Cancer Drugs are Expensive:

Recent policy approaches and pitfalls

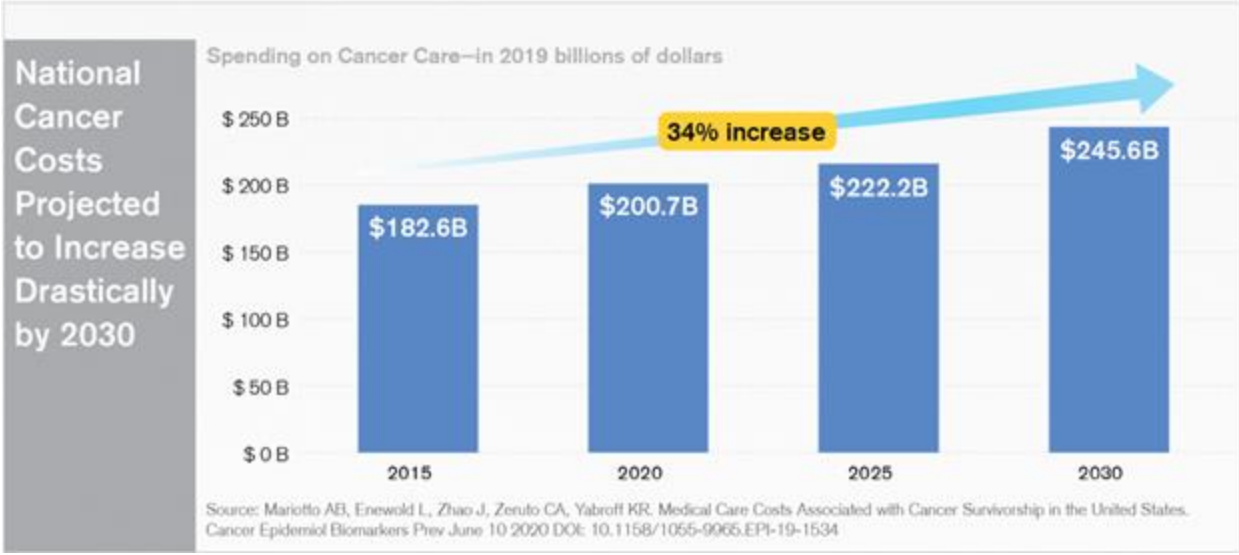
Samyukta Mullangi, MD MBA

Medical Director of Oncology at **Thyme Care**

Medical Oncologist at **Tennessee Oncology**

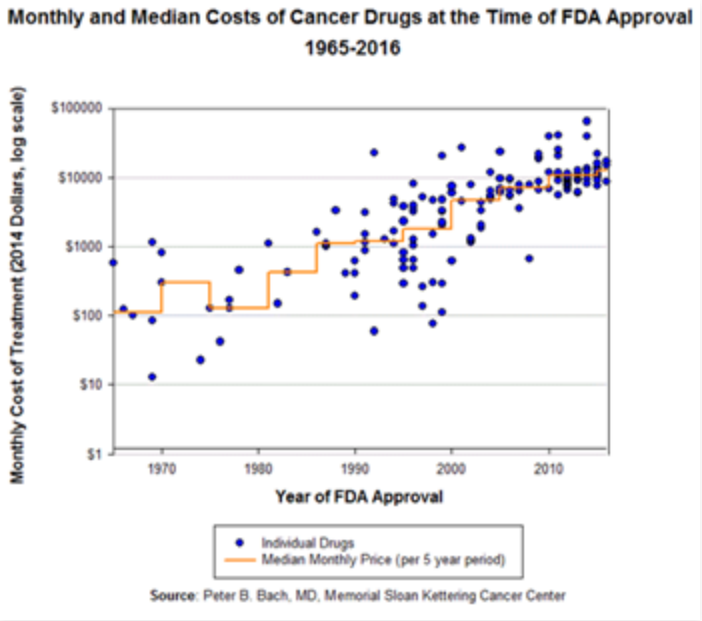
NORTH CAROLINA Oncology Association

The annual cost of cancer care is expected to approach $246B by 2030.

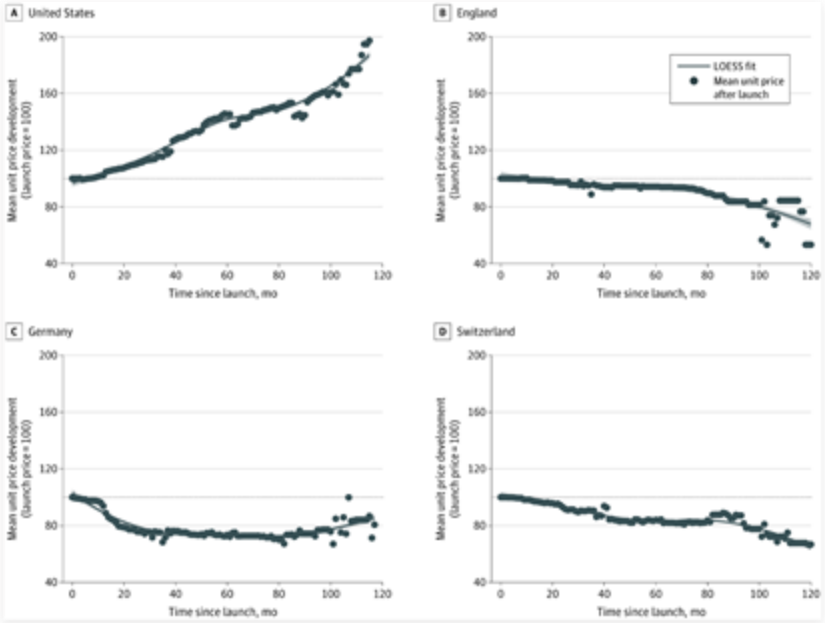


Source: https://www.fightcancer.org/sites/default/files/National%20Documents/Costs-of-Cancer-2020-10222020.pdf

Launch prices are high, but post-approval prices in cancers continue to rise, unique to the US.



Source: https://www.mskcc.org/research-programs/health-policy-outcomes/cost-drugs



Source: https://jamanetwork.com/journals/jamaoncology/fullarticle/2781390

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The Challenge

Cancer is prevalent, these issues continue to compound over time.

- Cancer is the second leading cause of death in the USA
- 15 million people live with cancer
- 1.7 million new cases every year

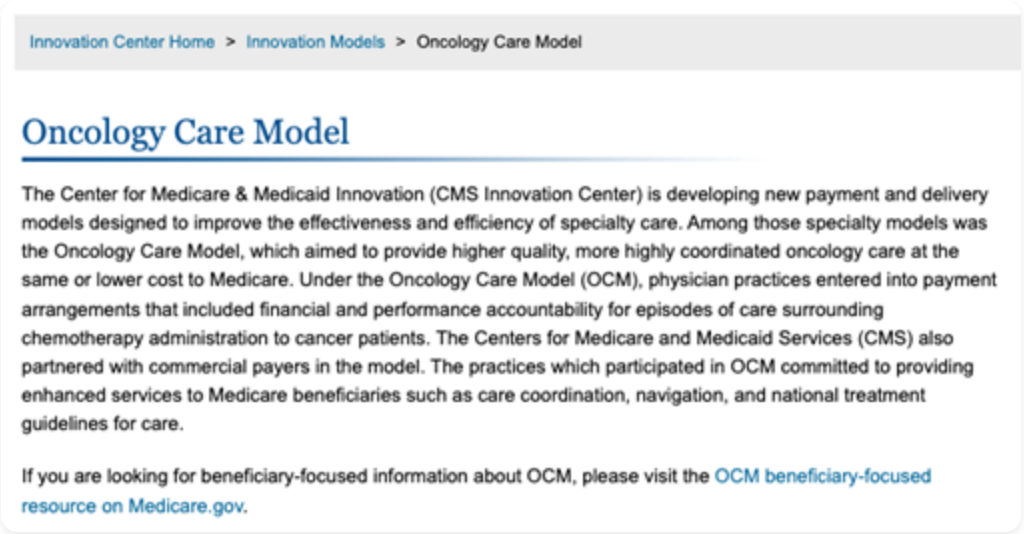
- Overall spend on cancer grew by 20% for commercially-insured pts, and 40% for Medicare pts in last decade
- Expected to grow with aging population, and treatment innovations

- Patients experience high **financial toxicity**, particularly in first 2 years after the initial cancer diagnosis
- Significant disparities by SES, race/ethnicity, zip code

Agenda

1. OCM → EOM
2. Inflation Reduction Act
3. Implications for community oncology

The Oncology Care Model was our largest value-based payment model experiment to date.



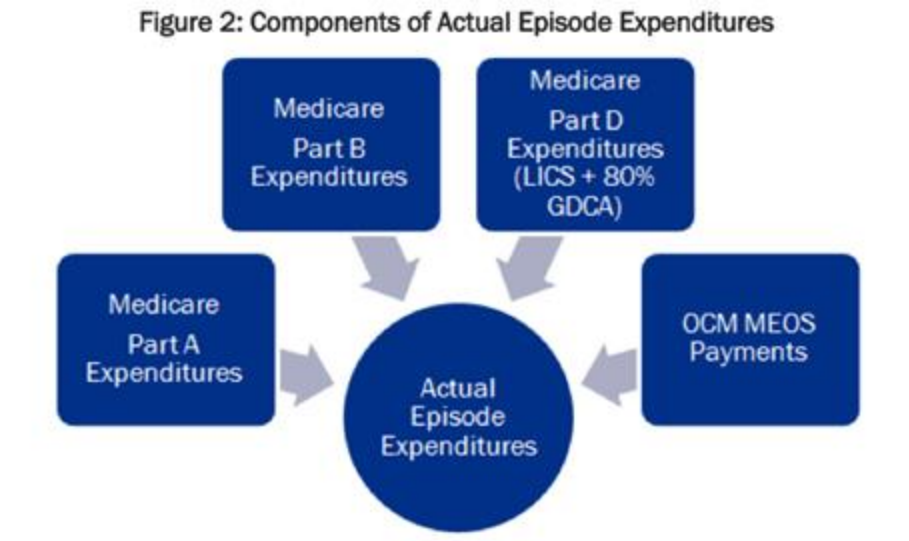
Innovation Center Home > Innovation Models > Oncology Care Model

Oncology Care Model

The Center for Medicare & Medicaid Innovation (CMS Innovation Center) is developing new payment and delivery models designed to improve the effectiveness and efficiency of specialty care. Among those specialty models was the Oncology Care Model, which aimed to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. Under the Oncology Care Model (OCM), physician practices entered into payment arrangements that included financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The Centers for Medicare and Medicaid Services (CMS) also partnered with commercial payers in the model. The practices which participated in OCM committed to providing enhanced services to Medicare beneficiaries such as care coordination, navigation, and national treatment guidelines for care.

If you are looking for beneficiary-focused information about OCM, please visit the OCM beneficiary-focused resource on Medicare.gov.

The OCM was a total cost of care model, and included drug prices.



Source: https://innovation.cms.gov/files/x/ocm-cancercodelists.pdf

The Challenge

Cancer is not monolithic, which can make novel payment models challenging.

The heterogeneity of cancer

As many cancers as there are types of tissue in the body – each different in terms of prognosis and treatment.

The diversity of treatments

Our 4 most expensive cancers – breast, prostate, lung, and liver – all show different cost phenotypes in drug, radiation, inpatient utilization, and end-of-life care intensity

Lack of consensus on opportunities for cost reduction

There are not many clear-cut opportunities for cheaper therapeutic substitution

Reliance on case mix

How to optimize for scale AND specificity

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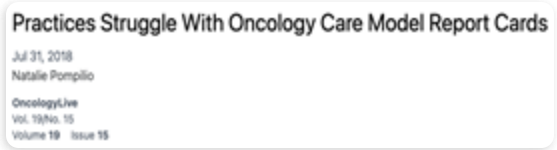
The OCM had mixed reviews



The Oncology Care Model

Editorial

November 9, 2021

Medicare Spending, Utilization, and Quality in the Oncology Care Model

Raymond U. Osarogiagbon, MBBS[1]; Samyukta Mullangi, MD[2]; Deborah Schrag, MD, MPH[2,3]

Author Affiliations

JAMA. 2021;326(18):1805-1806. doi:10.1001/jama.2021.18765

Viewpoint

December 20, 2018

The Oncology Care Model and Other Value-Based Payment Models in Cancer Care

Emeline M. Avila, MD, MBA[1]; Stephen M. Schleicher, MD, MBA[2]; Samyukta Mullangi, MD, MBA[3]

Author Affiliations

JAMA Oncol. 2019;5(3):298-299. doi:10.1001/jamaoncol.2018.5735

Viewpoint

July 1, 2021

The Oncology Care Model at 5 Years—Value-Based Payment in the Precision Medicine Era

Samyukta Mullangi, MD, MBA[1]; Stephen M. Schleicher, MD, MBA[2]; Ravi B. Parikh, MD, MPP[3,4]

Author Affiliations

JAMA Oncol. 2021;7(9):1283-1284. doi:10.1001/jamaoncol.2021.1512

Viewpoint

March 15, 2016

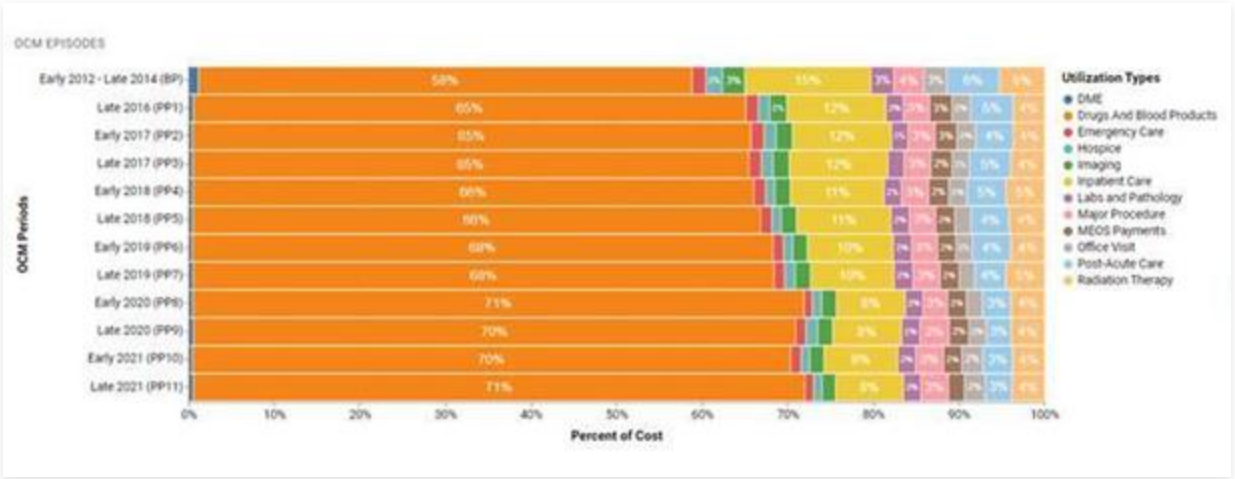
Health Care Delivery Innovations That Integrate Care? Yes!
But Integrating What?

Regina E. Herzlinger, DBA[1]; Stephen M. Schleicher, MD, MBA[2]; Samyukta Mullangi, MD, MBA[3]

Author Affiliations

JAMA. 2016;315(11):1109-1110. doi:10.1001/jama.2016.0505

Takeaway 1: Cost patterns in cancer have shifted over time



2012-2021, share of cost of a treatment episode attributed to cancer therapeutics climbs from 58% -> 71%

Source: Dr Basit Chaudhry, Tuple Health

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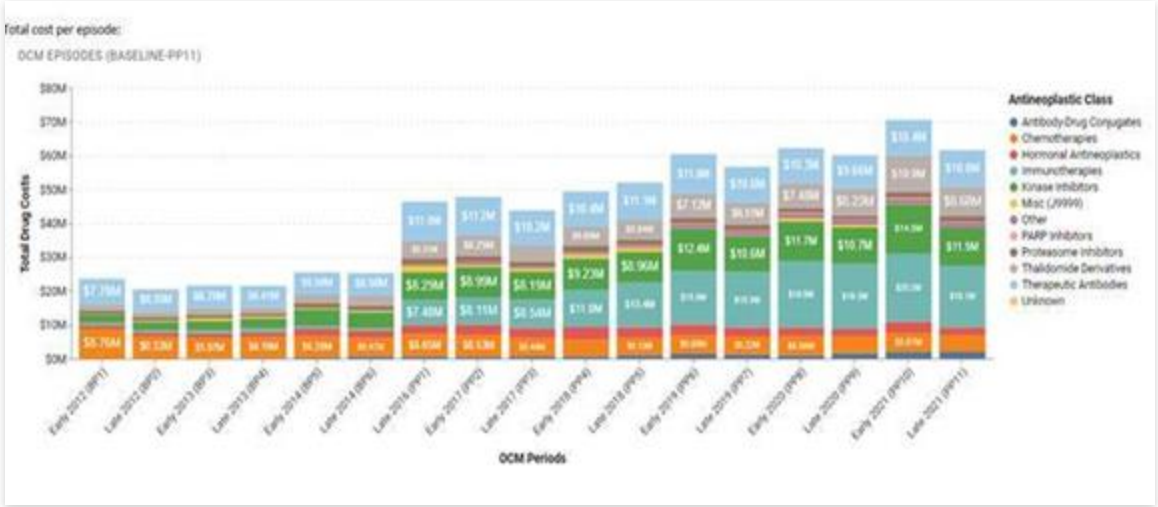
Takeaway 1: Cost patterns in cancer have shifted over time



In the last 7 years, there is exponentially increasing use of immunotherapies and targeted therapies in cancer

Source: Dr Basit Chaudhry, Tuple Health

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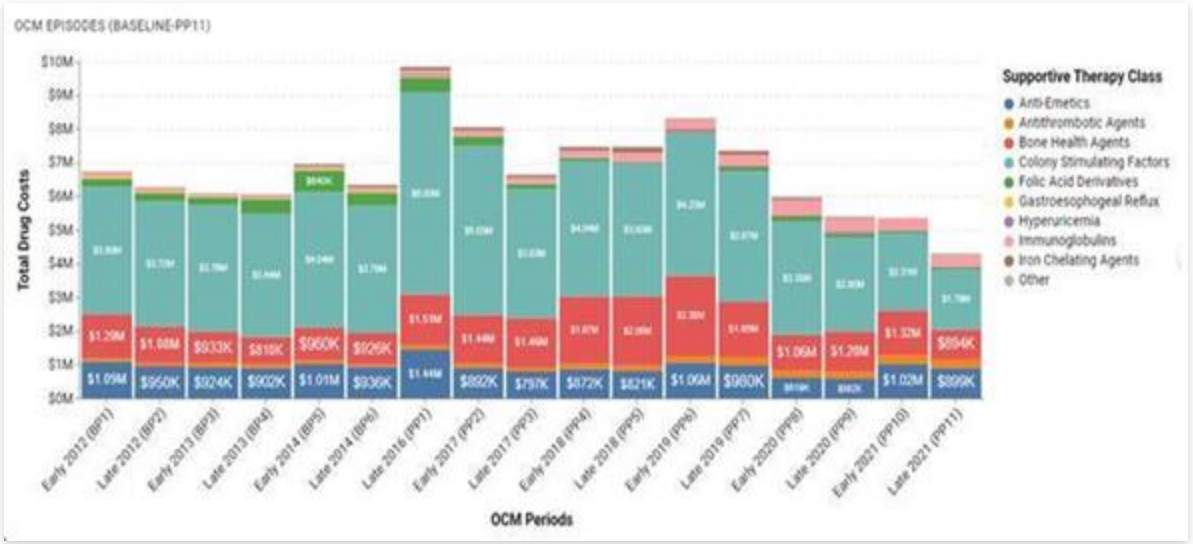
Takeaway 1: Cost patterns in cancer have shifted over time

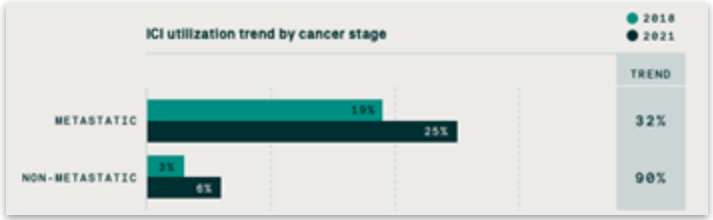


2012-2021,the cost ratio of supportive drugs to therapeutic drugs goes from 29.5% to 7.5%

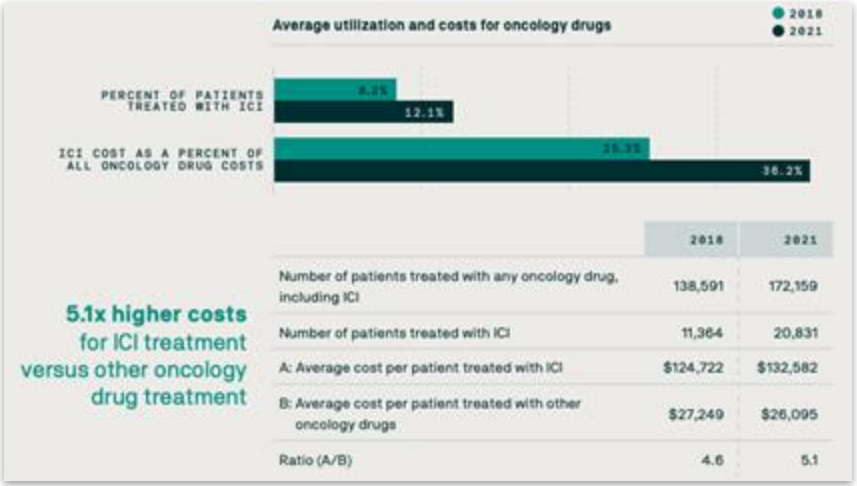
Source: Dr Basit Chaudhry, Tuple Health

NORTH CAROLINA Oncology Association

Implications of increasing use of ‘novel’ therapies



Immunotherapies increasingly indicated for earlier stage cancers



	2018	2021
Number of patients treated with any oncology drug, including ICI	138,591	172,159
Number of patients treated with ICI	11,364	20,831
A: Average cost per patient treated with ICI	$124,722	$132,582
B: Average cost per patient treated with other oncology drugs	$27,249	$26,095
Ratio (A/B)	4.6	5.1

As immunotherapy use has increased, IO-associated drug spend now accounts for over a third of total spend on oncology medical treatments.

In 2021, average drug cost when IO included - $132,582
Average drug cost without IO - $26,095

Source: Evernorth, https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2023-07/Real-World_Data_In_Cancer_Care.pdf

OCM's methodologies to account for novel drugs' impact on TCOC felt inadequate.

Viewpoint

October 31, 2019

The Oncology Care Model—Why It Works and Why It Could Work Better

Accounting for Novel Therapies in Value-Based Payment

Aaron J. Lyss, MBA[1,2]; Susanna N. Supalla, PhD[3]; Stephen M. Schleicher, MD, MBA[1,2]

> Author Affiliations

JAMA Oncol. 2020;6(8):1161-1162. doi:10.1001/jamaoncol.2019.4385

Analysis of 118 lung cancer episodes with expenditures above target costs revealed that

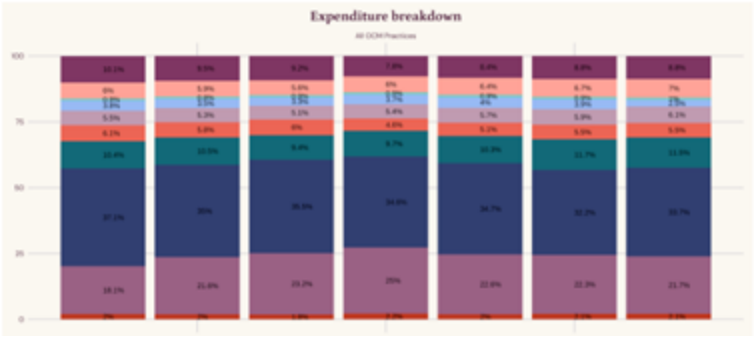
- in over half of episodes, there were no ED visits, hospitalizations, or post-acute care care

- in two-thirds, the costs of care were higher than target due to the use of IO in second-line treatments - which became standard of care during the OCM model period

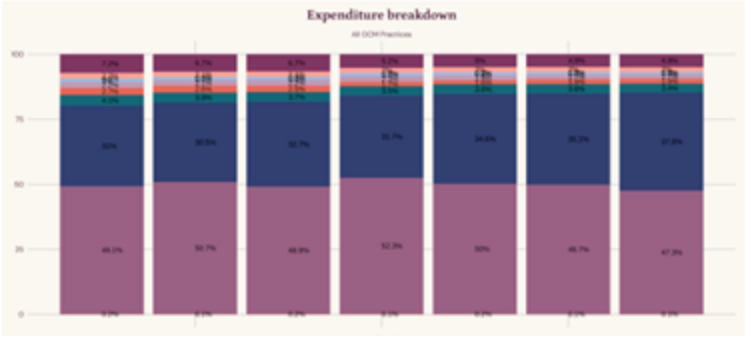
Source: https://jamanetwork.com/journals/jamaoncology/article-abstract/2753561

NORTH CAROLINA Oncology Association

Takeaway 2: Key contributors and ‘impactable spend’ varies by cancer type



Breast cancer, all OCM practices



Multiple myeloma, all OCM practices

Source: Thyme care analysis of aggregated OCM data

CMS's new iteration of value-based care: the Enhancing Oncology Model

Newsroom Press Kit Data Contact Blog Podcast

Fact sheet

Enhancing Oncology Model

Jun 27, 2022 | Innovation models

Share

Overview

The Centers for Medicare & Medicaid Service's (CMS) Innovation Center's new, voluntary Enhancing Oncology Model (EOM) is intended to transform care for cancer patients, reduce spending, and improve quality of care. It is designed to test how best to place cancer patients at the center of the care team that provides high-value, equitable, evidence-based care. EOM aims to improve care coordination, quality, and health outcomes for patients while also holding oncology practices accountable for total costs of care to make cancer care more affordable and accessible for beneficiaries and Medicare, which are key priorities described in the CMS Innovation Center's strategy refresh.

EOM aligns with President Biden's Cancer Moonshot pillars and priorities of supporting patients, caregivers, and survivors, and addressing inequities. On February 2, 2022, the Biden-Harris Administration reignited the Cancer Moonshot effort by setting a goal of reducing the cancer death rate by at least 50% over the next 25 years and improving the experience of people and their families living with and surviving cancer.

Key differences between OCM and EOM

- Only 7 cancer types (from 21), and no low-risk prostate, breast or bladder cancers
- $70 MEOS (monthly) payments (from $140)
- Narrower and less favorable “safe zone” to access shared savings
- Mandatory downside risk
- More granular adjustments to account for case mix problem: novel therapy trend factor applied at disease level, not practice level; HER2 and metastatic status to influence cancer episode cost
- Increased practice reporting: clinical characteristics, ePROs, social determinants of health

Several EOM programmatic design choices were inevitable - exclusion of low-risk cancers

IS OCM GENERATING NET SAVINGS FOR MEDICARE?

Medicare (0.3 percent of TEP, or $131 per episode). The opposite was true in lower-risk episodes, where the relative increase in gross payments, combined with MEOS payments, generated substantial losses for Medicare (11.6 percent of TEP, or $838 per episode). The patterns were similar in PP4, with Medicare losses being much greater for lower-risk episodes.

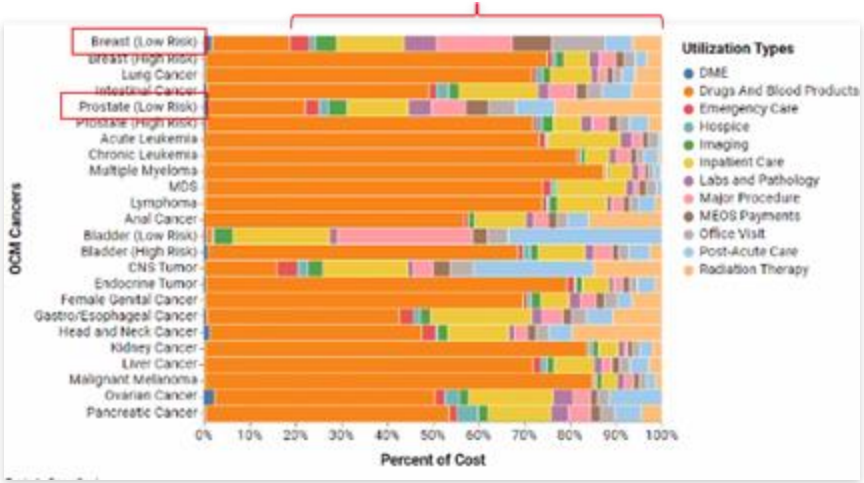
Exhibit 17: Including Gross Payment Reductions and MEOS (But Not PBP), OCM Resulted in Greater Medicare Net Losses for Lower-Risk Episodes than for Higher-Risk Episodes

Cancer Episode Risk Group	Number of Episodes	Gross Impact on TEP	MEOS Payments	Impact on TEP + MEOS (Losses)	Losses as Percentage of TEP	Losses per Episode
PP3						
Lower-risk episodes	41,344	$8,986,210	$25,644,224	$34,630,434	11.6%	$838
Higher-risk episodes	87,380	-$52,347,692	$63,820,574	$11,472,882	0.3%	$131
PP4						
Lower-risk episodes	43,454	$7,230,649	$27,658,538	$34,889,187	10.7%	$803
Higher-risk episodes	89,748	-$58,134,601	$66,475,986	$8,341,385	0.2%	$93

Source: Medicare claims 2014–2018, OCM first true-up reconciliation data. MEOS: Monthly Enhanced Oncology Services payment. PP: Performance Period. TEP: total episode payments.

Low-risk breast/prostate/bladder episodes led to significant losses to CMS even before MEOS

For low-risk cancers, ~80% of cost of care was due to acute care utilization and radiation therapy



Source: https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5

Basit Chaudhry, Tuple

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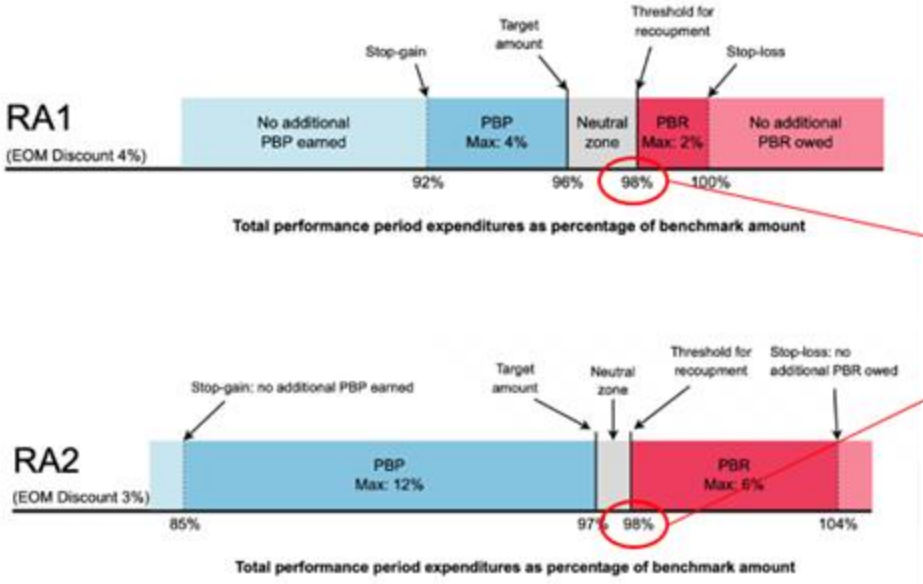
Several EOM programmatic design choices were inevitable - narrower safe zone/ mandatory risk



Both risk arrangement options require a minimum of a 2% savings before practices can access performance based payments

Source: CMS EOM Payment methodology technical files, https://innovation.cms.gov/media/document/eom-payment-methodology, page 33

EOM widely viewed as a more challenging model, less participation due to a selection bias problem.

This Issue | Views 702 | Citations 0 | Altmetric 5

Viewpoint

February 16, 2023

Next-Generation Alternative Payment Models in Oncology—Will Precision Preclude Participation?

Samyukta Mullangi, MD, MBA[1]; Ravi B. Parikh, MD, MPP[2,3]; Stephen M. Schleicher, MD, MBA[4]

> Author Affiliations

JAMA Oncol. 2023;9(4):457-458. doi:10.1001/jamaoncol.2022.7179

Avalere

July 21, 2023 | Insights & Analysis | Federal and State Policy

CMMI Releases EOM Participation and Lessons Learned from OCM

Summary

The CMMI's EOM began on July 1 with 44 participants. A recent OCM evaluation report described net losses to CMS and lessons that can be applied to EOM.

Source: https://jamanetwork.com/journals/jamaoncology/article-abstract/2801587

Differences and overlaps with pathway programs

Original Investigation | Health Policy

May 9, 2023

Association of Patient, Physician, and Practice-Level Factors with Uptake of Payer-Led Oncology Clinical Pathways

Samyukta Mullangi, MD, MBA[1]; Xiaoxue Chen, MPH[2]; Timothy Pham, PharmD, PhD[2]; et al

> Author Affiliations | Article Information

JAMA Netw Open. 2023;6(5):e2312461. doi:10.1001/jamanetworkopen.2023.12461

JCO Oncology Practice > List of Issues > Newest Content >

ORIGINAL REPORTS | Business of Oncology

Association Between Oncology Clinical Pathway Utilization and Toxicity and Cost Outcomes in Patients With Metastatic Solid Tumors

Check for updates

Ying Liu, PhD[1]; Samyukta Mullangi, MD, MBA[2]; David Debono, MD[1]; Xiaoxue Chen, MPH[1,3]; Timothy Pham, PhD, PharmD[1]; Michael J. Fisch, MD, MPH[4]; ...

JCO Oncology Practice > List of Issues > Volume 16, Issue 5 >

SPECIAL SERIES: SCIENCE OF PRACTICE | ORIGINAL CONTRIBUTIONS

Utilization of Clinical Pathways Can Reduce Drug Spend Within the Oncology Care Model

Check for updates

Andrew Hertler, MD[1]; Sang Chau, PharmD[1]; Rani Khetarpal, MBA[1]; Ed Bassin, PhD[1]; Jeff Dang, PhD[1]; Daniel Koppel, MS[1]; ...

Many practices have implemented point-of-care decision-support tools - such as clinical pathways - to standardize drug prescribing.

Key differences are that OCM/EOM are total-cost-of-care models and allow for oncologist discretion in treatment planning, whereas pathways are more prescriptive to the oncologist.

However, studies show that pathway compliance is synergistic with participation in OCM, and pathway adoption can help practices succeed in VBC.

Community onc practices have their own unique opportunities and challenges in value-based care

JCO Oncology Practice > List of Issues > Volume 17, Issue 12 >

CARE DELIVERY REVIEWS

Secret Sauce—How Diverse Practices Succeed in Centers for Medicare & Medicaid Services Oncology Care Model

Ronald M. Kline, MD[1,2]; Sibel Blau, MD[3]; Nikolas R. Buescher, MHS[4]; Amy R. Ellis[3]; J. Russell Hoverman, MD, PhD[5]; Randall A. Oyer, MD[4]; Lalan S. Wilfong, MD[5]; and Gabrielle B. Rocque, MD, MSPH[6]

[1]Formerly Clinical Lead for the Oncology Care Model and Formerly Team Lead for Oncology Care First
[2]Currently United States Office of Personnel Management, Washington, DC
[3]Northwest Medical Specialties, Tacoma, WA
[4]Penn Medicine, Lancaster General Health, Lancaster, PA
[5]Texas Oncology, Dallas, TX
[6]Divisions of Hematology & Oncology, and Gerontology, Geriatrics, & Palliative Care, Department of Medicine, University of Alabama, Birmingham, Birmingham, AL

Source: https://ascopubs.org/doi/full/10.1200/OP.21.00165

How did different business models fare in the OCM

- Academic medical centers
- Non-academic hospital-owned practices
- Small community oncology practices
- Large community oncology practices

Community onc practices have their own unique opportunities and challenges in value-based care

Small community onc practices	Large community onc practices
Rapid clinical trial activation	Variable implementation by location
Capital resources	Larger capital and human resources
Physicians are owners	Centralized loci of decision making
Rapid workflow adjustments	Can dedicate staff to workflows/ reporting
Rapid tech adoption, ex ePROs	Lower per-patient cost for new tech, more money for tech

Despite the challenges, participating in the EOM will be valuable

Drive Accountable Care

Aim: *Increase the number of beneficiaries in a care relationship with accountability for quality and total cost of care.*

Accountable care reduces fragmentation in patient care and cost by giving providers the incentives and tools to deliver high-quality, coordinated, team-based care. Models should increase the number of beneficiaries in accountable care relationships with providers, such as advanced primary care providers and ACOs. Quality of care and outcome measures should be measures that matter and include patient values and perspective.

Measuring Progress:

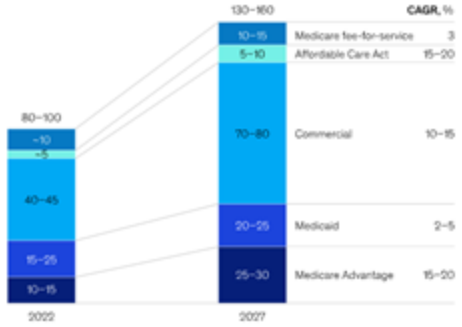
- All Medicare fee-for-service beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.
- The vast majority of Medicaid beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.

Private Payers Outpace Public Insurance in Value-Based Care Push

New research from Insights by Xtelligent Healthcare media revealed private payers are more likely than their public counterparts to be participating in value-based reimbursement models.

Value-based care models are expected to grow across all lines of business.

Lives in all value-based care models,[1] million lives



[1]Includes pay-for-performance or quality to full capitation.

McKinsey & Company

Source: https://innovation.cms.gov/strategic-direction
https://revcycleintelligence.com/news/private-payers-outpace-public-insurance-in-value-based-care-push
https://www.mckinsey.com/industries/healthcare/our-insights/investing-in-the-new-era-of-value-based-care#/

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Practices benefit from the experience through critical skill-building

- Deep programmatic understanding of these models
- Experience with analyzing claims data and historic patterns of utilization
- Creating the necessary conditions for physician acceptance, which may involve changing compensation structure
- Patient-centered workflows and processes
- Patient-reported outcomes
- Strategies to reduce drug costs - clinical pathways, formulary management, evolving the role of pharmacists, harnessing behavioral responses/ nudges, safe waste minimization
- Nimble and ongoing data analysis to identify high-risk patients and make timely adjustments to practice

The Inflation Reduction Act

"The most substantial drug payment and coverage legislation enacted since the Medicare Modernization Act of 2023"

Drew Angerer / Getty Images

Key provisions of the IRA

- First, IRA provides HHS secretary with authority to negotiate Medicare prescription drug prices
  - Part D in 2026, Part B in 2028
  - In previous reform packages, this included commercial.. This was whittled down
- Limits the rate at which companies increase the prices of existing prescription drugs in Medicare by requiring the payment of inflationary rebates
  - This approach has worked effectively in Medicaid
- Restructures the Medicare Part D benefit
  - Limits patient's OOP costs
  - Rebalances the bearing of risk for stakeholders

Source:https://www.healthaffairs.org/content/forefront/understanding-democrats-drug-pricing-package

IRA: drug pricing provisions (1)

The IRA provides HHS tools to compel drug companies to agree to a Maximum Fair Price (MFP).

- Levers of influence include hefty excise taxes, exclusion of all of a manufacturer's drugs from Medicare and Medicaid markets.
- Incorporates ceilings based on discounts - initially 25%, rising to 60% from a previous non-Federal Average Manufacturer Price (FAMP)
- Slow ramp up.. Up to 100 total drugs (between Part B and D) by 2031

Lots of open questions about approach and impact

Figure 1. Value Assessment Factors Currently Used by Third-Party HTAs vs. Factors Referenced in IRA Negotiation Provisions

	Currently Assessed Value Attributes	Inflation Reduction Act Value Attributes
Clinical Benefit versus Risk	✓	✓
Other Benefits and Disadvantages	✓	✓
Value (Cost-Effectiveness)*	✓	
Comparative Effectiveness **	✓	✓
Unmet Need/Rarity	✓	✓
Novelty	✓	✓
Budget Impact	✓	
Contextual Considerations	✓	
Research and Development Costs		✓
Production and Distribution Costs		✓

Source: https://www.healthaffairs.org/content/forefront/drug-pricing-reform-inflation-reduction-act-implications-part-1
https://avalere.com/insights/inflation-reduction-act-renews-focus-on-value-assessment-in-the-us

IRA: drug pricing provisions (2)

Within the medical benefit, providers are reimbursed with a percentage add-on payment on top of ASP

- Generally ASP + 6%, with sequestration, this is more like ASP + 4.3%
- The nature of the ASP is that it is the average net price among all providers

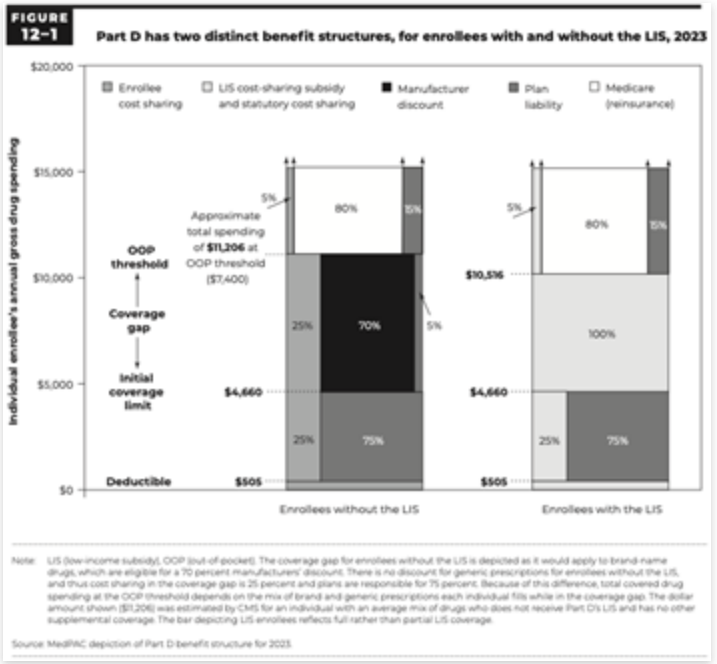
Now the add-on payment will be based on the MFP

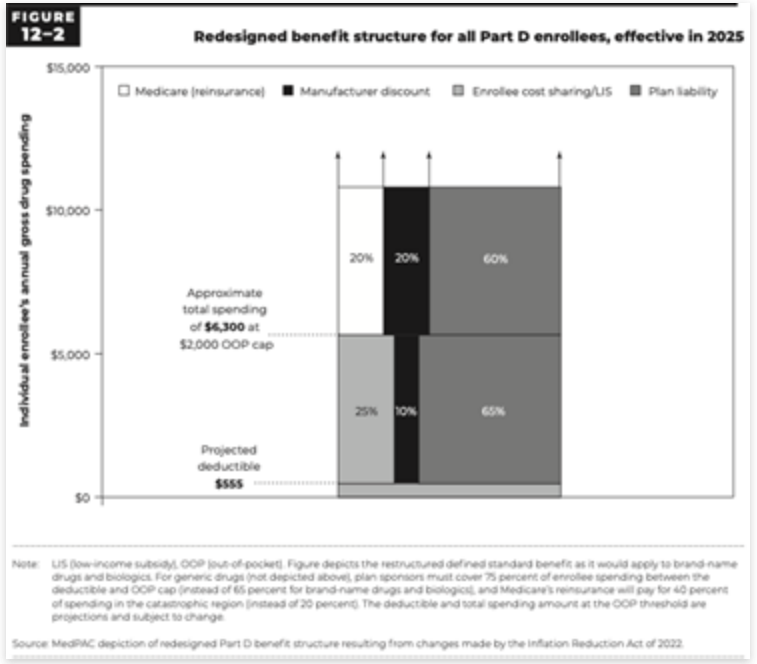
Further, a substantial # commercial and MA contracts are structured based on the ASP.

Medical oncology, followed by rheum, heaviest hit

Source: https://avalere.com/insights/ira-medicare-part-b-negotiation-shifts-financial-risk-to-physicians

IRA: Part D benefit redesign





Source: https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf

IRA: how are patients and practices impacted?

- Accelerates the lifecycle of Part B and Part D products - this will likely lead to increased launch prices.
- Wider spillover effects anticipated in Medicaid and commercial markets.
    - Medicaid uses a mandatory 23.1% discount to the launch price

- Patient abandonment of oral drugs will likely decrease.

- Plan utilization management will likely increase (strict formularies, fail-first step therapy, prior authorizations)

- Oncologists may prescribe differently

- Consolidation and acquisition of community oncology will continue to accelerate

Source: https://avalere.com/insights/how-will-the-ira-impact-product-launch-prices
https://www.obroncology.com/leading-thoughts/this-is-a-big-deal-the-ira-will-change-practice

Thank you!

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