers are willing to steer utilization toward lower-cost biosimilars, especially if they are viewed as interchangeable.

Factors Ranked as Most Important in Coverage Decision Making

<table>
<thead>
<tr>
<th>Factor</th>
<th>Average Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnitude of cost differential</td>
<td>2.24</td>
</tr>
<tr>
<td>FDA interchangeability designation</td>
<td>2.56</td>
</tr>
<tr>
<td>Nature of FDA approval</td>
<td>3.72</td>
</tr>
<tr>
<td>Therapeutic area</td>
<td>4.08</td>
</tr>
<tr>
<td>Support/opposition within medical community</td>
<td>4.48</td>
</tr>
<tr>
<td>CMS coverage</td>
<td>4.52</td>
</tr>
<tr>
<td>Support/opposition within patient community</td>
<td>6.4</td>
</tr>
</tbody>
</table>

Most Payers Expect Discounts of 20-30% in Oncology and 20-40% in RA

Payers Expect to Steer Utilization Toward Biosimilars Using Traditional Utilization Management Techniques
Payers May Consider a Biosimilar to Be Interchangeable Based on Factors Other than FDA Designation

► As previously mentioned, payers ranked FDA interchangeability designation as one of the top 3 factors in coverage decision making for biosimilars

► However, 76% of respondents indicated that they would be willing to consider a biosimilar to be interchangeable even if it has not received a formal designation by the FDA, based on sources of information such as the following:

- Compendia listings
- Clinical trials
- Clinical evidence demonstrating efficacy and safety
- NCCN guidelines
- CMS coverage decisions
- KOL input
- Additional supporting documentation

When Initially Asked, the Majority of Payers Indicated that They Do Not Expect Coverage for Biosimilars to Vary Based on Clinical Trial Data

In general, do you expect your plan’s coverage to vary based on clinical trial data for biosimilars approved under the abbreviated pathway?

<table>
<thead>
<tr>
<th>Percentage of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>33%</td>
</tr>
</tbody>
</table>

| No                         |
| 67%                       |

However, When Further Probed, More Than Half of Payers Revealed that They Would Want to See Phase II or III Data

To grant more favorable coverage for a biosimilar as compared to the innovator product, the majority of payers (58%) would want to see Phase III clinical trial data.

At Parity

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>PK and PD data</td>
<td>42%</td>
</tr>
<tr>
<td>Phase I trial data</td>
<td>4%</td>
</tr>
<tr>
<td>Phase II trial data</td>
<td>21%</td>
</tr>
<tr>
<td>Phase III trial data</td>
<td>33%</td>
</tr>
</tbody>
</table>

More Favorable Biosimilar Coverage

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>PK and PD data</td>
<td>25%</td>
</tr>
<tr>
<td>Phase I trial data</td>
<td>0%</td>
</tr>
<tr>
<td>Phase II trial data</td>
<td>17%</td>
</tr>
<tr>
<td>Phase III trial data</td>
<td>58%</td>
</tr>
</tbody>
</table>


Discussion: US Market Access for Biosimilars

What do you believe are the most important implications of CMS’s recently proposed policies?

How do you think patient access to biosimilars might vary between Medicare and private payers?

In your view, what are the most significant unanswered questions regarding reimbursement for biosimilars?

Is Covance’s private payer research aligned with your understanding of payer attitudes toward biosimilars?

Additional questions?
Market Access Planning

► In many ways, the commercial path for biosimilars will be as challenging as that for a unique innovator biologic

► In order to facilitate market access for biosimilar products, manufacturers will need to engage in the full spectrum of market access and health economic planning activities.

► Manufacturers should begin these activities early in clinical development
Tactical Planning – CMS Reimbursement

► Early and frequent communication with CMS will be key to ensuring a favorable access landscape for Medicare beneficiaries at launch.
  • Temporary HCPCS Code
    • Manufacturers can informally request a Q-code
  • Regulatory Engagement
    • Submit comments on proposed regulations
      • OPPS comment deadline: August 31, 2015
      • MPFS comment deadline: September 8, 2015

Tactical Planning – CMS Reimbursement (Cont’d)

► There are several other, more formalized aspects of tactical reimbursement planning of which biosimilar manufacturers should be aware:
  • Permanent HCPCS Code Application
    – Annual deadline: applications due around the first business day each January
    – HCPCS Public Meetings held in the spring
    – If approved, new codes become effective the first day of the following year
  • OPPS Pass-Through Payment Application
    – Quarterly deadlines: applications due the first business day in March, June, September, or December
    – If granted, pass-through status typically takes effect roughly four months after application deadline
Customer Support

- Biosimilar manufacturers must offer customer support resources that are at least on par with those being offered by the market-leading innovator products, including:
  - Reimbursement Support
  - Financial Support
  - Provider Education

- These support resources will be especially important in specialty disease areas where providers have very high expectations regarding customer support.

Customer Support: Reimbursement Support

- Manufacturers offer reimbursement support for several reasons, including:
  - To remove barriers to successful payment of claims
  - To provide a resource for patients with coverage-related questions
  - To meet customer expectations concerning customer support
  - To provide an additional channel, besides the sales force, for building a relationship with customers

- A suite of reimbursement support services can be tailored to the specific needs of a product; however, key components of reimbursement support include:
  - General Coding & Reimbursement Guidance
  - Insurance Verification
  - Reimbursement Support: Key Components
  - Prior Authorization Support
  - Claims Support (Submission, Denials, Appeals)
Customer Support: Financial Support

- A financial support strategy must account for several different categories of patients, including those who are completely uninsured, and those who have insurance but cannot afford their out-of-pocket expenses.

- To account for these groups of patients, the following modes of financial support are typically offered:

  - "Free Product" Patient Assistance Programs
    - An option for uninsured patients who meet certain criteria
  
  - Copay Assistance Programs
    - An option for commercially insured patients
    - Cannot be provided to patients with public insurance (e.g., Medicare, Medicaid)

  - Copayment Foundation Referrals
    - An option for publicly insured patients who cannot afford their cost-sharing
    - Manufacturer programs can direct patients to these independent foundations

Customer Support: Why It Matters for Biosimilars

- Providing competitive customer service will be particularly important to ensuring favorable uptake for biosimilars for several reasons:
  - Biosimilar coding, coverage, and payment are “uncharted territory” for providers
  - Providers have become accustomed to a generally high level of customer support for all biologics, which has historically been offered due to the higher cost and more complex reimbursement associated with these products
  - As biosimilars enter the market, manufacturers of reference products may enhance their customer support offerings to maintain brand loyalty
  - As additional biosimilars of the same reference product are introduced, superior customer support will be one of the few ways in which a manufacturer will be able to differentiate their product

Offering competitive customer support will be crucial to differentiating a biosimilar against the originator product and other competing biosimilars.
Example Launch Planning Timeline: “Biosimilar X”

**ASSUMPTIONS:**
- **WILL LAUNCH MID-2016**
- **WILL BE FIRST BIOSIMILAR OF ITS REFERENCE PRODUCT**

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**2015**

- Conduct market access assessment to determine likely drivers of and barriers to **Biosimilar X** reimbursement
- Review proposed biosimilar payment policy in MPFS and OPPS rules, submit comments if deemed appropriate

**2016**

- Deploy sales force, reimbursement field team; launch HUB
- Submit hospital outpatient pass-through application by June 1, 2016 deadline
- Update educational resources to reflect pass-through status
- Engage with CMS to request a temporary HCPCS code, if deemed appropriate
- Begin evaluation of reimbursement HUB vendors
- Conduct market access assessment to determine likely drivers of and barriers to **Biosimilar X** reimbursement

**2017**

- Submit application for permanent HCPCS code (first business day in January 2017)
- Attend HCPCS public meeting to support application for permanent code, if deemed necessary

**2018**

- Update educational resources, website, and hotline materials to reflect new J-code
- Permanent HCPCS code announced (if granted)
- Permanent HCPCS code becomes effective

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**Example Launch Planning Timeline: “Biosimilar X” (Cont’d)**

- **WILL LAUNCH MID-2016**
- **WILL BE FIRST BIOSIMILAR OF ITS REFERENCE PRODUCT**

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**2017**

- HUB and reimbursement field team providing ongoing support

**2018**

- HUB and reimbursement field team providing ongoing support

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53 | Biosimilars Launch Workshop | July 2015
Public

54 | Biosimilars Launch Workshop | July 2015
Public
Discussion: Biosimilar Launch Planning Implications

► In your experience, what are the most critical aspects of launch planning for ensuring rapid adoption and optimal market access?

► In your opinion, what are the greatest launch-related challenges that biosimilar manufacturers will face?

► Concerning customer service, how do you expect the manufacturers of reference products to react to the launch of biosimilars?

► Additional questions?

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