THE ROLE OF BIOSIMILARS IN VALUE-BASED CARE: CASE STUDY BASED LEARNING

Kashyap Patel, MD, AboiM, BCMAS
Vice President, Community Oncology Alliance
Chairman, Clinical Affairs, Association of Community Cancer Centers
Medical Director, International Oncology Network
Consultant, Premier Applied Life Sciences
AKH Inc., Advancing Knowledge in Healthcare (Physician CME)

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of AKH Inc., Advancing Knowledge in Healthcare, ProCE, Inc., and the National Community Oncology Dispensing Association (NCODA). AKH Inc., Advancing Knowledge in Healthcare is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for Physicians.

AKH Inc., Advancing Knowledge in Healthcare designates this live activity for a maximum of 0.75 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosure: It is the policy of ProCE, Inc. and AKH Inc. to ensure independence, balance, objectivity, scientific rigor, and integrity in all of its continuing education activities. Faculty must disclose to the participants any significant relationships with commercial interests whose products or devices may be mentioned in the activity or with the commercial supporter of this continuing education activity. Identified conflicts of interest are resolved by AKH prior to accreditation of the activity and may include any of or combination of the following: attestation to non-commercial content; notification of independent and certified CME/CE expectations; referral to National Author Initiative training; restriction of topic area or content; restriction to discussion of science only; amendment of content to eliminate discussion of device or technique; use of other author for discussion of recommendations; independent review against criteria ensuring evidence support recommendation; moderator review; and peer review. Dorothy Caputo, MA, BSN, RN - AKH Director of Accreditations and AKH planners and reviewers have no financial relationships to disclose. The faculty speaker has no relevant commercial or financial relationships to disclose.

Disclaimer: This course is designed solely to provide the healthcare professional with information to assist in his/her practice and professional development and is not to be considered a diagnostic tool to replace professional advice or treatment. The course serves as a general guide to the healthcare professional, and therefore, cannot be considered as giving legal, nursing, medical, or other professional advice in specific cases. AKH Inc. specifically disclaim responsibility for any adverse consequences resulting directly or indirectly from information in the course, for undetected error, or through participant's misunderstanding of the content.

Disclosure of Unlabeled Use and Investigational Product: This educational activity may include discussion of uses of agents that are investigational and/or unapproved by the FDA. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

There is no commercial support for this CME activity.
LEARNING OBJECTIVES

- Explain the updates of MACRA and Value Based Care
- Formulate pathways to succeed in the Oncology Care Model and the role of biosimilars.
- Evaluate a case study of biosimilars and GCSF.
Session Outline

- MACRA and VBC
- Oncology care model and VBC
- Pathways to succeed in OCM and the role of biosimilars
- Case Study with Biosimilar GCSF
MACRA: Quality Payment Program (VBC)

Quality Payment Program (QPP)
- Pay for performance system
- Pay for physician services will be increased or decreased based upon quality reporting, resource use, EHR use and clinical improvement
- Default path unless part of qualified APMs

Oncology Care Model (OCM)
- CMMI policies encourage this route
- Physicians may participate in APMs that are either a
  - Qualified medical home
  - Advanced APMs with two sided risk
- Exempt from MIPS
- Qualifies for automatic 5% bonus annually
- Receive higher annual increase
OCM versus QPP

**OCM**
- One-and-two sided bundled payments model
- Monthly maintenance payments in addition to bundle
- One-sided (No downside risk) will still fall under QPP
- Two-sided model is less risk/less reward vs QPP
- From one sided risk to two sided risk, RR ratio is 8:1

**QPP**
- Reimbursement is revenue neutral: poorer performing practices are penalized and the money used to reward high performing practices
- Rewards potentially higher than two-sided OCM participants
- Risks also higher for poorer performers
- Overall risk rewards ratio would be 9:27 for top performers
QPP carries both high risk and high reward
QPP Composite Score Breakdown

2019:
- Quality: 50%
- Resource Use: 10%
- Advancing Care Information: 25%
- Improvement Activities: 15%

2020:
- Quality: 45%
- Resource Use: 15%
- Advancing Care Information: 25%
- Improvement Activities: 15%

2021:
- Quality: 30%
- Resource Use: 30%
- Advancing Care Information: 25%
- Improvement Activities: 15%
Objective: Reduce the total cost of care during a 6-month “Episode” using patient centric approach (expanded access, navigation etc.) and improve quality of care using patient centered care

Episode: commences with the initiation of chemotherapy, either infused/injected or oral. Includes patients on ongoing treatment; need to modify dispensing to reflect accuracy of data

Episode may continue beyond 6 months (for patients with stage IV disease), if they continue on either oral or IV chemo

Compensation:
(i) Monthly Enhanced Oncology Services payment (“MEOS”) (ii) performance-based payment

Enhanced Services:
OCM: Summary

- **Risk Arrangement**: 1-sided risk to December 31, 2018; option to assume 2-sided risk thereafter at the choice of practice.

- **OCM Discount**: Deduction from shared savings to determine Target Price: 4.0% 1-sided risk; 2.75% 2-sided risk.

- **Practice Redesign Activities**: OCM Participants must implement the 6 Practice Redesign Activities.

- **Clinical Data and Quality Measures**: Quality measures reported quarterly.

- **Monitoring**: Participants will be subject to reporting and monitoring.
### Possible Avenues of Cost Savings (projected)

<table>
<thead>
<tr>
<th>Source</th>
<th>% Cost Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug pathways compliance</td>
<td>1.0% to 3.0%</td>
</tr>
<tr>
<td>Avoidable ER utilization</td>
<td>0.6% to 1.1%</td>
</tr>
<tr>
<td>Avoidable hospital admissions</td>
<td>4.0% to 7.0%</td>
</tr>
<tr>
<td>Diagnostics – Choosing wisely (imaging, lab)</td>
<td>0.2% to 0.5%</td>
</tr>
<tr>
<td>End-of-life care management</td>
<td>0.9% to 1.9%</td>
</tr>
<tr>
<td>Use of generics and biosimilars</td>
<td>9% to 12%</td>
</tr>
<tr>
<td>Total savings</td>
<td>15.9% to 25.5%</td>
</tr>
<tr>
<td>Team</td>
<td>Team Building with sustained engagement</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Team</td>
<td>Team building with overnight retreats</td>
</tr>
<tr>
<td>Implement</td>
<td>Implement strategies to expand access leading to Patient centered cancer care (PCCC)</td>
</tr>
<tr>
<td>Consider</td>
<td>Consider biosimilars and generics; refer to NCCN evidence blocks</td>
</tr>
</tbody>
</table>
Team building

- SE Workshop
- OCM orientation meetings (initially weekly followed by monthly; ongoing review of feedback reports)
- On boarding employees
- Navigation certification
- Financial counselor
Team Building in OCM: SE workshop
Team Building using SE workshop
OCM and PCCC transition focusing on clinical care

- Patient Education Manuals
- Secondary Prevention
- Lifestyle Modification
- Expanded Access
- Partnership with Urgent Care Center
- Choosing Wisely
- NCCN Evidence Blocks
- In House Palliative Care
- In House Diagnostics
- Clinical Trials
Patient centered cancer care
Riverview Medical Center is proud to work with Carolinas Blood and Cancer Care to help you avoid hospital visits by offering medical care whenever you need us... 24 hours a day!

Illnesses and Conditions
- Chest and abdominal pain
- Asthma and breathing treatments
- Nausea, vomiting, constipation, diarrhea
- High blood pressure
- Pneumonia, bronchitis
- Dehydration

Diagnostic and Surveillance Testing Services
- Ability to collect and send-out lab specimens for over 2000 Bloodwork and Culture Tests
- In-House Testing for Pregnancy, Flu, Strep, Cardiac Risk, Glucose/Hba1c and Complete Blood Count
- X-Ray / Radiology / Ultrasound
- Infusions, fluids

What you need to do
If you need to be seen after-hours, please contact CBCC. They will coordinate with Riverview Medical Center who will be waiting on you!

Taking Care of Our Community Since 1986
We believe that a Service to Humanity is a Service to God

Need After-Hours Care?

Avoid the Hospital...
We are Open!

Riverview Medical Center
Family Medicine, Urgent Care, Occupational Medicine, Physical Therapy, Hospice & Palliative Care
1393 Celanese Rd. □ Rock Hill, SC 29732
803.329.3163 □ fax 803.327.7937
www.riverviewmed.com

Appointments and Walk-Ins Welcome
Open 24 hours, 7 days a week
## Summary of steps we envisioned for success in OCM

<table>
<thead>
<tr>
<th>Process/Intervention</th>
<th>Outcome</th>
<th>Savings</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekend access to MD</td>
<td>Reduced ER visit/hospitalization</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Triage process/Navigation</td>
<td>Reduced ER visit</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>On-site radiology</td>
<td>Increased convenience</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Weekend infusion</td>
<td>Reduced hospitalization</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Partnership with urgent care</td>
<td>Reduced ER visits and reduce hospitalization</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Biosimilars and generics</td>
<td>Reduce cost</td>
<td>Yes</td>
<td>unchanged</td>
</tr>
<tr>
<td>Nutrition and dietician</td>
<td>Better population health</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Supportive care pathways</td>
<td>Reduced ER visits and hospitalizations</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Palliative and spiritual care</td>
<td>Better psychosocial health</td>
<td>Yes</td>
<td>Better</td>
</tr>
<tr>
<td>Expenditure categories</td>
<td>Your practice</td>
<td>OCM practices</td>
<td>All practices providing cancer care</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------------</td>
<td>---------------</td>
<td>---------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Inpatient admissions to short-term acute care hospitals and CAHs, all cause</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excluding admissions for chemotherapy, bone marrow transplant, and cancer surgery</td>
<td>$576</td>
<td>$846</td>
<td>-31.9%</td>
</tr>
<tr>
<td></td>
<td>$527</td>
<td>$739</td>
<td>-28.7%</td>
</tr>
<tr>
<td></td>
<td>$913</td>
<td>$793</td>
<td>-36.9%</td>
</tr>
<tr>
<td></td>
<td>$793</td>
<td>$793</td>
<td>-33.5%</td>
</tr>
<tr>
<td>Unplanned readmissions within 30 days of discharge</td>
<td>$116</td>
<td>$186</td>
<td>-37.8%</td>
</tr>
<tr>
<td></td>
<td>$185</td>
<td>$185</td>
<td>-37.3%</td>
</tr>
<tr>
<td>Resulting from ED visit and/or observation stay:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resulting from ED visit only</td>
<td>$379</td>
<td>$550</td>
<td>-31.0%</td>
</tr>
<tr>
<td></td>
<td>$562</td>
<td>$562</td>
<td>-32.5%</td>
</tr>
<tr>
<td>Resulting from observation stay only</td>
<td>$335</td>
<td>$484</td>
<td>-30.8%</td>
</tr>
<tr>
<td></td>
<td>$488</td>
<td>$488</td>
<td>-31.3%</td>
</tr>
<tr>
<td></td>
<td>$7</td>
<td>$7</td>
<td>3.2%</td>
</tr>
<tr>
<td></td>
<td>$7</td>
<td>$7</td>
<td>3.2%</td>
</tr>
<tr>
<td>Resulting from ED visit that led to an observation stay</td>
<td>$37</td>
<td>$49</td>
<td>-23.9%</td>
</tr>
<tr>
<td></td>
<td>$48</td>
<td>$48</td>
<td>-23.2%</td>
</tr>
<tr>
<td>Resulting from neither ED visit nor observation stay</td>
<td>$199</td>
<td>$316</td>
<td>-37.1%</td>
</tr>
<tr>
<td></td>
<td>$334</td>
<td>$334</td>
<td>-40.5%</td>
</tr>
<tr>
<td>Observation stays not leading to admissions</td>
<td>$20</td>
<td>$22</td>
<td>-9.8%</td>
</tr>
<tr>
<td></td>
<td>$24</td>
<td>$24</td>
<td>-14.7%</td>
</tr>
<tr>
<td>Resulting from ED visit</td>
<td>$14</td>
<td>$14</td>
<td>1.1%</td>
</tr>
<tr>
<td></td>
<td>$15</td>
<td>$15</td>
<td>-5.2%</td>
</tr>
<tr>
<td>Not resulting from ED visit</td>
<td>$6</td>
<td>$7</td>
<td>-11.0%</td>
</tr>
<tr>
<td></td>
<td>$7</td>
<td>$7</td>
<td>-11.6%</td>
</tr>
<tr>
<td>ED visits not leading to admission or observation stay</td>
<td>$17</td>
<td>$24</td>
<td>-28.7%</td>
</tr>
<tr>
<td></td>
<td>$29</td>
<td>$29</td>
<td>-40.4%</td>
</tr>
<tr>
<td>Part B: Physician and DME</td>
<td>$1113</td>
<td>$1,061</td>
<td>+4/9%</td>
</tr>
<tr>
<td></td>
<td>$429</td>
<td>$429</td>
<td>+159.4%</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>$868</td>
<td>$806</td>
<td>+7.6%</td>
</tr>
<tr>
<td></td>
<td>$293</td>
<td>$293</td>
<td>+195.9%</td>
</tr>
</tbody>
</table>
Hospitalization: CBCCA versus OCM and all other practices (blue line)
The role of biosimilars in the OCM and VBC: Not a theory any more
The role of biosimilars in the OCM and VBC: Not a theory any more

Savings ($$$$) realized from Biosimilars

PROGRESSIVE INCREMENT IN SAVINGS FROM BIO SIM GCSF WITH DECLINING ASP

- 2016: $30,493.44
- 2017: $94,194.90
- 2018: $124,688.34
<table>
<thead>
<tr>
<th>Patient Experience</th>
<th>Average of Overall Rating and Composites (a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your practice</td>
<td>8.42</td>
</tr>
<tr>
<td>OCM practices</td>
<td></td>
</tr>
<tr>
<td>Percentiles</td>
<td></td>
</tr>
<tr>
<td>10th</td>
<td>7.97</td>
</tr>
<tr>
<td>20th</td>
<td>8.07</td>
</tr>
<tr>
<td>30th</td>
<td>8.14</td>
</tr>
<tr>
<td>40th</td>
<td>8.22</td>
</tr>
<tr>
<td>50th</td>
<td>8.27</td>
</tr>
<tr>
<td>60th</td>
<td>8.33</td>
</tr>
<tr>
<td>70th</td>
<td>8.41</td>
</tr>
<tr>
<td>80th</td>
<td>8.46</td>
</tr>
<tr>
<td>90th</td>
<td>8.53</td>
</tr>
<tr>
<td>Minimum</td>
<td>7.52</td>
</tr>
<tr>
<td>Maximum</td>
<td>9.16</td>
</tr>
</tbody>
</table>
Reduction in non chemo expenses (resulting from expanded access)

Comparison of CBCCA versus all other OCM practices - ER and hospitalization

- Observation stays not leading to admissions
- Resulting from ED visit
- Not resulting from ED visit
- ED visits not leading to admission or observation stay

Comparison of Median expenditure amount:

- Your Practice
- Median expenditure amount
Reduction in expenses related to ER visits (resulting from partnering with urgent care center)
CBCCA had higher overall office visits and chemo expenses and yet we achieved savings (in line with previously published work)
Potential for savings from hypothetical 30% savings based on previous case study of GCSF

<table>
<thead>
<tr>
<th>Medicare Payments</th>
<th>Biosimilar Drugs Payments (assumptions)</th>
<th>30% Saving on Biosimilar Drugs (assumptions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peg Filgrastim</td>
<td>2016</td>
<td>2016</td>
</tr>
<tr>
<td>Rituximab</td>
<td>2016</td>
<td>2016</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>2016</td>
<td>2016</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>2016</td>
<td>2016</td>
</tr>
<tr>
<td>Erythropoietin</td>
<td>2016</td>
<td>2016</td>
</tr>
</tbody>
</table>
Potential savings with Biosimilars in 2021; CBCCA case study (likely to be in market late 2019)
CBCCA
Growth from 2013-2018

Annual revenue growth of oncology practice 2013-2018: Case Study
Human potential is frequently ignored and undervalued, but highly rewarding step for success in any task no matter what challenges exist.

ER visit, Hospitalization, biosimilars, generics and expanded access are low hanging fruits for success in the OCM.

Two sided risk is worth considering if downside risk can be covered using reinsurance product (in process of developing with experts).

There is noticeable improvement in both employee morale and patient experience.
AUDIENCE POLLING QUESTIONS

How familiar are you with biosimilars

• On a scale of 1-5
• 1 = least
• 5 = most
AUDIENCE POLLING QUESTIONS

Are you aware of FDA approval process for biosimilars

• 1 = yes
• 2 = no
AUDIENCE POLLING QUESTIONS

Are you familiar with term *interchangeability designation*?

• 1-yes
• 2-no
AUDIENCE POLLING QUESTIONS

Are you familiar with extrapolation in biosimilars

• 1-yes
• 2-no
AUDIENCE POLLING QUESTIONS

Are you familiar with totality of evidence?

- 1-yes
- 2-no
AUDIENCE POLLING QUESTIONS

Are you aware of impact of biosimilars in Value Based Care

• 1-yes
• 2-no
AUDIENCE POLLING QUESTIONS

Have you used biosimilars?

• 1- yes
• 2- no
AUDIENCE POLLING QUESTIONS

Are you interested in learning more about biosimilars

• 1-yes
• 2-no
AUDIENCE POLLING QUESTIONS

How likely are you to use biosimilars?

• on a scale of 1-5;
• 1 being least
• 5 being the most
AUDIENCE POLLING QUESTIONS

Do you see a role for biosimilars in the Value Based Care and OCM?

• 1-yes
• 2-no
THANKS TO NCODA!

Platform for Knowledge Exchange

- Fall Summit & Spring Forum
- Patient-Centered Resources
- Discussion Board

Medically Integrated Dispensing Teams

- Effective Practices and Tools for:
  - Providers
  - Pharmacists
  - Nurses
  - Pharmacy Technicians
  - Administrators
  - Support staff
  - Patients
Questions?

2019 NCODA Fall Summit