Biosimilars in Oncology

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Practice President, Compass Oncology
Chair, National Policy Board Executive Committee
The US Oncology Network
August 2020
Plan

• The US Oncology Network
• Value-driven oncology care
• An overview of the biosimilars in oncology
• Incentives and Barriers to use
The US Oncology Network by the Numbers

- **20 years** of practice management experience
- **1,400+** affiliated physicians (>12,000 in US, 252 CTCA)
- **400+** sites in **25** states
- **75** value-based care contracts
- **25%** of physicians in the Oncology Care Model
- **$100M** invested in affiliated practices annually
- **20** differentiated drug contracts
- **$15M** value-based care technology investment
- **70,000+** patients enrolled in **1,500** clinical trials resulting in more than **70** FDA-approved cancer therapies
Cost Pressures in Oncology Care

Medicare Modernization Act 2003, Sequestration

Inability to Treat Medicare Patients

• 340B Pricing drives hospital growth
• Buy-and-Bill model excludes costs of acquisition, handling, delivery

Unlevel Playing Field

Improved Survival

Targeted Therapies

Novel Agents

Astronomical Drug Pricing

"Patient access to care is directly tied to the survival of smaller, independent practices."

Cliff Hudis, MD FACP, past president ASCO
Increasing pressures on independent providers results in rising costs

2018 Community Oncology Alliance Practice Impact Report

Trends in the Changing Landscape of Cancer Care
(Derived from current and past reports)

Cancer Care Becomes More Expensive When Community Oncology Practices Are Acquired by Hospitals


CONSOLIDATION CONTINUES

- 25% of practices grew (18% shrunk) from 2016 to 2017
- 9.4% decrease in practices from 2013 to 2017 (2,248 total oncology practices in the U.S.)

Yet the number of oncologists increased by 9.5% from 2013 (12,423 total U.S.-based oncologists)

DESPITE CONSOLIDATION, MOST PRACTICES REMAIN SMALL

- 76% employ 1-5 oncologists
- 72% have 1 site
- 21% employ 6-40 oncologists
- 25% have 2-5 sites
- 3% employ 41+ oncologists
- 4% have 6+ sites
Overview: Oncology Care Model

Model

Episodes are defined as 6 months of treatment.

Subsequent episodes can occur for the same patient.

Episodes begin with:
- Chemo claim or Part D claim (oral), hormone therapies included
- Office E&M visit
- Cancer DX

CMMI’s Goal

To advance “better care; smarter spending; healthier people”.

Who’s eligible to participate?

Medicare FFS beneficiaries starting chemo for all cancer types

Two forms of payment:
1. $160 per beneficiary per month fee (MEOS Payment)
2. Shared savings performance-based payment to incentivize practices to lower total cost of care
Key Components to the OCM

- Patient Navigation
- EHR promoting Interoperability
- Nationally Recognized Clinical Guidelines
- Institute of Medicine Care Management Plan
- 24/7 Access to Care
- Continuous Quality Improvement
- Cost Management
Realities of OCM Performance Based Payment

Path to OCM Performance Based Payment (PBP)

Opportunities for Improved Quality Outcomes and Cost Savings

- **Reduction in controllable hospitalizations and ER visits**
- **Improved hospice utilization**
- **And, drug utilization must be addressed to get over the total cost hump**

Inpatient, 16.4%
ER, 0.5%
Observation Stay, 0.5%
Radiation, 2.9%
Imaging, 3.3%

Drugs (Part B & D)
Other

*Data derived from OCM claims data.  April 2016 – March 2017
Drug costs have outstripped sustainability

Launch Price of New Cancer Drugs Compared with Household Income, 1975-2014

Oncology Treatment Modalities in Top Pharmaceutical Markets, Share of Sales, 2003-2013

The Promise of Biosimilars

- Access
- Competition
- Innovation

Exhibit 9: Price and Changes Following Biosimilar Introduction

<table>
<thead>
<tr>
<th>Country</th>
<th>Epothin Price Change</th>
<th>GCSF Price Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>-55%</td>
<td>-27%</td>
</tr>
<tr>
<td>France</td>
<td>-30%</td>
<td>-14%</td>
</tr>
<tr>
<td>Italy</td>
<td>-24%</td>
<td>-13%</td>
</tr>
<tr>
<td>Spain</td>
<td>-18%</td>
<td>-4%</td>
</tr>
<tr>
<td>UK</td>
<td></td>
<td>1%</td>
</tr>
</tbody>
</table>

Source: IMS Health, The Impact of Biosimilar Competition, Nov 2015
Note: Analysis based on publicly available prices
Biosimilarity

**Biosimilar Product**
A biosimilar is a biological product that is highly similar and has no clinically meaningful differences from an existing FDA-approved reference product.

**Highly Similar**
Comparative analysis of biosimilar vs. reference
State-of-the-art technology used to compare
Minor differences may exist, acceptable by FDA

**No Clinically Meaningful Differences**
No meaningful CLINICAL differences vs. reference product
Human pharmacokinetic / pharmacodynamic studies
Additional clinical studies may be required (if needed)

- Purity
- Molecular structure
- Bioactivity
- Pharmacokinetic and, if needed, pharmacodynamic studies
- Immunogenicity assessment
- Additional clinical studies as needed

www.fda.gov/biosimilars
Interchangeability

**Interchangeable Product**
An interchangeable product is a biosimilar product that meets additional requirements.

**Additional Requirements**
- Biosimilar expected to produce **SAME CLINICAL RESULT** as reference product
- Switching studies likely required
- Interchangeable product may be substituted for reference product without involvement of prescriber.

**NO PRODUCT HAS RECEIVED FDA INTERCHANGEABLE DESIGNATION TO DATE**

**NOTE:** Interchangeability **DOES NOT** mean SUPERIORITY

[www.fda.gov/biosimilars](http://www.fda.gov/biosimilars)
Therapeutic Interchange Policies
- Similar indications
- Marked differences in price
- Optimize medications for better clinical outcomes

Appropriate Use Policies
- ASCO choosing wisely
- De-implement low value care

Example: Supportive Care Drugs
# Oncology Biosimilars

<table>
<thead>
<tr>
<th>Biosimilar Name</th>
<th>Approval Date</th>
<th>Reference Product</th>
</tr>
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<tbody>
<tr>
<td>Nyvepria (pegfilgrastim-apgf)</td>
<td>June 2020</td>
<td>Neulasta (pegfilgrastim)</td>
</tr>
<tr>
<td>Ziextenzo (pegfilgrastim-bmez)</td>
<td>November 2019</td>
<td>Neluasta (pegfilgrastim)</td>
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<tr>
<td>Ruxience (rituximab-pvvr)</td>
<td>July 2019</td>
<td>Rituxan (rituximab)</td>
</tr>
<tr>
<td>Zirabev (bevacizumab-bvzr)</td>
<td>June 2019</td>
<td>Avastin (bevacizumab)</td>
</tr>
<tr>
<td>Kanjinti (trastuzumab-anns)</td>
<td>June 2019</td>
<td>Herceptin (trastuzumab)</td>
</tr>
<tr>
<td>Trazimera (trastuzumab-qyyp)</td>
<td>March 2019</td>
<td>Herceptin (trastuzumab)</td>
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<tr>
<td>Ontruzant (trastuzumab-dttb)</td>
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<td>Herceptin (trastuzumab)</td>
</tr>
<tr>
<td>Herzuma (trastuzumab-pkrb)</td>
<td>December 2018</td>
<td>Herceptin (trastuzumab)</td>
</tr>
<tr>
<td>Truxima (rituximab-abbs)</td>
<td>November 2018</td>
<td>Rituxan (rituximab)</td>
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<tr>
<td>Udenyca (pegfilgrastim-cbqv)</td>
<td>November 2018</td>
<td>Neulasta (pegfilgrastim)</td>
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<td>Nivestym (filgrastim-aafi)</td>
<td>July 2018</td>
<td>Neupogen (filgrastim)</td>
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<td>Fulphila (pegfilgrastim-jmdb)</td>
<td>June 2018</td>
<td>Neluasta (pegfilgrastim)</td>
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<td>Retacrit (epoetin alfa-epbx)</td>
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<td>Mvasi (Bevacizumab-awwb)</td>
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<td>Avastin (bevacizumab)</td>
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<tr>
<td>Zarxio (Filgrastim-sndz)</td>
<td>March 2015</td>
<td>Neupogen (filgrastim)</td>
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</table>

![Image of biosimilars icons]
# US Oncology Pathways Decision Support, CVP

**NCCN Recommendations:** CHOP + Rituximab x 6 cycles followed by ISRT (category 1) or CHOP + Rituximab x 6 cycles +/- ISRT (category 2A).

- For patients who are not candidates for chemotherapy, involved-site radiation therapy (ISRT) is recommended.
- For patients that have poor left ventricular function, NCCN recommends the following category 2A regimens: CEOP + Rituximab, CEPP + Rituximab, DA-EPOCH + Rituximab, CDOP + Rituximab, or GCVP + Rituximab.
- For patients that are very frail and those >80 yrs with comorbidities, NCCN recommends the following category 2A regimens: CEPP + Rituximab, CDOP + Rituximab, Mini-CHOP + Rituximab, or GCVP + Rituximab.
- An FDA-approved biosimilar is an appropriate substitute for Rituximab.

## Medical Info

### Value Pathways Evidence

<table>
<thead>
<tr>
<th>SHOW</th>
<th>Clinical Trials At This Practice (4)</th>
<th>Value Pathways</th>
<th>NCCN</th>
<th>NCCN Category of Evidence</th>
<th>Neutropenic Risk</th>
<th>Emetogenic Risk</th>
<th>Action</th>
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<td>✓</td>
<td>2A</td>
<td>intermediate</td>
<td>high</td>
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<td>CHOP + Rituximab x 6 cycles</td>
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<td>high</td>
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<td>CHOP + Rituximab/Hyamunidase x 6 cycles</td>
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<td>✓</td>
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<td>intermediate</td>
<td>high</td>
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<tr>
<td>Rituximab IV + miniCHOP Q21D</td>
<td>✓</td>
<td>✓</td>
<td>2A</td>
<td>intermediate (10-30%)</td>
<td>moderate-high (60-89%)</td>
<td>SELECT</td>
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<tr>
<td>Rituximab IV BIOSIMILAR + CHOP Q21D (3 cycles)</td>
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<td>✓</td>
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<td>intermediate (10-30%)</td>
<td>moderate-high (60-89%)</td>
<td>SELECT</td>
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<tr>
<td>Rituximab IV BIOSIMILAR + CHOP Q21D (6 cycles)</td>
<td>✓</td>
<td>✓</td>
<td>2A</td>
<td>intermediate (10-30%)</td>
<td>moderate-high (60-89%)</td>
<td>SELECT</td>
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</tr>
<tr>
<td>Rituximab IV BIOSIMILAR + miniCHOP Q21D</td>
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<td>✓</td>
<td>2A</td>
<td>intermediate (10-30%)</td>
<td>moderate-high (60-89%)</td>
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<tr>
<td>Rituximab IV &amp; SQ + CHOP Q21D (3 cycles)</td>
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<td>✓</td>
<td>2A</td>
<td>intermediate (10-30%)</td>
<td>moderate-high (60-89%)</td>
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Biosimilar Uptake (Network): 2020
Biosimilar use All Network new + existing

Data source: Impact Analytics Team, iKM administration data; Accessed: 2020.06.30, data valid through 2020.06.23
Biosimilar Uptake (Network): 2020

Biosimilar use All Network new patient starts

Data source: Impact Analytics Team, iKM administration data; Accessed: 2020.06.30, data valid through 2020.06.23
Biosimilar Preparedness

Clinical Confidence

Patient Confidence

Operational Excellence
Practice Transformation

It’s About Transformation

- Buy-in
- Sustainability
- Evidence-Based Decision Support
- Care Team Roles and Processes
- Engaged Patients, Shared Decision-Making
- Universality of Information
- De-Escalating Unnecessary Care
- Market Players all engaged toward common goal

Delivering a healthy future