



Evidence-Based ONCOLOGY™

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ALSO IN THIS ISSUE



VALUE-BASED PURCHASING AND MORE.

A session of the Institute for Value-Based Medicine® (IVBM) in Nashville, Tennessee, offered highlights of where value-based purchasing works and where it doesn't, as well as an overview of where the Oncology Care Model (OCM) has succeeded and where it needs work, [SP350-SP351](#).

RADIATION ONCOLOGY.

Miranda Lam, MD, presented the attendees at IVBM with data and issues surrounding CMS' proposal for the mandatory Radiation Oncology Model, [ajmc.com/link/4408](#).



LAM

COA PAYER EXCHANGE SUMMIT. Community Oncology Alliance (COA) invites shared stories of success with the OCM as well as challenges as practices weigh the future of 2-sided risk in Tyson's Corner, Maryland, [SP356-SP358](#).

AMCP NEXUS. Data collaboration, genomic testing, and the review of the pharmaceutical pipeline were highlights of the Academy of Managed Care Pharmacy (AMCP) Nexus 2019 meeting in National Harbor, Maryland, [SP358-SP361](#).

MULTIPLE MYELOMA DISPARITIES.

New results show that novel therapies for multiple myeloma take longer to reach African American and Hispanic patients, [SP370](#).



COMMENTARY

Empower Physicians to Fight Financial Toxicity With Biosimilars

Kathy Oubre, MS

ONCOLOGY PRACTICES SEE THE TOLL financial toxicity¹ exacts on patients and their families every day. The financial burdens of cancer treatment are damaging even when they don't directly affect care—and research shows that all too often, they do. Patients struggling under the burdens of cancer care are more likely to be nonadherent with their prescribed treatment regimen, failing to fill prescriptions, delaying office visits, and forgoing critical diagnostic tests.² More affordable care is better care, and payers should empower providers to steer patients toward superior-value options whenever available. When it comes to oncology biologics, this means giving providers the power to prescribe biosimilars.

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ONCOLOGY CARE FIRST

Can Cancer Care Lead the Way Toward a Value-Based Future?

Keely Macmillan, MPH

THE 2019 MEDICARE TRUSTEES REPORT forecasts insolvency of the Hospital Insurance Trust Fund in 2026, sooner than prior projections.¹ A significant contributor to this unsustainable healthcare cost curve for Medicare beneficiaries is cancer-related spending.² To address this challenge, Medicare is engaging oncologists through new, value-based programs to identify ways to reduce inefficiency and unwarranted variation in spending.

On November 1, 2019, CMS released an informal request for information (RFI) on Oncology Care First (OCF), the highly anticipated successor to the current Oncology Care Model (OCM), which sunsets in 2021. The RFI, which solicits feedback through the extended deadline of December 13, 2019, is an important step in the development of successful models with robust engagement.³

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ADVOCACY PERSPECTIVE

Improving Survival in Lung Cancer: Commitment of The Lung Ambition Alliance

Giorgio Scagliotti, MD, PhD

FOR TOO LONG, lung cancer has had one of the worst prognoses of any cancer. It is the leading cause of cancer-related deaths worldwide (**Figure 1**); only 1 in 5 people with lung cancer will be alive 5 years after diagnosis.^{1,2}

New advances are creating the opportunity to transform the diagnosis, treatment, and management of lung cancer. However, survival rates have improved only modestly and are lagging behind those of other common cancers (**Figure 2**).³ The time for us to act is now: to come together as a community, to bend the lung cancer survival curve faster, and to significantly improve patient outcomes in this devastating disease.

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Approximately **1 in 5** cancer deaths are attributed to **lung cancer**.

SP387



Source: World Health Organization, International Agency for Research on Cancer, Latest global cancer data: Cancer burden rises to 18.1 million new cases and 9.6 million cancer deaths in 2018. [who.int/cancer/PRGlobocanFinal.pdf](#). Accessed November 22, 2019.

COMMENTARY

Empower Physicians to Fight Financial Toxicity With Biosimilars

Kathy Oubre, MS



OUBRE
Kathy Oubre, MS, is the chief operating officer of the Pontchartrain Cancer Center, with locations in Covington and Hammond, Louisiana.

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Biosimilars offer lower-cost alternatives to the biologic agents driving up the cost of prescription drugs. Biologics accounted for nearly 75% of the annual increase in net US spending on medicines in 2018.³ The availability of biosimilars introduces competition based on price, offering a lower-cost alternative in the short term and helping to restrict—or even reverse—longer-term price growth. As a growing number of biologics used in oncology treatment, such as trastuzumab, encounter biosimilar competition, providers have the opportunity to significantly reduce prescription drug costs for their patients. Where biosimilars, which are certified as clinically equivalent by the FDA, are the correct treatment option, failure to prescribe them is a failure to address financial toxicity. Ultimately, it's a failure to hold the oncology profession to the highest, most comprehensive standard of patient care.

Although provider education can play an important role in biosimilar uptake, in certain cases, patients' insurers prevent providers from prescribing these products. Anticompetitive rebating practices ("rebate walls") by originator manufacturers incentivize payers to adopt "fail-first" preferences for costlier originator drugs, eliminating a patient's option to choose a lower-cost biosimilar when available. Because biosimilars are clinically equivalent, a fail-first policy preferencing an originator is an effective ban on coverage of its biosimilars.

In a higher-profile case of rebate-induced limiting of patient and prescriber choice, UnitedHealthcare adopted a fail-first preference for Amgen originator biologic Neulasta over pegfilgrastim biosimilars Udenyca and Fulphila.⁴ This summer, the Federal Trade Commission initiated an investigation of Johnson & Johnson's contracting practices surrounding infliximab originator Remicade, examining potential exclusionary conduct against Pfizer biosimilar Inflectra.⁵

Ironically, in October, UnitedHealthcare granted Amgen's own oncology biosimilars, Mvasi and Kanjinti, preferred status on its commercial and community plan formularies. It seems payers do not have a formulary preference against all biosimilars, just those of manufacturers unable or unwilling to offer more attractive rebate contracts.⁶

Payers can argue that the savings from larger rebate packages accrue to the benefit of their entire insured population. However, any savings from contracts that exclude oncology biosimilars come at the direct expense of the patients who are forced to pay higher out-of-pocket costs for expensive originator biologics. It's a cruel trade-off and one that denies physicians the ability to alleviate the financial toxicity of oncology treatment and harms the quality

UnitedHealthcare Patients Will Switch to Biosimilar Epoetin Alfa in 2020

Coverage by Kelly Davio

UNITEDHEALTHCARE HAS REVISED its community and commercial plans' coverage of erythropoiesis-stimulating agents, according to a November 1, 2019, plan revision.¹ Effective January 1, 2020, patients who are receiving the reference epoetin alfa, Epogen or Procrit, will be required to switch to Pfizer's biosimilar, Retacrit.

Patients who wish to remain on the reference epoetin alfa will need to meet medical necessity criteria; Epogen or Procrit is considered medically necessary if a patient had minimal clinical response to Retacrit and a physician attests that a superior response would be expected from Epogen or Procrit, or if the patient has a history of intolerance to, contraindication to, or failure of Retacrit that a physician attests would not be expected with Epogen or Procrit.

Additionally, coverage for Retacrit will not require prior authorization for patients who meet diagnosis-specific criteria for indications including anemia due to chronic kidney disease, anemia due to chemotherapy, and anemia associated with myelodysplastic disease.

The new policy does not apply to community plans in Kansas or Louisiana.¹

This revision to UnitedHealthcare's coverage comes after the payer made a prior notable move to prefer biosimilars of anti-cancer drugs.² In August of this year, UnitedHealthcare indicated that starting in October, it would prefer Amgen's biosimilar bevacizumab (Mvasi) and biosimilar trastuzumab (Kanjinti), to the reference drugs, Avastin and Herceptin, respectively.

UnitedHealthcare has also made biosimilar filgrastim (Zarxio) a preferred product over follow-on filgrastim (Granix, or tbo-filgrastim), the reference filgrastim (Neupogen), and a competing biosimilar, filgrastim (Nivestym).

Finally, a representative from UnitedHealthcare previously told The Center for Biosimilars® in an email that the payer planned to add biosimilar infliximab (Inflectra) to a preferred position along with the brand-name infliximab (Remicade). ♦

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COMMENTARY

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of care delivered to patients. Moreover, these policies inhibit the multiproduct biosimilar competition that can generate greater savings over time.

In May, the FDA finalized guidance on how biosimilars can achieve interchangeability, which would give pharmacists the ability to substitute them for originator biologics without the express guidance of the prescribing physician, as they can for small molecule generics.⁷ Although this is a step in the right direction, it won't extend full biosimilar access for patients being treated today or for some time in the future.

Payers can argue that the savings from larger rebate packages accrue to the benefit of their entire insured population. However, any savings that from contracts that exclude oncology biosimilars come at the direct expense of the patients who are forced to pay higher out-of-pocket costs for expensive originator biologics.

Today, however, payers have the option to simply do the right thing, rejecting attempts to block biosimilar access and respecting physicians' ability to prescribe as they know best. If only they're allowed to compete on a level playing field, biosimilars may hold the key to savings for patients struggling with financial toxicity. The oncology provider community should demand better, making clear that antibiosimilar formulary policies infringe on providers' ability to offer care in a manner that promotes the best outcomes for our patients. ♦

AUTHOR INFORMATION

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First Rituximab Biosimilar, Truxima, Launches in United States

TEVA AND CELLTRION LAUNCHED their biosimilar rituximab, Truxima, in the United States, with the product reaching patients beginning November 11, 2019. Truxima is being offered at a 10% discount off the list price of reference product Rituxan.¹

Truxima will be available for \$845.55 for a 100-mg vial and \$4227.75 for a 500-mg vial, though these costs do not take into account additional rebates or discounts that may apply.

"We are pleased to announce the launch of the first rituximab biosimilar, Truxima, with our marketing partner Teva in the United States," Hyoun-Ki Kim, vice chairman of Celltrion Healthcare, said in a statement. "We believe that the introduction of Truxima into the United States market will contribute to addressing unmet needs of United States patients as well." Teva is also offering patient support services through its Comprehensive Oncology Reimbursement Expertise program.

Truxima was approved by the FDA in November 2018 to treat adults with CD20-positive, B-cell non-Hodgkin lymphoma either as monotherapy or in combination with chemotherapy.² Like its reference product, Truxima has a label that carries a boxed warning alerting providers and patients to the risk of fatal infusion reactions, skin and mouth reactions, hepatitis B reactivation, and a rare but serious brain infection. The drug is also approved to treat chronic lymphocytic leukemia.

Notably, although the reference rituximab also carries indications for inflammatory diseases including rheumatoid arthritis, Celltrion sought approval only for indications in oncology; when members of the FDA's Oncologic Drugs Advisory Committee asked about the reasoning behind seeking indications in cancer treatment only, a Celltrion representative stated, "We are only seeking approval in 3 [oncology] indications given the patent and exclusivity landscape at this time."

In light of a patent settlement with Genentech, however, Celltrion and Teva are now submitting an application to the FDA for the indications of rheumatoid arthritis, granulomatosis with polyangiitis, and microscopic polyangiitis.

News of the launch comes shortly after Pfizer, the license holder of the other FDA-approved rituximab biosimilar, Ruxience, announced its plans to launch its product in the United States in January 2020.³ ♦

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