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**PATHWAYS BY PAYERS.** Findings presented at the Academy of Managed Care Pharmacy 2021 meeting showed that despite the growth of oncology clinical pathways, there are still plenty of barriers to adoption, even when doctors want to use them, [SP124](#).

**WHAT FDA GIVETH ...**

In 3 days of hearings, FDA panelists recommended that a pair of accelerated approvals should be withdrawn, after subsequent trials did not confirm early findings that led to the indications, [SP126](#).

**IN SCLC, NOW WHAT?**

Practically speaking, what does it mean when 2 well-known PD-1 inhibitors are no longer indicated in small cell lung cancer (SCLC)? Fox Chase's Martin J. Edelman, MD, weighs in, [SP128](#).



EDELMAN

## CONFERENCE COVERAGE



In its second virtual annual meeting, the Community Oncology Alliance tackles pricing and payment reform, [SP130-SP134](#).

Recent advances and new methodologies in treating cholangiocarcinoma, [SP134](#).



Overcoming hurdles to biosimilar uptake in oncology, [SP136](#).

## PRACTICE TRANSFORMATION

**A Social Worker Leads ACCC, and Her Timing Is Perfect***Mary Caffrey*

**IMPROVING HEALTH EQUITY.** Developing practice-based solutions for reducing barriers and improving outcomes. Making the case for supportive care. Building a culture that supports professional well-being. Championing resiliency.

This would be an important agenda for any president of the Association of Community Cancer Centers (ACCC), but given the year that health care workers have just experienced, the ACCC has the right message at the right time. And that's because the group has selected a timely messenger: For only the third time in its history, the ACCC president is a social worker.

Krista Nelson, MSW, LCSW, OSW-C, took the reins of ACCC on March 5, 2021, during the group's 47th Annual Meeting and Cancer Center Business Summit, held virtually.<sup>1</sup> Nelson's theme for her presidency "Real-World Lessons from COVID-19: Driving Oncology Care Forward," incorporates a mission of promoting psychosocial and supportive care, not just externally but also among internal stakeholders. This fits with her call to support the needs of the multidisciplinary cancer care team. From Nelson's vantage point, the emerging care model is one where the case manager is far from an afterthought, and may, in fact, be the patient's first stop.

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Krista Nelson, MSW, LCSW, OSW-C, has made resiliency and well-being of the cancer care team a core tenet of her term as president of the Association of Community Cancer Centers.

## POLICY

**Observations Regarding the Average Sales Price Reimbursement Methodology***Susan Weidner; Michael Diaz, MD; Cass Schaedig; and Lucio N. Gordan, MD***Introduction**

**IN THE UNITED STATES,** CMS is the single largest payer for health care. In 2019, Medicare enrolled more than 60 million beneficiaries, and enrollment is expected to exceed 80 million by 2030.<sup>1,2</sup> Medicare Part B provides coverage for beneficiaries for drugs and biologics that are administered in physician offices or hospital-based clinics by infusion or injection. It also covers certain other drugs, including some oral anti-cancer therapies, oral antiemetics, immunosuppressive drugs, and home infusions.<sup>3</sup> In 2017, 7 of the top 10 drugs reimbursed by Medicare Part B were mainly, or exclusively, for oncology or related supportive care indications and accounted for over \$8.7 billion in spending.<sup>4</sup> This amount is expected to increase as the majority of new cancers in the United States are diagnosed in the Medicare-aged population, which is expanding as baby boomers age.<sup>5</sup>

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## PAYMENT MODELS

**Biosimilars Drive Savings in Medicare's Oncology Care Model***Keely Macmillan, MSPH*

**MEDICARE VALUE-BASED** care programs are under great scrutiny to ensure that they can drive demonstrable savings and quality improvement. Adoption of higher-value biosimilar drugs by participants in Medicare's Oncology Care Model (OCM) could drive the pilot program closer to its goal of generating net savings to Medicare.<sup>1</sup>

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# Biosimilars Drive Savings in Medicare's Oncology Care Model

KEELY MACMILLAN, MSPH

## CONTINUED FROM COVER

Oncology practices participating in the OCM are responsible for the quality and total cost of care—including drug spending and inpatient admissions—for their patients receiving chemotherapy.<sup>1</sup> Drug spending constitutes approximately two-thirds of the program's total spending.<sup>2</sup> Part B drug spending alone accounts for about 45% of OCM spending.<sup>2</sup> The most recent program evaluation, published in January 2021, included data from 6-month episodes triggered through January 1, 2019 (performance periods [PPs] 1-5), and found that the program successfully achieved reductions in per-episode spending. However, these reductions were insufficient to cover new funds from the Center for Medicare and Medicaid Innovation (CMMI): (1) Monthly Enhanced Oncology Service (MEOS) payments made to participating practices to support care redesign and enhanced oncology services, and (2) additional performance-based payments (PBPs) that practices receive if they meet financial and quality goals.<sup>3</sup>

Notably, because of the relative novelty of biosimilar drugs on the market and the significant lag in claims-based analyses, the most recent program evaluation largely predates the uptake of these lower-cost alternatives. The March 2021 release of initial PP7 OCM reconciliation data, reflecting 6-month episodes triggered between July 2, 2019, and January 1, 2020, offered the first opportunity to observe most biosimilar cost comparisons, and this signals more favorable program evaluations once these data are incorporated into findings.

## Biosimilars Support Value-Based Care

Because there are no clinically meaningful differences between biosimilars and their reference products and they are generally available at lower costs, biosimilars present an opportunity to reduce Medicare spending without impacting the quality of care provided to patients.<sup>4</sup> Administered by infusion or injection in a physician's office or hospital outpatient department setting, all cancer biosimilar drugs are reimbursed under Medicare Part B, which sets drug prices using the Average Sales Price (ASP) methodology.<sup>5</sup> CMS calculates the ASP quarterly by using the weighted average sales price data submitted by drug manufacturers; these data include discounts such as rebates and volume, prompt payment, and cash payment discounts.<sup>6</sup> There is a 6-month lag between the payment allowance limits set by Medicare—generally 106% of ASP—and the ASP data submitted by drug manufacturers.

As an example of the price differential between biosimilars and their originator products, the current Medicare Part B payment allowance limits<sup>7</sup> for trastuzumab (Herceptin) biosimilars range from 12.5% to 35.3% lower than that of the originator product, as shown in **Table 1**. In another example, the current Part B payment allowance limits for bevacizumab (Avastin) biosimilars range from 20.9% to 27.1% lower than that of the originator product, as shown in **Table 2**.

## Availability of Biosimilar Drugs<sup>7</sup>

As shown in the **Figure**, conversion to biosimilar products as a cost savings lever largely materialized after the program went live. The only 2 biosimilar products approved by the FDA prior to the start of the OCM on July 1, 2016, were filgrastim-sndz (Zarxio), the reference product of which is filgrastim (Neupogen), and infliximab-dyyb (Inflectra), the reference product of which is infliximab

(Remicade). Filgrastim is a supportive care medication used to treat low white blood cell count, which can occur in patients undergoing chemotherapy, and infliximab is an immunosuppressive drug that treats rheumatoid arthritis, among other conditions. The FDA did not approve the first biosimilar for cancer treatment, bevacizumab-awwb (Mvasi), the reference product of which is bevacizumab (Avastin), until the model's third performance period. Of the 5 biosimilars for trastuzumab, a drug used to treat certain breast and stomach cancers, 3 were approved by the FDA during the OCM's PP6 (episodes starting between January 2, 2019, and July 1, 2019). The length of time between a drug's approval and its entrance to the market can vary. There is also a lag between the a drug's approval date and its addition to the ASP drug pricing files. For example, rituximab-abbs (Truxima), the first biosimilar for rituximab (Rituxan), which treats conditions including non-Hodgkin lymphoma and chronic lymphocytic leukemia, was approved in November 2018 and added to the Medicare ASP Pricing File in January 2020. This lag in information could delay the uptake of cost-effective drugs. Once a practice adopts a »



Keely Macmillan, MSPH, is senior vice president, Policy Solutions and Management, Archway Health

**TABLE 1.** Medicare Part B Payment Allowance Limits for Trastuzumab (Herceptin) Biosimilars (effective April 1, 2021-June 30, 2021)

Short description	HCPCS code dosage	Payment limit	Variance in payment limit from originator product
Inj trastuzumab excluding biosimilar	10 mg	93.68	N/A
Inj trastuzumab-dttb (Ontruzant)	10 mg	80.16	-14.4%
Inj trastuzumab-pkrb (Herzuma) 10 mg	10 mg	81.99	-12.5%
Inj trastuzumab-dkst (Ogivri)	10 mg	60.66	-35.3%
Inj trastuzumab-qyyp (Trazimera)	10 mg	68.11	-27.3%
Inj trastuzumab-anns (Kanjinti)	10 mg	66.29	-29.2%

All doses are 10 mg and given by injection.

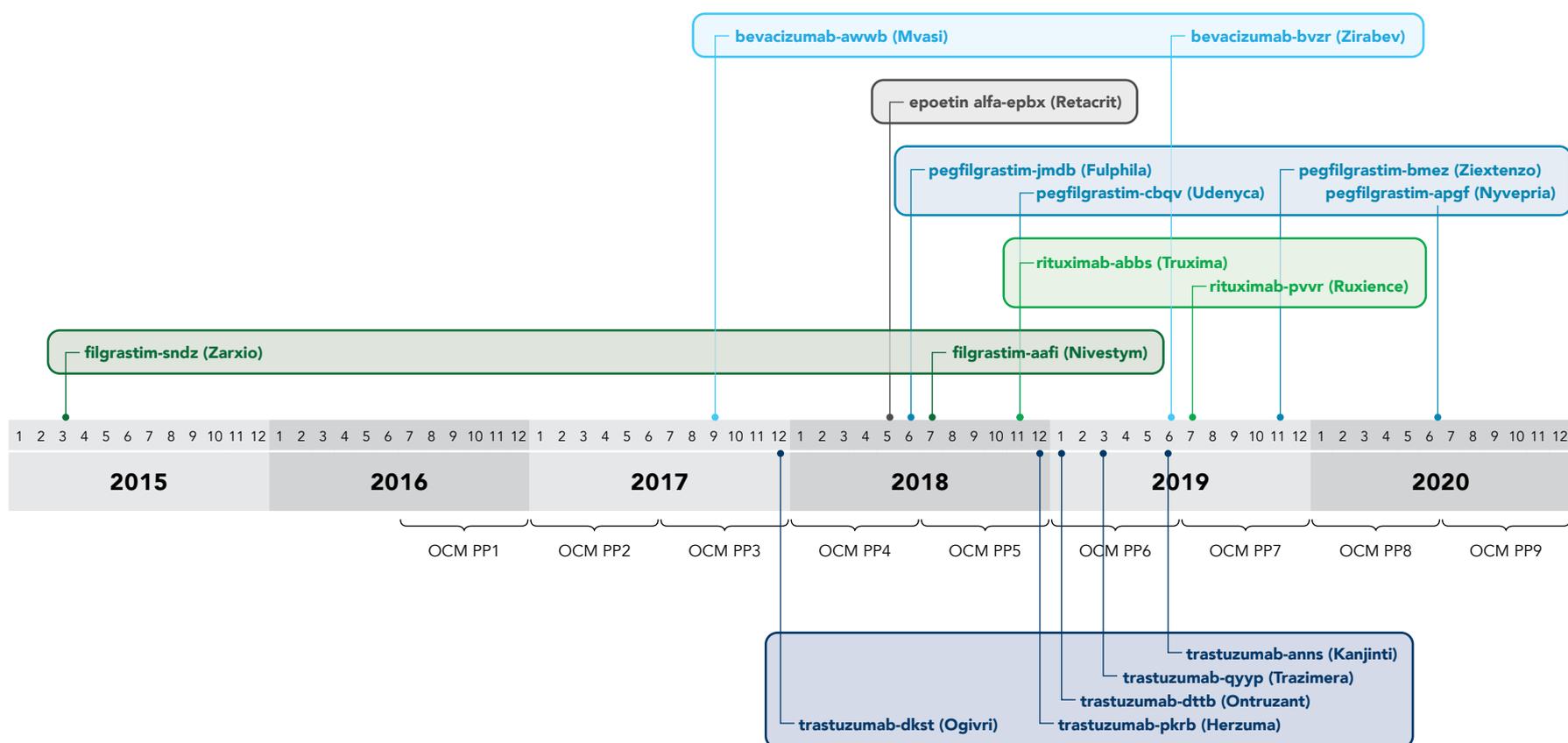
HCPCS, Healthcare Common Procedure Coding system; inj, injection; N/A, not applicable.

**TABLE 2.** Medicare Part B Payment Allowance Limits for Avastin (Bevacizumab) Biosimilars (effective April 1, 2021-June 30, 2021)

HCPCS code	Short description	HCPCS code dosage	Payment limit	Variance in payment limit from originator product
J9035	Inj bevacizumab	10 mg	72.51	N/A
Q5107	Inj bevacizumab-awwb (Mvasi)	10 mg	52.89	-27.1%
Q5118	Inj bevacizumab-bvzr (Zirabev)	10 mg	57.34	-20.9%

HCPCS, Healthcare Common Procedure Coding system; inj, injection; N/A, not applicable

FIGURE. Timeline of FDA Approval for Biosimilar Drugs<sup>8</sup>



Source: FDA; data compiled by Archway Health.  
OCM indicates Oncology Care Model; PP, Performance Period.

biosimilar, it is not uncommon for the conversion to take a year or more.

### Previewing the Full-Scale Potential of Biosimilar Conversion

The first biosimilar for filgrastim was approved in March 2015, so trends in its adoption can be observed from the start of the OCM. One of the key findings of the January 2021 OCM program evaluation was the “pronounced shift toward use of biosimilar filgrastim (vs more-costly originator filgrastim)”<sup>3</sup> among OCM participants. The OCM evaluation described that, among episodes in which filgrastim, a granulocyte colony-stimulating factor, was used, participation in the model was associated with “faster adoption and greater use of less-costly biosimilar filgrastim.”<sup>3</sup> This finding suggests that there may be broader adoption of biosimilars by OCM practices as more of these products become available on the market, a trend Archway Health has identified in the analysis of more recent claims data.

### Emerging Results Show Savings From Biosimilars

In March, CMMI released initial PP7 reconciliation data to OCM participants. Archway analyzed these data to evaluate the cost savings impact when practices switch to certain biosimilar drugs. Three examples of the impact of biosimilar adoption on Medicare spending are as follows:

**BREAST CANCER AND TRASTUZUMAB.** Among breast cancer episodes in which the patient was treated

with trastuzumab, the average amount Medicare spent on the drug for a 6-month episode of care was approximately \$25,000 to \$30,000, varying by practice. Trastuzumab is generally used in fewer than 8% of breast cancer episodes in the OCM, but the cost of the drug constitutes more than half of total episodic spending for breast cancer episodes in which the drug was used and nearly 7% to 10% of total cost of care across all breast cancer episodes. Among practices that switched to biosimilar trastuzumab-anns (Kanjinti), spending for the drug was reduced by more than 14% (\$3500-\$4200) per breast cancer episode in which the drug was used. For 1 medium-sized practice with a volume of 1000 breast cancer episodes per year that are covered under traditional Medicare, the conversion to trastuzumab-anns can generate \$250,000 to \$500,000 in savings to Medicare annually, some of which the practice can earn back in PBPs. Savings opportunities will fluctuate quarterly as ASP data are updated.

**LYMPHOMA AND RITUXIMAB.** Among lymphoma episodes in which a patient was treated with rituximab, Archway found that the average 6-month episodic drug cost for rituximab ranged between \$18,000 and \$22,000, varying by practice. Rituximab is used in approximately 70% of lymphoma episodes in the OCM; on average, the cost of the drug constituted more than one-third of total episode spending for lymphoma episodes in which the drug was used. Practices that switched to rituximab-abbs (Truxima) saved nearly 8% of the cost of rituximab (\$1400-\$1700) per episode on average. **Table 3** shows

the cost differential for a 6-week course of treatment in which the patient is administered 80 units of either rituximab or rituximab-abbs per treatment. For reference, **Table 3** shows the Part B payment allowance limits for rituximab and rituximab-abbs between January 1, 2020, and March 31, 2020, a time period contained within the 6-month runout period of PP7. For 1 medium-sized practice with 150 lymphoma episodes a year covered under traditional Medicare, the conversion to rituximab-abbs could generate between \$150,000 and \$200,000 savings to Medicare annually, some of which the practice can earn back as a bonus payment if quality goals are met.

**SMALL INTESTINE/COLON CANCER AND BEVACIZUMAB.** Among small intestine/colon cancer episodes in which the patient was treated with bevacizumab, Archway found that the average 6-month episodic drug spend ranged between \$18,000 and \$23,000. On average, the cost of the drug constituted more than 40% total spending for small intestine/colon cancer episodes in which the drug was used, and the drug is used in more than one-third of these episodes in the OCM. Practices that switched to bevacizumab-awwb (Mvasi) saved nearly 14% of the cost of bevacizumab (\$2500-\$3100) per episode on average. Bevacizumab is used to treat a relatively large number of OCM cancer types beyond small intestine/colorectal, including central nervous system tumor, female genitourinary cancer (ovary and other than ovary), head and neck, kidney, and lung. Cost savings to Medicare that result from

the conversion to a bevacizumab biosimilar are substantial, but they vary based on the mix of cancer types treated at a given practice.

Once these data are folded into programmatic evaluations, the OCM will potentially be credited with greater savings than early reports have indicated. PP8 marked the turning point in which practices that had yet to earn PBP had to enter the 2-sided risk track or exit the program. As a result, the program shed nearly 30% of its participants, shrinking from 176 practices to 127.<sup>1</sup> The combination of savings from biosimilar adoption along with CMMI no longer paying out MEOS to 30% of the original practice participants could put the program on a path to achieve net savings to Medicare. With the OCM sunsetting at the end of this year, it is critical for CMMI to launch the program's successor, so momentum in the shift toward value-based cancer care is not lost.

### Alignment with Aggregate Stop Loss Insurance

Because the adoption of biosimilars serves to control costs at a population level, it aligns well with a population-level approach to downside risk protection. Practices that have adopted biosimilars and are participating in or considering the 2-sided risk track in the OCM should evaluate aggregate stop loss protection, designed to limit overall losses, because aggregate policies generally have lower premiums than do specific policies, and aggregate policies can account for practice-level cost reduction efforts.

### Benefits of Biosimilar Conversion in Other Value-Based Models of Care

Oncology practices that have adopted biosimilars have a strategic advantage over their competitors in other value-based models of care. In Medicare's new Direct Contracting program, which went live on April 1, 2021, Direct Contracting Entities (DCEs) are at full risk for total cost of care for all Part A and Part B spending, including Part B drugs, and they are highly incentivized to partner with high-value specialists. There are 53 active Global and Professional DCEs, and in many cases, a single DCE has multiple geographic locations; the state of Florida has 15 active DCEs alone. Another cohort of DCEs will go live on January 1, 2022, and oncology practices should be prepared for the growing presence of DCEs in their local markets.

**TABLE 3.** Medicare Part B Payment Allowance Limits (effective January 1, 2020-March 31, 2020)

HCPCS code	Short description	HCPCS code dosage	Payment limit
J9312	Inj rituximab	10 mg	94.411
Q5115	Inj rituximab-abbs (Truxima)	10 mg	87.092

Week	Date of administration	Units administered	Rituximab cost	Rituximab-abbs (Truxima; biosimilar) Cost	Savings from biosimilar
1	Jan 1, 2020	80	\$5921	\$5462	(\$459)
2	Jan 7, 2020	80	\$5921	\$5462	(\$459)
3	Jan 14, 2020	80	\$5921	\$5462	(\$459)
4	Jan 21, 2020	80	\$5921	\$5462	(\$459)
5	Jan 28, 2020	80	\$5921	\$5462	(\$459)
6	Feb 4, 2020	80	\$5921	\$5462	(\$459)
Total for		480	\$35,529	\$32,775	(\$2754)

HCPCS, Healthcare Common Procedure Coding system; inj, injection.

The adoption of biosimilars can also support value-based risk contracts with self-insured employers and commercial payers. However, one challenge that oncology practices face in the adoption of biosimilars is misalignment with commercial payers that may list different biosimilars on their formularies. On April 20, 2021, CMMI director Liz Fowler, PhD, JD, spoke<sup>9</sup> during the spring conference of the National Association of Accountable Care Organizations about CMMI's effort to determine how its value-based care models can transform health care delivery in the long term. In discussing CMMI's priorities, Fowler declared that "we need to do a better job with multipayer alignment." Ideally the successor program to OCM, expected to be announced later in 2021, will continue to incorporate a cross-payer approach to further drive value-based cancer care. ♦

#### REFERENCES

1. Oncology Care Model. CMS. Updated May 4, 2021. Accessed May 7, 2021. <https://innovation.cms.gov/innovation-models/oncology-care>
2. Archway Health analysis of Medicare Part A, B and D claims data.
3. Hassol A, West N, Newes-Adeyi G, et al; Abt Associates; The Lewin Group; Harvard Medical School; Geisel School of Medicine at Dartmouth; General Dynamics Information Technology. Evaluation of the Oncology Care Model: performance periods 1-5. CMS Innovation Center. January 2021. Accessed May 8, 2021. <https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5>
4. Dangi-Garimelli S. Saving costs while maintaining quality of care—the value of biosimilars in oncology. *The American Journal of Managed*

*Care*. November 8, 2018. Accessed May 8, 2021. <https://www.ajmc.com/view/saving-costs-while-maintaining-quality-of-care-dash-the-value-of-biosimilars-in-oncology>

5. Competitive Acquisition Program. HHS § 414.904 (2010). Average sales price as the basis for payment. Accessed May 8, 2021. <https://www.govinfo.gov/content/pkg/CFR-2010-title42-vol3/pdf/CFR-2010-title42-vol3-sec414-904.pdf>
6. Part B drugs payment systems. MedPAC. Updated October 2017. Accessed May 8, 2021. [http://www.medpac.gov/docs/default-source/payment-basics/medpac\\_payment\\_basics\\_17\\_partb\\_final.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0)
7. Medicare Part B Average Sales Price: 2021 ASP drug pricing files. CMS. March 4, 2021. Accessed May 8, 2021. <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files>
8. Biosimilar product information. FDA. December 17, 2020. Accessed May 8, 2021. <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>
9. Raths D. With CMMI at "crossroads," director Liz Fowler re-evaluating payment models. Healthcare Innovation. April 20, 2021. Accessed May 8, 2021. <https://www.hcinnovationgroup.com/policy-value-based-care/alternative-payment-models/article/21219367/with-cmmi-at-crossroads-director-liz-fowler-reevaluating-payment-models>

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