Biosimilars in Oncology

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The US Oncology Network
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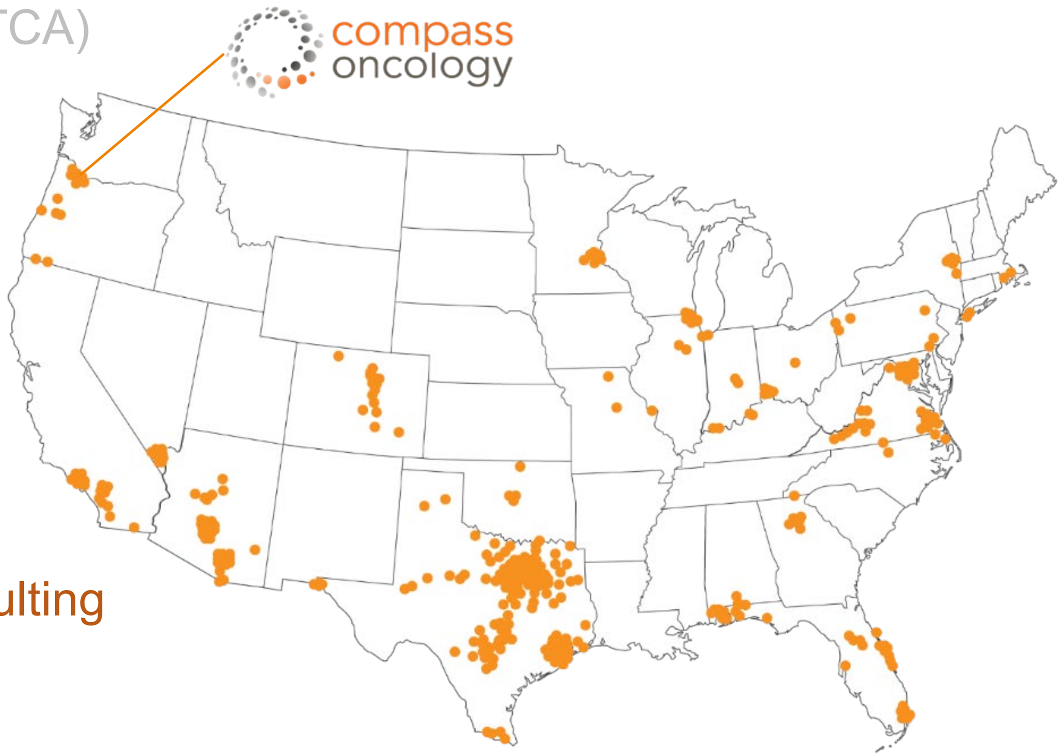
Plan

- 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



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Cost Pressures in Oncology Care

Medicare Modernization Act 2003, Sequestration

Significant impact to drug margin

Improved Survival

Targeted Therapies

Novel Agents

Astronomical Drug Pricing

Unlevel Playing Field

Inability to Treat Medicare Patients

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

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

Cliff Hudis, MD FACP, past president ASCO

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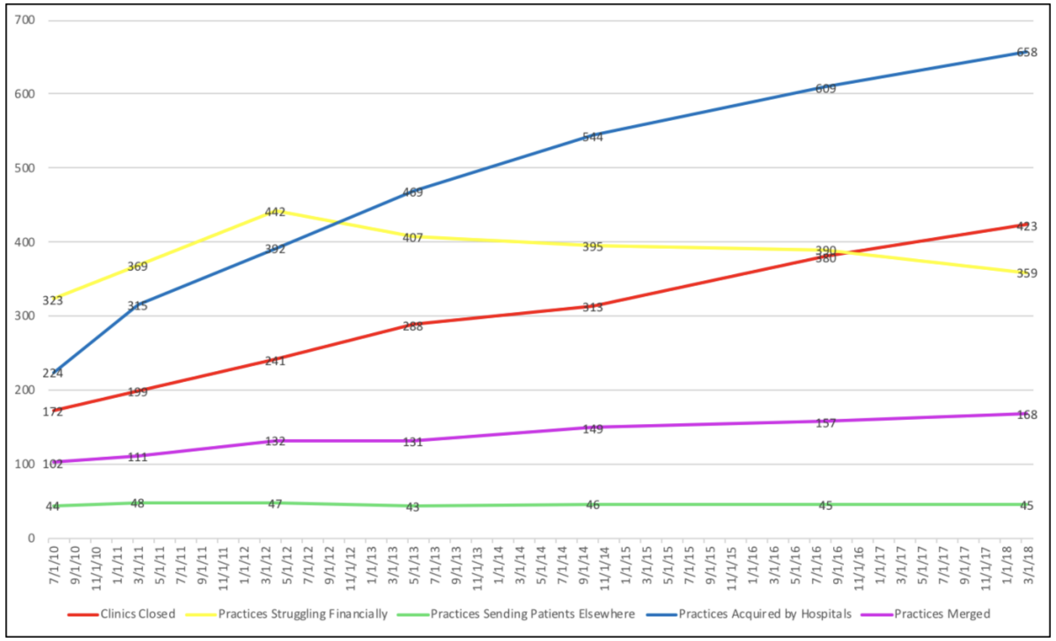
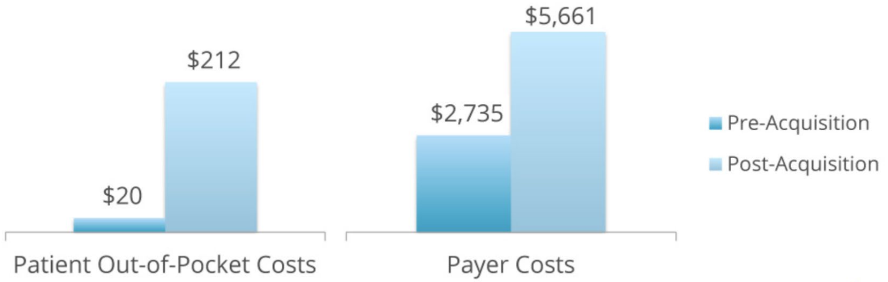
Increasing pressures on independent providers results in rising costs

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



Reference: (1) When doctors sell out, hospitals cash in. Community Oncology Alliance. July 8, 2013. http://www.communityoncology.org/site/blog/detail/2013/07/08/july-8-2013-when-doctors-sell-out-hospitals-cash-in.html Accessed April 16, 2015.

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

21% employ **6-40** oncologists

3% employ **41+** oncologists

72% have **1** site

25% have **2-5** sites

4% have **6+** sites

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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

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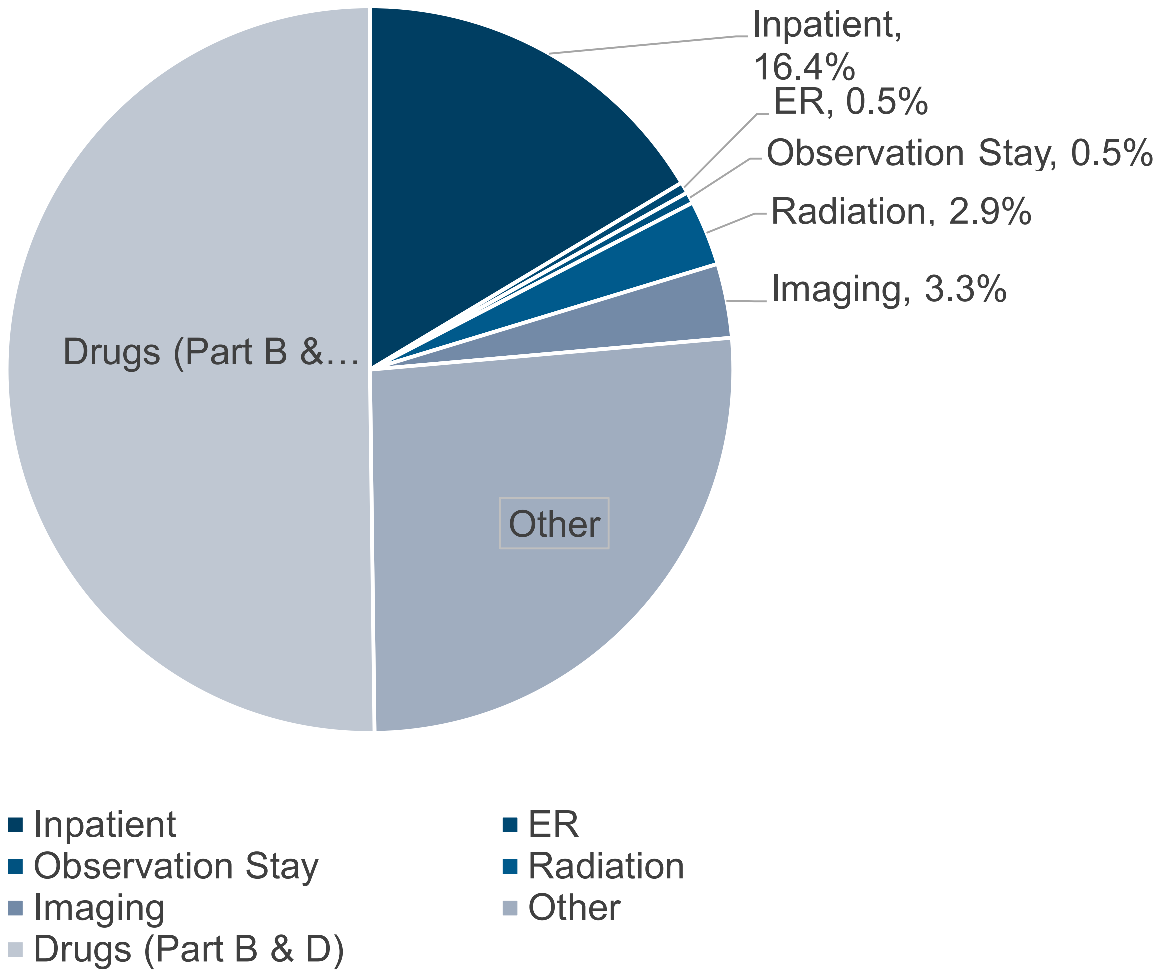
Realities of OCM Performance Based Payment

Path to OCM Performance Based Payment (PBP)



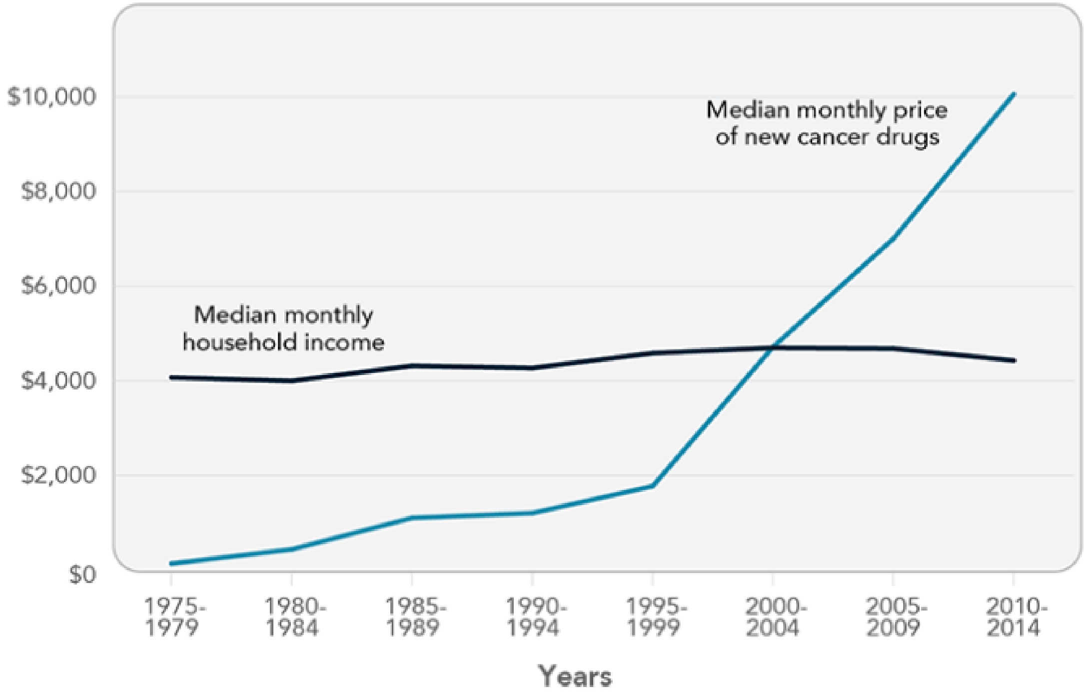
Opportunities for Improved Quality Outcomes and Cost Savings

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

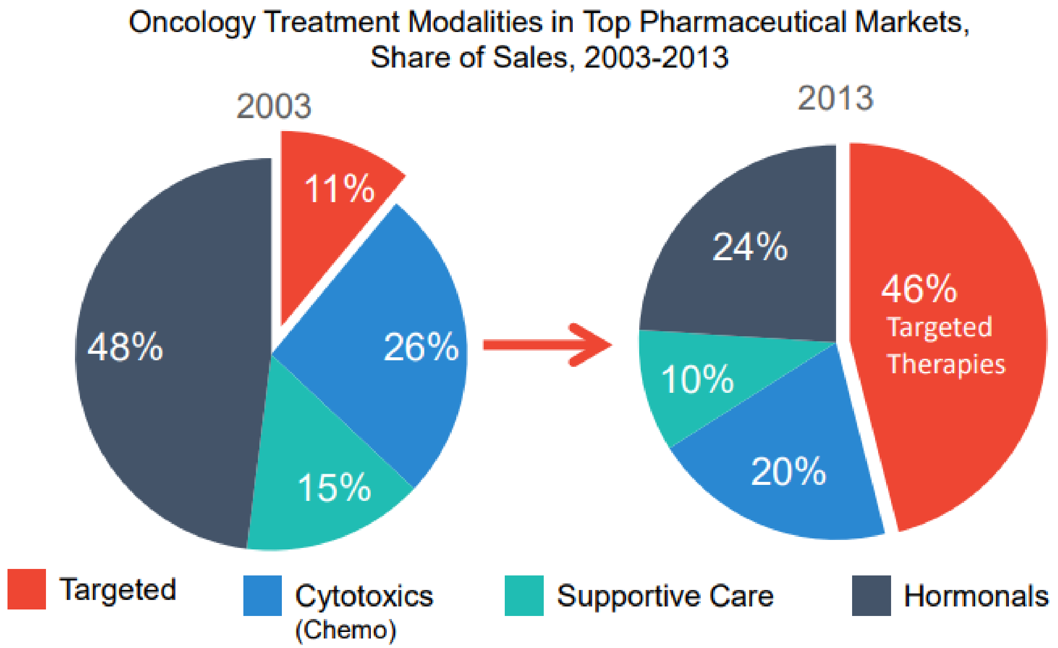
*Data derived from OCM claims data. April 2016 – March 2017

Drug costs have outstripped sustainability

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



Source: Prasad V, Jesus K, Mailankody S. The high price of anticancer drugs: origins, implications, barriers, solutions. Nat Rev Clin Oncol. 2017. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28290490



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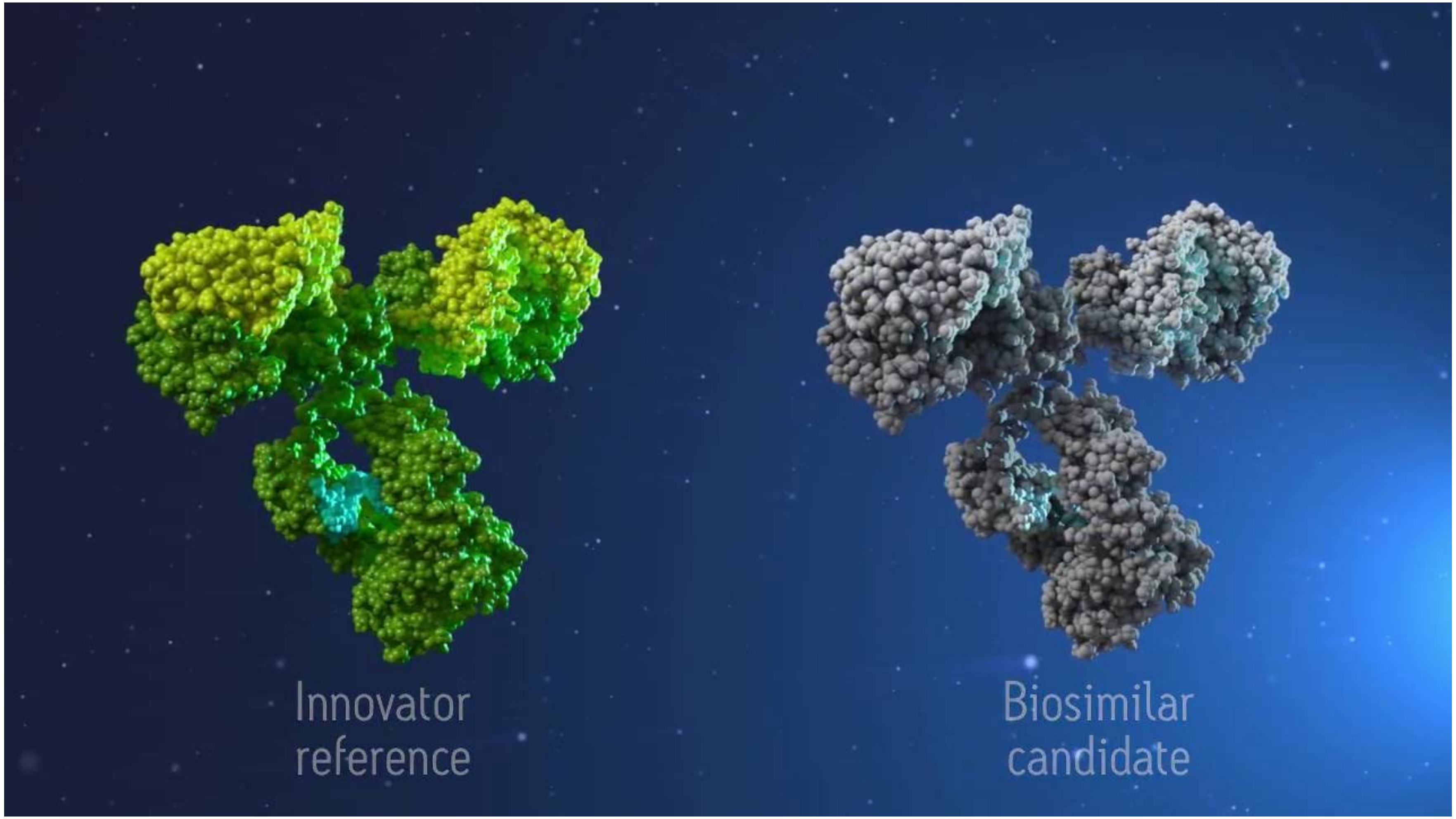
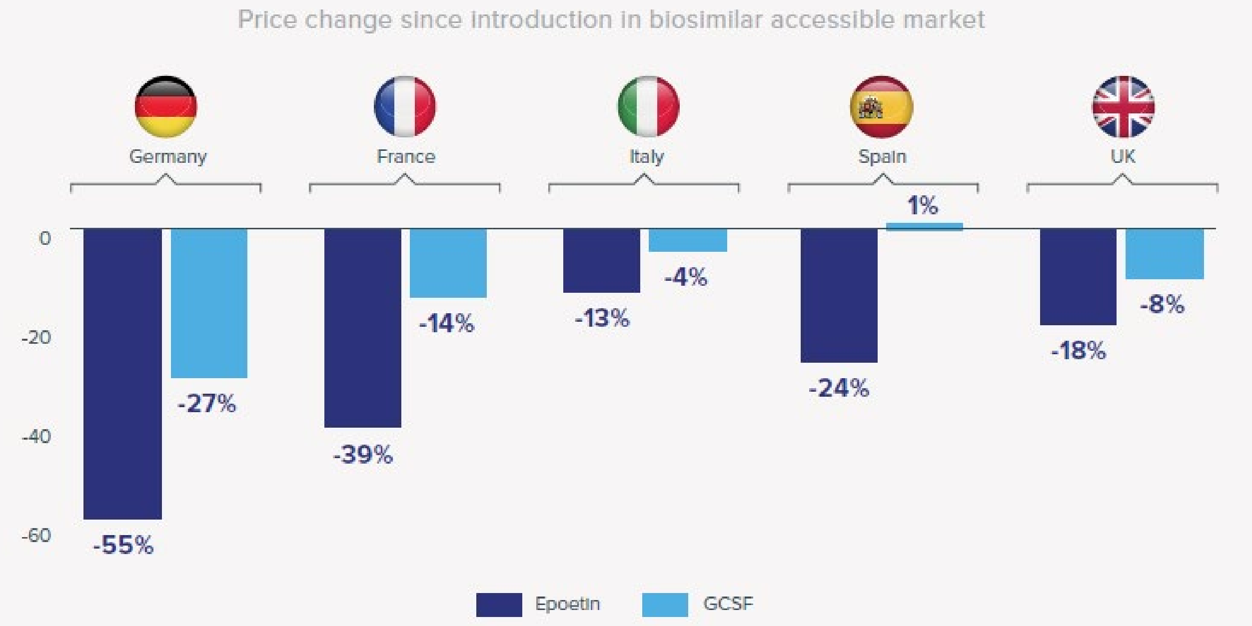

Innovator
reference
Biosimilar
candidate

The Promise of Biosimilars

- Access
- Competition
- Innovation

Exhibit 9: Price and Changes Following Biosimilar Introduction



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

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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

Purity | Molecular structure | Bioactivity

No Clinically Meaningful Differences

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

Pharmacokinetic and, if needed, pharmacodynamic studies | Immunogenicity assessment | Additional clinical studies as needed

Studies may be done independently or combined.

www.fda.gov/biosimilars

Interchangeability

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 INTERCHANGABLE DESIGNATION *TO DATE*

NOTE: Interchangeability DOES NOT mean SUPERIORITY

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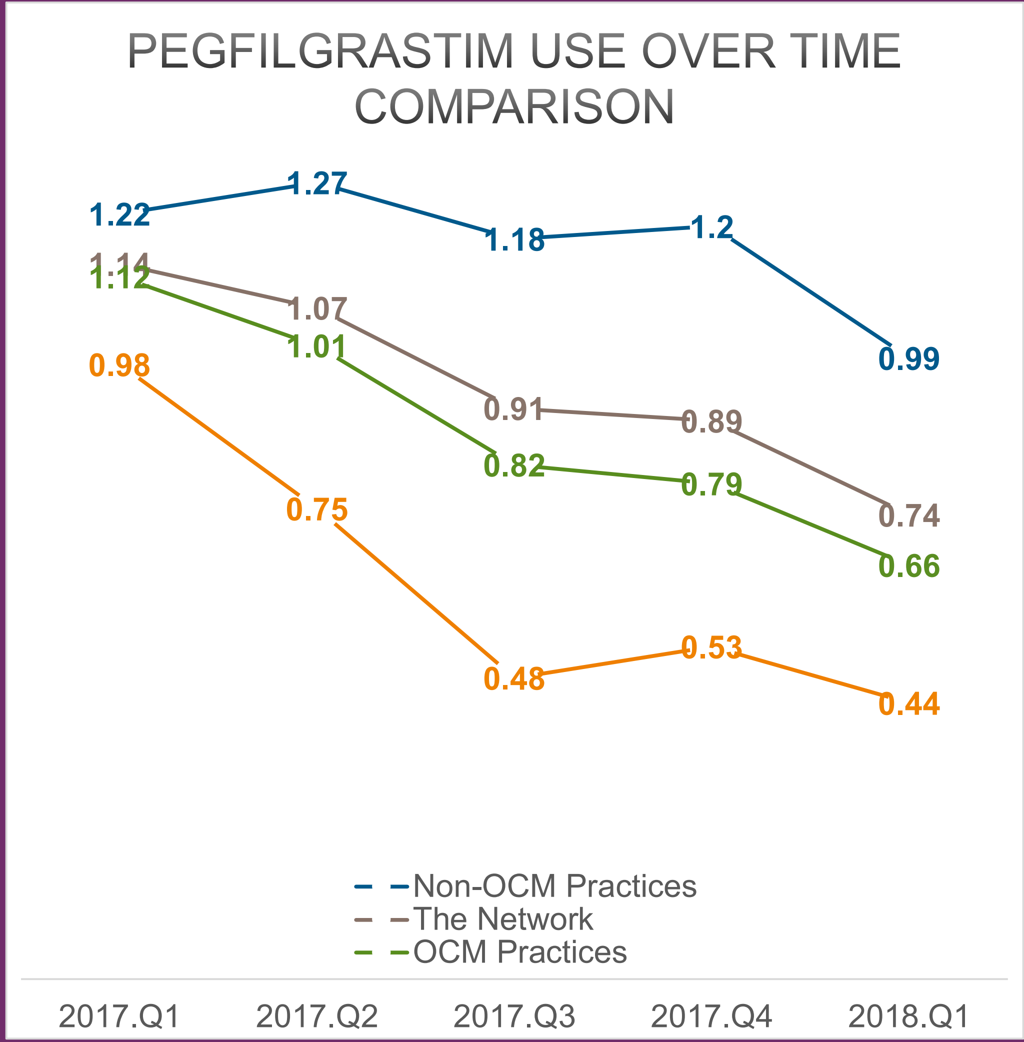
www.fda.gov/biosimilars

Example: Supportive Care Drugs



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

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Hoverman, J.R., Turnwald, B., Garey, J.S., Hayes, J., Mann, B.B., He, B., Wilfong, L.S., 2018. The institution of a white cell growth factor appropriate non-use policy for incurable metastatic solid tumors within a community oncology practice. JCO 36, 33–33. https://doi.org/10.1200/JCO.2018.36.30_suppl.33

Oncology Biosimilars

Biosimilar Name	Approval Date	Reference Product
Nyvepria (pegfilgrastim-apgf)	June 2020	Neulasta (pegfilgrastim)
Ziextenzo (pegfilgrastim-bmez)	November 2019	Neluasta (pegfilgrastim)
Ruxience (rituximab-pvvr)	July 2019	Rituxan (rituximab)
Zirabev (bevacizumab-bvzr)	June 2019	Avastin (bevacizumab)
Kanjinti (trastuzumab-anns)	June 2019	Herceptin (trastuzumab)
Trazimera (trastuzumab-qyyp)	March 2019	Herceptin (trastuzumab)
Ontruzant (trastuzumab-dttb)	January 2019	Herceptin (trastuzumab)
Herzuma (trastuzumab-pkrb)	December 2018	Herceptin (trastuzumab)
Truxima (rituximab-abbs)	November 2018	Rituxan (rituximab)
Udenyca (pegfilgrastim-cbqv)	November 2018	Neulasta (pegfilgrastim)
Nivestym (filgrastim-aafi)	July 2018	Neupogen (filgrastim)
Fulphila (pegfilgrastim-jmdb)	June 2018	Neluasta (pegfilgrastim)
Retacrit (epoetin alfa-epbx)	May 2018	Epogen (epoetin-alfa)
Ogivri (trastuzumab-dkst)	December 2017	Herceptin (trastuzumab)
Mvasi (Bevacizumab-awwb)	September 2017	Avastin (bevacizumab)
Zarxio (Filgrastim-sndz)	March 2015	Neupogen (filgrastim)

Neulasta

Epogen

Rituxan

Avastin

Herceptin

US Oncology Pathways Decision Support, CVP

DEBBIE ZZ (65 / F)

+ Add Photo

MRN: 1528821
DOB: 01/02/1955
Insurance:

Regimen Type

✔ Regimen Type:	Chemotherapy	EDIT

Diagnosis

✔ Primary Diagnosis:	Diffuse non-Hodgkin's lymphoma, large cell (disorder)

NHL Factors

✔ Stage:	IIA	EDIT
✔ Stage subtype:	Nonbulky	EDIT
✔ CD20 Result:	Positive	EDIT
✔ International Prognostic Index result::	2	EDIT

B-Cell Factors

✔ Diffuse Large B-Cell subtype:	Other	EDIT
✔ Line of Therapy:	1st Line or Induction	EDIT

☐ Search All Regimens

✔ = Used by decision support

NCCN Recommendation: CHOP + Rituximab x 3 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

Filter Chemotherapies by: APPLY CLEAR

SHOW Clinical Trials At This Practice (4)				Febrile Neutropenic Risk	Emetogenic Risk	Action

HIDE Treatment Options (15)	Value Pathways	NCCN	NCCN Category of Evidence	Febrile Neutropenic Risk	Emetogenic Risk	Action
CHOP + Rituximab (Biosimilar) x 6 cycles	✔	✔	2A	intermediate	high	SHOW OPTIONS
CHOP + Rituximab x 6 cycles	✔	✔	2A	intermediate	high	SHOW OPTIONS
CHOP + Rituximab/Hyaluronidase x 6 cycles	✔	✔	2A	intermediate	high	SHOW OPTIONS
Rituximab IV + miniCHOP Q21D	✔	✔	2A	intermediate (10-20%)	moderate-high (60-90%)	SELECT
Rituximab IV BIOSIMILAR + CHOP Q21D (3 cycles)	✔	✔	1	intermediate (10-20%)	moderate-high (60-90%)	SELECT
Rituximab IV BIOSIMILAR + CHOP Q21D (6 cycles)	✔	✔	2A	intermediate (10-20%)	moderate-high (60-90%)	SELECT
Rituximab IV BIOSIMILAR + miniCHOP Q21D	✔	✔	2A	intermediate (10-20%)	moderate-high (60-90%)	SELECT
Rituximab IV fb SQ + CHOP Q21D (3 cycles)	✔	✔	2A	intermediate (10-20%)	moderate-high (60-90%)	SELECT
Rituximab IV fb SQ + miniCHOP Q21D	✔	✔	2A	intermediate (10-20%)	moderate-high (60-90%)	SELECT

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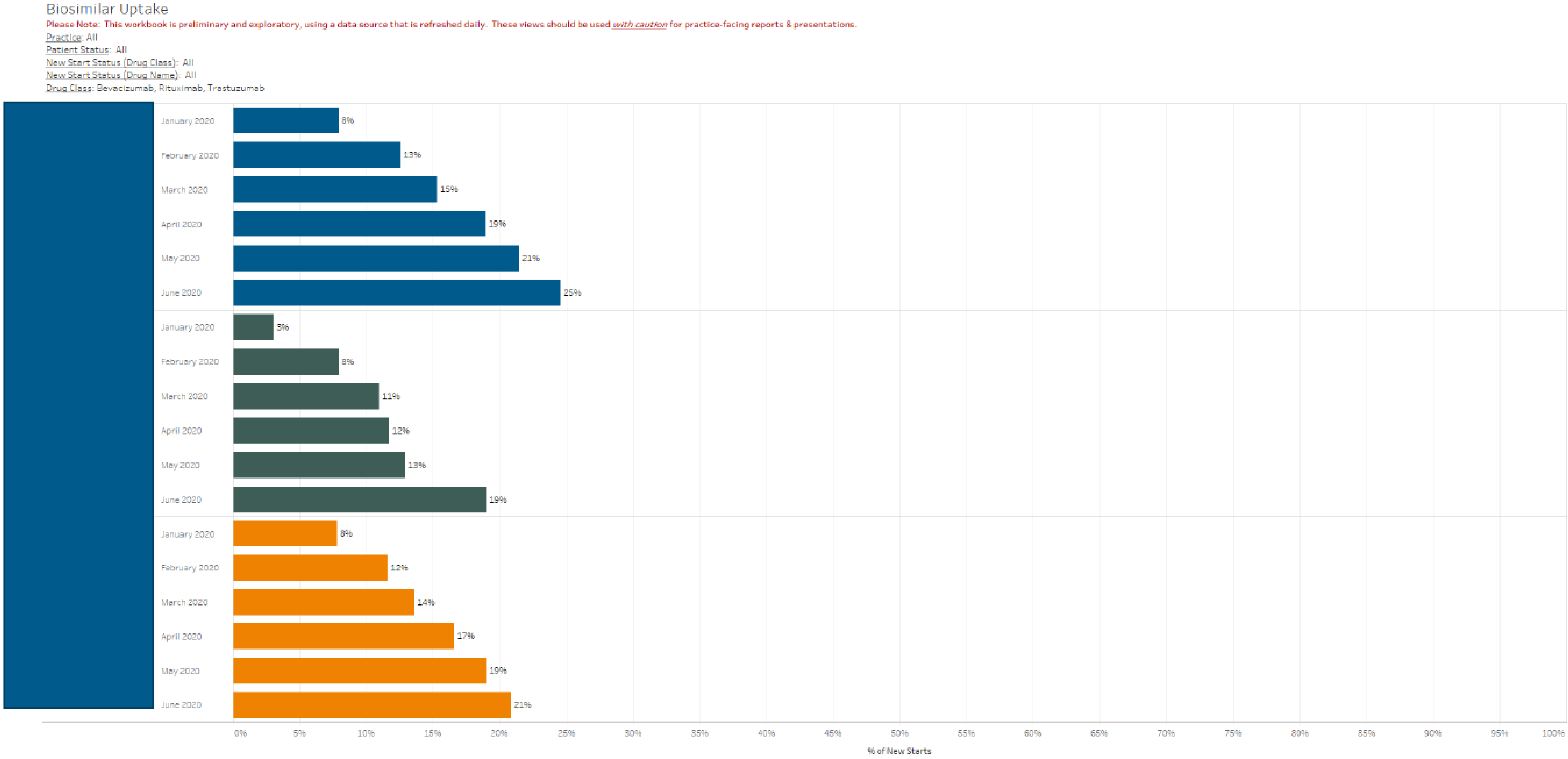
Biosimilar Uptake (Network) : 2020

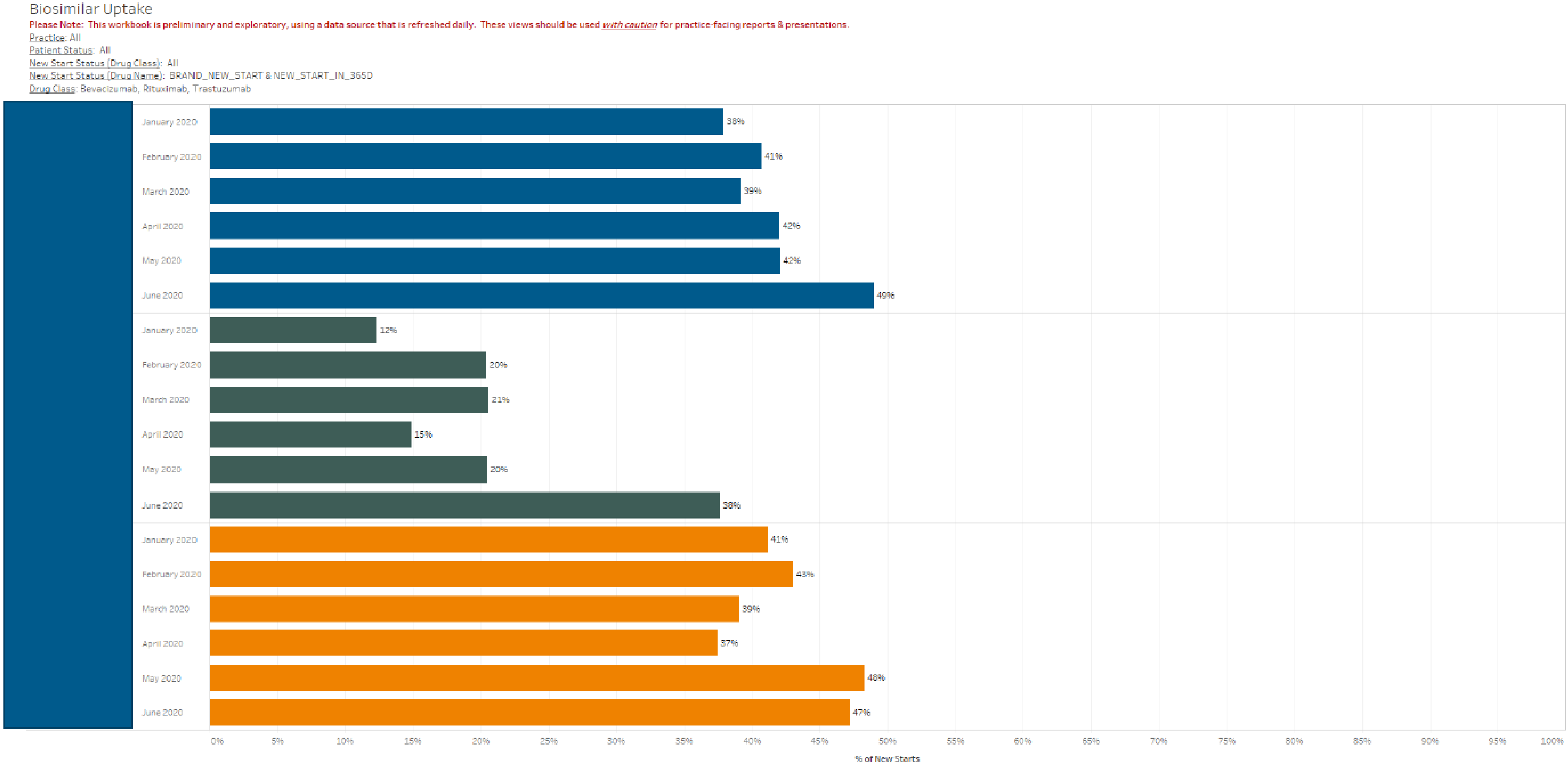
Biosimilar use All Network new + existing



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

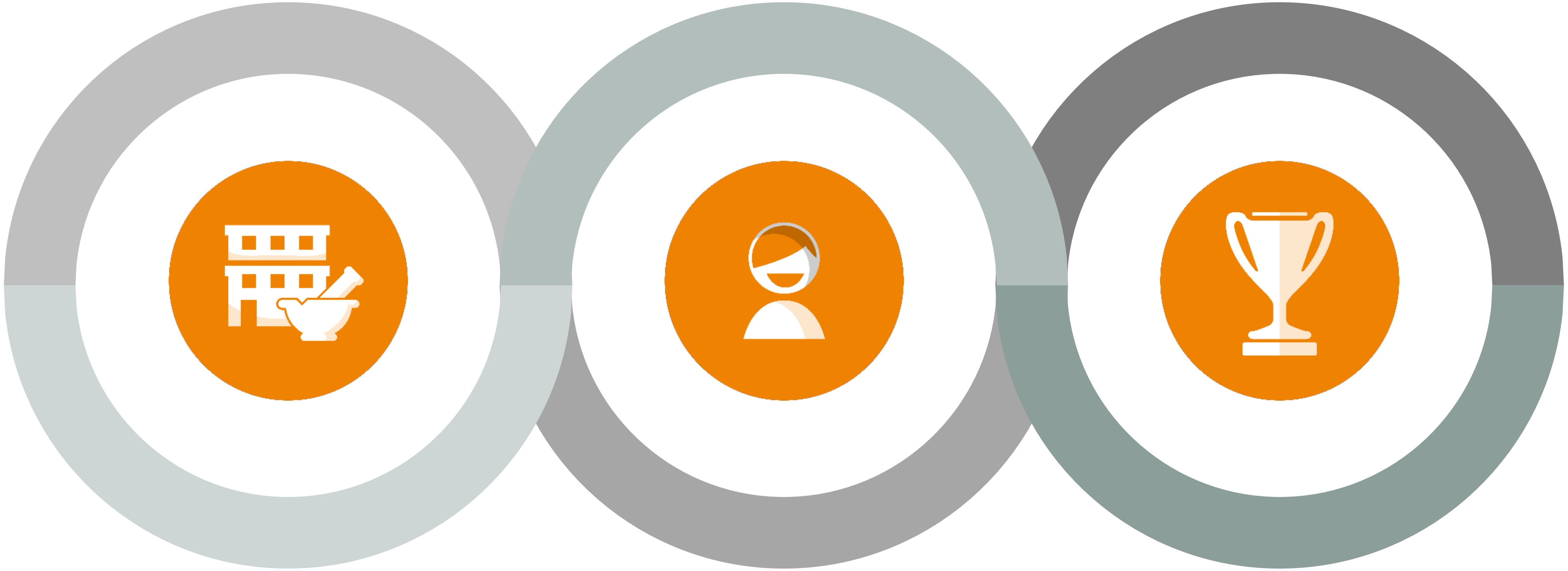
Biosimilar Uptake (Network) : 2020

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

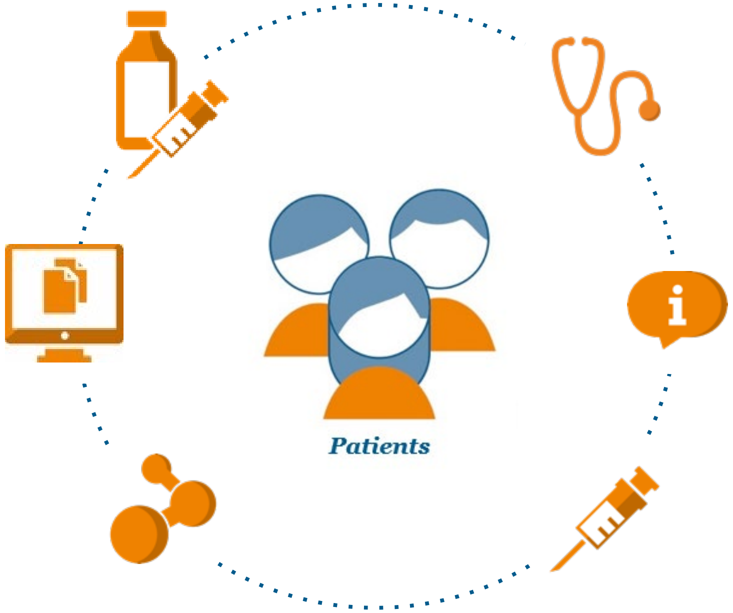


Clinical Confidence

Patient Confidence

Operational Excellence

Practice Transformation



Delivering a healthy future

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**