



Evidence-Based **ONCOLOGY**

JUNE 2019 VOL. 25 • NO. 6

ALSO IN THIS ISSUE



INSIGHTS THROUGH THE RISKY "MIDDLE ZONE" TO DRUG

DEVELOPMENT. Christopher P. Austin, MD, oversees a unique mission as director of the National Center for Advancing Translational Sciences (NCATS). On Austin's watch, the center works across scientific disciplines to find ways to speed the process of turning discoveries into therapies that improve public health. For more about NCATS' mission, and its role in advancing the development of cures,

BIOSIMILARS EDUCATION. Authors report results of an education program to increase physicians' confidence in using biosimilars and improve recognition of data for a trastuzumab biosimilar, SP188.

PATIENT PREFERENCE. An author from the National Community Oncology Dispensing Association discusses the gap between payer preferences for mail-order pharmacies and survey results that show patients prefer a medically integrated pharmacy, SP193.



REPORTS FROM

SESSIONS. The Institute for Value-Based Medicine® brought sessions to White Plains, New York, and

Chicago, Illinois, to discuss the Oncology Care Model and the shift to value-based cancer care, SP202-SP205



CONFERENCE COVERAGE. Reports from meetings of the Florida Society of Clinical Oncology Spring Session and ISPOR 2019, SP195-SP197.

PRECISION FINANCING TOOLS

MIT Group Brings Together Stakeholders to Brainstorm How to Pay for Curative Therapies Over Time

Mary Caffrey

PATIENTS TREATED WITH CHIMERIC antigen receptor (CAR) T-cell therapy describe a process that is a miracle. After all else has failed, these engineered cells made with a patient's own T cells are let loose in the bloodstream to attack the cancer. For many patients who have lost hope, the treatment brings complete remission.

But the miracle comes at a cost. There's the price of the treatment itself—either \$373,000 or \$495,000, depending on the indication—and the total cost rises above \$1 million, including administration and treating adverse effects once called "the worst flu you've ever had."2

Right now, major academic medical centers say they are losing money every time a Medicare patient receives CAR T-cell therapy, as a reimbursement solution remains on hold.² But with more lifesaving and life-changing durable, curative therapies in the pipeline, the question of how to pay for CAR T-cell treatment will hardly be the last logjam of its kind.



A Novartis company, AveXis, recently said it would offer paymentover-time options for a \$2.1 million single-treatment gene therapy for pediatric spinal muscular atrophy. A multistakeholder group at Massachusetts Institute of Technology has spent years exploring new payment options of this type for life-saving durable and curative therapies.

Credit: Novartis photo

CONTINUED ON SP214

ONCOLOGY CARE MODEL

Two-Sided Risk in the Oncology Care Model

Kashyap Patel, MD, ABOIM, BCMAS; Maharshi Patel, MBA; Taylor Lavender, BS, PA; Dhwani Mehta, MS, RD; Asutosh Gor, MD: Sashi Naidu, MD: and Chuck Newton, BS

THE US HEALTHCARE SYSTEM remains one of the most inefficient healthcare systems in the world. The Bloomberg Health-Care Efficiency Index ranked the United States 54th among 56 countries in 2018, tied with Azerbaijan and only ahead of Bulgaria. This occurs even though the United States spends \$10,244 per capita annually on healthcare, a figure representing 17% of the gross domestic product.2

Our expensive yet inefficient healthcare system has been blamed on a fragmented, disorganized, and uncoordinated delivery system, with silos and redundancies that create inefficiency.3 Despite rapid advancements in treatment, the discovery of new drugs, and new technology aimed at improving patient outcomes, the overall performance of the US healthcare system in aligning incentives has not met expectations

CONTINUED ON SP216

GAINING THE PAYER PERSPECTIVE

NCCN's Putnam Serving as Point of Contact for Payers, Employers to Keep Cancer Care "Accessible"

Mary Caffrey



A YEAR AGO, the National Comprehensive Cancer Network (NCCN) added the word "accessible" to its mission statement, stating that the group is "dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so that patients can live better lives."1

But innovative therapies won't reach patients unless payers and, increasingly, employers are willing to include them in benefit plans. So, in March, NCCN named Duane Putnam, BBA, as its director of Payer

CONTINUED ON SP221





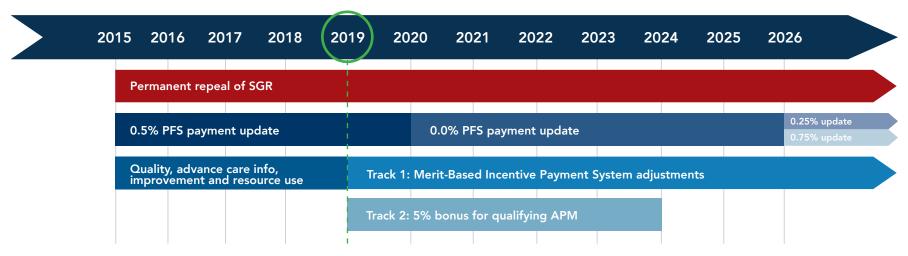


ONCOLOGY CARE MODEL

Two-Sided Risk in the Oncology Care Model

Kashyap Patel, MD, ABOIM, BCMAS; Maharshi Patel, MBA; Taylor Lavender, BS, PA; Dhwani Mehta, MS, RD; Asutosh Gor, MD; Sashi Naidu, MD; and Chuck Newton, BS

FIGURE 1. MACRA: Physician Payment Reforms Timeline



nt model; CHIP, Children's Health Insurance Program; MACRA, Medicare Access and CHIP Reauthorization Act of 2015; PFS, physician fee schedule; SGR, sustainable growth rate The Quality Payment Program (QPP) began in January 2017, with payment adjustments based on performance (to be fully implemented by January 2019). The QPP offers payment according to 1 of 2 tracks: (1) the Merit-based Incentive Payment System linked to performance including following defined, evidence-based clinical quality measures, and (2) APMs that provides financial incentives to clinicians to provide high-quality and cost-efficient care (Figure 2). 16,17

CONTINUED FROM COVER

Although these inefficiencies have become evermore glaring, oncology care is advancing at a rapid pace; improvements in survival rates in many types of cancer have led to more than 15.5 million US cancer survivors as of January 2016.4 In 2018, the FDA approved 19 new cancer drugs and biologics, and 38 new indications,⁵ as well as new molecular tests and companion diagnostics that will ultimately scale personalized treatment in oncology.

Reports from the National Academy of Medicine, formerly the Institute of Medicine, concluded that cancer treatment in the United States lacks in consistent quality and is neither patient-centric nor well-coordinated.^{3,6} The fee-for-service (FFS) payment model, used for decades in oncology and elsewhere in the United States, was not designed emphasize value or quality in cancer care. Under FFS, medical services are not bundled; they are paid for individually, thus incentivizing the provision of high-quantity, not necessarily high-quality, healthcare. The rapid, but hurried and disorganized, multidirectional advancements in payment models, such as pathways and capitations, were never formulated to affect the quality of care under the volume-driven model. Hence, despite many efforts to explore improving outcomes by using pathways and capitated models, outside of scant models demonstrating desired outcomes, most capitated models did not fulfill payers' expectations.7-9

In the United States, total spending on cancer care rose from \$27 billion in 1990 to \$124 billion in 2010, with projections of around \$157 billion by 2020.^{10,11} Total costs of cancer care for the US population are predicted to increase across all phases of care. 12 Cost drivers include technological innovation, rising hospital costs, and demographic shifts; as the population ages and people live longer, the risk of malignancy rises. 13 In the United States, oncology drug expenditures, excluding supportive care agents, rose 18% from 2014 to 2015, one of the largest single-year increases on record, driven by both the first full year of implementation of the Affordable Care Act (ACA) and the arrival of programmed cell death protein-1 inhibitors.14

Under the ACA, CMS established the Center for Medicare & Medicaid Innovation (CMMI) to test innovative payment models to incorporate the value element in the delivery of healthcare. CMS has developed value-based care (VBC) programs that reward healthcare providers with incentive payments for improving the quality of care, reducing costs, and improving the patient experience for Medicare beneficiaries. In October 2016, CMS finalized the rule for the Medicare Access and CHIP Reauthorization Act (MACRA) (Figure 1) of

2015¹⁵ that implemented the Quality Payment Program (QPP) (**Figure 2**). ^{16,17} An underlying tenant of VBC is to move away from the FFS model and toward performance-based payments. These programs tie payments to provider performance based on meeting specified quality metrics and practice reforms, with some practices already entering into payment arrangements that include financial and performance accountability for episodes of care involving chemotherapy administration to patients with cancer.

The QPP began in January 2017, with payment adjustments based on performance (to be fully implemented by January 2019). The QPP offers payment according to 1 of 2 tracks: (1) the Merit-based Incentive Payment System (MIPS) linked to performance including following defined, evidence-based clinical quality measures, and (2) Advanced Alternative Payment Models (AAPMs) that provide financial incentives to clinicians to provide high-quality and cost-efficient care (Figure 2). 16,17

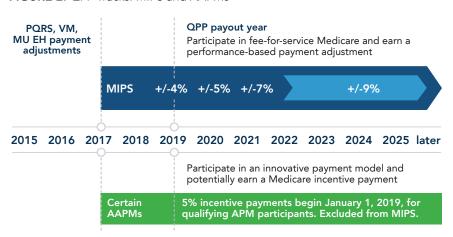
The Oncology Care Model

The Oncology Care Model (OCM), which launched on July 1, 2016, is one pilot program that is intended to shift reimbursement away from volume and tie payments to value under the broader umbrella of transitioning to VBC. The OCM is a cancer care delivery model that encourages participating providers and practices to align financial incentives to improve care, add the quality component, and enhance the patient experience while reducing the costs of care. The OCM with 2-sided risk is considered an AAPM. 18,19 It is a voluntary pilot and a part of CMS's broader initiative to improve the effectiveness and efficiency of cancer care. ²⁰ This program aims to provide higher-quality, more coordinated oncology care at the same or lower cost to Medicare than traditional FFS payments. When the program was announced and CMMI invited requests for applications in the spring of 2015, more than 400 oncology practices from across the country submitted letters of intent to participate in the 5-year pilot (2017-2022). Overall, 196 practices (covering 3200 oncologists; approximately 20% of all practicing oncologists from different settings) were selected to participate in the OCM. In addition, CMS encouraged private commercial payers to participate; 17 payers initially signed up, and 16 national and regional payers began implementing the OCM in 2017. At the time of launch in July 2017, 192 practices and 14 commercial payers were participating in

The OCM and the QPP have differences that are significant to oncologists (Figure 3). The OCM incorporates a 2-part payment system for physician

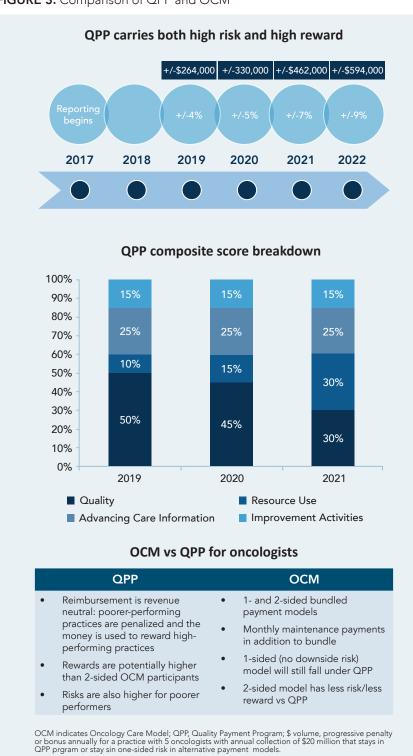
ONCOLOGY CARE MODEL

FIGURE 2. QPP Tracks: MIPS and AAPMs



AAPMs indicates Advanced Alternative Payment Models; MIPS, Merit-based Incentive Payment System; MU EHR, Meaningful Use of Electronic Health Record; PQRS, Physician Quality Reporting System; QPP, Quality Payment Program; VM, Physician Value-Based Payment Modifier.

FIGURE 3. Comparison of QPP and OCM



practices: a per-beneficiary Monthly Enhanced Oncology Services (MEOS) payment and a performance-based incentive payment (PBP) (Figure 4). The MEOS payment allows practices to improve care coordination by effectively managing and coordinating episodes of care for patients with cancer. The PBP is calculated retrospectively on a semiannual basis, based on the practice's achievements in quality measures and reductions in Medicare expenditures.

Fundamental Tenets of OCM

OCM providers are required to:

- Provide patient navigation
- Document a 13-point care plan in accordance with recommendations from the Institute of Medicine (now the National Academy of Medicine).
- Provide access to a qualified clinician 24/7, with realtime access to patients' medical records
- Use treatment in accordance with recognized treatment guidelines
- Monitor data to improve quality and gain shared savings
- Use electronic health records that are certified by the Office of the National Coordinator for Health Information Technology.

The multipayer OCM pilot's early feedback has provided a blueprint for not only quality improvement and payments linked to quality, but also for the way physicians think about and deliver care. Under the OCM, patients, caregivers, and their microecosystems become the central force that directs care in accordance with patient input, preference, and choice. The OCM has the potential to reduce healthcare costs while improving patient quality of life and outcomes.

CMMI has been reimbursing successful practices that have earned a PBP in the form of gain sharing to reward high performance and reduce the cost of care to below the target price. CMS will provide a discount of 4.0% for practices participating in the 1-sided risk model and 2.75% for practices participating in the 2-sided risk model. The savings offered will be adjusted by performance based on quality reporting. Participating practices are subject to monitoring, including on-site visits, by the CMMI team. CMMI has appropriately adjusted the risk factors to accommodate multiple comorbidities, dual-eligible status, surgical intervention, radiation therapy, and clinical trial participation.

The OCM is the first major initiative by CMS to pilot the transition from FFS toward VBC. CMMI has been relatively flexible and accommodating of changes made to the program in response to stakeholder input. However, areas of concern remain, including the main issue of the negative penalty for exceeding the target price of care.

Oncologists participating in the OCM are held responsible for the total cost of care, regardless of the origin of that cost. For example, if a patient under the OCM pilot is involved in a motor vehicle accident and requires hundreds of thousands of dollars' worth of interventions, the cost of this care will be part of the bundle that the oncologist will be responsible for. However, according to the Winsorization formula—which identifies Medicare beneficiaries outside of statistical variables, which limits its practice attributes—risk exposure will be capped at 95%.

Many lessons remain to be learned by oncologists participating in the OCM. This is compounded by the recent announcement of the MACRA final rule, where a negative risk exposure of an oncologist is limited to 3%, based on resource utilization, at the most versus the 20% risk exposure in the OCM.⁹

Conversely, the upside bonus for top performers in the QPP track under the MACRA final rule could exceed 20%. This may become further complicated, given the uncertainty surrounding the 2017 change in the federal administration and its healthcare agendas.

In terms of pure comparison, upon the launch of the OCM pilot, it appeared that OCM with 1-sided risk was the best option for oncologists, followed by MIPS and then OCM with 2-sided risk. However, acknowledging an extremely high downside riskexposing a practice to almost 20% risk, amounting to in excess of \$250,000 per provider—the original 2-sided risk parameters provided a model that could cause significant financial hardship to practices that fell on the wrong side of the model. That is why none of the participating practices opted for original 2-sided risk and why they instead remained under the no-risk model. As mentioned before, the upside potential for an exceptional performer practice or provider is significantly higher. This also contributed to a business case for providers to not opt for the original 2-sided risk model. Recognizing these limitations of 2-sided risks, CMMI altered

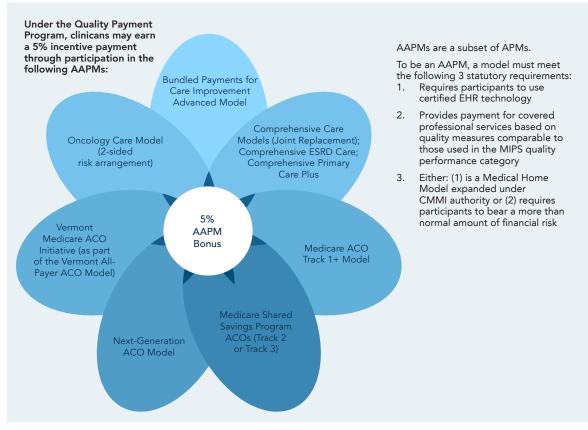
continued >

FIGURE 4. Fundamentals of OCM Payment



MEOS indicates Monthly Enhanced Oncology Services; PMPM, per member per month.

FIGURE 5. Overview of Requirements and Types of AAPMs



AAPM indicates advanced alternative payment model; ACO, accountable care organization; CMMI, the Center for Medicaid & Medicare Innovation; EHR, electronic health record; ESRD, end-stage renal disease; MIPS, merit-based incentive payment system.

TABLE 1. Overview of OCM, 2-Sided Risk and Alternative Risk Model

ORIGINAL

	MIPS	ОСМ	AAPM (2-sided risk)
QR practice Initiated	Yes	Yes	Yes
Claim (CMS) based QA	Yes	Yes	Yes
Penalty for overspending	Yes	No	Yes
Extra bonus	Yes (exceptions)	No	5% AAPM bonus

MODIFIED

ОСМ	OCM (no risk)	OCM (original 2-sided risk)	OCM-Alternative Risk Model
OCM Discount	4%	2.75%	2.5%
PBP Milestones	Actual expenses < target amount	Actual expenses < target amount	Actual expenses < target amount
PBP	Target amount minus actual expenses	Target amount minus actual expenses	Target amount minus actual expenses
Stop gain	20% of benchmark	20% of benchmark	16% of revenue + chemotherapy
Stop loss	N/A	20% of benchmark	8% of revenue + chemotherapy

AAPM indicates advanced alternative payment model; MIPS, Merit-based Incentive Payment System; OCM, Oncology Care Model; PBP, performance-based payments; QA, qualify assurance; QR, qualified registry

parameters to limit risk and make 2-sided risk a more attractive proposition. However, CMS subsequently modified the 2-sided risk model, and the new alternative risk model has significantly less financial risk for the practice than the previous +/-20% approach. In this modified risk model, risk is based upon expenses attributed to a provider and not the total cost of care per episode (**Figure 5, Tables 1-2**).

Although the metrics for no risk still are the most favorable for most practices, if a practice fails in the performance category for 3 consecutive periods, that practice is forced to accept the alternate model. Given the more favorable parameters of the alternative risk model, it is worth considering remaining in the OCM under 2-sided risk rather than leaving the model.

Summary of Risk OCM Models and Financial Impact

The 1-sided risk model allows for a practice to eliminate the financial challenges associated with downside risk. These practices may not qualify for the designation of AAPM and hence will not be eligible for the 5% AAPM bonus. They will also be subject to following the QPP requirement. However, by nature of the practice transformation process, these practices are already compliant with the majority of quality reporting, as well as other QPP requirements, and they will likely earn incremental bonuses up to 9% by 2022. Thus, a practice that is very efficient, has achieved a PBP, and has fulfilled all requirements is best suited to remain in the 1-sided risk model and optimize its performance in the QPP track. For those practices and providers considering 2-sided risk, the original 2-sided model provided the highest potential revenue for a top performer. However, the difference in top gains versus no risk would be less than \$100,000, versus the difference in top losses versus no risk of almost \$1 million. This high-risk profile is what led to no adoption of the original 2-sided risk model.

The practices that fail to achieve PBPs for 3 successive episodes will either need to shift to the 2-sided risk model or drop out of the OCM. In our analysis (hypothetical, based upon our own case study), the numbers show that the new 2-sided risk model has a more favorable maximum loss than the no-risk model, although gains are approximately half of what they would be under the no-risk model. As such, this new 2-sided risk model is a financially sound model for a typical physicians' office. Although the no-risk model remains the preferred OCM reimbursement model for most practices, the new 2-sided risk model is one that may not be financially toxic like its predecessor. As such, for practices without another option, it is still a viable model under which a practice can be a participant in the OCM and experience significant financial gains through its participation. The new 2-sided risk model is significantly more favorable than the previous model. In particular, for practices that have failed the 3-performance-periods test for the no-risk model, it may make sense to remain in the OCM under the new 2-sided model. This approach makes sense, since the financial downside can be mitigated by obtaining reinsurance, the cost of which can be offset by the gain in revenue through MEOS payments (Table 3, Figure 6).

TABLE 2. Comparison of financial risks in OCM and Risk-Based Contracts

ОСМ	OCM (No Risk)	OCM (original 2-sided risk)	OCM-new risk model
Recoupment	N/A	Actual amount < target amount	Actual amount < benchmark
Recoupment calculation	N/A	Actual expenses minus target amount	Actual expenses minus benchmark
Stop loss	N/A	20% of benchmark	8% of revenue plus chemo
AAPMs	N/A	Yes	Yes
AAPM bonus	N/A	5% of professional service	5% of professional services

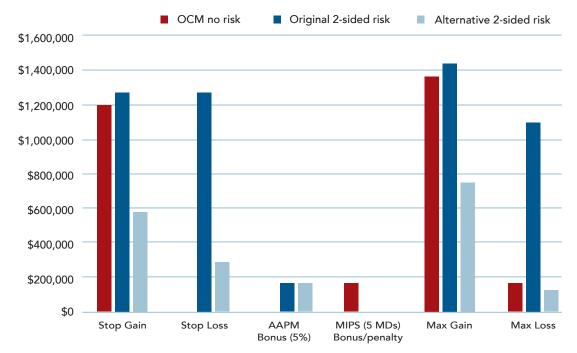
AAPM indicates advanced alternative payment model; OCM, Oncology Care Model

TABLE 3. A Hypothetical 6-Month Episode of the OCM

	OCM No Risk	OCM (original 2-sided risk)	Alternative 2-Sided Risk
Median PMPM expenditure	\$5205	\$5205	\$5205
Episode cost (benchmark)	\$31,230	\$31,230	\$31,230
Target amount	\$29,956	\$30,688	\$30,458
For practice with 200 patients	\$5,991,200	\$6,137,600	\$6,091,600
Stop gain	\$1,198,240	\$1,272,056	\$584,793
Stop loss	N/A	\$1,272,056	\$292,396
AAPM bonus (5%)	N/A	\$167,000	\$167,000
MIPS (5 MDs) bonus/penalty*	\$167,000	N/A	N/A
Max gain	\$1,365,240	\$1,439,056	\$751,793
Max loss	\$167,000	\$1,105,056	\$125,396

AAPM indicates advanced alternative payment model; MIPS, Merit-based Incentive Payment System; OCM, Oncology Care Model; PMPM, per member per month 'Refers to the fact that the practices has 5 physicians

FIGURE 6. Upside and Downside Potentials With 1-Sided Risk, Original 2-Sided Risk, and New Alternative 2-Sided Risk Model



AAPM indicates advanced alternative payment model; MIPS, Merit-Based Incentive Payment System; OCM, Oncology Care Mode

Protecting Downside Risk With Reinsurance

There are 2 types of reinsurance concepts that a provider needs to understand when accepting downside risk. These concepts are: (1) severity risk and (2) frequency risk.

Severity risk is the impact of a single large claim on the risk pool. For example, Medicaid plans worry

about an infant in the newborn intensive care unit or a patient with hemophilia with medical costs exceeding \$1 million.

Frequency risk is the impact of many low-level claims on your risk pool. For example, a year with widespread flu cases can cause an increase in hospitalizations and associated treatments. No one treatment is costly, but the increase in utilization can drastically affect the risk pool.

Severity risk is mitigated by what is called specific reinsurance and frequency risk is mitigated by aggregate reinsurance.

Conclusions

CMMI has paved the path for the transition from volume to value in oncology. Although concerns remain to be addressed, at least one-third of OCM practices have reached some type of PBP and accessed shared savings. It is possible to improve the patient experience and reduce cost of care while adhering to guidelines based on standard-of-care treatment. Some of the areas of cost improvement include expanded access, use of biosimilars and generic drugs, and following recommendations by the national professional societies (eg, the American Society of Hematology, the American Society of Clinical Oncology). Visits to the emergency department, reduced hospitalization, use of biosimilars and generics, and expanded access are low-hanging fruit for success, all of which can help practices optimize their performance in the OCM and/or newer payment models, even if they must adopt 2-sided risk.

We believe that realigning the workforce to provide patient-centered care will enhance the team-based approach, improve employee morale, improve the patient experience and care coordination, and ultimately lead to true value in healthcare. Human potential is frequently ignored and undervalued, but capturing it is a highly rewarding step for success in any task, no matter what challenges exist. By properly training and incentivizing the workforce around patient-centered care, practices can provide a recipe for their success in the OCM.

From CMMI's perspective, it may be worth considering adjustments based on regional and/or socioeconomic and demographic risk factors. Factors such as having a rural versus a suburban location or access to urgent care can affect outcomes. Such an alternative would reduce disparities in performance that are beyond an individual provider's control.

Based on our experience, transitioning to VBC is possible. Given the newer improved risk profile in the 2-sided risk model for the practices that must take 2-sided risk, it is worth considering by identifying the possibility of reinsurance, either by sharing part of upside potentials or sharing part of the MEOS payments. •

AUTHOR INFORMATION.

Authors Kashyap Patel, MD, ABOIM, BCMAS; Maharshi Patel, MBA; Taylor Lavender, BS, PA; Dhwani Mehta, MS RD; Asutosh Gor, MD, and Sashi Naidu, MD, are affiliated with Carolina Blood and Cancer Care Associates, based in Rock Hill, South Carolina. Chuck Newton, BS, is senior vice president of Risk Strategies Company, based in Midlothian, Virginia.

REFERENCES

- Miller L, Lu W. These are the economies with the most (and least) efficient healthcare. Bloomberg website. bloomberg.com/news/articles/2018-09-19/u-s-near-bottom-of-health-index-hong-kong-and-singapore-at-top. Published September 19, 2018. Accessed June 1, 2019.
- Sawyer B. Cox CP. How does health spending in the US compare to other countries? Peterson-Kaiser Health Care Tracker website. healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-average-wealthy-countries-spend-half-much-per-person-

continued >

- health-u-s-spends. Published December 7, 2018. Accessed April 15, 2019.

 Institute of Medicine. Cancer Care for the Whole Patient: Meeting Psychology.
- Institute of Medicine. Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs. Washington, DC: National Academies Press; 2008.
- American Cancer Society. Cancer treatment and survivorship facts & figures 2016-2017. American Cancer Society website. www.cancer.org/content/ dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/cancer-treatment-and-survivorship-facts-and-figures-2016-2017.pdf. Accessed April 19, 2019.
- Dietz C, Bin Han Ong M. FDA approves new cancer drugs and biologics in 2018—and don't forget two new endpoints and "real-time" review. *The Cancer Letter.* January 25, 2019. cancerletter.com/articles/20190125_2/. Accessed June 1, 2019.
- Levit LA, Balough EP, Nass SJ, Ganz PA. Institute of Medicine. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC: National Academies Press; 2013.
- Sprandio JD. Oncology patient-centered medical home. Am J Manag Care. 2012;18(SP4):SP191-192.
- Butcher L. How oncologists are bending the cancer cost curve. Oncology Times. 2013:35(1):5-6. doi: 10.1097/01.COT.0000425910.07033.fa.
- 9. Newcomer LN, Gould B, Page RD, Donelan SA, Perkins M. Changing

- physician incentives for affordable, quality cancer care: results of an episode payment model. *J Oncol Pract*. 2014;10(5):322-326. doi: 10.1200/IOP.2014.001488
- Sullivan R, Peppercorn J, Sikora K, et al. Delivering affordable cancer care in high-income countries. *Lancet Oncol*. 2011;12(10):933-980. doi: 10.1016/S1470-2045(1))70141-3
- Elkin EB, Bach PB. Cancer's next frontier: addressing high and increasing costs. JAMA. 2010;303(11):1086-1087. doi: 10.1001/jama.2010.283.
- Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010–2020. J Natl Cancer Inst. 2011;103(2):117-128. doi: 10.1093/jnci/djq495.
- National Cancer Institute. Cancer prevalence and cost of care projections. NIH website. costprojections.cancer.gov/. Accessed February 24, 2019.
- IMS Institute for Healthcare Informatics. Medicines use and spending in the US. A review of 2015 and outlook to 2020. Morning Consult website. morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf. Published April 2016. Accessed April 19, 2019.
- CMS. CMS finalizes the new Medicare Quality Payment Program. CMS website. cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/

- Provider-Partnership-Email-Archive-Items/2016-10-14-eNews-SE.html. Published October 14, 2016. Accessed April 19, 2019.
- Phelps A, Esquibel D, Joselow E. MACRA final rule raises performance standards for 2019. Deloitte website. deloitte.com/us/en/pages/regulatory/articles/macra-final-rule-understanding-revisions-for-cy-2019. html. Published November 8, 2018. Accessed March 2, 2019.
- Quality Payment Program. Executive summary. MACRA. qpp.cms.gov/ docs/QPP_Executive_Summary_of_Final_Rule.pdf. Published October 14, 2016. Accessed March 3, 2019.
- Dong LF, Pelizzari PM. Advanced APMs and qualifying APM
 participant status. Milliman website. milliman.com/insight/2016/
 Advanced-APMs-and-Qualifying-APM-Participant-status/. Updated
 November 16, 2016. Accessed August 31, 2017.
- Oncology Care Model. CMS website. cms.gov/newsroom/fact-sheets/ oncology-care-model. Published June 29, 2016. Updated April 4, 2019. Accessed April 25, 2019.
- Government Accountability Office. CMS Innovation Center: model implementation and center performance. Government Accountability Office website. gao.gov/assets/700/691721.pdf. Published March 2018. Accessed June 1, 2019.

COA Urges Delay in Downside Risk Deadline for OCM

Jaime Rosenberg

THE COMMUNITY ONCOLOGY ALLIANCE

(COA) has sent a letter to CMS' Center for Medicare & Medicaid Innovation (CMMI) urging a delay in the October 2019 deadline for practices participating in the Oncology Care Model (OCM) that have not yet achieved shared savings payments to make a decision on 2-sided risk.¹

Instead, COA is recommending a deadline of April 2020 in order to give practices a third set of reconciliation data, as well as results postimplementation of the updated risk adjusters for breast, prostate, and bladder cancer.

"Making the decision on whether to accept downside risk based on only 2 sets of reconciliation results/data after these key corrections to the methodology were made exposes practices to significant uncertainty rather than quantifiable risk," states the letter to Adam Boehler, deputy administrator for innovation and quality and director of CMMI.

A recent report from Avalere Health estimated that approximately 70% of OCM practices would owe payments if they were to transition to 2-sided risk.²

According to COA, pushing back the deadline to allow for additional results and time to decide on whether to assume downside risk will allow practices to gain key insight into their performance and incorporate risk in a more feasible pathway. It will also keep practices in the model and allow them additional flexibility necessary to evaluate the methodology changes and impact on their practice.

Results from performance period (PP) 3 revealed that just 30% of practices achieved shared savings, which was unchanged from PP2; however, the practices that achieved shared savings differed by performance period. The February 2019

reconciliation also caused practices to experience regressions in their PP2 true-up results resulting in a significant number of practices losing their shared savings.

The majority of practices are unable to determine why they're doing well or why they're not doing well when they get their results, explained Bo Gamble, director of strategic practice initiatives at COA, in an interview with *Evidence-Based Oncology*™, highlighting the need for clarity within performance reports. The complexity of the reports only adds to the frustration of the year-long lag in PP results, said Gamble.

"You can't change behavior that's a year old, and therefore, you're always chasing yourself trying to figure out how to improve," he said. "That's what's frustrating for people. They want to improve, but they want to know, 'what did I do last month that I can address this month?'"

A solution to this, according to Gamble, could come from tentative information offered to practices on a monthly basis rather quarterly. Practices should also be able to access a practice model where they can plug in their own data and determine how they're going to do in order to help them understand how their decisions today can impact their model in the future, he said.

In addition to addressing the lag time, there are 3 other areas that COA urged CMMI to address: price prediction, risk adjustment, and attribution and monthly enhanced oncology services payment recoupment.

"Applying price adjustments at the level of the practice, rather than the episode, leads to underpricing for practices that deviate from average national distributions; eg, of populationlevel characteristics of cancer types," states the letter. Other recommendations put forward by COA to address these challenges include:

Adjustments for emergent therapies should occur at the episode level, based on which drugs are actually prescribed to the patient, using staging data to determine whether the episode is eligible or ineligible.

CMMI should improve pricing for outlier patients so that practices are not penalized, or significantly over-targeted, due to few outlier episodes.

Adding surgeries related to all cancer types to the surgery list so that if patients have surgery for any type of cancer, they will have an increased target price reflecting the increased complexity of their cancer episode.

Practices should be notified as quickly as possible after an episode is triggered so that patients can be monitored and their care can be managed.

If practices do decide to take on 2-sided risk, there's also the question of what happens when the 5-year demonstration project ends, explained Gamble, who added that CMMI has not given an indication of what's to come once the project come to a close. When assuming risk under the OCM, practices are exempt from the Merit-based Incentive Payment System (MIPS). If OCM does not continue after the 5 years, practices are suddenly thrust into MIPS—a completely different program.

REFERENCES

- 1. COA letter to CMMI regarding challenges that need to be addressed in the OCM and future payment reform models [press release]. Washington, DC: Community Oncology Alliance; May 31, 2019. communityoncology.org/coa-letter-to-cmmi-regarding-challenges-that-need-to-be-addressed-in-the-ocm-and-future-payment-reform-models/. Accessed June 6, 2019.

 2. More than half of all OCM providers could owe CMS money
- More than half of all OCM providers could owe CMS money if required to join in 2-sided risk model [press release]. Washington, DC: Avalere Health; May 21, 2019. avalere.com/ press-releases/more-than-half-of-all-ocm-providers-could-owecms-money-if-required-to-join-in-2-sided-risk-model. Accessed June 6, 2019.