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Bringing Value-Based Care to Cancer Treatment Past, Present, and Future

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Value-based care presents a unique set of challenges to oncology practice. A cancer diagnosis is inherently devastating. A family receiving a dire diagnosis is unlikely to focus on reducing costs of care at the onset, instead hoping for all possible interventions to stop the spread of the cancer and achieve remission. With that in mind, cancer affects all parts of the mind and body, and involves the coordination of care between multiple specialists across disciplines and health systems, the number of which can vary dramatically depending on the type of cancer being treated. The resulting expenses can be staggering—the National Cancer Institute estimated costs for cancer care to be $190.2 billion in 2015, rising to $208.9 billion in 2020.[1] By 2030, that number is projected to increase to $246 billion.[2]

Acknowledging these high costs and the importance of care coordination in oncology care, the Centers for Medicare & Medicaid Services' (CMS') Center for Medicare and Medicaid Innovation (CMMI) brought its value-based care models to cancer treatment in 2016 through the now-concluded Oncology Care Model (OCM). The OCM sought direct physician and physician practice participation and contracting with CMS, in lieu of contracting through an intermediary on behalf of a provider network, and invited the participation of commercial payers. Despite its innovative approach, the OCM achieved mixed results, as Medicare suffered $377.1 million of losses from the program between 2016 and 2019.

In 2019, CMS announced Oncology Care First as a potential successor to the OCM, but updates on its development were sparse, and OCM expired without a successor. In July 2022, however, CMMI unveiled the Enhancing Oncology Model (EOM). The EOM is modeled after the lessons learned from the OCM, as further described below. Whether EOM's changes to OCM will go far enough to enable its success is unclear; however, EOM offers a view into CMMI's thinking around what value-based care in oncology may look like in the next five years, and provides a hint as to where CMMI may ultimately take value-based care in oncology over time. This article seeks to explore the key

considerations from CMMI's value-based care approach to value-based care in oncology in the past, present, and future.

Value-Based Care's Past: The OCM

CMMI's first centralized attempt at introducing value-based care to the delivery of cancer treatment began on July 1, 2016, with the OCM. By the time the program ended on June 30, 2022, the program featured 122 participating practices and five commercial payer partners.[3] The stated aim of the OCM was to "improve health outcomes for patients with cancer, improve the quality of cancer care, and reduce spending for cancer treatment."[4]

Patient Population

The OCM focused on care for patients receiving cytotoxic chemotherapy, hormonal therapy, biologic therapy, immunotherapy, and combinations of those therapies. In crafting this focus, CMMI made eligible for the OCM any Medicare beneficiary covered by Part A and B of Medicare, with fee for service Medicare as their primary payer, receiving one of the aforementioned therapies.[5]

Participation

Under prior CMMI models, CMS contracts indirectly with providers for participation in CMMI models, relying instead on direct contracts with provider network entities (such as, for example, accountable care organizations). The two most prominent examples of this participation model are two of CMS' most successful: the Kidney Care Choices model and Medicare Shared Savings Program. In a departure from this traditional hub-and-spoke entity model focus, CMMI only permitted direct participation by providers and physician practices in the OCM. Specifically, physician group practices and solo practitioners that prescribe cancer chemotherapies and that are currently enrolled in Medicare were the only eligible participants in OCM. Expressly excluded from participation, likely due to heightened costs incurred by rural and underserved populations, were physician practice groups that partnered with critical access hospitals, rural health clinics, and federally qualified health centers to provide chemotherapy.

Role of Commercial Payers

Acknowledging that an average of 50% of oncology practice patients are Medicare beneficiaries, CMMI sought to involve commercial payers in the OCM.[6] Payers that were interested in participating were required to (1) commit to participate in the OCM for its full five-year duration, (2) sign a Memorandum of Understanding with CMMI, (3) enter into agreements with OCM participating practices that contained certain requirements around high quality care, (4) share model methodologies with CMMI, and (5) provide payments to participants for the provision of enhanced services and for their performance. The Memorandum of Understanding required that commercial payers

adopt the same two-prong payment methodology as the OCM, in that payers were required to offer payment for enhanced services (discussed below) and a performance-based payment calculated on a methodology designed to assess a practice's performance on measures of utilization, cost of care, and/or quality of care for an episode of care.[7]

Enhanced Services Requirement

The OCM required participating practices to offer certain enhanced services to their OCM-eligible patients as a condition to participate in the OCM. Those services included (1) providing OCM beneficiaries with 24 hours/7 days per week access to a clinician with real-time access to patients' medical records, (2) attesting to Stage 1 of meaningful use, with the intention of attesting to Stage 2 of meaningful use by the end of the third performance year, (3) collecting and reporting data on certain care metrics, (4) providing the core functions of patient navigation for all OCM beneficiaries, (5) document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan[8], and (6) reporting when care is either consistent with the clinical guidelines of the American Society of Clinical Oncology or the National Comprehensive Cancer Network.

Economic Model

The OCM was a multi-track model with an enhanced payment per beneficiary. Participants could select a risk track featuring only upside risk or a track where the first two performance years were only upside risk and the following three years offered two-sided risk. Participants were eligible to receive shared savings if their actual chemotherapy episode expenditures were less than the benchmark set by CMMI. CMMI applied a 4% discount to determine the target price for chemotherapy episodes. Payments, if earned, were then scaled by participant-specific performance multipliers based on the achievement and improvement of quality measures.[9] Participants also received a $160 per-beneficiary-per-month payment for beneficiaries during each six-month episode, regardless of whether the beneficiary received chemotherapy during the six-month episode. CMMI considered this payment as compensation for the performance of the enhanced services described above.

Results

The OCM's financial results were ultimately mixed. Findings from a review of the program between July 2016 and July 2019 found that the program reduced costs only slightly in instances with higher-risk episodes, and increased for lower-risk episodes. OCM led to a relative reduction in total episode payments, but failed to generate net savings for Medicare. The report found that four common higher-risk cancer episodes drove the reduction in total episode payment: lung cancer, lymphoma, colorectal cancer, and high-risk breast cancer. Overall, OCM resulted in an estimated $377.1 million in cumulative net losses to the Medicare program over two and half years.[10]

The Present

On June 27, 2022, CMMI announced[11] the EOM. The EOM will commence on July 1, 2023 and continue until June 30, 2028. Applications to participate in EOM closed on September 30, 2022.

Patient Population

Unlike the OCM's focus on patients receiving a certain type of cancer treatment, EOM focuses on patients with certain types of cancer: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. In moving away from an eligibility focus on the receipt of chemotherapy and similar therapies to patients that suffer from certain high-cost cancers, CMS narrowed the population of patients eligible for inclusion under the EOM. Notably, OCM's greatest financial success came with treating patients with high-risk breast cancer, lung cancer, lymphoma, and colorectal/small intestine cancer, all of which are covered by the EOM.[12]

Participation

Participation in the EOM is limited to physician practice groups that are enrolled in Medicare and engaged in the provision of oncology services. This narrows the list of eligible participants from the OCM. Under the EOM model, individual physicians cannot directly participate as they could with OCM. The participating practice must include at least one physician or mid-level practitioner enrolled in Medicare that (1) furnishes Evaluation and Management services to Medicare beneficiaries receiving chemotherapy for a cancer diagnosis, (2) bills under the federal taxpayer identification number of the participating practice for the services, (3) has reassigned his or her right to receive Medicare payments to the participating practice, and (4) appears on the participating practice's "EOM Practitioner List"—the list of "EOM Practitioners" approved by CMS for participation in EOM. Additionally, at least one "EOM Practitioner" must be a Medicare-enrolled physician with an individual NPI designating a specialty code of Hematology/Oncology or Medical Oncology.

As with OCM, EOM allows for the pooling of two or more participating practices. Pooling of participating practices mean that the episode of care expenditures for two or more EOM participating practices are considered together for payment calculations, both to set cost of care benchmarks and to determine shared savings or shared losses amounts. Pooling offers the opportunity for participating practices to further pool resources and collaborate to achieve the Practice Redesign Activities (PRAs) (defined and discussed below).

Care Partners

For health care providers that do not wish to participate directly in EOM, EOM offers "Care Partner" participation. A Care Partner includes any Medicare-enrolled provider or

supplier that engages in at least one of the PRAs during a performance period and (1) has entered into a Care Partner arrangement with an EOM Participant; (2) is identified on EOM Participant's Care Partner list, and (3) is not an EOM Practitioner. EOM Participants must submit a proposed Care Partner list with their application to participate in EOM and resubmit the list at least semi-annually, but solely to the extent the Care Partner arrangement contemplates financial remuneration. Notably, the EOM Request for Applications expressly states that fraud and abuse waivers are not being published for EOM at this time, meaning any Care Partner relationship will need to be closely scrutinized to ensure compliance with the federal Anti-Kickback Statute (AKS) and Stark Laws.

Role of Commercial Payers

Like OCM, EOM is a multi-payer model that will encourage "other payers" (e.g., commercial payers, Medicare Advantage plans, and state Medicaid agencies) to align with the model's structure and requirements. Practically speaking, this means that commercial payers are able, and encouraged, to implement a private version of the EOM, as they were encouraged to implement a private version of the OCM. To participate, the payer must collaborate with at least one EOM Participant and enter into a memorandum of understanding with CMS. CMS has offered to provide "other payers" with aggregated model-level de-identified participant data, among other benefits. In carrying out their collaborations with physician practice groups (PGPs), payers should closely analyze the applicability of fraud, waste, and abuse considerations given the lack of waivers contemplated for the EOM, with a mind towards the AKS and the recent implementation of value-based care safe harbors and CMS-sponsored model exemption.

Participant Redesign Activities (PRA)

EOM requires participating PGPs to complete a total of eight PRAs, or enhanced services that each EOM Participant must provide to beneficiaries, which are compensated with a separate per beneficiary per month payment. The PRAs include providing 24/7 access to a clinician with real-time access to a practice's medical records, patient navigation services, the design of an extensive care plan for patients, use of a health-related social needs screening tool (a new health equity PRA), and implementation of electronic Patient Reported Outcomes (a report that serves as another health-equity focused requirement from CMS and comes directly from the patient without amendment or interpretation).

Economic Model

Unlike with OCM, EOM offers only two-sided risk models to its participants. Participants will be eligible for both shared savings and shared losses. EOM offers participants the choice of two risk models. The first model offers limited upside and downside risk. Participants selecting this limited risk model receive a benchmark for total performance

period expenditures, which is then discounted by 4% for purposes of determining whether a participant has earned shared savings or shared losses. Participants that achieve a total episode cost between 92% and 96% of the benchmark are eligible for savings (with a 4% of benchmark stop-gain); participants achieving between 96% and 98% of the benchmark receive neither savings nor are responsible for losses; participants that achieve 98% to 100% of the benchmark are responsible for shared losses. As an illustration, if a participant has a $1 million benchmark and has performance period expenditures of $900,000, the participant would be eligible for $40,000 of shared savings (maximum shared savings of 4% of the benchmark, achieving shared savings at 90% of the benchmark). Comparatively, if the same participant has performance period expenditures of $1.2 million, it would be responsible for $20,000 of shared losses.

The second risk model offers greater shared savings in exchange for a more limited discount off the benchmark and a higher share of shared losses. The calculated benchmark is discounted by 3% for purposes of determining whether a participant has earned shared savings or shared losses. Participants are eligible to share in savings where the participant achieves 85% to 97% of the benchmark; participants achieving between 97% and 98% of the benchmark are neither eligible for shared savings nor responsible for shared losses; participants whose total performance expenditures fall between 98% and 104% of the benchmark are responsible for shared losses (with a stop-loss equal to 6% of the benchmark). As an illustration, if a participant has a $1 million benchmark and has performance period expenditures of $900,000, the participant would be eligible for $100,000 of shared savings. Comparatively, if the same participant has performance period expenditures of $990,00, it would be responsible for $10,000 of shared losses.

Similar to OCM, EOM Participants can bill CMS for a Monthly Enhanced Oncology Services (MEOS) fee. The MEOS fee is intended to fund the PRAs provided by PGPs and is priced at $70 per beneficiary per month (a reduction from $160 in the OCM) where the beneficiary is not a Medicare dual-eligible beneficiary, and $100 per beneficiary per month where the beneficiary is a Medicare dual-eligible beneficiary.

Opportunities for Service Providers

EOM provides an opportunity for third-party service providers (and, in particular, privately-backed administrative services providers or data analytics support organizations) to support interested managed practices in achieving the PRAs, which are likely to require a significant financial and administrative investment on the part of the EOM Participant. Administrative services providers that support a network of oncology practices eligible for EOM could also position those practices for success under the program's pooling requirements, as intraoperative and overlapping data systems improve their ability to achieve shared savings.

Considerations for Payers

The partnership model contemplated by EOM offers a unique opportunity to vertically integrated payers to work with their affiliated oncology practice groups to achieve meaningful shared savings that reward both parties. Such payers likely already have pre-existing care coordination resources that can be deployed for EOM Participants to achieve the PRAs and leveraged across alternative payment models. Further, payers may also see this as an opportunity to enhance their partnerships with individual in-network oncology practices in the transition to value-based care. Because EOM lacks centralized contracting entities, payers can directly interface with participants and develop better care coordination for their covered members. In doing so, however, payers should be mindful of program waivers, if and when released, and relevant fraud, waste, and abuse laws given the direct interface with provider groups and two-sided risk structure of the EOM program.

Drug Costs: A Barrier to Beating the Benchmark

No matter the extent to which a participating practice group can deliver efficient care, one of the highest costs for patients over a six-month period for cancer treatment are often drug costs. For 2020, annual per-patient spending on oncology drugs was $18,761 for patients covered by Part B of Medicare. For Part D patients, spending increased to $52,016 on an annual basis.[13] That's just out-of-pocket expenditures. Most cancer drugs launched between 2009 and 2014 were priced at more than $100,000 for one year of treatment, and even with negotiated pricing, the Medicare program is absorbing significant costs for these drugs on an annual basis per patient.[14] While cancer drug costs are only one part of high value cancer care, they present a unique challenge to generate savings on a per-patient basis and achieve positive results against CMMI's benchmarks.

The Future

What the future holds for the OEM and the application of value-based care principles in oncology remains murky. Given the financial results of the OCM, and the incremental changes presented by the OEM, whether OEM will introduce financial savings to the Medicare program is uncertain. Certain initiatives that may help overcome some of the barriers to financial success, such as the Inflation Reduction Act's mandate to CMS to negotiate certain Medicare Part B drug prices, may set OEM participants up for greater success towards the end of the model's lifespan, assuming cancer drugs make the list of 15 drugs (20 beginning in 2029) to be negotiated each year.[15]

We expect that OEM will, however, further care coordination, social equity considerations, and overall quality of care for each patient. Given CMS' stated goal of having all Medicare fee-for-service beneficiaries in a care relationship with accountability for quality and total cost of care by 2030,[16] we expect that the OEM will, if nothing else, lay a stronger groundwork than the OCM that will allow for the continued design of value-based care programs for the delivery of oncology services.

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[1] NAT'L CANCER INST., CANCER TRENDS PROGRESS REPORT, FINANCIAL BURDEN OF CANCER CARE (April 2022), https://progressreport.cancer.gov/after/economic_burden.
[2] Abt Associates et al., *Evaluation of the Oncology Care Model: Performance Periods 1-5* (Jan. 2021), *available at* https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5 (hereinafter, the "CMS Report").
[3] The five participating payers were Aeta, BlueCross BlueShield of South Carolina, Cigna Life & Health Insurance Company, Priority Health, and the University of Arizona Health Plan. *See* CTRS. FOR MEDICARE & MEDICAID SRVCS., Oncology Care Model https://innovation.cms.gov/innovation-models/oncology-care.
[4] CTRS. FOR MEDICARE & MEDICAID SERVS., ONCOLOGY CARE MODEL REQUEST FOR APPLICATIONS (Feb. 2015), https://innovation.cms.gov/files/x/ocmrfa.pdf (hereinafter, the "OCM RFA").
[5] Also among the eligibility criteria were the requirement that the beneficiary does not have end-stage renal disease and was not covered under United Mine Workers. *See* OCM RFA.
[6] OCM RFA.
[7] CTRS. FOR MEDICARE & MEDICAID SERVS., ONCOLOGY CARE MODEL MEMORANDUM OF UNDERSTANDING, https://innovation.cms.gov/files/x/ocm-mou.pdf.
[8] OCM RFA.
[9] Quality measures included communication and care coordination, person- and caregiver-centered experience and outcomes, and clinical quality of care.
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[15] CTRS. FOR MEDICARE & MEDICAID SERVS., *Saving Money with the Inflation Reduction Act*, https://www.medicare.gov/about-us/inflation-reduction-act (last visited December 15, 2022).
[16] CTRS. FOR MEDICARE & MEDICAID SERVS., INNOVATION CENTER STRATEGY REFRESH, https://innovation.cms.gov/strategic-direction-whitepaper.

