# **Evaluation of the Oncology Care Model:** *Performance Periods* 1–5



*Final* January 2021

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#### Contract #HHSM-500-2014-000261

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## **Executive Summary**

In February 2015, the Centers for Medicare & Medicaid Services (CMS) invited oncology physician group practices to participate in the <u>Oncology Care Model (OCM</u>), an alternative payment model based on six-month episodes for cancer care. OCM tests whether financial incentives can improve quality and reduce Medicare spending. OCM applies to Medicare fee-for-service (FFS) beneficiaries with any type of cancer, who are undergoing chemotherapy treatment.<sup>1</sup> The Model, launched on July 1, 2016, combines attributes of medical homes (patient-centeredness, care coordination, accessibility, evidence-based guidelines, and continuous quality improvement) with financial incentives for providing services efficiently and with high quality.<sup>2</sup>

OCM features a two-pronged financial incentive strategy. Practices can bill for additional money on a monthly basis to support care improvements. Specifically, participating practices may bill Medicare a \$160 Monthly Enhanced Oncology Service (MEOS) fee for FFS Medicare beneficiaries, which is intended to support the practice in providing enhanced oncology services such as increased access to timely ambulatory care, and patient navigation.

Practices also can earn money in the form of retrospective performance-based payments (PBP) if they are able to meet Model cost and quality goals. Participating OCM practices are paid under Medicare's FFS billing rules, then CMS combines all Medicare-covered services that their chemotherapy patients receive into six-month episodes. If practices meet performance quality goals, they can receive a PBP that CMS calculates by comparing all expenditures during an episode (including MEOS payments) to risk-adjusted historical benchmarks, minus a discount that CMS retains.

The OCM evaluation uses mixed methods, integrating comprehensive quantitative and qualitative data analyses based on Medicare administrative data and claims, patient surveys, case study interviews, and other inputs.

The *First Annual Report from the Evaluation of the Oncology Care Model: Baseline Period* explained the construction of the evaluation comparison group, and described the trends during a multi-year baseline period for both the OCM and comparison groups. The *Evaluation of the Oncology Care Model: Performance Period One* report measured program implementation and impacts for the first six-month performance period (PP), covering episodes that began between July 1, 2016 and January 1, 2017 and ended by June 30, 2017. The *Evaluation of the Oncology Care Model: Performance Periods 1-3 report* assessed care delivery changes and model impacts through PP3, covering episodes that began between July 1, 2016 and January 1, 2018 and had ended by June 30, 2018.

This *Evaluation of the Oncology Care Model: PP1–5* report addresses model impacts through the fifth PP (including episodes that began between July 1, 2016 and January 1, 2019, all of which had ended by June 30, 2019). At the end of PP5, 176 practices were actively participating in the Model.

Cancer is not a single disease, and each type of cancer has different treatments, side effects, costs, and potential for savings. CMS assigns each cancer episode to one of 24 cancer types. Three types of cancer are categorized for the Model as lower-risk episodes (low-intensity prostate cancer episodes, low-risk breast cancer episodes, and low-risk bladder cancer episodes). These cancers are treated with hormonal therapies, and patients typically have fewer side effects from their cancer or treatment; episode costs are

<sup>&</sup>lt;sup>1</sup> Chemotherapy is defined for OCM purposes as cytotoxic chemotherapy, biologic therapy, immunotherapy, or hormonal therapy for cancer.

<sup>&</sup>lt;sup>2</sup> More information about OCM can be found at <u>https://innovation.cms.gov/initiatives/oncology-care/</u>

also modest. The remaining cancers are considered higher-risk episodes, and episode costs are much higher; treatment typically involves cytotoxic chemotherapy and/or immunotherapy that often has side effects. Because lower-risk episodes and higher-risk episodes have such different treatments, severity, and costs, many analyses in this report consider them separately. For some analyses, we also report OCM impacts separately for the most common higher-risk cancer episodes (e.g., lung cancer, high-risk breast cancer, colorectal cancer, myeloma, lymphoma) to understand differing OCM impacts.

The OCM evaluation measures impacts of OCM compared with a matched group of comparison episodes that were attributed to oncology physician practices that are not participating in the Model. In both OCM and comparison episodes, total episode payments (TEP) rose from about \$28,500 at baseline (before OCM began) to an average of \$33,200 over PP1–5. This report addresses whether that increase was lower in OCM episodes than in comparison episodes, whether OCM had differential impacts on certain types of cancer or specific cancer services, and how these impacts were achieved.

#### Summary of Key Findings

#### Medicare Payments and Savings/Losses

# (1) TEP increased rapidly in both OCM and comparison episodes, but rose \$297 less (p<0.05) in OCM episodes. While this difference was

statistically significant, it was small, representing 1 percent of baseline payments. (Medicare payments are referred to as Total Episode Payments, or TEP, in this report.<sup>3</sup>

• Relative payment reduction was concentrated in certain types of higher-risk episodes. Higher-risk episodes, which made up about twothirds of all episodes, averaged about \$46,500 during PP1–5. TEP increased in both OCM and comparison higher-risk episodes, but by \$503 less in OCM episodes. The *relative reduction* in TEP was most notable for four common higherrisk episodes: lung cancer (TEP relative reduction of \$1,292), lymphoma (relative reduction of \$1,017), colorectal cancer (relative reduction of \$879), and high-risk breast cancer (relative reduction of \$790).

• Impacts in Part A and B payments but not in

#### Some Key Acronyms in This Report:

**PP:** Performance Period. Episodes that start during a six-month window. This report discusses impacts in the first five PPs (episodes starting 7/1/16 through 1/1/19).

- **TEP:** Total Episode Payments. Per-episode calculation that does not include MEOS, performance incentives, or beneficiary copays.
- **MEOS:** Monthly Enhanced Oncology Services payment. The additional \$160 per-beneficiary monthly fee that participating practices may bill for, to help support their transformation efforts.
- **PBP:** Performance-based payments. Incentive payments that participants are able to earn based on their success in reducing expenditures enough to meet Model requirements.

**Part D.** For higher-risk episodes, OCM was responsible for a relative reduction in both Medicare Part A and Part B payments, but had no impact on Part D payments. The relative reduction in perepisode payments due to OCM was \$212 for Medicare Part A services (e.g., hospitalizations, institutional post-acute care), and \$287 for Part B payments (e.g., physician's services, drugs administered to patients in outpatient settings). The relative reduction in Part B payments for higherrisk episodes was mainly due to non-chemotherapy drugs, many of which are supportive care drugs used to prevent toxic side effects of chemotherapy such as infection, nausea, and bone damage.

<sup>&</sup>lt;sup>3</sup> TEP includes payments for all cancer and non-cancer care during an episode as defined for OCM; TEP does not include MEOS payments.

With model payments included, OCM resulted in net losses for

Medicare.

• **Relative increase in payments for lower-risk episodes.** For lower-risk episodes, which made up about one-third of all episodes, TEP averaged about \$7,500 during PP1–5. TEP increased slightly more in OCM episodes than in comparison episodes (by \$151).<sup>4</sup>

The direction of these offsetting impacts are shown in Exhibit ES-1.

## Exhibit ES-1: OCM Led to Lower Payment Increases for Higher-Risk Episodes, but Led to Greater Payment Increases for Lower-Risk Episodes

|                      | Impact Estimates PP1 Through PP5 |                    |                    |                    |  |  |  |  |
|----------------------|----------------------------------|--------------------|--------------------|--------------------|--|--|--|--|
|                      | TEP                              | Part A<br>Payments | Part B<br>Payments | Part D<br>Payments |  |  |  |  |
| All episodes         | +                                | +                  |                    |                    |  |  |  |  |
| Lower-risk episodes  |                                  |                    |                    | No OCM<br>Impact   |  |  |  |  |
| Higher-risk episodes | •                                | +                  | -                  | inpact             |  |  |  |  |

Source: Medicare claims 2014-2019.

spending (losses)

**Notes:** A green arrow indicates a statistically significant relative reduction at p<0.1. A red arrow indicates a statistically significant relative increase at p<0.1. PP: performance period. TEP: total episode payment.

#### (2) After Including Model Payments Made to Practices, OCM Resulted in Net Losses for Medicare.

Participating practices can bill CMS for MEOS, and if quality and financial goals are met, practices receive PBP. For OCM to result in net savings for Medicare, the Model needs to reduce per-episode payments enough to cover the MEOS and PBP payments. If per-episode payments do not decline enough to cover these Model payments (i.e., if OCM does not constrain TEP increases), OCM will result in net losses for Medicare. The combined MEOS and PBP payments for the first four PPs<sup>5</sup> were greater than the small gross reduction in TEP, resulting in *net losses* to Medicare ranging from \$65M to \$100M in each PP (Exhibit ES-2).

| Exhibit ES-2: OCM Resulted in Net Losses for Medicare  |                |                |                 |                 |              |  |  |  |  |  |  |
|--|----------------|----------------|-----------------|-----------------|--------------|--|--|--|--|--|--|
|  | PP1            | PP2            | PP3             | PP4             | Total PP 1-4 |  |  |  |  |  |  |
| Gross Savings:<br>Estimated change in<br>gross Medicare<br>spending due to TEP<br>relative reduction | - \$12,443,592 | -\$38,918,897* | -\$42,694,680** | -\$50,665,174** | -144,722,343 |  |  |  |  |  |  |
| Net Medicare   | \$100,427,424  | \$72,669,902*  | \$65,802,010**  | \$76,766,478**  | 315,665,814  |  |  |  |  |  |  |

#### Exhibit ES-2: OCM Resulted in Net Losses for Medicare

\*Statistically significant at p<0.10. \*\*Statistically significant at p<0.05. \*\*\*Statistically significant at p<0.01 **Source:** Medicare claims 2014–2018. OCM first true-up reconciliations, PP1–PP4.<sup>6</sup>

Notes: PP: performance period. TEP: total episode payments. Orange=not statistically significant.

<sup>&</sup>lt;sup>4</sup> Lower-risk cancer episodes include breast and prostate cancers treated only with hormonal therapies, and bladder cancers treated with intra-vesicular therapies (local therapies instilled into the bladder).

<sup>&</sup>lt;sup>5</sup> At the time this report was written, MEOS and PBP amounts were available for PP1 through PP4, but not for PP5.

<sup>&</sup>lt;sup>6</sup> CMS reconciles PBPs several times (these are referred to as true-ups) for each PP, as claims are processed during the months after a PP ends. We used the first true-up for each PP because it is available sooner, and because the subsequent true-up yields only very small changes in overall estimates.

Although gross spending declined in all PPs, net Medicare losses declined for three consecutive PPs and then rose in PP4. This was in part because more practices qualified for PBP in PP4, and those payments were larger than in prior periods.

#### **Cancer Treatment Patterns**

The opportunity to earn PBP is intended to motivate participating practices to avoid low-value, costly treatments that have little likelihood of benefitting patients. Observations about the impact of the model in these areas include:

- Little Evidence of Value-Oriented Changes in Chemotherapy Drug Treatments. The chemotherapy drugs used to treat common cancers were very similar in OCM and comparison episodes, and changed similarly over time, with no observed savings to Medicare from more efficient treatment patterns. There is little evidence that OCM is driving value-oriented selection of chemotherapy regimens.
- No Evidence of Value-Oriented Changes in Radiation Therapy. In situations where clinical guidelines recommend fewer radiation fractions, changes were small and similar for OCM and comparison episodes.
- More-Cost-Conscious Use of Part B Non-Chemotherapy Drugs. Episode payments for Part B non-chemotherapy drugs went up less in OCM episodes than in comparisons, which may reflect more-cost-conscious use of costly supportive therapies. For example, OCM episodes had higher-value patterns of drugs used to prevent neutropenia and cancer-related bone fractures.

#### **Patient-Centered Care**

OCM requirements emphasize timely access to care, patient navigation, and care coordination, as well as shared decision making and advance care planning (ACP). Together, these improvements could help avoid emergency department (ED) visits and hospital use, improve end-of-life (EOL) care, and enhance patient satisfaction. Observations about the impact of the model in these areas include:

- Patients Continued To Rate Care Experience Very Highly. Most cancer patients responding to our survey rated their cancer care very highly at the start of the Model, and there were no overall changes over time and no pattern indicating differences between OCM and comparison respondents.
- No Meaningful OCM Impact on ED Visits or Hospitalizations Overall, or for Chemotherapy-Related Toxicity. During the first three program years, OCM practices focused on preventing ED visits and hospitalizations, in order to improve quality of care and reduce episode payments. Strategies included identifying and closely monitoring high-risk patients, improving phone triage to quickly help patients manage symptoms, and expanding access to same-day urgent care. Despite these efforts, OCM had no observable impact on outpatient ED visits or hospitalizations overall. OCM also had no impact on hospitalizations due to chemotherapy toxicity, and the impact on ED visits for chemotherapy toxicity was so slight as not to be clinically meaningful.
- Fewer Hospitalizations at the End of Life. Hospitalizations in the last month of life declined slightly for OCM patients who died, but there was essentially no change for comparison patients, resulting in a statistically significant 1.1 percentage point relative reduction in End of Life (EOL) hospitalizations due to OCM. This also led to a relative reduction in TEP of \$539 (p≤0.05). The small relative reduction in hospitalizations in the last month of life did not affect family members' perceptions about the quality of EOL care. According to family members who responded to our survey, deceased patients received good EOL care before OCM began, and there were no changes over time and no differences between OCM and comparisons.
- No OCM Impact on Hospice Care Use or Timing. Many OCM practices attempted to improve EOL care by hiring palliative care specialists and enhancing access to palliative care, encouraging patients and their families to engage in ACP, and documenting patient wishes and proxy decision

makers. However, OCM had no observable impact on the use of hospice care, or the duration or timing of hospice care across the model as a whole.

## 1. Oncology Care Model Background and Evaluation

#### 1.1. Background of Oncology Care Model

The Centers for Medicare & Medicaid Services (CMS) is operating the Oncology Care Model (OCM) to reduce Medicare payments, improve the quality of care beneficiaries receive, and save taxpayer money, by fostering coordinated, high-quality, cost-effective cancer care. OCM focuses on Medicare fee for service (FFS) beneficiaries with cancer who are undergoing chemotherapy treatment.<sup>7</sup> OCM combines attributes of medical homes<sup>8,9</sup> (patient-centeredness, accessibility, evidence-based guidelines,<sup>10</sup> and continuous monitoring for improvement opportunities) with financial incentives for providing these services efficiently and with high quality.

OCM features a two-pronged financial incentive strategy. First, practices may bill for additional money to support care improvements. A participating practice may bill Medicare a \$160 Monthly Enhanced Oncology Service (MEOS) fee for each FFS Medicare beneficiary with a chemotherapy episode that is attributed to the practice. This money is intended to support enhanced oncology services, including the following:

- 24/7 patient access to an appropriate clinician who has real-time access to the practice's medical records
- Core functions of patient navigation
- A documented Care Plan for every OCM patient containing 13 components recommended by the <u>Institute of Medicine</u>
- Cancer treatment that is consistent with nationally recognized clinical guidelines

Second, practices can receive money in the form of retrospective performance-based payments (PBP) if they are able to meet Model cost and quality goals. Participating OCM practices are paid under Medicare's FFS billing rules, then CMS combines all Medicare-covered services that their chemotherapy patients receive into six-month episodes. Practices that meet performance quality and savings goals can receive PBP. CMS calculates PBP by comparing all expenditures during an episode (including MEOS payments) to risk-adjusted historical benchmarks, minus a discount that CMS retains. These payments are adjusted to reflect performance on quality measures. These adjustments are one mechanism to ensure that efficiency efforts that participating practices undertake are consistent with maintaining quality.

The six-year OCM began with six-month episodes starting on July 1, 2016, and will operate for 11 consecutive performance periods (PPs). The last episodes will end on June 30, 2022. Some practices

<sup>&</sup>lt;sup>7</sup> Chemotherapy is defined for OCM purposes as systemic therapies including cytotoxic chemotherapy, hormonal therapy, biologic therapy, immunotherapy, and combinations of these therapies.

<sup>&</sup>lt;sup>8</sup> Demartino JK and Larsen JK. Equity in Cancer Care: Pathways, Protocols, and Guidelines. *J Natl Compr Canc Netw* Oct. 1, 2012;10, Supplement 1:S1–S9.

<sup>&</sup>lt;sup>9</sup> Page RD, Newcomer LN, Sprandino JD, et al. *The Patient-Centered Medical Home in Oncology: From Concept to Reality.* 2015 ASCO Educational Book. Retrieved on June 7, 2016 from <a href="http://meetinglibrary.asco.org/content/11500082-156">http://meetinglibrary.asco.org/content/11500082-156</a>.

<sup>&</sup>lt;sup>10</sup> Demartino JK and Larsen JK. Equity in Cancer Care: Pathways, Protocols, and Guidelines. *J Natl Compr Canc Netw* Oct. 1, 2012;10, Supplement 1:S1–S9.

participate in OCM on a partnership basis by pooling with other practices. This is usually because one or more oncologists work part-time in two related practices.<sup>11</sup>

Participating OCM practices (and pools) may voluntarily adopt two-sided risk, in which any Medicare payments more than 2.5 percent above the target are repaid to CMS. Accepting two-sided risk meets the Quality Payment Program's criteria for being an advanced alternative payment model. Beginning in PP8, two-sided risk will be required for those that have not earned at least one PBP in the first four PPs, or their participation will be terminated.

Additional details about OCM, including previous evaluation reports, are available on the CMS website.

#### 1.2. OCM Evaluation

The OCM evaluation measures the impact of the Model on Medicare spending, quality of care, clinician perceptions, and patient care experiences. The evaluation examines care provided by practices that volunteered to participate in OCM, and compares changes over time in this group with changes in a comparison group that was carefully matched to Model participants in the baseline period, prior to the start of the model. This difference-in-differences (DID) evaluation approach measures whether changes over the course of the Model are different in the OCM group than in the comparison group. This report focuses on all cancer types combined, and for several key outcome measures also presents separate results for the group of higher-risk episodes, the group of lower-risk episodes, and specific cancer types.

The evaluation uses data from many sources to measure impacts and the underlying changes driving these impacts. Data sources include Medicare administrative data; case studies and interviews; and surveys completed by patients, families, and practice leaders. The evaluation also takes advantage of inputs and data submitted by participating practices.

This report focuses on six-month episodes that began during the first five PPs (July 1, 2016 through January 1, 2019), all of which had ended by June 30, 2019. The report includes Medicare spending and utilization results; information from surveys of patients whose episodes began during the first five PPs; qualitative data collected during case studies; and program data reported by participants through Model Year Three. Information in this report about net impacts of OCM on Medicare payments reflects MEOS and PBP information for PP1 through PP4.

#### 1.3. Organization of This Report

Chapter 2 describes the evaluation data and methods. Chapters 3–13 contain evaluation findings through the first five PPs. Chapter 3 – 6 address impacts of OCM on episode payments, service utilization, and Medicare spending. Chapter 7 addresses impacts of OCM on cancer treatment, adoption of new treatments, and supportive care. Chapter 8 focuses on patient care experiences. Chapter 9 addresses palliative care and end-of-life care, and chapter 10 addresses survival. Chapter 11 explores differential impacts based on beneficiary demographics. Chapter 12 examines changes OCM practices made to align physician compensation and performance feedback with OCM quality incentives. Chapter 13 assembles evidence about unintended consequences of OCM.

Throughout these chapters, we explain the data and analyses, and point readers to appendixes containing additional information that may be of interest. Chapter 14 offers a brief conclusion.

<sup>&</sup>lt;sup>11</sup> For more about how CMS handles pooling arrangements in OCM, see: <u>https://innovation.cms.gov/Files/x/ocm-pp3beyond-pymmeth.pdf</u>

#### ONCOLOGY CARE MODEL BACKGROUND AND EVALUATION

The following icons are used throughout this report to indicate the data sources for each analysis:

- Patient Survey
- Medicare Claims
- Case Study
   Interviews
- Practice Leader
   Survey

## 2. Data and Methods

This chapter summarizes the data, measures, and methods used to evaluate OCM. Additional detail can be found in **Appendix A (Methods)**.

#### 2.1. Evaluation Data

#### 2.1.1 Secondary Data and Purposes

The OCM evaluation uses the following secondary data:

- Medicare FFS Parts A and B Claims and Part D Prescription Drug Event Data: to construct measures of health care use and payments, and analyze changes in treatment patterns.
- Other administrative CMS data including beneficiary enrollment and coverage information, beneficiary characteristics, and beneficiaries involved in other CMS initiatives: to control for any beneficiary differences between OCM and comparison groups, support subgroup analyses, and select beneficiaries for surveys.
- CMS Health Professional Shortage Area and Area Health Resource files: to control for local differences between markets of OCM and comparison practices.
- Proprietary Office-Based Physician File<sup>12</sup> and academic medical school affiliation:<sup>13</sup> to control for ownership/affiliation and size differences between intervention and comparison practices.
- OCM Data Registry—Practice-Reported Quality Measures. OCM practices are required to submit data to the OCM Data Registry for each PP, including quality measures and other clinical data such as cancer stage, biomarkers, and gene mutations. While the total number and type of practice-reported quality measures changed over time, practices consistently submitted data on two quality measures: a pain assessment and management composite measure, and a measure for screening for depression and providing follow-up plans as needed. We analyzed those two measures.

#### 2.1.2 Primary Data and Purposes

Primary data were collected and analyzed to explore issues not illuminated by analysis of secondary data. Primary data included; a patient survey, a survey of OCM practice leaders, and case study interviews.



Patient Survey: Performance Based Payment (PBP) is adjusted for quality, including patientreported care experiences collected by surveying patients served by each of the OCM participating practices. The patient survey is also used in the evaluation to measure changes

over time in patient experiences. The patient survey is also used in the evaluation to measure enanges over time in patient experiences that may be due, at least in part, to OCM. Survey domains include: access, effective communication, exchange of information, symptom management, shared decision making, patient self-management, and EOL care. (EOL questions are asked of the family members of deceased cancer patients.) The patient survey uses the following questionnaires:<sup>14</sup>

1. The **main** questionnaire sent to a sample of cancer patients each quarter whom we believe to be alive at the time of survey mailing. This asks about care experiences and current health status.

<sup>&</sup>lt;sup>12</sup> <u>http://www.skainfo.com/databases/physician-data</u>

<sup>&</sup>lt;sup>13</sup> Welch, P. and Bindman, A.B. Town and gown differences among the largest medical groups in the US. *Journal of Academic Medicine* July 2016;91(7):1007–14.

<sup>&</sup>lt;sup>14</sup> The questionnaires for the patient/caregiver survey are available in the *Evaluation of the Oncology Care Model: Performance Period One – Appendix* volume, available at <u>https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1-appendix.pdf</u>

- 2. A tailored **alternative** questionnaire sent to the family proxies of cancer patients who had died by the time the survey was mailed (i.e., died during or soon after their six-month care episode). This survey asks the same care experience questions as the main survey, but does not ask about current health status (because patients are deceased), and asks about EOL care.
- 3. A **proxy** questionnaire sent to the family members of cancer patients who were alive for the initial survey mailing (whether or not they responded), but who died during the subsequent year; this asks about EOL care.

#### **RELATED SECTIONS**

Survey methods and response rates for the patient/proxy surveys, and component questions for each composite, are described in Appendix Α.

Practice leader survey methods and response rates are in Appendix A; **Appendix F** contains the questionnaire for the practice leader survey.



Practice Leader Survey: Survey of administrators in participating OCM practices, to collect information not available through other data sources, including about attributes of cancer care delivery and use of compensation-based physician performance incentives. We conducted the survey twice, to measure changes over time during the Model: Wave 1 data was collected from October 2016 through February 2017, during PP1-PP2, and Wave 2 data was collected from May through June 2019, during PP6.



Case Study Interviews: Case studies conducted with 12 practices we visited during Model Year Three (July 2018–June 2019), and consistent themes from prior years' case studies.

#### 2.2. Outcome Measures by Data Source

The following sections describe the measures we constructed using data from each source.

#### 2.2.1 Claims-Based Measures

We used Medicare claims data to compute changes in health care use and payments, as well as EOL care measures, for the OCM and comparison group episodes. All outcome measures were calculated at the episode level (not the practice level), with the exception of EOL and survival measures, which were calculated at the person level because death or survival is at the person-level, and the impact of services provided during an episode may extend beyond the end of that episode (e.g., a person's survival may continue for months or years after treatment is complete).

The Medicare spending measures in this report include Total Episode Payments (TEP), which is composed of standardized Parts A&B Medicare payments, and Part D Medicare payments.<sup>15</sup> We report Part A payments for acute care hospitalizations, post-acute care services,<sup>16</sup> and hospice care. We report Part B payments for Part B physician evaluation and management (E&M) visits, radiation therapy, imaging and laboratory testing.

Total Episode Payment: TEP is composed of standardized Part A&B Medicare payments, and Part D Medicare payments, for services received during a sixmonth episode. TEP includes all care, cancer-related and otherwise, and reflects all services received by the beneficiary during their episode, whether the care was delivered by clinicians at their attributed practice or not. TEP excludes the MEOS payments.

<sup>15</sup> Part D payments comprise low-income cost-sharing and reinsurance payments as reflected on Part D Prescription Drug Events (PDEs).

<sup>16</sup> Post-acute care includes home health (HHA) care and care received at skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals.

We also report Part B payments for chemotherapy drugs and non-chemotherapy drugs (such as supportive care drugs), and Part D payments for prescription drugs. Finally, we also present beneficiary cost-sharing (deductible and coinsurance costs) for Parts A, B, and D.

The *utilization* measures in this report include hospitalizations in acute care hospitals (ACHs), ED visits, Part A post-acute care services, and select Part B outpatient services (e.g., physician visits, imaging and radiation therapy services). We also report ED visits and ACH hospitalizations due to complications from chemotherapy. Measures of EOL and hospice care are reported in three domains: hospital-based care and chemotherapy at the end of life; hospice care use and timing; and place of death.

Several spending and utilization analyses were conducted separately for *higher-risk versus lower-risk* episodes. Most medical treatments for cancer are intensive and costly and require frequent office visits, and can have severe side effects. For some patients, these intensive treatments are intended to cure (eradicate) cancer; for patients with incurable cancer, the goal is to prolong life with reasonable quality (i.e., treatment with palliative intent). Whether intensive cancer treatments are for curative or palliative purposes, patients require close monitoring to mitigate severe side effects. About two-thirds of OCM and comparison episodes are considered to be higher-risk. For three cancer types (low-risk breast cancer, low-intensity prostate cancer, low-risk bladder cancer), responsible for about one third of episodes, medical treatments are much less intensive, with lower risk for severe side effects and infrequent need for office visits, symptom management, or monitoring.<sup>17</sup>

Claims-based *clinical measures* focus on whether OCM affected:

- Use of new treatments, including immunotherapy
- Chemotherapy treatments for the most common cancers
- Guideline-based symptom management and high-value use of supportive care drugs
- Use of radiation therapy during chemotherapy episodes
- Substitution of biosimilar drugs
- Patient adherence to (high-cost) oral treatment regimens; timely initiation of adjuvant chemotherapy following surgery
- The mix of episodes for metastatic and non-metastatic cancer

#### 2.2.2 Patient Survey Measures

Since OCM began we have been surveying patients treated by participating practices, with samples drawn every quarter. Twice, patients treated by comparison practices were also surveyed, to support a DID analysis to measure whether changes over time in the OCM group differ from those in the comparison group. For the DID analysis, we used survey responses from patients treated by OCM and comparison practices at the start of the Model (episodes beginning early in PP1) and similar patients surveyed two years later (episodes beginning in PP5).

We combined the main and alternative patient surveys to learn about care during (or soon after) the last OCM episode. For each wave, we calculated six composite patient experience scores as follows: access (six survey questions), affective communication (four questions), enabling patient self-management (eight questions), exchanging information (four questions), shared decision making (four questions), and

<sup>&</sup>lt;sup>17</sup> A patient's disease trajectory may include multiple episodes, some categorized as higher-risk and some categorized as lower-risk. For example, after surgery some breast cancer patients may start with intensive chemotherapy treatment for several months (a higher-risk episode), followed by 5–10 years of hormonal therapy (lower-risk episodes)—and if there is a recurrence, may have another higher-risk episode of intensive treatment.

symptom management (eight questions). In addition, there is a single survey question about the respondent's overall rating of the cancer care team.

We combined the alternative and decedent surveys to learn about EOL care, including an overall rating of the cancer care team, as well as whether clinicians always showed respect, listened carefully, were direct and straightforward, explained things clearly, and spent enough time with the patient. In addition, we asked whether clinicians ever gave conflicting information, and if they followed the patient's EOL wishes. We also asked about preferences regarding place of death, and whether those preferences had been met.

#### 2.2.3 OCM Data Registry—Practice-Reported Quality Measures

We analyzed practice-reported data on two quality measures that OCM practices submit to CMS: a pain assessment and management composite measure, and a measure about screening for depression and providing follow-up plans as needed. We assessed these practice-reported measures in light of patient-reported pain and emotional problems, to understand whether practices' efforts were adequately addressing patients' needs.

We also analyzed the Aggregate Quality Score (AQS) that CMS awards based on a practice's achievement on five quality measures, to understand whether practices are meeting quality goals.

#### 2.3. Analytic Methods

We followed the OCM program methodology to construct six-month episodes and attribute each episode to a single practice with an oncologist.<sup>18</sup> Episodes were defined based on beneficiary eligibility<sup>19</sup> and qualifying trigger events (e.g., chemotherapy), and each episode was attributed to the practice that provided the plurality of E&M visits for cancer. The main evaluation methods are briefly described below. Throughout the report, findings with p<0.10 are noted as statistically significant. We also indicate when outcomes are statistically significant at levels of p<0.05 and p<0.01.

#### 2.3.1 Comparison Group Selection

As described in detail in the *Evaluation Baseline Report* and *Evaluation Report for PP1*, (and accompanying appendices) we selected a comparison group of non-OCM practices<sup>20</sup>—and episodes for their patients with traditional FFS Medicare—that were similar to the OCM practices/episodes in the baseline period, before OCM began. The comparison group represents what would have occurred in the absence of OCM and allows us to identify the impact of the Model using a DID framework (see Section 2.3.4 below). Using propensity score matching, we selected 538 oncology practices that had statistically similar characteristics to the OCM practices in the baseline period, based on eligibility to participate in OCM, historic patterns of E&M billing, and observable episode, practice, market, and beneficiary characteristics.

#### 2.3.2 Intent to Treat Design

Practices that ended OCM participation before the end of PP5 were included in the analysis, in line with our intent-to-treat design for the OCM evaluation. This intent-to-treat design avoids biases that ensue

<sup>&</sup>lt;sup>18</sup> <u>https://innovation.cms.gov/Files/x/ocm-cancercodelists.pdf</u>, accessed on June 17, 2019.

<sup>&</sup>lt;sup>19</sup> In order for a beneficiary's episode to be included in the sample, the beneficiary had to meet the following eligibility criteria for all six months of their episode (or until their death if they died during the episode): Enrolled in Medicare Parts A and B, did not receive the End Stage Renal Disease (ESRD) benefit, had Medicare as the primary payer, and was not covered under Medicare Advantage. In addition, the beneficiary had to have at least one qualifying evaluation & management (E&M) visit with a cancer diagnosis during the episode period.

<sup>&</sup>lt;sup>20</sup> For evaluation purposes, a comparison practice is defined as claims submitted under a single Tax Identification Number.

| Period                               | Number of Episodes |           |  |  |  |
|--------------------------------------|--------------------|-----------|--|--|--|
| (Episodes Initiating)                | ОСМ                | COMP      |  |  |  |
| PP                                   |                    |           |  |  |  |
| Baseline-3 (7/2/14–1/1/15)           | 113,552            | 134,074   |  |  |  |
| Baseline-2 (1/2/15-7/1/15)           | 117,335            | 138,560   |  |  |  |
| Baseline-1 (7/2/15–1/1/16)           | 114,994            | 132,971   |  |  |  |
| Hold-Out Period (1/2/16–<br>6/30/16) | -                  | -         |  |  |  |
| PP1 (7/1/16–1/1/17)                  | 126,654            | 145,234   |  |  |  |
| PP2 (1/2/17–7/1/17)                  | 128,238            | 146,648   |  |  |  |
| PP3 (7/2/17–1/1/18)                  | 124,327            | 138,790   |  |  |  |
| PP4 (1/2/18–7/1/18)                  | 132,814            | 145,987   |  |  |  |
| PP5 (7/2/18–1/1/19)                  | 129,418            | 140,333   |  |  |  |
| All Periods                          |                    |           |  |  |  |
| All Episodes                         | 987,332            | 1,122,597 |  |  |  |

Episodes by Performance Periods Used in This Report

Source: Medicare claims 2014–2019.

**Notes:** COMP: comparison episodes. OCM: OCM episodes. PP: performance period.

when impact is measured only for those that remain in the Model for its full duration, and are as a consequence more likely to have successfully implemented the Model. Furthermore, an intent-totreat approach captures the extent to which key components of OCM, such as enhanced services, information sharing, and patient education, continue after Model termination. By the end of PP5, 26 practices had terminated OCM participation. These 26 practices represented only four percent of OCM episodes in the intervention period, and it is unlikely that the retention of terminated practices materially influenced the impacts presented in this report.

#### 2.3.3 Cumulative Analysis based on Current Programmatic Definitions

CMS made important programmatic changes to improve OCM during the period this report covers. Most notably, CMS improved how episodes are attributed to the responsible physician group practice, by only attributing episodes to practices that had at least one oncologist submitting claims. CMS also made the distinction between higher-risk and lowerrisk prostate and breast cancer episodes. CMS applied

these changes starting in PP3.<sup>21</sup> For evaluation purposes, we applied these program rules retroactively to the baseline period and initial PPs, to ensure consistency in methods across periods and support the analysis of trends over time. For this and other minor technical reasons, the episodes we used to measure impacts differ slightly from the episodes CMS used to determine PBP and MEOS payments, but we used the CMS program episode counts when calculating net savings/losses for Medicare.

#### 2.3.4 DID Impact Analyses

We used difference-in-difference (DID) regression analyses to estimate the impacts of OCM, controlling for observable factors unrelated to OCM that could influence outcomes. DID is a statistical technique that measures the change in an outcome between the baseline period and the intervention period (in this case, among OCM episodes), relative to the change in a comparison group (in this case, comparison episodes) during the same time period.

The baseline period includes all six-month episodes for three pre-Model performance periods: specifically, those that began between July 2, 2014 and January 1, 2016, the last of which had ended by June 30, 2016. We employed a six-month hold-out period from January 2, 2016 through June 30, 2016 for which episodes were omitted from the evaluation to ensure no overlap between baseline and intervention episodes. The intervention period examined in this report includes five performance periods worth of sixmonth episodes: specifically, episodes that began on July 1, 2016 through January 1, 2019, all of which had ended by June 30, 2019.

This report includes results of DID analyses for claims-based utilization measures, payment measures, EOL care, and clinical measures. For a subset of key outcomes, we estimated impacts on cancer subgroups (e.g., higher-risk and lower-risk episode groupings, prevalent cancers) and beneficiary race

<sup>&</sup>lt;sup>21</sup> The revised OCM methodology is available at: <u>https://innovation.cms.gov/Files/x/ocm-pp3beyond-pymmeth.pdf</u>

subgroups. Subgroup impacts were estimated when we had adequate statistical power (i.e., sufficient episode volume) to detect meaningful differences between the OCM and comparison groups. We also used DID analyses to examine changes over time in patient care experiences for OCM patients relative to the changes for comparison patients.

DID impact estimates are presented along with upper and lower confidence intervals (at the 90 percent level) to show the degree of certainty about each result. Narrow confidence intervals indicate more-precise estimates. A confidence interval that does not encompass zero is a statistically significant result and is also shown with asterisks indicating the level of significance (\*10 percent, \*\*5 percent, \*\*\*1 percent).<sup>22</sup>

RELATED SECTIONS

**Appendix A** contains additional information about model specifications used in DID analyses, sensitivity tests, probability analyses, and the calculation of Medicare payments and net impact inclusive of MEOS and PBP.

We conducted sensitivity analyses for selected key outcome

measures. Sensitivity tests examined whether impact estimates changed when we varied model specifications, the time period measured, or the practice or episode samples used (see **Appendix A**).

#### 2.3.5 Estimating Net Impact on Medicare Spending

OCM's overall net impact on Medicare spending is the sum of changes in TEP, MEOS payments, and the PBP payments paid by Medicare to practices during PP1 through PP4.<sup>23</sup> To compute the estimated gross reduction in TEP, we first calculated the episode-level impact on TEP using our DID model. We multiplied this per-episode TEP impact by the number of episodes CMS attributed to OCM practices. To compute the net change in Medicare payments, we added total MEOS and PBP payments to our estimate of gross changes in TEP.

For PP3 and PP4, we also calculated the impact on Medicare spending (excluding PBP) separately among lower-risk episodes and higher-risk episodes. To compute savings/losses for lower-risk episodes, we aggregated MEOS payments specifically for lower-risk episodes, and added the gross reduction in TEP estimated for lower-risk episodes. We completed the same calculation of savings/losses for higher-risk episodes. We did not include PBP payments in these calculations, because PBP is paid at the practice level, not at the episode level.

For binary outcomes, we report the baseline and intervention adjusted absolute percentages as well as the absolute percentage point impact from the DID model with the upper and lower 90 percent confidence intervals. We also include the relative percentage change since baseline.

<sup>&</sup>lt;sup>23</sup> At the time of this report, first true-up reconciliation results with MEOS and PBP payments were available for the first four PPs, but not the fifth.

## 3. Is OCM Successful in Lowering Medicare Payments?

A key objective of OCM is to lower Medicare spending while maintaining or improving quality of care. The main measure of Medicare spending is TEP, which includes Medicare payments but not MEOS or PBP.

It is important to first understand the steep upward trend in cancer episode payments. In the baseline period before OCM began, TEP averaged about \$28,500 in both OCM and comparison episodes, and this increased to an average of more than \$33,200 in PP1–5 as treatment costs continued to rise. We evaluated whether the upward trend in TEP differed for OCM and comparison episodes, and which components of Medicare payment (Part A, B, or D) contributed to any relative changes. We also examined the impact of OCM among higher-risk and lower-risk episodes, and for individual cancer types, because the potential to reduce TEP may not be the same for every type of cancer. We estimated the impact of OCM overall through the first five PPs, and separately in each individual PP, to understand whether impacts evolved as the Model matured.

#### Key Findings

Total Episode Payment Impacts:

- TEP for both OCM and comparison episodes rose rapidly between the baseline and PP1-5, but TEP for OCM episodes increased \$297 less, which represents 1 percent of the baseline value. (See Section 3.1.)
- TEP for higher-risk episodes increased for both OCM and comparison episodes, but increased \$503 less in OCM higher-risk episodes. This relative reduction due to OCM was largest for four types of episodes: lung cancer, lymphoma, colorectal cancer, and high-risk breast cancer. (See Section 3.3.)
- For lower-risk episodes, TEP increased \$151 more in OCM episodes than in comparison episodes.

Payment subpart Impacts:

- The small relative reduction in TEP due to OCM was mainly driven by Part B payments, and especially payments for supportive care drugs. (See Section 3.2.)
  - Shifts toward less-costly but still effective white blood cell growth factors (used to reduce risk of infection), and less-costly bone modifying agents (used to prevent fractures), were among the changes in Part B supportive care drugs.
- Part A payments declined slightly in both OCM and comparison episodes, and declined \$114 more in OCM episodes.
- OCM had no impact on Part D prescription drug payments.
- OCM also had no impact on beneficiary cost-sharing for Part A, B and D services combined, or on patientreported out-of-pocket spending. (See Section 3.4.)

#### 3.1. Is OCM Reducing TEP During Six-Month Episodes? Does This Differ for Higher-Risk versus Lower-Risk Episodes?

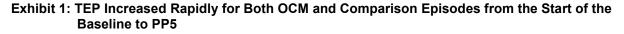
OCM practices can reduce TEP through many mechanisms, including (but not limited to) using lowercost drugs, preventing unnecessary ED visits and hospitalizations, reducing unnecessary imaging services and other outpatient services, and encouraging timely hospice care referral.

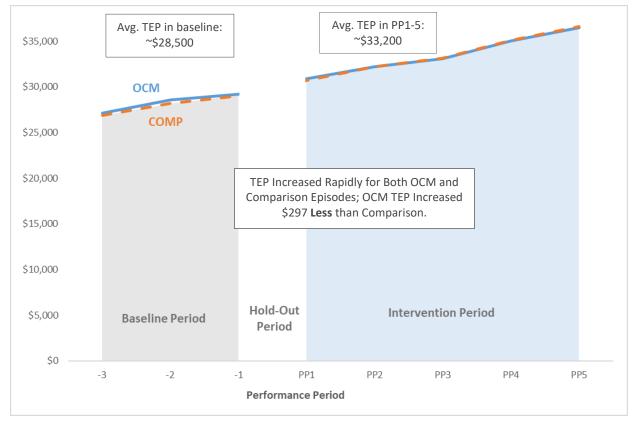
#### OCM led to a statistically significant reduction in TEP through PP5.



TEP increased rapidly for both OCM and comparison episodes, as shown in **Exhibit 1**. The increase was nearly 16 percent in OCM episodes and 17 percent in comparison episodes. TEP increased by \$297 less in OCM episodes than in comparison episodes (p<0.05), representing 1 percent of the mean OCM baseline value. This small, relative reduction in

TEP <sup>24</sup> began in PP2 and continued through PP5. It was not enough in any PP, however, to offset the averaged billed MEOS payments of \$704 per episode.





**Source**: Medicare claims 2014–2019. COMP: comparison group. OCM: OCM episodes. PP: performance period. TEP: total episode payments.

Treatment patterns, clinical severity, and episode costs vary considerably for different types of cancer. We applied OCM program rules to assign each OCM and comparison episode to one of 24 cancer types (and a group of miscellaneous non-reconciliation-eligible cancers).<sup>25</sup> We further grouped episodes for low-risk breast, low-intensity prostate, and low-risk bladder cancers into a "lower-risk" category, and classified the remainder, including episodes for non-reconciliation-eligible cancer types, into a "higher-risk" category.

During PP1–5, in both the OCM and comparison episodes, TEP averaged about \$46,500 for higher-risk episodes (about two-thirds of episodes) and about \$7,500 for lower-risk episodes (the remaining one-third of episodes).

<sup>&</sup>lt;sup>24</sup> We calculated average billed MEOS payments using PP1 through PP4 first true-up reconciliation results; PP5 first-true up results were not available at the time of this report.<sup>25</sup> Non-reconciliation-eligible cancers are eligible for MEOS but are excluded from CMS's calculations of PBP.

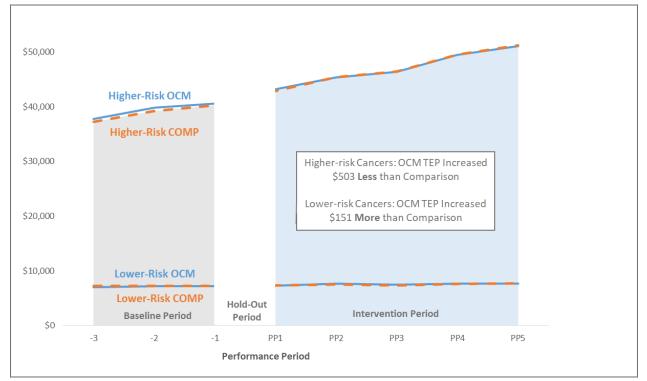
<sup>&</sup>lt;sup>25</sup> Non-reconciliation-eligible cancers are eligible for MEOS but are excluded from CMS's calculations of PBP.

# TEP rose less in OCM higher-risk episodes than in comparison episodes, but TEP rose more in OCM lower-risk episodes.

In our previous report for PP1–3, we showed that TEP increased less in OCM higher-risk episodes than in comparison higher-risk episodes, but increased more for lower-risk episodes. That pattern continued. As shown in **Exhibit 2**, TEP for OCM higher-risk episodes increased by almost 17 percent, from \$39,934 to \$46,697 per episode; this was \$503 less than the increase for comparison episodes (p<0.01). The relative reduction of \$503 represented 1.3 percent of the mean OCM baseline value.

In contrast, TEP rose slightly more in OCM lower-risk episodes than in lower-risk comparison episodes, by 151 (2.1 percent; p < 0.05). This relative increase represented 2.1 percent of the mean OCM baseline value of 7,226.

#### Exhibit 2: TEP Increased Rapidly for Higher-Risk Episodes and Stayed Relatively Flat for Lower-Risk Episodes. For Higher-Risk Episodes, the OCM Trend Was Somewhat Better Than the Comparison Trend, Because Slightly Higher OCM TEP in the Baseline Period Did Not Persist



**Source**: Medicare claims 2014–2019. COMP: comparison group. OCM: OCM intervention group. PP: performance period. TEP: total episode payments.

|                      | OCM TEP performance relative to<br>comparison group | Size of this relative change |  |  |
|----------------------|---|------------------------------|--|--|
| Higher Risk Episodes | \$503 less increase (p<0.01)                        | 1.3% of baseline             |  |  |
| Lower Risk Episodes  | \$151 more increase (p<0.05)                        | 2.1% of baseline             |  |  |
| All Episodes         | \$297 less increase (p<0.05)                        | 1.0 % of baseline            |  |  |

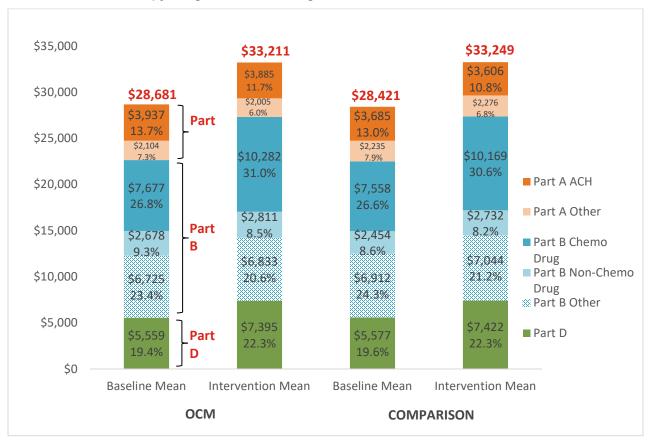
Source: Medicare claims 2014–2019.

One possible explanation for the different impacts of OCM on payments for higher- and lower-risk episodes is that treatment during higher-risk episodes typically involves more hospitalizations and ED visits, and many costly components (e.g., surgery, radiation therapy, advanced imaging, costly drugs), some of which may be amenable to reductions. Lower-risk episodes mainly involve hormonal therapies (for breast and prostate cancer) or intra-vesicular therapies (for bladder cancer); treatments that require periodic prescription refills or office-based treatments, and little more. There may therefore be fewer opportunities to reduce use and payments in lower-risk episodes. It is also possible that enhanced navigation and follow-up with even low-risk patients led OCM practices to identify and address additional patient complaints that might otherwise have gone unexplored (and potentially would have resolved without intervention), leading to small increases in services and payments.

# 3.2. On Which Components of Medicare Payments Is OCM Having the Most impact: Part A, Part B, or Part D? Does This Differ By Cancer Type?

TEP is composed of Part A, B and D payments. Part A payments include (in order of magnitude): inpatient care at ACHs, hospice care, and post-acute care. Part B payments include infused and injected drugs (e.g., chemotherapy drugs, supportive care drugs), physician services, radiation therapy, imaging, other outpatient services, and durable medical equipment. Part D payments are for prescription drug events.<sup>26</sup> OCM may have differential impacts on these three payment components if practices focus on reducing costs and improving quality in specific service settings. As described earlier, TEP increased 16 to 17 percent between the baseline and PP1-5 in OCM and comparison episodes. The largest increases, in dollars, were in payments for Part B chemotherapy drugs and Part D drugs (**Exhibit 4**).

<sup>&</sup>lt;sup>26</sup> For more information about Part A, B, and D coverage, see: <u>https://www.medicare.gov/what-medicare-covers/what-part-a-coverage-hospital-care</u>





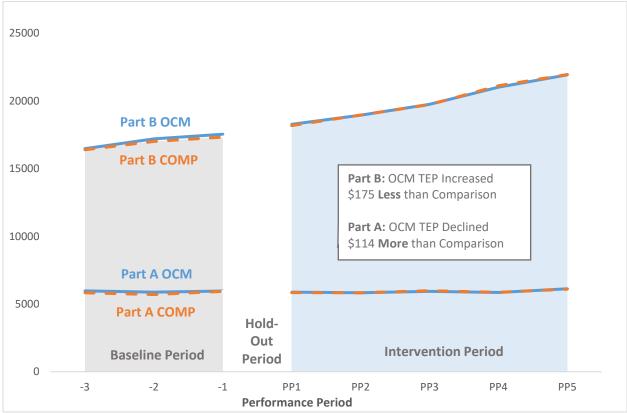
#### Source: Medicare claims 2014-2019.

**Notes**: Part D payments are calculated as the sum of low-income cost-sharing and reinsurance amounts, as reflected in Part D Events (PDE). ACH: acute care hospitals. COMP: comparison group. Int: Intervention period, PP1–5. OCM: OCM intervention group. TEP: total episode payments. Exhibit is based on all episodes. When limiting to beneficiaries enrolled in Part D, Part D payments made up 23 percent of TEP for OCM episodes in the baseline period and 27 percent of TEP for OCM episodes in the intervention period.

# *OCM led to a relative reduction in Part A episode payments and Part B episode payments, but had no impact on Part D episode payments.*

As described above, during the first five PPs, there was a small relative reduction in TEP of \$297 due to OCM, for all episodes combined. This came mainly from payments for Part A (which declined in both OCM and comparison episodes, but by \$114 more in OCM episodes) and from Part B (which rose in both OCM and comparison episodes, but by \$175 less in OCM episodes). Both of these relative reductions due to OCM were statistically significant (**Exhibits 5 and 6**).





Source: Medicare claims 2014–2019. COMP: comparison group. OCM: OCM episodes.

|                  | ОСМ              |             | СОМР             |          | Impact Estimates Through PP5 |            |            |                   |
|------------------|------------------|-------------|------------------|----------|------------------------------|------------|------------|-------------------|
| Measure          | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| TEP without MEOS | \$28,681         | \$33,211    | \$28,421         | \$33,249 | -\$297**                     | -\$504     | -\$91      | -1.0%             |
| Part A Payments  | \$6,042          | \$5,890     | \$5,920          | \$5,882  | -\$114**                     | -\$203     | -\$25      | -1.9%             |
| Part B Payments  | \$17,080         | \$19,926    | \$16,924         | \$19,945 | -\$175*                      | -\$340     | -\$9       | -1.0%             |
| Part D Payments  | \$6,664          | \$8,924     | \$6,716          | \$8,939  | \$36                         | -\$97      | \$169      | 0.5%              |

#### Exhibit 6: OCM Led to Relative Reductions in Overall TEP, Driven by Part A and Part B Payments

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

**Notes:** <sup>a</sup> Part D payments are calculated as the sum of low-income cost-sharing and reinsurance amounts, as reflected on the PDE. COMP: comparison group. DID: difference-in-difference. Int.: intervention period. LCL: lower confidence limit. MEOS: Monthly Enhanced Oncology Services payment. OCM: OCM intervention group. PP: performance period. TEP: total episode payments. UCL: upper confidence limit.

#### **Part A Payments**

#### Part A payments declined in both OCM and comparison episodes, but slightly more in OCM episodes.

Part A payments were 6,042 for OCM episodes in the baseline period (21 percent of TEP), and declined on average by 152 per episode during PP1–5; comparison episodes were 5,920 in the baseline period and declined by 38 per episode. Thus, OCM reduced Part A payments by 114 (p<0.05) more per episode relative to comparison episodes, representing a change of almost 2 percent of the mean OCM baseline. The relative reduction in Part A episode payments for individual PPs ranged from \$130 to \$158.

During case studies conducted in the first three years of the Model, we asked about opportunities to reduce episode spending. While hospital-based services (ED visits, hospitalizations) were not the largest element of episode costs, most leaders in the practices we visited expressed optimism about their ability to reduce these costs. They focused on reducing preventable hospital use through the following strategies: anticipating chemotherapy toxicity and ensuring that beneficiaries have necessary supportive therapy (e.g., antiemetics to reduce nausea and vomiting); faster response to beneficiary phone calls about chemotherapy side effects and pain; expanded access to same-day urgent care in the clinic setting; and more-proactive outreach to identify and address beneficiary needs. In addition, most OCM practices educated beneficiaries to "call us first" before going to a hospital ED. Participating practices made these changes because they expected that preventing, or quickly addressing, chemotherapy side effects would reduce Part A payments for hospital care and Part B payments for outpatient ED visits.

Despite practices' focus on reducing hospitalizations, OCM had no statistically significant impact on payments for ACH hospitalizations, or on any measure of ACH use, including ACH hospitalizations per episode, ICU admissions, or 30day unplanned readmissions. Payments for ACH hospitalizations accounted for more than 60 percent of Part A payments, but OCM had no impact on these payments.



See <u>Section 5</u> for additional details about OCM impacts on hospital-based services, and other services covered under Part A.

#### **Part B Payments**

#### Part B payments rose in both OCM and comparison episodes, but less in OCM episodes.

Part B payments averaged \$17,080 in OCM episodes during the baseline period before OCM began, and accounted for 60 percent of TEP. Part B payments in OCM episodes increased to \$19,926 in PP1-5, but the increase was \$175 less than would have been expected in the absence of OCM; p<0.10) (Exhibit 7). While this relative reduction due to OCM was statistically significant, it was small, representing 1 percent of the mean OCM baseline value.

Many leaders in the practices we visited acknowledged that Part B drugs are a major component of episode costs, but stated that drug prices and price increases are beyond their control. Many practice leaders and oncologists told us that they feel cost should not influence decisions about which chemotherapy or immunotherapy drugs to use in treating cancer, unless there is a clear therapeutically-equivalent and less costly treatment approach. Practice leaders may therefore have concentrated on opportunities to reduce Part B drug spending without asking oncologists to change anticancer treatment. For example, they focused on supportive care drugs, and situations where pharmacists can play a role in selecting lower-cost alternatives (e.g., biosimilars, some anti-emetics). Many practices also described efforts to standardize treatment patterns by adopting pathways programs or templated order sets, some of which are designed to incorporate cost as a factor in drug regimens.

OCM had no impact on Part B payments for chemotherapy drugs. Part B payments for chemotherapy drugs were \$7,677 for OCM episodes during the baseline period, and accounted for 27 percent of TEP. Part B payments for chemotherapy drugs in OCM episodes rose to \$10,282 in PP1–5. This rapid increase in payments for chemotherapy drugs was similar in comparison episodes. This is consistent with the reluctance practice leaders and oncologists expressed about considering cost when making treatment decisions, and with the drug price increases they described.

OCM led to a relative reduction in Part B payments for non-chemotherapy drugs. About 9 percent of TEP was for Part B non-chemotherapy drugs, for which payments in OCM episodes increased from \$2,678 to \$2,811 per episode. Payments in comparison episodes were similar, but the increase was less in OCM episodes, by \$145 (p<0.01). As suggested during our case studies, this relative reduction due to OCM was mainly in payments for supportive care drugs.

RELATED SECTIONS

details about the OCM impacts on use of specific services, and <u>Section 7.3</u> regarding supportive care drugs.

OCM had no impact on payments for radiation therapy. Radiation therapy uses high-energy radiation to kill cancer cells. Sometimes radiation is used after cancer surgery to kill any residual cancer cells, even when there is no definite tumor to shrink or destroy. Radiation may be from an external source, or from implanted radiation-emitting particles. Radiation therapy payments made up about 3 percent of TEP.

OCM led to slight relative decreases for imaging services, but not for E&M visits or laboratory services. Imaging services include various scans (e.g., CT, MRI) that can be used to find and measure tumors and to monitor for potential new tumors (metastases). Payments for imaging services, which made up about 3 percent of TEP, rose slightly less in OCM episodes than in comparisons (by \$18; p<0.01).

|                                       | ОСМ              |             | CO               | MP          | Impact Estimates Through PP5 |            |            |                   |
|---------------------------------------|------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|
| Measure                               | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| All Part B Payments                   | \$17,080         | \$19,926    | \$16,924         | \$19,945    | -\$175*                      | -\$340     | -\$9       | -1.0%             |
| Chemo Payments                        | \$7,677          | \$10,282    | \$7,558          | \$10,169    | -\$6                         | -\$141     | \$129      | -0.1%             |
| Chemo Administration Payments         | \$628            | \$666       | \$667            | \$696       | \$9                          | -\$5       | \$22       | 1.4%              |
| Cancer E&M Payments                   | \$389            | \$375       | \$353            | \$335       | \$3                          | -\$5       | \$12       | 0.9%              |
| Non-Cancer E&M Payments               | \$897            | \$893       | \$877            | \$881       | -\$7                         | -\$21      | \$6        | -0.8%             |
| Radiation Therapy Payments            | \$807            | \$809       | \$904            | \$891       | \$15                         | -\$7       | \$37       | 1.8%              |
| Imaging Payments                      | \$812            | \$824       | \$813            | \$843       | -\$18***                     | -\$29      | -\$8       | -2.2%             |
| Non-Chemo Drug Payments               | \$2,678          | \$2,811     | \$2,454          | \$2,732     | -\$145***                    | -\$218     | -\$72      | -5.4%             |
| Labs Payments                         | \$452            | \$472       | \$415            | \$435       | -\$0                         | -\$12      | \$11       | -0.1%             |
| Other Payments,<br>not Including MEOS | \$2,710          | \$2,761     | \$2,832          | \$2,904     | -\$21                        | -\$63      | \$21       | -0.8%             |

| Exhibit 7: Part B Payments Rose Less in OCM Episodes Than in Comparisons, Mainly Due to Non- |
|--|
| Chemotherapy Drugs   |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01

Source: Medicare claims 2014–2019.

Notes:. COMP: comparison group. DID: difference-in-differences. E&M: evaluation and management. Int.: intervention period. LCL: lower confidence limit. MEOS: Monthly Enhanced Oncology Services payment. OCM: OCM intervention group. UCL: upper confidence limit.

#### Part D Payments

#### OCM had no impact on Part D payments.

In the baseline period, Part D payments accounted for 23 percent of TEP, and rose from \$6,664 to \$8,924 among OCM episodes, an increase of more than 30 percent. This steep increase was similar in comparison episodes, and OCM had no relative impact. As a sensitivity analysis, we assessed the OCM impact on Part D gross drug costs, which includes payments from all payers (i.e., beneficiary, Part D plan, Medicare, third party payer). Results were very similar and OCM had no impact on Part D gross drug costs.

For higher-risk episodes, Part A payments rose by \$212 less than in comparison episodes (p<0.01) and Part B payments rose by \$287 less than in comparison episodes (p<0.05). OCM had no impact on Part D episode payments for higher-risk episodes (**Exhibit 8**).

In contrast, TEP rose by \$151 more for lower-risk OCM episodes than for comparison episodes (2.1 percent; p<0.05), representing 2.1 percent of the mean OCM baseline value of \$7,226. The increase was primarily due to Part B payments, which increased by \$80 more in OCM episodes (p<0.10).

## Exhibit 8: For Higher-Risk Episodes, TEP and Part A & B Payments Rose Relatively Less in OCM Episodes, But For Lower-Risk Episodes, TEP and Part B Payments Rose More

| Doursent             | ОСМ              |          | СОМР             |          | Impact Estimates Through PP5 |         |            |                   |  |  |
|----------------------|------------------|----------|------------------|----------|------------------------------|---------|------------|-------------------|--|--|
| Payment<br>Category  | Baseline<br>Mean | Int Mean | Baseline<br>Mean | Int Mean | DID                          | 90% LCL | 90%<br>UCL | Percent<br>Change |  |  |
| Higher-Risk Episodes |                  |          |                  |          |                              |         |            |                   |  |  |
| TEP                  | \$39,934         | \$46,697 | \$39,441         | \$46,707 | -\$503***                    | -\$802  | -\$204     | -1.3%             |  |  |
| Part A Payments      | \$7,987          | \$7,802  | \$7,817          | \$7,845  | -\$212***                    | -\$339  | -\$85      | -2.7%             |  |  |
| Part B Payments      | \$23,565         | \$27,841 | \$23,370         | \$27,933 | -\$287**                     | -\$526  | -\$49      | -1.2%             |  |  |
| Part D Payments      | \$10,490         | \$13,920 | \$10,371         | \$13,740 | \$61                         | -\$132  | \$255      | 0.6%              |  |  |
| Lower-Risk Episode   | es               |          |                  |          |                              |         |            |                   |  |  |
| TEP                  | \$7,226          | \$7,510  | \$7,329          | \$7,461  | \$151**                      | \$39    | \$264      | 2.1%              |  |  |
| Part A Payments      | \$2,292          | \$2,235  | \$2,248          | \$2,136  | \$55                         | -\$22   | \$133      | 2.4%              |  |  |
| Part B Payments      | \$4,459          | \$4,768  | \$4,581          | \$4,811  | \$80*                        | \$7     | \$152      | 1.8%              |  |  |
| Part D Payments      | \$534            | \$570    | \$558            | \$576    | \$18                         | -\$18   | \$54       | 3.3%              |  |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. TEP: total episode payments. UCL: upper confidence limit.

# 3.3. For Which Types of Cancer is OCM Having the Most Impact on Medicare Payments?

# The relative reduction in TEP for higher-risk episodes was primarily concentrated in episodes for high-risk breast cancer, lung cancer, colorectal cancer, and lymphoma. For three of these four, the main driver was a relative reduction in Part B payments.

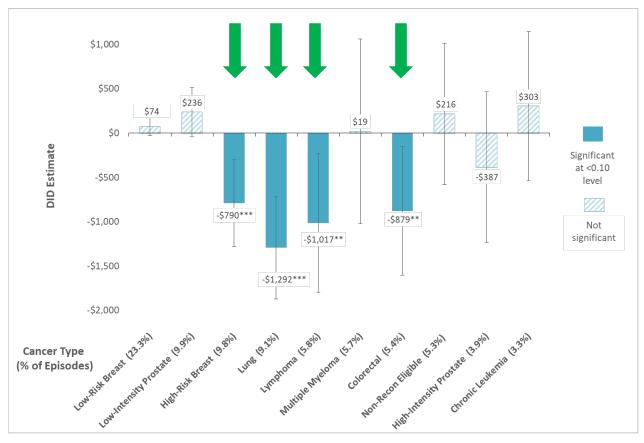
We examined OCM's impact on the nine cancer types with the highest episode volume, as well as the group of miscellaneous non-reconciliation-eligible cancers. The higher-risk episodes that generally had the largest episode volume-high-risk breast cancer, lung cancer, lymphoma, and colorectal/small intestine cancer—were also those for which the OCM trend was better (i.e., where TEP increases over time were lower in OCM episodes than in comparison episodes) (Exhibit 9). These four cancers collectively represented more than 30 percent of all episodes, and 45 percent of higher-risk episodes, and the average OCM baseline TEP exceeded \$35,000 for each of them. TEP increased less in OCM episodes relative to comparison episodes for the three solid tumor cancers (high-risk breast cancer, lung cancer, and colorectal cancer) primarily due a relative reduction in Part B payments, and especially payments for Part B nonchemotherapy drugs such as supportive therapy drugs. For



<u>Section 7.3</u> contains detailed analysis of supportive care drugs used to mitigate sides effects of chemotherapy, including:

- White blood cell growth factors to lower risk of infection
- Bone modifying agents used to prevent fracture
- Antiemetics used to prevent/reduce nausea

lymphoma episodes (which is a hematologic cancer, not a solid tumor) the relative reduction in TEP for OCM was not attributable to any single payment component.





#### OCM was associated with relative reductions in TEP for high-risk breast cancer episodes.

About 10 percent of all episodes, and 15 percent of higher-risk episodes, were for treatment of high-risk breast cancer. Among high-risk breast cancer episodes, TEP increased by more than \$5,000 in both OCM and comparison episodes, from the baseline period to PP1–5. However, the increase in TEP was \$790 less in OCM episodes (p<0.01), representing 2.2 percent of the mean OCM baseline value of \$35,533 (**Exhibit 10**). This relative reduction in TEP was almost sufficient to offset the average billed MEOS payments of \$799 for high-risk breast cancer episodes.<sup>27</sup>The reduction in TEP was almost entirely due to Part B payments, which rose by \$769 less in OCM episodes than in comparisons (p<0.01). Part B payments for chemotherapy drugs rose by \$468 less than in comparison episodes (p<0.05), and Part B payments for non-chemotherapy drugs, such as supportive therapy, rose by \$250 less than in comparison episodes (p<0.01).

DID: difference-in-differences. TEP: total episode payments.

Average billed MEOS for high-risk breast cancer was based on PP3 and PP4 first true-up reconciliation data. High-risk and low-risk breast cancer were not differentiated in the PP1 and PP2 reconciliation data.

| High-Risk       | ОСМ              |          | CO               | MP       | Impact Estimates |            |            |                   |
|-----------------|------------------|----------|------------------|----------|------------------|------------|------------|-------------------|
| Breast Cancer   | Baseline<br>Mean | Int Mean | Baseline<br>Mean | Int Mean | DID              | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| TEP             | \$35,533         | \$40,907 | \$34,418         | \$40,582 | -\$790***        | -\$1,279   | -\$302     | -2.2%             |
| Part A Payments | \$4,982          | \$4,772  | \$4,925          | \$4,634  | \$81             | -\$97      | \$260      | 1.6%              |
| Part B Payments | \$24,977         | \$27,336 | \$24,305         | \$27,434 | -\$769***        | -\$1,167   | -\$371     | -3.1%             |
| Part D Payments | \$6,866          | \$10,982 | \$6,447          | \$10,595 | -\$32            | -\$334     | \$270      | -0.5%             |

# Exhibit 10: OCM Led to a Relative Reduction in TEP and Part B Payments in High-Risk Breast Cancer Episodes

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. TEP: total episode payments. UCL: upper confidence limit.

#### OCM was associated with relative reductions in TEP for lung cancer episodes.

Lung cancer episodes represented nearly 9 percent of all episodes, and accounted for 14 percent of higher-risk episodes. TEP for lung cancer episodes rose by more than \$10,000 from the baseline period to PP1–5. The increase in TEP was \$1,292 less in OCM episodes than in comparison episodes (p<0.01), representing 3.2 percent of the mean OCM baseline value of \$39,918 (**Exhibit 11**). The relative reduction in TEP was nearly twice the average MEOS payment of \$734 for lung cancer episodes.<sup>28</sup> The relative reduction in TEP was especially evident in PP4 (\$1,537; (p<0.01), and in PP5 (\$1,984; p<0.01).

For lung cancer episodes, the relative reduction in TEP was primarily due to Part B payments, which rose \$833 less than in comparison episodes (p<0.05), and to a lesser extent Part A payments, which rose \$259 less than in comparison episodes (p<0.1). The relative reduction in Part B payments was due in part to non-chemotherapy drugs, for which relative reductions ranged from \$224 to \$394 across the PPs.

#### Exhibit 11: OCM Led to a Relative Reduction in TEP and Part B Payments in Lung Cancer Episodes

|                 | ОСМ              |          | СОМР             |          | Impact Estimates |            |         |                   |  |
|-----------------|------------------|----------|------------------|----------|------------------|------------|---------|-------------------|--|
| Lung Cancer     | Baseline<br>Mean | Int Mean | Baseline<br>Mean | Int Mean | DID              | 90%<br>LCL | 90% UCL | Percent<br>Change |  |
| TEP             | \$39,918         | \$51,285 | \$39,215         | \$51,874 | -\$1,292***      | -\$1,870   | -\$714  | -3.2%             |  |
| Part A Payments | \$9,411          | \$9,065  | \$9,107          | \$9,020  | -\$259*          | -\$507     | -\$10   | -2.7%             |  |
| Part B Payments | \$27,058         | \$37,459 | \$26,621         | \$37,855 | -\$833**         | -\$1,398   | -\$268  | -3.1%             |  |
| Part D Payments | \$4,525          | \$6,295  | \$4,601          | \$6,591  | -\$221           | -\$625     | \$183   | -4.9%             |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

Source: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. TEP: total episode payments. UCL: upper confidence limit.

#### OCM was associated with relative reductions in TEP for colorectal cancer episodes.

Colorectal/small intestine cancer episodes represented about 5 percent of all episodes and 8 percent of higher-risk episodes. TEP declined slightly in OCM episodes and increased slightly in comparison episodes, for a relative reduction of \$879 due to OCM (p<0.05). This represented 2.4 percent of the mean OCM baseline value of \$36,022 (Exhibit 12). As with lung cancer and high-risk breast cancer, the impact of OCM was mainly in Part B payments. For colorectal cancer, Part B payments declined in OCM episodes and increased in comparison episodes, yielding a relative reduction of \$777 (p<0.05). This was

<sup>&</sup>lt;sup>28</sup> Average billed MEOS for lung cancer was based on PP1–PP4 first-true up reconciliation data.

especially evident in payments for Part B non-chemotherapy drugs, for which there was a relative reduction of \$454 per episode (p<0.10).

|                 | ОСМ              |          | СОМР             |          | Impact Estimates |          |         |                   |  |
|-----------------|------------------|----------|------------------|----------|------------------|----------|---------|-------------------|--|
| Colorectal      | Baseline<br>Mean | Int Mean | Baseline<br>Mean | Int Mean | DID              | 90% LCL  | 90% UCL | Percent<br>Change |  |
| TEP             | \$36,022         | \$35,971 | \$35,103         | \$35,931 | -\$879**         | -\$1,605 | -\$153  | -2.4%             |  |
| Part B Payments | \$25,977         | \$25,713 | \$25,256         | \$25,769 | -\$777**         | -\$1,351 | -\$202  | -3.0%             |  |
| Part D Payments | \$2,608          | \$2,952  | \$2,515          | \$2,675  | \$185            | -\$47    | \$417   | 7.1%              |  |

Exhibit 12: OCM Slowed the Growth in TEP and Part B Payments for Colorectal Cancer

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

Source: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. TEP: total episode payments. UCL: upper confidence limit. Part A payments are not included in this table because the impact estimate could not be reliably reported due to failure of the parallel trends assumption.

#### OCM was associated with relative reductions in TEP for lymphoma episodes.

About 6 percent of all episodes, and 9 percent of higher-risk episodes, were for lymphoma. TEP for lymphoma episodes increased by more than \$4,000 per episode for both OCM and comparison episodes from the baseline period to PP1–5. TEP rose \$1,017 less in OCM episodes than in comparison episodes (p<0.05), representing 2.3 percent of the mean OCM baseline value of \$43,357 (Exhibit 13). Unlike the three solid tumor cancers above, no single payment component had a statistically significant impact on TEP. Rather, relative reductions Part A, Part B, and Part D payments combined to generate the relative reduction in TEP for lymphoma episodes.

#### Exhibit 13: OCM Led to a Relative Reduction in TEP for Lymphoma Episodes

| Lymphoma        | ОСМ              |          | СОМР             |          | Impact Estimates |          |         |                   |  |
|-----------------|------------------|----------|------------------|----------|------------------|----------|---------|-------------------|--|
|                 | Baseline<br>Mean | Int Mean | Baseline<br>Mean | Int Mean | DID              | 90% LCL  | 90% UCL | Percent<br>Change |  |
| TEP             | \$43,357         | \$47,990 | \$44,035         | \$49,685 | -\$1,017**       | -\$1,803 | -\$232  | -2.3%             |  |
| Part A Payments | \$7,534          | \$7,404  | \$7,451          | \$7,726  | -\$405           | -\$844   | \$34    | -5.4%             |  |
| Part B Payments | \$30,963         | \$35,251 | \$31,623         | \$36,247 | -\$336           | -\$915   | \$242   | -1.1%             |  |
| Part D Payments | \$6,475          | \$7,140  | \$6,633          | \$7,600  | -\$301           | -\$787   | \$185   | -4.7%             |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

Source: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. TEP: total episode payments. UCL: upper confidence limit.

#### 3.4. Is OCM Impacting Beneficiary Cost-Sharing or Out-of-Pocket Spending?

Financial burden for beneficiaries may pose barriers to seeking appropriate care and treatment, and may adversely affect health outcomes. Conversely, reducing financial burden could lower barriers, improve adherence to treatment regimens, improve outcomes, and have other benefits for beneficiaries.

We assessed the impact of OCM on beneficiary financial burden in two ways. First, we used Medicare claims to measure beneficiary cost-sharing, which reflects the deductibles and coinsurance/copays that beneficiaries are responsible for when receiving services and drugs paid for by Medicare Part A, Part B,

and Part D. <sup>29,30</sup> Many beneficiaries have supplemental insurance that covers the cost-sharing amounts for Part A and Part B, but there is no supplemental insurance for Part D cost-sharing (and some beneficiaries do not enroll in Part D). Beneficiaries who require assistance with Part D prescription drug costs/copayments must pursue individual arrangements, such as grants from foundations. Supplemental coverage and other financial assistance is not reflected in claims-based measures of cost-sharing. For these reasons, we also measured the impact of OCM on beneficiary financial burden by asking survey respondents how much they paid out of pocket (OOP) in the past year for cancer-related care and services.

All OCM practices we visited throughout the evaluation told us that they advise Medicare beneficiaries about the OOP costs that insurance will not cover, and most try to locate additional resources (e.g., charitable foundations) for beneficiaries with high OOP costs and

financial hardship. When no other assistance is available, some practices help beneficiaries find financial support to cover other expenses (e.g., rent, utility bills, transportation) so they can better afford their cancer care OOP costs. The financial counselors at one practice told us that OCM instilled a renewed focus on finding financial assistance, reducing stress for beneficiaries who might otherwise have declined treatment because of the financial burden.

A few practices told us they share both OOP costs and total cost of treatment with beneficiaries, even with those who will have low OOP costs. A few other practices told us that they discontinued sharing information about total cost of cancer treatment, because beneficiaries find this confusing and mainly want to know their OOP costs.

#### **Insights from the Field**

An OCM practice created a shared decision making tool that compares total cost of care, OOP costs, potential risks and benefits, expected survival, and impact on quality of life for each potential treatment option an oncologist is weighing for a patient— including the option of no treatment. In a small pilot test, patients were interested in seeing total cost as well as OOP cost. An oncologist described one patient who selected a lower-cost treatment regimen as the more socially responsible choice, even though OOP costs were the same.

#### OCM had no impact on beneficiary cost-sharing or patient-reported OOP spending.

Cost-sharing, as measured using Medicare claims data, rose from about \$5,500 to over \$6,200, for both the OCM and comparison episodes. OCM had no relative impact on beneficiary cost-sharing for Part A, B, and D services combined (Exhibit 14). Part B beneficiary cost-sharing rose by \$56 less in OCM episodes than in comparisons (p<0.05), and this difference was statistically significant starting in PP2. Conversely, Part D beneficiary cost-sharing increased by \$20 more than in OCM than comparison episodes (p<0.05), and this was consistent in all five PPs.

<sup>&</sup>lt;sup>29</sup> For Part A and B cost-sharing, beneficiaries may have secondary insurance (Medicaid or supplemental/employer-based policies), but these supplemental payments are not included in the cost-sharing measures. Part D cost-sharing applies only to beneficiaries enrolled in Part D plans. Part D beneficiary costsharing includes payments made by some third-party payers (e.g., state pharmacy assistance programs, charities) that reduce the beneficiary's liability, but does not include payments that reduce beneficiary liability from other types of supplemental sources (e.g., group health plans, worker's compensation, TRICARE).

<sup>&</sup>lt;sup>30</sup> Part D beneficiary cost-sharing involves multiple elements that depend on the Part D plan's benefit structure (e.g., defined standard, enhanced alternative), including formulary coverage, drug tiers benefit coverage phases (e.g., initial, catastrophic), pharmacy types, and other factors.

|  | ОСМ              |             | СОМР             |             | Impact Estimates Through PP5 |            |            |                   |
|--|------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|
| Measure                                      | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| Total Beneficiary Cost-Sharing               | \$5,587          | \$6,216     | \$5,535          | \$6,209     | -\$45                        | -\$93      | \$3        | -0.8%             |
| Part A Beneficiary Cost-Sharing              | \$461            | \$441       | \$446            | \$429       | -\$3                         | -\$10      | \$4        | -0.7%             |
| Part B Beneficiary Cost-Sharing              | \$4,509          | \$5,085     | \$4,463          | \$5,096     | -\$56**                      | -\$102     | -\$11      | -1.2%             |
| Part D Beneficiary Cost-Sharing <sup>a</sup> | \$739            | \$830       | \$751            | \$821       | \$20**                       | \$6        | \$33       | 2.7%              |

#### Exhibit 14: OCM Reduced Beneficiary Cost-Sharing for Part B Services, but Led to Small Increases in Part D Cost-Sharing

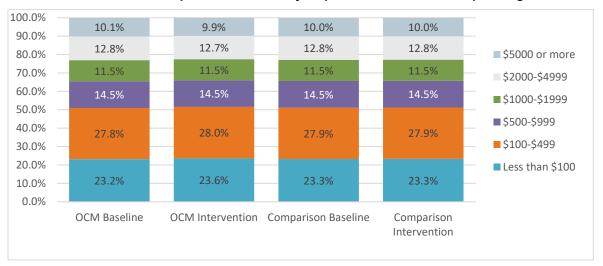
Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01 **Source:** Medicare claims 2014–2019.

**Notes:** <sup>a</sup>Part D beneficiary cost-sharing is calculated as the sum of patient-paid amount and other true out-of-pocket (TrOOP) amounts, as reflected on the PDE. Part A and Part B cost-sharing (deductibles and co-insurance) are often covered by supplemental insurance and may not reflect out-of-pocket costs. COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.



In our patient survey, we ask about OOP spending for cancer-related services, drugs, and care. There were no differences between OCM and comparison survey respondents in the baseline survey, and no changes over time in either group, as shown in **Exhibit 15**.

#### Exhibit 15: OCM Had No Impact on Beneficiary-Reported Out-Of-Pocket Spending



**Source:** Patient Surveys, Alternative Surveys, and End-of-Life Surveys at baseline (April–September 2016) and intervention period (July–December 2018).

Based on these two measurement approaches, we conclude that OCM did not affect beneficiary financial burden.

## 4. Is OCM Generating Net Savings for Medicare?

While OCM led to a relative reduction in episode payments, this does not mean that OCM generated net savings for Medicare, because TEP does not include the monthly additional payments (referred to as MEOS) or the Performance Based Payment (PBP) incentive amounts that Medicare pays to participating practices. We calculated the overall net financial impact of OCM on Medicare by incorporating MEOS and PBP payments, along with the relative reductions in TEP, for PP1 through PP4.<sup>31</sup> For PP3 and PP4, we also calculated the impact of OCM—including MEOS but not PBP— separately for higher-risk episodes and lower-risk episodes, to understand whether savings or losses to Medicare differed between those two categories.<sup>32</sup>

#### **Key Findings**

- Overall, the gross savings in TEP, when applied to all episodes, was less than the combined MEOS and PBP payments, translating to net losses for Medicare.
- Including the gross impacts on Medicare payments, plus MEOS and PBP payments, OCM resulted in net losses to Medicare in each PP (PP1–PP4), ranging from \$66 million to \$100 million per period. Total estimated losses for Medicare for the first four PPs combined was \$315.6 million.
- OCM led to losses for both higher-risk and lower-risk episodes, and losses were greater for lower-risk episodes.

#### OCM resulted in net losses to Medicare in each PP (PP1-PP4).

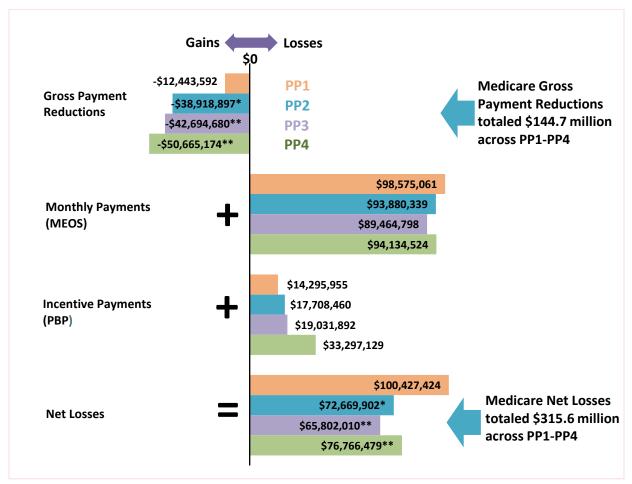
From PP1 through PP4, OCM led to cumulative net Medicare losses of \$315.6 million (Exhibit 16). Net losses were largest in PP1 (\$100.4 million), and smallest in PP3 (\$65.8 million).

Net gains/loss is a product of three pieces: the gross reduction in Medicare payments, the MEOS payments, and the PBPs. The gross payment reductions (due to the relative reductions in TEP) ranged from about \$12M to \$50M across the PPs. MEOS payments were fairly consistent across the PPs. Finally, PBP payments were larger in PP4 (\$33.3 million) than in PP3 (\$19 million).<sup>33</sup> This led to greater net losses in PP4 than in PP3, despite larger gross payment reductions in PP4. In every PP except PP1, the gross payment reductions were sufficient to cover PBP payments (which ranged from \$14M to \$33M), but were not ever enough to cover MEOS payments (which ranged from \$89M to \$98M).

<sup>&</sup>lt;sup>31</sup> At the time of this report, first true-up reconciliation results were not available for PP5. Thus, the gross results presented in the prior chapter cover PPs 1 to 5 while the net results presented in this chapter only cover PPs 1-4.

<sup>&</sup>lt;sup>32</sup> Since PBP is paid to practices and not defined for each episode, we did not include PBP in the savings/losses estimates for higher- and lower-risk episodes.

<sup>&</sup>lt;sup>33</sup> PBPs are a function of practices meeting cost and quality thresholds. The size of the payment is determined in part by the degree to which practices exceed cost thresholds. The methodology for determining this threshold and calculating the PBP is an actuarial-based projection, and is distinct from the difference-in-difference approach used in the evaluation to assess of gross savings. For information please see the <u>OCM PBP</u> <u>Methodology Report.</u>





Asterisks denote statistically significant impact estimates at \*p<0.10 and\*\*p<0.05.

Source: Medicare claims 2014–2018. OCM first true-up reconciliation reports, PP1–PP4.

**Notes**: MEOS: Monthly Enhanced Oncology Services payment. PBP: performance-based payments. PP: Performance Period. TEP: total episode payments.

# OCM led to Medicare net losses for both higher-risk and lower-risk episodes; losses were greater for lower-risk episodes.

As described earlier, TEP (without MEOS) averaged about \$7,500 for lower-risk episodes (roughly onethird of episodes), and about \$46,500 for higher-risk episodes (the remaining two-thirds of episodes). OCM practices can submit claims for MEOS payments for both categories of cancer episodes. It may be more challenging to reduce TEP enough to cover MEOS for the lower-risk episodes, where MEOS payments could be nearly 13 percent of TEP, than for higher-risk episodes, where MEOS payments would be only 2 percent of TEP.

To understand how the two categories of episodes contributed to Medicare losses, we focused on PP3 and PP4, and added MEOS payments to the gross TEP impact, separately for higher-risk and lower-risk episodes. We did not include PBP paid to practices in this analysis, since PBPs are not episode-level payments and cannot be readily be assigned to specific episodes.

In PP3, when including gross payment reductions and MEOS payments (but not PBP), OCM resulted in net losses to Medicare of \$34.6M for lower-risk episodes (**Exhibit 17**), and net losses of \$11.5M for higher-risk episodes. Without considering PBP, the PP3 gross payment reductions for higher-risk episodes was almost enough to "cover" MEOS payments, leading to relatively modest losses for

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<br>of<br>Episodes | Gross<br>Impact on<br>TEP | MEOS<br>Payments | Impact on<br>TEP + MEOS<br>(Losses) | Losses as<br>Percentage<br>of TEP | Losses<br>per<br>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.

## 5. Is OCM Affecting Service Use Patterns?

As described in the sections above, OCM led to relative reductions in TEP, Part A payments, and Part B payments. In this section, we examine OCM practices' care transformation efforts, and resulting service use changes, to understand how those payment reductions were achieved.

#### **Key Findings**

OCM did not have a measurable impact on key utilization measures. This was somewhat unexpected because during evaluation case studies, OCM practices described efforts to streamline triage of patient phone calls, and to bring patients into the clinic to address chemotherapy toxicity, in an effort to reduce ED visits and hospitalizations. Specifically:

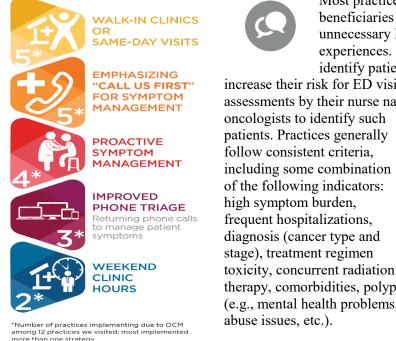
- OCM had no impact on Outpatient ED visits or payments. These measures changed similarly in OCM and comparison episodes.
- OCM had no overall impact on ACH use.
- OCM had no meaningful impact on ED visits or hospitalizations for chemotherapy-related toxicity during higher-risk episodes.
- OCM had no impact on E&M services or payments.
- OCM led to small relative reductions in payments for imaging services, but had no impact on payments
  or use of radiation therapy services.

We did not find any OCM impacts on specific hospital or outpatient service utilization (other than drugs) that explain the payment reductions noted earlier. It is likely that OCM practices each made small changes in different ways based on their unique context and patient populations that together reduced TEP payments. However, these changes were not sufficiently consistent to generate a statistically significant impact on the use of any specific type of service.

# OCM practices continued to focus on preventing ED visits and hospitalizations as their main strategy to reduce Medicare payments.

The OCM practices we visited in the first three years of the Model focused primarily on reducing ED visits. This was an important focus for virtually every practice we visited, even though most practices acknowledged that drug costs, not ED visits, are the main driver of episode costs. Many interviewees suggested that preventing ED visits is one of the few strategies that an oncology practice can implement to both reduce Medicare spending and improve patients' care experiences. The most common tactics for reducing ED visits are described below.

#### Exhibit 18: Strategies to **Reduce ED Visits (among** Year 3 case studies)



To reduce ED visits, many OCM practices focused on identifying beneficiaries with high medical and social needs and offering proactive outreach, close monitoring, and care coordination.



Most practices we've visited identify high-risk beneficiaries and monitor them closely, to prevent unnecessary ED visits and improve patient care experiences. Most do not use a standardized tool to identify patients with medical or social needs that

increase their risk for ED visits. Rather, practices rely on expert assessments by their nurse navigators, care coordinators, and

Insights from the Field

An academic practice created an algorithm to identify patients likely to visit an ED. It incorporates diagnosis, toxicity of chemotherapy, comorbidities, social supports, and demographic/social factors, as well as past ED utilization.

therapy, comorbidities, polypharmacy, age, and psychosocial issues (e.g., mental health problems, lack of social support, substance abuse issues, etc.).

#### Despite practices' efforts to reduce ED visits, OCM had no overall impact on ED visits, or on acute care hospitalizations.



There was no OCM impact on measures of acute care hospitalization. Payments for ACH hospitalizations comprised almost 14 percent of TEP, and 65 percent of Part A payments, during episodes. As noted earlier, OCM had no impact on ACH payments. OCM also had no effect on

any measure of ACH use (Exhibit 19). Hospitalizations declined similarly and slightly in OCM and comparison episodes, as did ICU admissions and 30-day unplanned readmissions. There was no additional impact of OCM beyond



For more details on payments for ACH hospitalizations, see Section 3.2: components of Medicare payments Part A, Part B and Part D.

what was occurring in comparison episodes. It is possible that other pressures, unrelated to OCM, were reducing hospital-based care during this time period. For example, the Medicare hospital readmission reduction program<sup>34</sup> emphasizes the prevention of unplanned readmissions, which would affect both OCM and comparison episodes.

<sup>34</sup> An explanation of the Medicare Hospital Readmission Reduction Program can be found here: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program

|   | 00                   | M           | COI              | MP          | Impact Estimates Through PP5 |            |            |                   |  |  |  |  |
|---|----------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|--|--|--|--|
| Measure                                       | Baseline<br>Mean     | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |  |  |  |
| ACH Hospital Measures                         |                      |             |                  |             |                              |            |            |                   |  |  |  |  |
| Occurrence of ACH<br>Hospitalization          | 27.5%                | 25.6%       | 26.1%            | 24.1%       | 0.2%                         | -0.2%      | 0.5%       | 0.6%              |  |  |  |  |
| Number of ACH Hospitalizations                | 0.433                | 0.400       | 0.407            | 0.374       | 0.001                        | -0.007     | 0.008      | 0.2%              |  |  |  |  |
| Number of ACH Days                            | 8.576                | 8.300       | 8.465            | 8.225       | -0.038                       | -0.138     | 0.063      | -0.4%             |  |  |  |  |
| ACH Payments                                  | \$3,937              | \$3,885     | \$3,685          | \$3,606     | \$27                         | -\$50      | \$105      | 0.7%              |  |  |  |  |
| Readmission Measures                          | Readmission Measures |             |                  |             |                              |            |            |                   |  |  |  |  |
| Occurrence of 30-Day<br>Unplanned Readmission | 20.9%                | 20.3%       | 20.3%            | 20.0%       | -0.3%                        | -0.7%      | 0.2%       | -1.2%             |  |  |  |  |
| Number of 30-Day Unplanned<br>Readmissions    | 0.095                | 0.086       | 0.087            | 0.079       | -0.001                       | -0.004     | 0.001      | -1.5%             |  |  |  |  |
| 30-Day Unplanned Readmission<br>Payments      | \$889                | \$847       | \$813            | \$778       | -\$8                         | -\$38      | \$22       | -0.9%             |  |  |  |  |
| ICU Measures                                  |                      |             |                  |             |                              |            |            |                   |  |  |  |  |
| Occurrence of ACH ICU<br>Admissions           | 10.0%                | 9.5%        | 9.3%             | 9.0%        | -0.2%                        | -0.5%      | 0.1%       | -2.2%             |  |  |  |  |
| Number of ACH ICU Admissions                  | 0.124                | 0.118       | 0.114            | 0.112       | -0.003                       | -0.008     | 0.001      | -2.6%             |  |  |  |  |

#### Exhibit 19: OCM Had No Impact on Measures of Acute Care Hospitalizations

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source:** Medicare claims 2014–2019.

**Notes:** ACH: acute care hospitals. ACH: acute care hospitals. COMP: comparison group. DID: difference-in-differences. ICU: intensive care unit. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

OCM had no impact on ACH hospitalizations overall or during higher-risk episodes, but led to a small relative increase in hospitalizations during lower-risk episodes (6 more hospitalizations per 1,000 lower-risk episodes; p<0.05). This was mainly evident in episodes for low-risk breast cancer, in which ACH hospitalizations declined, but slightly less so than in comparison episodes. Since beneficiaries with low-risk breast cancer would not be expected to need hospitalization for problems related to their cancer, it is possible that the relative increase in hospitalizations does not indicate a quality concern. For example,

increased monitoring and calls with these patients may have uncovered non-cancer symptoms or issues that clinicians felt warranted additional attention (e.g., a patient mentioning chest pain to her nurse navigator, who referred her for a cardiac work-up, leading to hospitalization for cardiac care). OCM had no impact on hospital use during episodes for any of the other common cancer types (Appendix B-Payment and Utilization Analyses).

#### OCM had no impact on ED visits or related payments.

OCM had no impact on outpatient ED visits or payments overall, or for higher-risk or lower-risk episodes.

#### Among higher-risk episodes, OCM had no clinically meaningful impact on chemotherapy-related hospitalizations.

For beneficiaries with higher-risk episodes, side effects of toxic chemotherapy are a leading cause of ED visits and

#### **Insights from the Field**

- Three OCM practices we visited changed where they refer beneficiaries for imaging services, directing them to lower-cost imaging centers.
- One practice's internally-developed treatment pathways include imaging and lab services, which helped reduce imaging and lab payments by replacing costly PET scans with CT scans for routine monitoring of advanced cancer.
- One OCM practice followed National Comprehensive Cancer Network (NCCN) guidelines and shifted inpatient chemotherapy treatments for many beneficiaries with leukemia, lymphoma, sarcoma, or germ cell tumors to the lesscostly outpatient setting.

hospitalizations. Many practices told us that they use systematic approaches/tools to identify beneficiaries undergoing especially toxic treatments and support them in the clinic setting. Despite these efforts, OCM had no impact on chemotherapy-related hospitalizations among episodes for higher-risk episodes. As shown in **Appendix B**, OCM led to a slight 0.3 percent relative reduction (p<0.10) in the occurrence of a chemotherapy-related outpatient ED visit, which we judge to be not clinically meaningful. We compared early (PP1–PP3) versus late (PP4–PP5) effects, in case impacts took longer to manifest, and found no statistically significant differences between the two time periods.

#### The OCM impact on other outpatient services varied.

OCM led to a very small relative reduction in the number of standard and other imaging services per episode (46 fewer imaging services per

1,000 episodes). This is consistent with a slightly lower increase in payments for imaging services, as noted earlier.

Outpatient rehabilitation therapy includes physical therapy, occupational therapy, and speech-language pathology services. OCM had no clinically meaningful impact on the occurrence of episodes with any outpatient therapy visit, or on the number of outpatient therapy visits per episode (**Exhibit 20**).



For more details on payments for imaging and other services, <u>see Section 3.2</u>, on Medicare payments—Part A, Part B, and Part D—and **Appendix A**.

### Exhibit 20: OCM Led to Small Relative Reductions in Imaging Payments, but Had No Impact on E&M Services or Related Payments

|  | OC               | М           | CON              | ΛP          | Impa     | ct Estimat | es Throug  | h PP5             |  |  |  |
|--|------------------|-------------|------------------|-------------|----------|------------|------------|-------------------|--|--|--|
| Measure  | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID      | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |  |  |
| E&M Services                                     |                  |             |                  |             |          |            |            |                   |  |  |  |
| Number of E&M Services                           | 21.013           | 19.526      | 20.200           | 18.845      | -0.133   | -0.594     | 0.328      | -0.6%             |  |  |  |
| E&M Payments                                     | \$1,285          | \$1,267     | \$1,230          | \$1,216     | -\$4     | -\$22      | \$14       | -0.3%             |  |  |  |
| Number of Cancer-Related E&M Services            | 5.284            | 5.082       | 5.038            | 4.797       | 0.039    | -0.058     | 0.137      | 0.7%              |  |  |  |
| Cancer E&M Payments                              | \$389            | \$375       | \$353            | \$335       | \$3      | -\$5       | \$12       | 0.9%              |  |  |  |
| Imaging Services                                 |                  |             |                  |             |          |            |            |                   |  |  |  |
| Number of Standard and Other<br>Imaging Services | 4.441            | 3.953       | 4.400            | 3.958       | -0.046*  | -0.086     | -0.006     | -1.0%             |  |  |  |
| Number of Advanced Imaging<br>Services           | 3.491            | 3.532       | 3.523            | 3.599       | -0.035   | -0.084     | 0.014      | -1.0%             |  |  |  |
| All Imaging Payments                             | \$812            | \$824       | \$813            | \$843       | -\$18*** | -\$29      | -\$8       | -2.2%             |  |  |  |
| Standard and Other Imaging<br>Payments           | \$206            | \$204       | \$199            | \$201       | -\$4     | -\$9       | \$0        | -2.1%             |  |  |  |
| Advanced Imaging Payments                        | \$606            | \$621       | \$614            | \$642       | -\$14**  | -\$23      | -\$5       | -2.3%             |  |  |  |
| Outpatient Therapy Services                      |                  |             |                  |             |          |            |            |                   |  |  |  |
| Occurrence of Outpatient Therapy<br>Services     | 8.6%             | 9.0%        | 8.8%             | 9.5%        | -0.2%*   | -0.5%      | -0.0%      | -2.8%             |  |  |  |
| Number of Outpatient Therapy<br>Services         | 1.748            | 1.850       | 1.779            | 1.879       | 0.003    | -0.061     | 0.067      | 0.2%              |  |  |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

Source: Medicare claims 2014–2019.

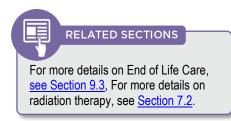
Notes: COMP: comparison group. DID: difference-in-differences. E&M: evaluation and management. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

### **OCM** had no impact on the use of post-acute care services or hospice care.

As discussed earlier, OCM had no impact on Part A payments for care provided by hospices, skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, or long-term care hospitals. Similarly, OCM had no impact on use of hospice care, skilled nursing facility care, or HHA services, overall or for any individual PP.

#### OCM had no impact on payments or use of radiation therapy services.

OCM had no impact on Part B radiation therapy services or payments. The lack of impact on radiation therapy is consistent with findings from other analyses that show no OCM impact on low-value long-course or intensity-modulated radiotherapy (IMRT) radiation therapy for breast cancer treatment, or on shorter courses of radiation therapy for bone metastases.



### 6. Is OCM Affecting Payments for Chemotherapy and Other Drugs, or Patient Adherence to Drug Treatment Regimens?

We examined use of, and payment for, Part B chemotherapy drugs and non-chemotherapy drugs; the latter include drugs often prescribed in conjunction with cancer treatment (e.g., supportive care drugs). We assessed payments for Part D drugs overall, the vast majority of which were for oral chemotherapy medications. Because better adherence to oral drug treatment regimens could lead to increases in Medicare payments, we also assessed adherence to costly Part D drugs.

#### Key Findings

- OCM led to a relative reduction in payments for Part B non-chemotherapy drugs. This was especially true for supportive care drugs that are used to prevent and manage side effects of chemotherapy treatment.
  - o Impacts were mainly in higher-risk episodes.
- OCM had no impact on Part B payments for chemotherapy drugs, and no impact on Part D payments, both of which are important contributors to TEP.
- OCM did not improve overall adherence to Part D (oral) drug treatment regimens for chronic myelogenous leukemia (CML), high-intensity prostate cancer, or low-risk breast cancer episodes. On the other hand, OCM led to modest improvements in adherence to high-cost oral drugs for prostate cancer and for CML among Black beneficiaries, who had lower adherence than White beneficiaries before OCM began.

#### 6.1. Is OCM Affecting Part B Chemotherapy or Non-Chemotherapy Drug Payments?

Part B payments are a large component of TEP, especially payments for Part B drugs, and as described earlier, OCM led to a relative reduction in Part B payments. We explored changes in payment for Part B chemotherapy drugs and non-chemotherapy drugs. Within the latter category we drilled down to examine supportive care drugs, and specific types of supportive care drugs, to understand the drivers of Part B payment reductions.

#### OCM had no impact on Part B payments for chemotherapy drugs.



Payment for Part B chemotherapy drugs averaged \$7,677, or 27 percent of TEP, for OCM episodes in the baseline period. This increased to \$10,282,

or 31 percent of TEP, in PP1–5. The dollar amounts and large increases were very similar in comparison episodes, and OCM had no impact on payments for Part B chemotherapy

drugs. This is consistent with many interviewees' comments that they do not want cost to influence the drugs oncologists use to treat cancer. OCM also had no overall impact on payments for Part B



See Sections 3.2 and  $\underline{7.3}$  for more on supportive care drugs.

chemotherapy drugs for either higher-risk or lower-risk episodes. The only common cancer type where OCM had an impact on Part B chemotherapy payments was high-risk breast cancer episodes, for which payments declined by \$468 (p<0.05) relative to comparisons, representing 3.6 percent of the mean OCM baseline value. This relative reduction was unrelated to payments for novel therapies, which were similar in OCM and comparison episodes.

### IS OCM AFFECTING PAYMENTS FOR CHEMOTHERAPY AND OTHER DRUGS, OR PATIENT ADHERENCE TO DRUG TREATMENT REGIMENS?

#### OCM reduced spending on Part B non-chemotherapy drugs, especially for supportive care drugs.

Payment for non-chemotherapy drugs averaged \$2,678 or 9 percent of TEP in OCM episodes during the baseline period. This increased slightly to \$2,811 in PP1–5. This increase was \$145 less than the increase for comparison episodes (p<0.01). The relative reduction in non-chemotherapy drug payments increased in magnitude over time, to \$208 in PP5 (p<0.01).

The reduction in payments for Part B non-chemotherapy drugs was primarily for supportive care drugs, for which payments rose by \$150 less than in comparison episodes (p<0.01) Supportive care drugs include antiemetic (i.e., anti-nausea) medications; white blood cell, red blood cell, and platelet growth factors; and bone-modifying agents to prevent fractures. More than half of the relative reduction in supportive care drug payments was due to payments for white blood cell growth factors (**Exhibit 21**).

|  | 00               | M           | CO               | MP          | Impact Estimates Through PP5 |            |            |                   |  |
|--|------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|--|
| Measure  | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| Part B Payments <sup>†</sup>                       | \$17,080         | \$19,926    | \$16,924         | \$19,945    | -\$175*                      | -\$340     | -\$9       | -1.0%             |  |
| Part B Chemo Payments                              | \$7,677          | \$10,282    | \$7,558          | \$10,169    | -\$6                         | -\$141     | \$129      | -0.1%             |  |
| Part B Non-Chemo Drug<br>Payments                  | \$2,678          | \$2,811     | \$2,454          | \$2,732     | -\$145***                    | -\$218     | -\$72      | -5.4%             |  |
| Sub-categories of Non-Chemo P                      | art B Drugs      |             |                  |             |                              |            |            |                   |  |
| Part B Supportive Care Drug<br>Payments            | \$2,215          | \$2,238     | \$2,054          | \$2,227     | -\$150***                    | -\$216     | -\$84      | -6.7%             |  |
| Part B White Blood Cell<br>Growth Factors Payments | \$1,282          | \$1,319     | \$1,233          | \$1,356     | -\$86***                     | -\$138     | -\$34      | -6.7%             |  |

#### Exhibit 21: OCM Had No Impact on Payments for Part B Chemotherapy, but Led to Relative Reductions in Payments for Non-Chemotherapy Drugs, Especially Supportive Care Drugs

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

Source: Medicare claims 2014-2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

<sup>†</sup>The individual drug payment measures in this table are not mutually exclusive or exhaustive components of Part B payments; as a result, the individual measures do not sum to overall Part B payments.

### The relative reduction in Part B payments for non-chemotherapy drugs was mainly among higher-risk cancer episodes.

The relative reduction in Part B non-chemotherapy drug payments, specifically payments for supportive care drugs, was concentrated in higher-risk episodes. This is because higher-risk episodes are for cancers treated with intensive and often toxic chemotherapies, and patients can require costly supportive drugs to prevent or ameliorate side effects. OCM had no impact on payments for supportive care drugs during lower-risk episodes, because the necessary treatments do not typically cause harmful side effects and supportive care drugs are not needed.

For higher-risk OCM episodes, TEP was \$39,934 in the baseline period. Part B non-chemotherapy drug payments were \$3,698 or 9 percent of TEP, and increased to \$3,887 in PP1–5. Amounts and increases were similar in comparison episodes, but Part B non-chemotherapy drug payments rose by \$232 less in OCM episodes than in comparisons (p<0.01). Most of this relative reduction was due to payments for supportive care drugs (-\$223, p<0.01). The relative reductions in non-chemotherapy drug payments and supportive care drug payments during higher-risk episodes were evident in every PP and grew over time (**Appendix B**). The cancer types with the greatest relative reduction in Part B non-chemotherapy drug payments included colorectal cancer, high-risk breast cancer, high-intensity prostate cancer, and lung cancer. The following sections describe Part B episode drug payments for these four cancer types.

#### IS OCM AFFECTING PAYMENTS FOR CHEMOTHERAPY AND OTHER DRUGS, OR PATIENT ADHERENCE TO DRUG TREATMENT REGIMENS?

#### During colorectal cancer episodes, OCM was associated with a relative reduction in payments for nonchemotherapy drugs, and had no impact on chemotherapy drug payments.

OCM had no impact on Part B chemotherapy drug payments in colorectal cancer episodes, which were essentially unchanged for both OCM or comparison episodes. However non-chemotherapy drug payments declined among OCM episodes and increased among comparison episodes (**Exhibit 22**). The relative reduction in non-chemotherapy drug payments was large (\$454; p<0.10) and rose over time, reaching \$870 (p<0.01) in PP5.

An important contributor to the relative reduction in non-chemotherapy drug payments was most likely the drug levoleucovorin, which is given to augment or amplify chemotherapeutic effects and is neither a chemotherapy drug nor a supportive care drug. Within the category of non-chemo drugs, for colorectal cancer episodes, OCM had no impact on payments for supportive care drugs. Colorectal cancer rarely metastasizes to the bone, and bone-supporting medications are generally not needed. In addition, chemotherapy regimens for colorectal cancer are less likely to cause severe nausea or neutropenia than is true of treatment for some other cancers (e.g., lung cancer, breast cancer), with less need for antiemetics or white blood cell growth factors.

#### Exhibit 22: For Colorectal Cancer Episodes, OCM Led to a Relative Reduction in Part B Non-Chemotherapy Drug Payments

|  | 00               | ОСМ         |                  | MP          | Impact Estimates Through PP5 |            |            |                   |  |
|--|------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|--|
| Colorectal Cancer                                  | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| Part B Payments <sup>†</sup>                       | \$25,977         | \$25,713    | \$25,256         | \$25,769    | -\$777**                     | -\$1,351   | -\$202     | -3.0%             |  |
| Part B Chemo Payments                              | \$12,029         | \$12,043    | \$11,934         | \$11,919    | \$29                         | -\$403     | \$462      | 0.2%              |  |
| Part B Non-Chemo Drug Payments                     | \$4,617          | \$4,315     | \$4,025          | \$4,177     | -\$454*                      | -\$837     | -\$70      | -9.8%             |  |
| Sub-categories of Non-Chemo Drugs                  |                  |             |                  |             |                              |            |            |                   |  |
| Part B Supportive Care Drug Payments               | \$3,163          | \$3,724     | \$3,058          | \$3,623     | -\$4                         | -\$252     | \$244      | -0.1%             |  |
| Part B White Blood Cell Growth Factors<br>Payments | \$2,172          | \$2,624     | \$2,170          | \$2,620     | \$3                          | -\$243     | \$249      | 0.1%              |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

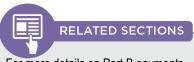
Source: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

<sup>†</sup>The individual drug payment measures in this table are not mutually exclusive or exhaustive components of Part B payments; as a result, the individual measures do not sum to overall Part B payments.

### During episodes for high-risk breast cancer, OCM was associated with a relative reduction in payments for non-chemotherapy drugs and for chemotherapy drugs.

In high-risk breast cancer episodes, OCM led to a relative reduction in non-chemotherapy drug payments (\$250; p<0.01) (**Exhibit 23**). Payments increased over time for both OCM and comparison episodes, but less so for OCM. By PP5, the relative reduction in non-chemotherapy drug payments exceeded \$350 (**Appendix B**). The relative reduction in non-chemotherapy drug payments was due to supportive care drugs (\$296; p<0.01) and particularly white blood cell growth factors (\$156; p<0.05).



For more details on Part B payments, see <u>Section 3.2</u>, Medicare payments— Part A, Part B, and Part D.

As mentioned earlier, high-risk breast cancer was the only cancer that had a significant relative reduction in Part B chemotherapy drug payments (-\$468, p<0.05). That reduction, combined with the reduction in Part B non-chemotherapy drug payments, almost entirely explains the overall relative reduction in Part B payments of \$769 for high-risk breast cancer episodes.

### Exhibit 23: For High-Risk Breast Cancer Episodes, OCM Led to Relative Reductions in Payments for Part B Chemotherapy Drugs and Non-Chemotherapy Drugs

|  | 00               | М           | CO               | MP          | Impac     | t Estimates | s Throug   | h PP5             |
|--|------------------|-------------|------------------|-------------|-----------|-------------|------------|-------------------|
| High-Risk Breast Cancer                            | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID       | 90%<br>LCL  | 90%<br>UCL | Percent<br>Change |
| Part B Payments <sup>†</sup>                       | \$24,977         | \$27,336    | \$24,305         | \$27,434    | -\$769*** | -\$1,167    | -\$371     | -3.1%             |
| Part B Chemo Payments                              | \$13,130         | \$14,909    | \$12,476         | \$14,723    | -\$468**  | -\$791      | -\$145     | -3.6%             |
| Part B Non-Chemo Drug Payments                     | \$4,313          | \$4,748     | \$4,142          | \$4,826     | -\$250*** | -\$400      | -\$99      | -5.8%             |
| Sub-categories of Non-Chemo Drugs                  |                  |             |                  |             |           |             |            |                   |
| Part B Supportive Care Drug Payments               | \$4,186          | \$4,479     | \$4,057          | \$4,646     | -\$296*** | -\$444      | -\$147     | -7.1%             |
| Part B White Blood Cell Growth Factors<br>Payments | \$2,275          | \$2,557     | \$2,233          | \$2,671     | -\$156**  | -\$264      | -\$49      | -6.9%             |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

<sup>†</sup>The individual drug payment measures in this table are not mutually exclusive or exhaustive components of Part B payments; as a result, the individual measures do not sum to overall Part B payments.

### During episodes for high-intensity prostate cancer, OCM was associated with a relative reduction in payments for non-chemotherapy drugs and had no impact on chemotherapy drug payments.

In episodes for high-intensity prostate cancer, OCM had no statistically significant impact on Part B payments for chemotherapy drugs. However, OCM reduced Part B non-chemotherapy drug payments by 354 (p<0.10) relative to comparisons (**Exhibit 24**). Much of the reduction in non-chemotherapy drug payments was for supportive care drugs, although this was inconsistent across the PPs (**Appendix B**). The reduction in non-chemotherapy drug payments was responsible for about half of the overall decline in Part B payments.

### Exhibit 24: For High-Intensity Prostate Cancer Episodes, OCM Led to Relative Reductions in Payments for Non-Chemotherapy Drugs, Especially Supportive Care Drugs

|  | 00               | M           | CO               | MP          | Impac   | ct Estimate | es Throug  | h PP5             |
|--|------------------|-------------|------------------|-------------|---------|-------------|------------|-------------------|
| High-Intensity Prostate Cancer                     | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID     | 90%<br>LCL  | 90%<br>UCL | Percent<br>Change |
| Part B Payments <sup>†</sup>                       | \$18,136         | \$19,110    | \$17,686         | \$19,363    | -\$703* | -\$1,379    | -\$27      | -3.9%             |
| Part B Chemo Payments                              | \$6,436          | \$6,890     | \$6,244          | \$7,004     | -\$306  | -\$848      | \$235      | -4.8%             |
| Part B Non-Chemo Drug Payments                     | \$5,773          | \$6,179     | \$5,343          | \$6,103     | -\$354* | -\$661      | -\$47      | -6.1%             |
| Sub-categories of Non-Chemo Drugs                  |                  |             |                  |             |         |             |            |                   |
| Part B Supportive Care Drug Payments               | \$4,758          | \$4,839     | \$4,310          | \$4,671     | -\$280* | -\$530      | -\$31      | -5.9%             |
| Part B White Blood Cell Growth Factors<br>Payments | \$2,034          | \$2,263     | \$1,885          | \$2,255     | -\$141  | -\$329      | \$47       | -6.9%             |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. **Source**: Medicare claims 2014–2019.

**Notes**: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

<sup>†</sup>The individual drug payment measures in this table are not mutually exclusive or exhaustive components of Part B payments; as a result, the individual measures do not sum to overall Part B payments.

During episodes for lung cancer, OCM was associated with a relative reduction in non-chemotherapy drug payments, and had no impact on chemotherapy drug payments.

#### IS OCM AFFECTING PAYMENTS FOR CHEMOTHERAPY AND OTHER DRUGS, OR PATIENT ADHERENCE TO DRUG TREATMENT REGIMENS?

In episodes for lung cancer, OCM had no statistically significant impact on Part B payments for chemotherapy drugs. Part B non-chemotherapy drug payments declined for both OCM and comparison episodes, but declined by \$246 more in OCM episodes (p<0.05) (**Exhibit 25**); this was inconsistent across the PPs (**Appendix B**). This relative reduction was mainly due Part B supportive care drugs (\$320; p<0.01), and especially white blood cell growth factors (\$216; p<0.05). The reduction in non-chemotherapy drug payments accounted for about one-third of the overall reduction in Part B payments of \$833.

#### Exhibit 25: For Lung Cancer Episodes, OCM Led to Relative Reductions in Payments for Non-Chemotherapy Drugs, Especially Supportive Care Drugs

|  | 00               | M           | COI              | MP          | Impact Estimates Through PP5 |            |            |                   |  |
|--|------------------|-------------|------------------|-------------|------------------------------|------------|------------|-------------------|--|
| Lung Cancer  | Baseline<br>Mean | Int<br>Mean | Baseline<br>Mean | Int<br>Mean | DID                          | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| Part B Payments <sup>†</sup>                       | \$27,058         | \$37,459    | \$26,621         | \$37,855    | -\$833**                     | -\$1,398   | -\$268     | -3.1%             |  |
| Part B Chemo Payments                              | \$12,647         | \$23,565    | \$12,297         | \$23,633    | -\$417                       | -\$929     | \$95       | -3.3%             |  |
| Part B Non-Chemo Drug<br>Payments                  | \$4,261          | \$3,791     | \$3,850          | \$3,626     | -\$246**                     | -\$438     | -\$53      | -5.8%             |  |
| Sub-categories of Non-Chemo                        |                  |             |                  |             |                              |            |            |                   |  |
| Part B Supportive Care Drug<br>Payments            | \$3,956          | \$3,300     | \$3,618          | \$3,282     | -\$320***                    | -\$501     | -\$140     | -8.1%             |  |
| Part B White Blood Cell Growth<br>Factors Payments | \$2,645          | \$2,168     | \$2,420          | \$2,159     | -\$216**                     | -\$369     | -\$63      | -8.2%             |  |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01. COMP: comparison group. **Source**: Medicare claims 2014–2019.

**Notes**: DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

<sup>†</sup>The individual drug payment measures in this table are not mutually exclusive or exhaustive components of Part B payments; as a result, the individual measures do not sum to overall Part B payments.

# 6.2. Is OCM Affecting Payment for Part D Drugs, or Patient Adherence to Part D (Oral) Treatment Regimens?

#### OCM had no impact on payments for Part D drugs, overall or for most cancer types.

Part D payments are entirely for prescription drugs (chemotherapy and non-chemotherapy). Since over 90 percent of Part D payments were for chemotherapy drugs in the intervention period, we did not assess impacts separately for chemotherapy and non-chemotherapy drugs as we did for Part B.

As discussed earlier, OCM had no overall impact on Part D payments. OCM also had no impact on Part D payments in higher-risk or lower-risk episodes. High-intensity prostate cancer was the only common cancer for which OCM had a statistically significant impact on Part D payments, which increased by \$699 more in OCM episodes than in comparison episodes (p<0.05), representing 3.5 percent of the mean OCM baseline value of \$19,856. Two novel therapies used in the treatment of high-intensity prostate cancer, abiraterone and enzalutamide, were the main drivers of the relative increase in Part D payments—these two drugs together accounted for over 95 percent of Part D payments during episodes for high-intensity prostate cancer.

#### Adherence to Oral Drug Treatment Regimens

Many OCM practices told us that their improvement efforts emphasized enhanced patient education and addressing barriers such as high OOP costs that could impair adherence to oral treatment regimens. We explored the impact of these efforts to lower barriers and improve patient adherence to oral (Part D) treatment regimens. Improved adherence could lead to higher Part D payments if patients fill their prescriptions on time.

#### IS OCM AFFECTING PAYMENTS FOR CHEMOTHERAPY AND OTHER DRUGS, OR PATIENT ADHERENCE TO DRUG TREATMENT REGIMENS?

Much like case studies in previous years, half of the practices we visited reported that they work to ensure that their patients on oral treatment regimens are taking their drugs and refilling prescriptions on time. Patient navigators, care coordinators, or pharmacists at these practices call or meet with patients to educate them about their oral drugs, assess tolerance, monitor for side effects, check that prescriptions are being taken as scheduled, and address financial or other barriers. For example, at one practice, patient navigators offer to fill patients' pill boxes to enhance adherence, and two practices told us they've established standard schedules for medication adherence phone calls (e.g.,

#### **Insights from the Field**

An OCM practice called their cancer patients before refilling prescriptions and found that 20 percent did not know how to safely take their medications, and 30 percent did not know what their medications were for. The practice revamped their patient education, with a required video for all patients who are prescribed oral cancer treatments.

weekly during the first month and monthly thereafter). Another practice focuses on hospital discharge transitions to assess medication changes, discontinue unneeded prescriptions, and ensure that patients fill any new prescriptions promptly. In addition, OCM practices are required to discuss expected out-ofpocket costs with patients, and this may help to identify and address financial barriers to adherence. (Other research indicates that adherence is higher for individuals with lower out-of-pocket costs.)<sup>35,36</sup>

In our *Evaluation Report: PP 1–3* report we assessed the impact of OCM on adherence to Part D (oral) drugs for two cancer types for which expensive Part D chemotherapy drugs play a key role: chronic myelogenous leukemia (CML) and high-intensity prostate cancer. We concluded that OCM did not impact adherence to Part D drugs for these conditions. We updated the analyses for this report and also examined adherence to hormonal therapies for low-risk breast cancer episodes. We also assessed whether adherence differed for subgroups of beneficiaries by race/ethnicity.<sup>37</sup>

#### OCM did not improve adherence to Part D (oral) drug treatment regimens for CML, high-intensity prostate cancer, or low-risk breast cancer episodes.



Despite the efforts of some OCM practices to educate patients, address barriers, and improve adherence, OCM had no overall impact on improved adherence among beneficiaries taking tyrosine kinase inhibitors for CML, enzalutamide or abiraterone for prostate cancer, or hormonal therapy for breast cancer (Appendix D-Clinical Analyses).

#### OCM led to modest improvements in adherence to CML and prostate cancer drugs among Black beneficiaries.

Oral drug adherence in the baseline period was lower for Black beneficiaries than for White beneficiaries, particularly for the high-cost tyrosine kinase inhibitors for CML and abiraterone/enzalutamide for prostate cancer. OCM led to improved adherence to these drugs among Black beneficiaries, but did not change adherence for White or Hispanic beneficiaries (Appendix D).

<sup>35</sup> Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. J Clin Oncol. 2014;32(4):306-311.

<sup>36</sup> Winn AN, Keating NL, Dusetzina SB. Factors associated with tyrosine kinase inhibitor initiation and adherence among Medicare beneficiaries with chronic myeloid leukemia. J Clin Oncol. 2016;34(36):4323-4328.

<sup>37</sup> We define adherence as the proportion of days covered (PDC), or the number of days in a period for which a beneficiary has sufficient medication (i.e., refilled their prescriptions on time or early), divided by the number of days in the period. For example, if a beneficiary fills a prescription for 30 tablets of a once-daily medication every 30 days for a 180-day period, their PDC is 100 percent (PDC capped at 100 percent). If a beneficiary fills a prescription for 30 days on day 1, day 40, day 100, and day 160, the PDC would be 110/180, or 61.1 percent.

### 7. Is OCM Affecting Choice of Cancer Treatments?

OCM requires practices to follow national clinical guidelines, and incentivizes practices to select lesscostly treatment options when appropriate, and to reduce low-value care. This chapter explores clinical impacts of OCM, including whether OCM is affecting choice of treatment regimens or use of new costly treatments, switching to higher-value supportive care drugs (e.g., granulocyte colony stimulating factors or GCSFs), avoiding low-value radiation therapy, and timely chemotherapy after cancer surgery.

#### **Key Findings**

- OCM had no impact on choice of drug treatment regimens, or adoption of new treatments, for any of the common cancer types we examined.
- OCM did not limit access to high-cost immunotherapy treatment.
- Shifts toward more value-based care:
  - OCM led to more value-based use of GCSFs for breast cancer, but not for lung or colorectal cancer.
  - OCM led to a pronounced shift toward use of biosimilar filgrastim (versus more-costly originator filgrastim).
  - OCM led to more value-based use of bone modifying agents.
- OCM led to a shift toward clinically appropriate and less-costly antiemetic (anti-nausea) treatments.
- OCM had no impact on timely chemotherapy after surgery for colorectal cancer or breast cancer.
- OCM did not lead to more appropriate use of radiation therapy after breast cancer surgery, or palliative radiation for bone metastases.
- OCM had no impact on the timeliness of chemotherapy after surgery for colorectal cancer or breast cancer.

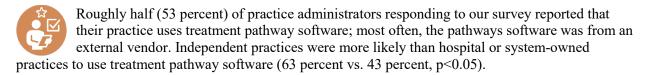
#### 7.1. Is OCM Affecting Adherence to National Consensus Guidelines? Choice of Treatment Regimens? Adoption of New Treatments?

#### Strategies to Enhance Guideline Adherence

OCM requires that practices adhere to evidence-based guidelines. All the practices we visited throughout the evaluation told us that they follow clinical guidelines from the National Comprehensive Cancer Network (NCCN) and/or the American Society of Clinical Oncology (ASCO), and use these guidelines for both OCM and non-OCM patients. At most practices, pharmacists and oncologists work together to develop and revise treatment regimen templates and order sets based on newly published literature and evidence-based guidelines. Most also have pharmacy and therapeutics committees that review treatment regimens and recommend formulary changes, as necessary.

#### Some OCM practices use treatment pathways software programs to standardize cancer treatment.

Some practices we visited use treatment pathways software programs to standardize regimens across all their oncologists, or were in the process of negotiating contracts with pathways software vendors. Others developed their own pathways rather than purchasing vendor products. For example, a large academic medical center developed its own treatment pathways that are not automated in a software program but are available in PDF format on the practice's intranet. Although most practices that use or plan to use treatment pathways are not doing so explicitly because of OCM, practice leaders acknowledge the potential advantages of pathways, including regimen standardization and cost reduction, which are consistent with OCM objectives. Among those that have not adopted treatment pathways software systems, reasons included high license fees and implementation costs, lack of interoperability with their electronic health record system, or not wanting to interfere with oncologists' treatment decisions.



Of the remaining 47 percent of practices that do not use treatment pathways software, nearly 80 percent have multiple approaches for updating regimens and order sets to reflect current evidence-based guidelines. The most common approaches for updating regimens and order sets are pharmacy and therapeutics committees (62 percent of practices that do not use treatment pathways software), having physician leaders review and approve all new or revised order sets (58 percent), and having a designated staff member/committee routinely purge obsolete regimens/order sets (56 percent). Only 30 percent of practices without treatment pathways software require that physician leaders' approve and use of drugs for indications that the Food and Drug Administration (FDA) has not yet approved (i.e., off-label use).

#### **Treatment Regimens**

When selecting a cancer treatment plan for a patient, oncologists often have a range of potentially appropriate chemotherapy treatment options to choose from. Selection of a specific chemotherapy regimen is usually based on effectiveness of the treatment, toxicities of the treatment, and individual patient characteristics. Chemotherapy regimens also vary in their associated costs, and OCM incentives could lead to value-based changes in chemotherapy regimen selection (i.e., preferential selection of lesscostly chemotherapy regimens, all else being equal<sup>38</sup>).



Several practices we visited consider themselves early adopters of new treatments. For some, this is because they are heavily involved in clinical trials. Physician-investigators explained that they and their colleagues become quite familiar with new drugs during the trial phase, and

transition smoothly to using the drugs as "standard care" after FDA approval. None of these practices reported a change in their clinical trial involvement, or earlier or delayed adoption of new drugs, as a result of OCM.

We evaluated the choice of the initial chemotherapy treatment regimens during episodes for four common cancer types.

#### OCM did not affect the initial chemotherapy regimens oncologists selected to treat common cancers, or the use of new treatments.



Descriptive analysis of treatment regimens indicates very similar patterns of initial chemotherapy treatment regimens in OCM and comparison episodes for lung cancer, colorectal cancer, high-risk breast cancer, and high-intensity prostate cancer, and changes between baseline and intervention periods were quite similar in the two groups. This suggests that OCM did not

affect patient access to new and often expensive therapies, but also suggests that OCM did not lead to preferential selection of less-costly chemotherapy treatment approaches. Detailed descriptions of episodeinitiating chemotherapy regimens for lung, colorectal, high-risk breast, and high-intensity prostate cancer episodes are included in Appendix D.

#### Access to High-Cost Immunotherapy

In recent years the FDA has approved new immunotherapies (monoclonal antibodies against PD-1, PD-L1, and CTLA-4), and expanded the indications for existing immunotherapies. Immunotherapies are

Jackman DM, Zhang Y, Dalby C, et al. Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients With Stage IV Non-Small-Cell Lung Cancer. J Oncol Pract. 2017;13(4):e346-e352. doi:10.1200/JOP.2017.021741

proven to enhance survival for patients with lung cancer,<sup>39</sup> melanoma,<sup>40</sup> and a wide range of other cancer types. Immunotherapies are also very costly. Consequently, immunotherapies should be reserved for situations where there is clear evidence of potential for benefit, and avoided in situations where FDA approval or clinical guideline recommendations are lacking. We examined use of high-cost immunotherapies, at any point during an episode, for all cancer types for which there was at least one cancer site-specific FDA approval or guideline recommendation by the end of 2018. We also assessed whether costly immunotherapies were being used inappropriately to treat cancers (all types combined) when there were no such FDA approvals or recommendations.

#### OCM did not limit access to high-cost immunotherapy treatment.

Immunotherapy use increased between the baseline and PP1–5 for both OCM and comparison episodes. Immunotherapies were used in at least 5 percent of episodes during the baseline period for three cancer types (melanoma, lung cancer, and kidney cancer).

In the baseline period, immunotherapy use was lower in OCM episodes than in comparison episodes for melanoma and lung cancer. During PP1–5 rates in OCM episodes exceeded the rates in comparison episodes, yielding a relative increase due to OCM. Thus, OCM not only did not limit access to high-cost immunotherapies for these cancer types, it may have increased access (with associated costs).

OCM did not affect use of immunotherapy for treatment of kidney cancer (see Exhibit 26).

### Exhibit 26: OCM Led to a Relative Increase in Use of Immunotherapies for Lung Cancer and Melanoma, but Not for Kidney Cancer

|                       | # of E | pisodes | 00       | CM      | CON      | /IP     | Impact Estimates Through PP5 |       |      |         |  |
|-----------------------|--------|---------|----------|---------|----------|---------|------------------------------|-------|------|---------|--|
|                       |        |         |          |         |          |         | DID<br>Percent-              |       |      |         |  |
| Use of                |        |         | Baseline | Int.    | Baseline | Int.    | age<br>Point                 | 90%   | 90%  | Percent |  |
| Immunotherapy         | ОСМ    | COMP    | Percent  | Percent | Percent  | Percent | Impact                       | LCL   | UCL  | Change  |  |
| Lung cancer           | 91,762 | 100,411 | 7.6%     | 42.9%   | 9.2%     | 42.0%   | 2.5%*                        | 0.4%  | 4.7% | 33.4%   |  |
| Kidney cancer         | 10,616 | 12,365  | 13.3%    | 43.6%   | 12.2%    | 42.6%   | -0.1%                        | -1.8% | 1.5% | -1.1%   |  |
| Malignant<br>melanoma | 9,147  | 10,731  | 62.0%    | 82.8%   | 67.1%    | 84.9%   | 2.9%**                       | 0.9%  | 4.9% | 4.6%    |  |

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01. **Source:** Medicare claims 2014–2019.

Notes: COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

All other cancer types had minimal immunotherapy use in the baseline period (less than 5 percent of episodes), and thus we did not conduct DID analyses. Instead, we compared use in OCM and comparison practices during PP1–5. Among cancer types that had low levels of immunotherapy use at baseline, and that had immunotherapy FDA approvals or guideline-recommended uses by the end of 2018, use of immunotherapy increased for both OCM and comparison episodes (**Exhibit 27**). Immunotherapy use increased more for OCM episodes than for comparison episodes for cancers of the head and neck, high-risk bladder cancer, and liver cancer. For other cancer types with immunotherapy approvals or guideline-recommended uses, trends in the use of immunotherapy did not differ between OCM and comparison

<sup>&</sup>lt;sup>39</sup> Mok TSK, Wu YL, Kudaba I, et al. Pembrolizumab versus chemotherapy for previously untreated, PD-L1expressing, locally advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): a randomised, openlabel, controlled, phase 3 trial. *Lancet*. 2019;393(10183):1819-1830.

<sup>&</sup>lt;sup>40</sup> Robert C, Long GV, Brady B, et al. Nivolumab in previously untreated melanoma without BRAF mutation. N Engl J Med. 2015;372(4):320-330.

episodes. There was also very little use ( $\leq 1.2$  percent of episodes) of immunotherapy for cancers where there were no FDA approvals or guideline-recommended uses, and no difference between OCM and comparison episodes.

| Use of Immunotherapy           |         | odes in Int.<br>I (PP1–5) | Int.  | Mean  | Int. Trend | 90%<br>UCL | 90%<br>LCL |
|--------------------------------|---------|---------------------------|-------|-------|------------|------------|------------|
|                                | OCM     | COMP                      | OCM   | COMP  | int. rrenu | UCL        | LUL        |
| Head and neck cancer           | 9,639   | 10,142                    | 28.1% | 28.3% | 0.4%*      | 0.03%      | 0.8%       |
| High-risk bladder cancer       | 8,990   | 9,732                     | 33.8% | 31.4% | 1.2%***    | 0.7%       | 1.6%       |
| Gastroesophageal cancer        | 9,534   | 10,596                    | 7.1%  | 7.0%  | -0.1%      | -0.3%      | 0.2%       |
| Liver cancer                   | 6,667   | 7,839                     | 12.9% | 11.0% | 0.4%*      | 0.03%      | 0.8%       |
| Anal cancer                    | 1,928   | 1,944                     | 6.6%  | 9.7%  | -0.3%      | -0.7%      | 0.2%       |
| Non-reconciliation-eligible    | 31,737  | 44,947                    | 12.0% | 11.2% | -0.1%      | -0.3%      | 0.1%       |
| All other higher-risk episodes | 283,322 | 300,706                   | 1.1%  | 1.2%  | 0.0%       | 0.0%       | 0.0%       |

#### Exhibit 27: For Cancers with Low Baseline Use of Immunotherapy, OCM Was Associated with Small Relative Increases in Use for Some Cancer Types, and Not for Others

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01. **Source:** Medicare claims 2014–2019. **Notes:** Models compared use in the intervention period only (rather than DID analyses) because use in the baseline period was minimal. COMP: comparison group. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

As noted above in the analysis of initial chemotherapy regimens, patterns of initial treatment for lung cancer, colorectal cancer, high-risk breast cancer, and high-intensity prostate cancer were similar for OCM and comparison practices.

These findings demonstrate that OCM increased the use of immunotherapy in circumstances where immunotherapy treatments were part of guideline-recommended care. Moreover, there was minimal use of immunotherapies for cancer types for which immunotherapy drugs were not generally approved or recommended, indicating that oncologists in both OCM and comparison practices reserved these costly treatments for situations with evidence of potential benefit.

# 7.2. Is OCM Incentivizing More Appropriate Use Of Radiation Therapy During Chemotherapy Treatment Episodes?

Radiation therapy is an integral component of cancer treatment. During chemotherapy treatment episodes, radiation therapy may be used concurrently with or after chemotherapy. It may be delivered as part of curative treatment, or with palliative intent to reduce pain from bone metastases. The number of radiation treatments (called fractions) is prescribed by the treating radiation oncologist, and there are different types of



radiation treatment. In FFS Medicare, a claim is submitted for each fraction, and payment is higher for types of radiation that are more technically complex, such as intensity-modulated radiation therapy (IMRT), an advanced modality that manipulates a radiation beam to conform to the shape of a tumor. In some cases, radiation oncologists can reduce cost of care and improve value by prescribing fewer radiation fractions and/or by using less complex types of radiation therapy. As described earlier, OCM had no impact on payments for radiation therapy, or on overall number of services (fractions).

We explored three specific opportunities to improve care and reduce episode payments related to radiation: more use of radiation after breast cancer surgery; less use of low-value IMRT for curativeintent breast cancer treatment after lumpectomy; and fewer fractions during episodes with palliative-intent radiation therapy for painful bone metastases (all cancer types). Reductions in the first could suggest less use of recommended treatment (i.e., lower quality); reductions in the latter two would suggest a shift toward higher-value care.

#### OCM had no impact on recommended radiation therapy after breast cancer surgery.

Post-operative radiation therapy following breast lumpectomy or mastectomy reduces the risk for local and regional cancer recurrence.<sup>41,42</sup> We looked for increases in use of radiation within 180 days after lumpectomy or mastectomy as a possible signal of improved quality. We identified beneficiaries with high-risk breast cancer episodes who were treated with chemotherapy following lumpectomy or mastectomy, many of whom could also be treated with radiation after surgery. We assessed the likelihood of receiving any post-operative radiation during an OCM-defined episode, and found no OCM impact on radiotherapy use (more details in **Appendix D**).

### Among high-risk breast cancer episodes that involved radiation therapy, OCM had no impact on following guidelines to avoid using post-operative IMRT radiation.

We also looked for changes in the type of radiation treatment used, that could signal a shift toward lower cost, clinically equivalent care. Among episodes for high-risk breast cancer episodes that did include radiation therapy after surgery, we examined use of IMRT rather than conventional radiation therapy. IMRT is a more technologically complex form of radiation therapy. For breast cancer treatment, IMRT has not been shown to improve outcomes or decrease toxicity compared with conventional radiation therapy, and it costs more. This lack of value led to a *Choosing Wisely* recommendation from the American Society for Radiation Oncology: *Do not routinely use IMRT to deliver whole breast radiotherapy as part of breast conservation therapy.*<sup>43</sup>

Among episodes for high-risk breast cancer that involved radiation therapy, use of post-operative IMRT radiation decreased over time from 15.6 percent to 12.7 percent in OCM episodes, and from 17.4 percent to 15.2 percent in comparison episodes. We conclude that use of IMRT shifted to better align with American Society for Radiation Oncology/Choosing Wisely recommendations in both OCM and comparison episodes, with no statistically significant relative impact of OCM (Appendix D).

### OCM had no impact on following guidelines that emphasize fewer palliative radiation treatments for bone metastases.

Patients with cancer (of any type) that has metastasized to the bone may receive palliative radiation treatment to alleviate pain, reduce fracture risk, and/or prevent neurologic impairment due to spinal cord compression. Longer radiation treatment courses (more fractions) do not improve symptom relief compared with shorter schedules, and fewer treatments are more convenient for patients and less costly for patients and payers. As a result, in 2013 the American Society for Radiation Oncology recommended

<sup>&</sup>lt;sup>41</sup> Darby S, McGale P, Correa C, et al. Effect of radiotherapy after breast-conserving surgery on 10-year recurrence and 15-year breast cancer death: meta-analysis of individual patient data for 10,801 women in 17 randomised trials. *Lancet* Nov 12, 2011;378(9804):1707–1716.

<sup>&</sup>lt;sup>42</sup> McGale P, Taylor C, Correa C, et al. Effect of radiotherapy after mastectomy and axillary surgery on 10-year recurrence and 20-year breast cancer mortality: meta-analysis of individual patient data for 8135 women in 22 randomised trials. *Lancet* Jun 21, 2014;383(9935):2127–2135.

<sup>&</sup>lt;sup>43</sup> Choosing Wisely. American Society for Radiation Oncology: Ten Things Physicians and Patients Should Question. Last updated 06/18/2018. Available from: <u>https://www.choosingwisely.org/societies/americansociety-for-radiation-oncology/</u>

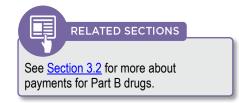
that radiation oncologists should avoid using treatment courses of longer than 10 fractions when delivering palliative treatment for bone metastases.<sup>44</sup>

We evaluated the number of radiation fractions during episodes with radiation therapy for bone metastases (as determined from diagnosis codes). The use of 10 or fewer fractions increased from the baseline period to the intervention period for both OCM and comparison episodes, and OCM had no impact on guideline-concordant treatment with 10 or fewer radiation fractions. Rates of the lowest-cost and most convenient treatment regimen of a single fraction<sup>45</sup> decreased slightly in both OCM and comparison episodes between the baseline and intervention periods, with no effect of OCM (see **Appendix D**).

#### 7.3. Is OCM Affecting Use Of Supportive Care Medications?

As noted earlier, OCM led to Part B payment reductions for supportive care medications, overall and for specific cancer types. Supportive care medications, including white blood cell growth factors, anti-nausea medications, and bone-modifying agents, are a critical component of safe and effective cancer treatment.

Supportive care medications can also be costly. Oncology practices have opportunities to reduce TEP by using lower-cost supportive care medications that meet patients' needs. In several common clinical situations, oncologists can select between different supportive care medications with similar efficacy but very different costs.



The sections below evaluate OCM impacts on the use of supportive care medications during cancer treatment for clinically defined patient subgroups. Specifically, we analyzed OCM impacts on the use of 1) bone-modifying agents, 2) white blood cell growth factors (i.e., granulocyte colony stimulating factors, or GCSFs), and 3) anti-nausea medications (antiemetics).

#### Use of Bone-Modifying Medications for Patients with Bone Metastases



Bone metastases are common in patients with certain types of metastatic cancer, including breast cancer, prostate cancer, and lung cancer. The NCCN clinical practice guidelines recommend use of bone-modifying medications to reduce the risk of cancer-associated bone fracture for most patients with bone metastases from breast cancer, lung cancer, or castrate-prostate cancer <sup>46,47,48</sup>

resistant prostate cancer. 46,47,48

<sup>&</sup>lt;sup>44</sup> American Society for Radiation Oncology. Choosing Wisely. Ten Things Physicians and Patients Should Question. Last updated 06/18/2018. Available from: <u>https://www.choosingwisely.org/societies/americansociety-for-radiation-oncology/</u>

<sup>&</sup>lt;sup>45</sup> Additional details in Appendix D.

<sup>&</sup>lt;sup>46</sup> National Comprehensive Care Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2020–March 6, 2020. Available from: <u>https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf</u>.

<sup>&</sup>lt;sup>47</sup> National Comprehensive Care Network. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 3.2020–February 11, 2020. Available from: <u>https://www.nccn.org/professionals/physician\_gls/pdf/nscl.pdf</u>.

<sup>&</sup>lt;sup>48</sup> National Comprehensive Care Network. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2020–March 16, 2020. Available from: <u>https://www.nccn.org/professionals/physician\_gls/pdf/prostate.pdf</u>.

Two types of bone-modifying medications prevent fractures from bone metastases: bisphosphonates (zoledronic acid and pamidronate) and denosumab. Use of either denosumab or a bisphosphonate is consistent with NCCN guidelines for treatment of bone metastases to prevent fractures in patients with breast cancer, prostate cancer, or lung cancer. Bisphosphonates are relatively inexpensive intravenous drugs that are available in generic formulations. For the bisphosphonates, the Medicare payment amount for a single dose of zoledronic acid is \$53,<sup>49</sup> and it is administered every 3–12 weeks; the payment amount and dosing schedule for pamidronate are similar. Denosumab is a newer monoclonal antibody given by subcutaneous injection, and no generic or biosimilar equivalents are available. The Medicare payment amount for a single dose of denosumab is \$2,330, and denosumab is administered every four weeks. Given the clinical equivalency of bisphosphonates and denosumab, and the substantially higher cost of denosumab, use of a bisphosphonate for treatment of bone metastases can be considered higher value in most situations. This presents an opportunity for OCM practices to reduce Medicare episode payments while meeting patient needs.

To evaluate the impact of OCM on use of bone-modifying medications during cancer treatment, we conducted two sets of analyses. Both analyses focused on episodes for treatment of breast cancer (high-risk or low-risk), prostate cancer (high-intensity or low-intensity), or lung cancer, with one or more diagnosis codes for bone metastasis during an episode or in the 180 days preceding the episode. First, we tested whether OCM affected whether *any* bone-modifying

#### Insights from the Field

During case studies, oncologists described efforts to prioritize use of bisphosphonates rather than the more-costly denosumab to reduce the risk of fractures for patients with bone metastases.

medication was used, as is generally recommended in these situations. Second, we tested whether OCM affected the *choice* of higher-value bisphosphonates versus lower-value denosumab. (We note that not all uses of denosumab are low-value, however, as denosumab is a preferred medication for patients with impaired kidney function.)

#### OCM led to relatively higher-value use of bone-modifying medications.

Use of any bone-modifying treatment for bone metastases from breast, prostate, or lung cancer was very similar in OCM and comparison episodes, and OCM did not affect the proportion of episodes that included use of a bone-modifying medication. Among episodes when a bone-modifying medication was used, use of the more costly (and lower-value) denosumab was similarly high in both OCM and comparison episodes at baseline (approximately 65 percent for breast cancer, 72 percent for prostate cancer, and 59 percent for lung cancer). Use of denosumab increased somewhat in both groups; however, the increases were less in OCM episodes than in comparison episodes, suggesting that OCM encouraged a more cost-conscious approach to bone-modifying medications (**Exhibit 28**).

<sup>&</sup>lt;sup>49</sup> Centers for Medicare and Medicaid Services. April 2020 ASP Pricing Files. March 2, 2020. Available from: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files

|  | # of E   | pisodes    | OC               | М            | CON              | IP           | Impact Estimates Through PP5   |            |            |                   |  |
|--|----------|------------|------------------|--------------|------------------|--------------|--------------------------------|------------|------------|-------------------|--|
| Use of Bone<br>Modifying Agents                    | ОСМ      | COMP       | Baseline<br>Mean | Int.<br>Mean | Baseline<br>Mean | Int.<br>Mean | DID Percentage<br>Point Impact | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| Use of any of the three bone-modifying medications |          |            |                  |              |                  |              |                                |            |            |                   |  |
| Breast cancer and<br>bone metastases               | 49,284   | 51,329     | 74.8%            | 72.3%        | 71.7%            | 68.9%        | 0.4%                           | -0.9%      | 1.7%       | 0.5%              |  |
| Prostate cancer and<br>bone metastases             | 49,793   | 60,714     | 68.3%            | 62.7%        | 64.1%            | 58.2%        | 0.3%                           | -1.5%      | 2.1%       | 0.5%              |  |
| Lung cancer and<br>bone metastases                 | 21,115   | 23,403     | 57.7%            | 51.4%        | 56.8%            | 50.9%        | -0.4%                          | -2.5%      | 1.8%       | -0.6%             |  |
| Among episodes wit                                 | h any bo | one-modify | ving medica      | ation, us    | e of denos       | umab         |                                |            |            |                   |  |
| Breast cancer and<br>bone metastases               | 35,975   | 35,934     | 65.4%            | 68.6%        | 65.8%            | 73.9%        | -5.0%***                       | -7.1%      | -2.8%      | -7.6%             |  |
| Prostate cancer and<br>bone metastases             | 32,337   | 36,275     | 72.5%            | 74.1%        | 72.4%            | 78.0%        | -4.0%***                       | -5.9%      | -2.2%      | -5.6%             |  |
| Lung cancer and<br>bone metastases                 | 11,658   | 12,036     | 59.9%            | 65.0%        | 58.9%            | 68.2%        | -4.1%**                        | -7.4%      | -0.9%      | -6.9%             |  |

#### Exhibit 28: OCM Led to Relative Reductions in the Low-Value Use of Bone Modifying Agents

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01.

Source: Medicare claims 2014–2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

#### Use of White Blood Cell Growth Factors (GCSFs)



Patients undergoing chemotherapy are at risk of developing bacterial infections, such as sepsis or pneumonia, because chemotherapy can suppress immune function by inhibiting production of white blood cells in the bone marrow. White blood cell growth factors, known as GCSFs (granulocyte colony stimulating factors), are often given prophylactically, starting with first

chemotherapy treatment, and continuing with subsequent treatments, to prevent infection, fever, and neutropenia (low white blood count).

The two commonly used GCSF medications are filgrastim and pegfilgrastim. Filgrastim is less costly than pegfilgrastim, but requires daily subcutaneous injections and laboratory monitoring for several days after each chemotherapy treatment. Pegfilgrastim is costly (the Medicare payment amount for pegfilgrastim was \$3,983 in the 2<sup>nd</sup> quarter of 2020); however, pegfilgrastim can be conveniently administered as a single injection given 24 hours after each chemotherapy treatment. Biosimilar pharmaceutical products are generally less costly than originator products, making biosimilars higher value. Biosimilar filgrastim products became available during the time period covered in this report.

Various chemotherapy regimens have different risk for causing fever, neutropenia, and immunosuppression. The NCCN classifies chemotherapy regimens as high-, intermediate-, or low-risk for causing fever and neutropenia. High risk is defined as greater than 20 percent risk of fever and neutropenia, intermediate as 10–20 percent risk, and low as less than 10 percent risk.<sup>50</sup>

<sup>&</sup>lt;sup>50</sup> National Comprehensive Care Network. NCCN Guidelines for Supportive Care: Hematopoietic Growth Factors. Version 2.0–March 27, 2019. Available from: <u>https://www.nccn.org/professionals/physician\_gls/default.aspx#supportive</u>

ASCO and NCCN guidelines recommend prophylactic use of GCSFs (starting with the first chemotherapy treatment) in patients receiving chemotherapy regimens that have a high risk of causing fever and neutropenia.<sup>51</sup> These guidelines also advise that patients receiving intermediate risk chemotherapy *may* benefit from prophylactic GCSFs, if patient characteristics indicate increased risk of fever and neutropenia. However, GCSFs are widely suspected to be overused for patients whose chemotherapy has intermediate risk for causing fever and neutropenia. Accordingly, ASCO's 2012 *Choosing Wisely* campaign included the recommendation: *Do not use white cell stimulating factors for prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.*<sup>52</sup> Patients receiving chemotherapy with a low risk should generally not be given prophylactic GCSFs.

We evaluated the impact of OCM on use of GCSFs during episodes when the chemotherapy regimen had intermediate or low risk for causing febrile neutropenia, where less use of GCSFs reflects higher-value care and should reduce Medicare

payments. We focused on three common cancers: highrisk breast cancer, lung cancer, and colorectal cancer. In high-risk breast cancer episodes we also assessed the impact of OCM on prophylactic use of GCSFs when chemotherapy regimens had a high risk for causing febrile neutropenia, where prophylactic use of GCSFs is recommended. In this latter analysis, we focused only on breast cancer because none of the commonly used

#### **Insights from the Field**

During case studies, several OCM practices mentioned that they are striving to ensure that GCSFs are used appropriately.

chemotherapy regimens for treatment of lung or colorectal cancer are classified as having high risk for causing febrile neutropenia. We anticipated that OCM incentives might lead to less use of prophylactic GCSFs when chemotherapy has an intermediate risk of causing febrile neutropenia, because these episodes have the greatest potential for reductions in use of prophylactic GCSFs. We expected little or no OCM impact on use of prophylactic GCSFs in episodes where the chemotherapy regimen had low risk for causing febrile neutropenia, because there should be little use of GCSFs in such episodes.

# OCM led to higher-value use of prophylactic GCSFs for episodes when the chemotherapy had intermediate risk for causing fever and neutropenia, but did not affect GCSF use in intermediate risk lung or colorectal cancer episodes.

*Breast Cancer:* Prophylactic GCSF accompanying chemotherapy regimens that have intermediate risk for causing fever and neutropenia is subject to clinical discretion and generally of lower value. Prophylactic GCSF use in such intermediate risk OCM and comparison episodes was relatively high at baseline, suggesting opportunities for reduction (which would reflect higher-value care). OCM led to a statistically significant 7.6 percentage point relative reduction in prophylactic GCSF use during intermediate-risk chemotherapy episodes (**Exhibit 29**).

Prophylactic use of GCSFs was appropriately very low during episodes when chemotherapy had low risk for causing fever and neutropenia, and OCM had no impact. Prophylactic use of GCSFs was appropriately quite high during episodes when chemotherapy had high risk of causing febrile neutropenia, and increased in both OCM and comparison episodes, consistent with guideline-recommended care.

*Lung Cancer:* OCM had no impact on prophylactic GCSF use during lung cancer episodes when chemotherapy had intermediate or low risk for causing neutropenia. Use of GCSFs declined in both OCM and comparison episodes when the chemotherapy regimen posed low risk of febrile neutropenia, but over

<sup>&</sup>lt;sup>51</sup> Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the Use of WBC Growth Factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. Oct 1 2015;33(28):3199–3212.

<sup>&</sup>lt;sup>52</sup> Schnipper LE, Smith TJ, Raghavan D, et al. American Society of Clinical Oncology identifies five key opportunities to improve care and reduce costs: the top five list for oncology. *J Clin Oncol*. May 10 2012;30(14):1715–1724.

10 percent of low-risk episodes (where guidelines discourage use) still had prophylactic GCSFs in both groups, suggesting additional room to improve.

*Colorectal Cancer:* Prophylactic GCSF use was quite low before OCM began, during colorectal cancer episodes when the chemotherapy regimen had intermediate or low risk for causing febrile neutropenia, with little room to improve, and there was no impact of OCM.

#### Exhibit 29: OCM Led to a Relative Reduction in Potentially Low-Value Prophylactic Use of GCSF during Breast Cancer Regimens that had Intermediate Risk for Causing Fever/Neutropenia, but No Had No Impact for Lung or Colorectal Cancer Episodes

| # of Ep                             | bisodes   | ОСМ   |   | COMP  |  | Impact Es  | Through PP5  |  |  |  |  |
|-------------------------------------|-----------|---|---|---|--|--|--|--|--|--|--|
| ОСМ                                 | COMP      | Base-<br>line<br>Mean   | Int.<br>Mean  | Base-<br>line<br>Mean   | Int.<br>Mean   | DID<br>Percentage<br>Point Impact  | 90%<br>LCL   | 90%<br>UCL   | Percent<br>Change  |  |  |
| Use of Growth Factors—Breast Cancer |           |   |   |   |  |  |  |  |  |  |  |
| 9,393                               | 9,851     | 84.2%   | 88.7%   | 85.5%   | 88.6%  | 1.3%   | -1.0%  | 3.6%   | 1.6%   |  |  |
| 2,986                               | 3,097     | 50.5%   | 50.3%   | 42.9%   | 50.3%  | -7.6%**  | -12.6%   | -2.7%  | -15.1%   |  |  |
| 13,792                              | 13,999    | 1.7%  | 1.6%  | 1.8%  | 1.9%   | -0.2%  | -0.8%  | 0.4%   | -11.6%   |  |  |
| -Lung                               | Cancer    |   |   |   |  |  |  |  |  |  |  |
| 16,441                              | 17,799    | 29.5%   | 26.6%   | 27.5%   | 25.8%  | -1.3%  | -3.4%  | 0.8%   | -4.4%  |  |  |
| 18,790                              | 20,906    | 18.1%   | 13.3%   | 16.4%   | 11.8%  | -0.3%  | -2.3%  | 1.8%   | -1.5%  |  |  |
| -Color                              | ectal Car | ncer  |   |   |  |  |  |  |  |  |  |
| 7,468                               | 7,606     | 10.3%   | 10.6%   | 11.6%   | 10.1%  | 1.9%   | -0.2%  | 3.9%   | 18.3%  |  |  |
| 10,613                              | 11,569    | 4.1%  | 3.2%  | 3.1%  | 3.0%   | -0.8%  | -1.8%  | 0.2%   | -19.3%   |  |  |
|                                     | OCM<br>   | Breast Cancer           9,393         9,851           2,986         3,097           13,792         13,999 | OCM         COMP         Base-<br>line           9.393         9.851         84.2%           2,986         3,097         50.5%           13,792         13,999         1.7%          Lung Cancer         16,441         17,799         29.5%           18,790         20,906         18.1%          Colorectal Cancer         7,468         7,606         10.3% | OCM         COMP         Base-line<br>line<br>Mean         Int.<br>Mean           o-Breast Cancer         Mean         Mean           9,393         9,851         84.2%         88.7%           2,986         3,097         50.5%         50.3%           13,792         13,999         1.7%         1.6%          Lung Cancer         16,441         17,799         29.5%         26.6%           18,790         20,906         18.1%         13.3%          Colorectal Cancer         7,468         7,606         10.3%         10.6% | OCM         COMP         Base-line<br>Mean         Int.<br>Mean         Base-line<br>Mean           9.393         9.851         84.2%         88.7%         85.5%           2,986         3,097         50.5%         50.3%         42.9%           13,792         13,999         1.7%         1.6%         1.8% <b>—Lung Cancer</b> 16,441         17,799         29.5%         26.6%         27.5%           18,790         20,906         18.1%         13.3%         16.4% <b>—Colorectal Cancer</b> 7,468         7,606         10.3%         10.6%         11.6% | OCM         COMP         Base-<br>line<br>Mean         Int.<br>Mean         Base-<br>line<br>Mean         Int.<br>Mean         Base-<br>line<br>Mean         Int.<br>Mean           9-Breast Cancer         9,393         9,851         84.2%         88.7%         85.5%         88.6%           2,986         3,097         50.5%         50.3%         42.9%         50.3%           13,792         13,999         1.7%         1.6%         1.8%         1.9%          Lung Cancer | Base-<br>line         Int.<br>Mean         Base-<br>line<br>Mean         Base-<br>line<br>Mean         DID<br>Percentage<br>Point Impact           9-Breast Cancer         9,393         9,851         84.2%         88.7%         85.5%         88.6%         1.3%           2,986         3,097         50.5%         50.3%         42.9%         50.3%         -7.6%**           13,792         13,999         1.7%         1.6%         1.8%         1.9%         -0.2%          Lung Cancer | Base-<br>line         Int.<br>Mean         Base-<br>line<br>Mean         DID<br>Percentage<br>Mean         90%<br>LCL           9-Breast Cancer         9,393         9,851         84.2%         88.7%         85.5%         88.6%         1.3%         -1.0%           2,986         3,097         50.5%         50.3%         42.9%         50.3%         -7.6%**         -12.6%           13,792         13,999         1.7%         1.6%         1.8%         1.9%         -0.2%         -0.8% <b>Lung Cancer</b> | Base-<br>line         Int.<br>Mean         Base-<br>line<br>Mean         Int.<br>Mean         Base-<br>line<br>Mean         Int.<br>Mean         DID<br>Percentage<br>Point Impact         90%<br>LCL         90%<br>UCL           9-Breast Cancer         9,393         9,851         84.2%         88.7%         85.5%         88.6%         1.3%         -1.0%         3.6%           2,986         3,097         50.5%         50.3%         42.9%         50.3%         -7.6%**         -12.6%         -2.7%           13,792         13,999         1.7%         1.6%         1.8%         1.9%         -0.2%         -0.8%         0.4% <b>C-Lung Cancer</b> 1         1         13.3%         16.4%         11.8%         -0.3%         -2.3%         1.8%           18,790         20,906         18.1%         13.3%         16.4%         11.8%         -0.3%         -2.3%         1.8% <b>Colorectal Cancer</b> 7,468         7,606         10.3%         10.6%         11.6%         10.1%         1.9%         -0.2%         3.9% |  |  |

**Source:** Medicare claims 2014-2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. GCSF: granulocyte colony stimulating factors. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit. Risk refers to risk for fever and neutropenia.

There was an OCM impact in decreasing prophylactic GCSF use during breast cancer episodes when chemotherapy had intermediate risk for causing febrile neutropenia, but OCM had no impact on lung or colorectal cancer episodes with intermediate risk chemotherapy. It is possible that OCM practices identified the frequent and increasing use of GCSF during intermediate risk breast cancer episodes as a priority opportunity for improving high-value care.

# In episodes when filgrastim GCSF was used, OCM was associated with faster adoption and greater use of less-costly biosimilar filgrastim (versus more-costly originator filgrastim).

Biosimilar filgrastim products were available during PP1–5. Biosimilar filgrastim offers the same benefits as originator filgrastim at a lower cost, which is an opportunity to reduce Medicare payments without impacting the quality of care. The biosimilar filgrastim-sndz was approved in March 2015 and the biosimilar filgrastim-aafi was approved in July 2018. Because the first approval occurred at the very end of the baseline period, we examined trends in adoption and use during PP1–5 episodes and did not conduct a DID analysis. (Biosimilar versions of pegfilgrastim are now available, but were not available during PP1–5.)

#### **Insights from the Field**

Oncologists and pharmacists at most practices we visited described systematic efforts to encourage routine prescribing of biosimilar growth factors.

"We limited antiemetics and growth factors to the lowest-price options available."

Pharmacy Director at an Independent OCM Practice

During episodes when filgrastim (originator or biosimilar) was

used, OCM episodes had faster adoption and greater use of biosimilar filgrastim than comparison

episodes (**Exhibit 30**). Rates of biosimilar use were generally similar in OCM and comparison episodes until PP3, but use increased more in OCM episodes during PP4-5 (see **Appendix D**). OCM practices' emphasis on biosimilar rather than originator filgrastim reflects a straightforward strategy of therapeutic substitution that reflects more value-based use of GCSFs.

#### Exhibit 30: OCM Was Associated with Faster Adoption and Greater Use of Lower-Cost Biosimilar Filgrastim, Rather Than Originator Filgrastim, in PP1–5

|  | Percent<br>Use in<br>OCM<br>Episodes | Percent Use<br>in<br>Comparison<br>Episodes | Percentage | Differential<br>Trend<br>Estimate | 90%<br>LCL | 90%<br>UCL |
|--|--------------------------------------|---|------------|-----------------------------------|------------|------------|
| Use of Biosimilar in OCM and<br>Comparison Episodes          | 57.3%                                | 47.6%                                       | 9.8%*      | -                                 | 0.8%       | 18.8%      |
| Differential Rate of Adoption in OCM vs. Comparison Episodes | -                                    | -   | -          | 2.6%**                            | 1.0%       | 4.4%       |

Asterisks denote statistically significant estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01

Source: Medicare Claims 2014–2019.

**Notes:** Use of lower-cost biosimilar versus originator filgrastim, during breast, lung, or colorectal cancer episodes when filgrastim was used.. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

#### Use of Antiemetic (Anti-Nausea) Medications

Nausea is a common side effect of chemotherapy, and antiemetic (anti-nausea) medications are prescribed or administered as supportive care for most patients undergoing chemotherapy treatment. Some chemotherapy treatments are especially prone to causing nausea—they have a high emetic risk. The many antiemetic medications available differ in intensity. National guidelines specify the recommended prophylactic antiemetic combinations, given with the first chemotherapy cycle, for patients receiving chemotherapy that has low, moderate, or high emetic risk. These guidelines contain substantial leeway for use of or less intensive (and less costly) prophylactic

antiemetic medications (**Exhibit 31**). Attention to the cost of antiemetic drugs could reduce the use of high intensity/high cost antiemetic treatments in situations where less costly approaches should suffice. One can think about this as a ladder of options, with more intensive and expensive antiemetic combinations at the top. Physicians can reduce the intensity and cost of antiemetic treatments by moving down the ladder, as clinically appropriate.

#### **Insights from the Field**

During case studies, oncologists at several practices noted a focus on avoiding inappropriate use of high-cost anti-nausea drugs such as the NK1 antagonists fosaprepitant and aprepritant.

#### Exhibit 31: Guideline-Recommended Antiemetic Combinations for Prevention of Chemotherapy-Induced Nausea and Vomiting

| Drug or Combination                                   | Chemotherapy Emetic Risk Category for<br>Appropriate Use | Relative Cost |
|---|--|---------------|
| NK1 antagonist with long-acting serotonin antagonist  | Moderate or high emetic risk                             | \$\$\$\$      |
| NK1 antagonist with short-acting serotonin antagonist | Moderate or high emetic risk                             | \$\$\$        |
| Long-acting serotonin antagonist with olanzapine      | Moderate or high emetic risk                             | \$\$          |
| Long-acting serotonin antagonist                      | Moderate emetic risk <sup>‡</sup>                        | \$\$          |
| Short-acting serotonin antagonist                     | Low or moderate emetic risk                              | \$            |
| Dexamethasone, metoclopramide, or prochlorperazine    | Low emetic risk  | \$            |

**Notes:** Table adapted from the NCCN Antiemesis Guideline, v2.2020. Dexamethasone should be given as an additional antiemetic for patients receiving moderate or high emetic risk chemotherapy. Where not specifically listed, olanzapine may be given as an additional antiemetic during moderate or high emetic risk chemotherapy. Subcutaneous granisetron, a long-acting serotonin antagonist, is approved by the FDA for the prevention of chemotherapy-induced nausea and vomiting in patients receiving highly emetic chemotherapy with anthracycline and cyclophosphamide combinations.

We evaluated the OCM impact on use of prophylactic antiemetics by analyzing episodes with intravenous chemotherapy regimens with high, moderate, or low emetic risk. We focused on two classes of costly antiemetic drugs: long-acting serotonin antagonists (palonosetron and subcutaneous granisetron) and NK1 (neurokinin-1) antagonists (aprepitant, fosaprepitant, netupitant, fosnetupitant, and rolapitant). Serotonin antagonists (both short- and long-acting) are among the most commonly used antiemetic drugs, and they are recommended for all patients receiving chemotherapy with moderate or high emetic risk. Long-acting serotonin antagonists have more durable effects in preventing nausea than short-acting serotonin antagonists, but they are also more costly. NK1 antagonists are a newer class of antiemetics that are used in combination with a serotonin antagonist (either short- or long-acting), primarily for patients receiving chemotherapy that has high or moderate emetic risk. NK1 antagonists are the most costly class of antiemetics, and Medicare payment is more than \$200 for each administration (per CMS payment limit allowances for Part B drugs).<sup>53</sup> We anticipated that OCM might lead to reduced prophylactic use of NK1 antagonists and/or long-acting serotonin antagonists, in episodes when the chemotherapy has moderate or high emetic risk. With multiple possible combinations for antiemetic therapy, oncologists have opportunities to select higher-value (lower-cost) antiemetic strategies that effectively control chemotherapy-induced nausea.

### OCM led to higher-value use of prophylactic antiemetic medications during episodes with chemotherapy regimens that had moderate or high emetic risk.

During episodes when chemotherapy regimens had high or moderate emetic risk, OCM led to relative reductions in the use of both NK1 antagonists and long-acting serotonin antagonists, the most costly antiemetic options (**Exhibit 32**). OCM led to a 6.0 percentage point relative reduction in use of prophylactic NK1 antagonists during episodes with high emetic risk chemotherapy, and a 3.5 percentage point relative reduction in use of NK1 antagonists during episodes with moderate emetic risk chemotherapy ( $p \le 0.01$  for both). The relative reduction in the use of NK1 antagonists was greater in PP4-5 than in PP1-3 (**Appendix D**). OCM also led to a 4.5 percentage point relative reduction in prophylactic use of long-acting serotonin antagonists during episodes with high emetic risk chemotherapy, and a 4.4 percentage point relative reduction in use of long-acting serotonin antagonists during episodes with high emetic risk chemotherapy, and a 4.4 percentage point relative reduction in use of long-acting serotonin antagonists during episodes with high emetic risk chemotherapy, and a 4.4 percentage point relative reduction in use of long-acting serotonin antagonists during episodes with moderate emetic risk chemotherapy ( $p \le 0.01$ ). Before and after implementation of OCM, both OCM and comparison episodes had consistently high use of antiemetic combinations that were consistent with national guidelines and/or FDA approved uses (see **Appendix D**).

As noted above, the relative reductions in use of costly antiemetic medications likely reflects a cascading strategy of value-based substitutions—stepping down one rung on the ladder of antiemetic intensity, when clinically appropriate. For example, short-acting serotonin antagonists may be substituted for long-acting serotonin antagonists in some protocols calling for dual therapy with NK1 and serotonin antagonists. In other situations, a long-acting serotonin antagonist may be substituted for dual therapy with NK1 and serotonin antagonists. If nausea was not well-controlled by the higher- value (lower-cost) antiemetic substitutions prompted by OCM, we would expect to see more ED visits for chemotherapy-associated symptoms, and more survey respondents complaining of nausea and vomiting, but neither happened (see **Appendix C-Survey Analyses** and **Section 8.1**). We therefore conclude that OCM practices identified opportunities to reduce use of costly antiemetics, without impairing control of nausea and vomiting.

<sup>&</sup>lt;sup>53</sup> CMS, 2020 ASP Drug Pricing Files. Accessed at https://www.cms.gov/medicare/medicare-part-b-drug-averagesales-price/2020-asp-drug-pricing-files on June 19, 2020.

|  | # of E  | pisodes | ОСМ              |              | CON              | IP           | Impact Estimates Through PP5              |            |            |                   |
|--|---------|---------|------------------|--------------|------------------|--------------|---|------------|------------|-------------------|
| Measure                                      | осм     | СОМР    | Baseline<br>Mean | Int.<br>Mean | Baseline<br>Mean | Int.<br>Mean | DID<br>Percent-<br>age<br>Point<br>Impact | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| High emetic risk episo                       | des     |         |                  |              |                  |              |   |            |            |                   |
| Receipt of NK1<br>antagonist                 | 15,730  | 18,609  | 79.2%            | 77.4%        | 73.0%            | 77.3%        | -6.0%***                                  | -9.0%      | -3.1%      | -7.6%             |
| Receipt of long- acting serotonin antagonist | 15,730  | 18,609  | 74.0%            | 69.5%        | 68.0%            | 68.0%        | -4.5%**                                   | -8.2%      | -0.7%      | -6.0%             |
| Moderate emetic risk e                       | pisodes |         |                  |              |                  |              |   |            |            |                   |
| Receipt of NK1<br>antagonist                 | 91,953  | 103,693 | 25.8%            | 31.1%        | 23.2%            | 31.9%        | -3.5%*                                    | -6.6%      | -0.4%      | -13.4%            |
| Receipt of long-acting serotonin antagonist  | 91,953  | 103,693 | 67.8%            | 65.2%        | 60.7%            | 62.6%        | -4.4%**                                   | -7.8%      | -1.0%      | -6.5%             |
| Low emetic risk episod                       | des     |         |                  |              |                  |              |   |            |            |                   |
| Receipt of long-acting serotonin antagonist  | 86,242  | 98,565  | 13.7%            | 9.8%         | 12.1%            | 8.4%         | -0.3%                                     | -1.4%      | 0.9%       | -2.0%             |

#### Exhibit 32: OCM Led to Higher-Value Antiemetic Use for Patients Receiving Chemotherapy with High or Moderate Emetic Risk

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01. **Source:** Medicare claims 2014–2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit. Baseline trends were not parallel for OCM and comparison episodes in receipt of NK1 antagonists during episodes with high emetic risk chemotherapy. Results of the DID analysis presented here were consistent in sensitivity analyses that allowed for differential baseline trends.

# OCM had no impact on prophylactic use of antiemetic medications during episodes when the chemotherapy regimens had low emetic risk.

The prophylactic use of costly antiemetics was appropriately low in both OCM and comparison episodes where chemotherapy regimens had low emetic risk. There was no impact of OCM on prophylactic use of long-acting serotonin antagonists, and prophylactic use of NK1 antagonists was so low that we did not conduct a DID analysis.

#### The shift toward high-value care did not lead to greater symptom burden for patients.

Our patient survey asks about eight different symptoms, including pain, energy level, emotional problems, nausea, breathing, coughing, constipation, and neuropathy. In the first survey wave, at the start

of the model, there were no reported differences in the rates of these symptoms between OCM and comparison survey respondents. If the shift toward higher-value care led to inadequate symptom control, over time we would expect more OCM survey respondents to report symptoms than those in the comparison group. This did not happen: and there was no differential impact of OCM on patient-reported symptoms (see **Appendix C**).



See <u>Section 8.1</u> for more on patientreported symptom management.

#### 7.4. Is OCM Affecting Timeliness of Chemotherapy After Cancer Surgery?

Consensus recommendations call for timely initiation of adjuvant chemotherapy following curative-intent surgery. There is evidence from observational studies that delays in initiating post-operative chemotherapy are associated with worse outcomes.<sup>54,55</sup> Timely chemotherapy after surgery is also more patient-centered. These considerations led the ASCO Quality Oncology Practice Initiative (QOPI) to include measures of timeliness of adjuvant chemotherapy as quality measures. Specifically, the QOPI measures include timeliness of adjuvant chemotherapy (defined as within two months after surgery) for patients with stage III colon cancer (QOPI measure 58).<sup>56</sup> Although QOPI does not currently have a similar measure for breast cancer, prior research suggests that chemotherapy delays of more than 60 days are also associated with worse outcomes.<sup>57</sup>

OCM could impact timeliness of adjuvant chemotherapy, as least somewhat, if practices are better able to coordinate care and share records with other providers such as surgeons, pathologists, and hospitals, and can streamline new-patient intake and appointment scheduling. During case studies, several practices described efforts to reduce delays between patients' hospital discharge after surgery and appointments with the medical oncologist. It is important to recognize, however, that timeliness of adjuvant chemotherapy depends on many factors, some of which are beyond the control of medical oncology practices, such as timeliness of referrals from surgeons, and patients' recovery following surgery.

For each chemotherapy episode, we identified beneficiaries who had a qualifying surgical procedure within the 180 days before the start of the episode. We assessed timing of adjuvant chemotherapy (based on the QOPI definition of adjuvant treatment within 60 days after surgery) for two clinical scenarios: (1) adjuvant chemotherapy following colon/rectum resection for colorectal cancer, and (2) adjuvant chemotherapy following lumpectomy/mastectomy for breast cancer (high-risk breast cancer episodes). Since claims data do not contain information about disease stage, we identified adjuvant chemotherapy based on receipt of chemotherapy following presumed curative surgery.

### **OCM** had no impact on the timeliness of chemotherapy after surgery for colorectal cancer or breast cancer.

Overall, among patients with OCM and comparison episodes who underwent surgery, approximately 60 percent of colorectal cancer patients and nearly three-quarters of breast cancer patients received chemotherapy within 60 days after surgery; the remainder experienced longer delays. Despite the efforts OCM practices described to improve transition coordination and reduce treatment delays, there was no improvement, and no impact of OCM on the proportion of beneficiaries with colorectal cancer or breast cancer whose first chemotherapy episode began within 60 days after surgery (see **Appendix D**).

<sup>&</sup>lt;sup>54</sup> Chavez-MacGregor M, Clarke CA, Lichtenstein DY, Giordano SH. Delayed Initiation of Adjuvant Chemotherapy Among Patients with Breast Cancer. JAMA Oncol. 2016;2(3):322–329.

<sup>&</sup>lt;sup>55</sup> De Melo Gagliato D, Gonzalez-Angulo AM, Lei X, Theriault RL, Giordano SH, Valero V, Hortobagyi GN, Chavez-MacGregor M. Clinical impact of delaying initiation of adjuvant chemotherapy in patients with breast cancer. J Clin Oncol 2014; 32: 735-744.

<sup>&</sup>lt;sup>56</sup> ASCO QOPI 2019 Reporting. Accessed on March 11, 2020 but since discontinued by ASCO.

<sup>&</sup>lt;sup>57</sup> Chavez-MacGregor M, Clarke CA, Lichtenstein DY, Giordano SH. Delayed Initiation of Adjuvant Chemotherapy Among Patients with Breast Cancer. *JAMA Oncol.* 2016;2(3):322–329.

### 8. Is OCM Improving Patient Care Experiences?

We assessed patient care experiences through two different lenses: directly, via a patient survey, and indirectly, through case studies and the information practices report to CMS about their efforts to identify and manage pain and depression.

#### **Key Findings**

- OCM had no impact on any of six patient-reported composite measures of care experience.
- Practices told us that screening for pain and depression is becoming more frequent and systematic due • to OCM.
- Practices give themselves high grades for pain management, less so for depression screening and management.

#### 8.1. Is OCM Affecting Patient-Reported Care Experiences or Overall Ratings of the Cancer Care Team?

We survey OCM patients every quarter throughout the Model period. We also surveyed comparison patients twice: at the start of the Model (episodes beginning April 2016-September 2016) and during PP5 (episodes beginning July 2018–December 2018) to measure the impact of OCM on care experience. For patients who died during or soon after their OCM episodes, we asked family members (proxy respondents) to complete the survey.

#### OCM had no impact on any of six composite measures of patient experience, or on overall satisfaction with the cancer care team.

The patient survey contains six composites, each calculated based on responses to several survey questions related to patient experience and satisfaction. (See Appendix A for the survey questions that make up each composite.) Most of the composite measures were rated quite

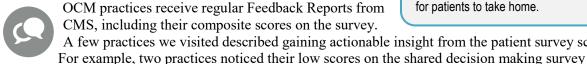
highly by respondents in both the OCM and comparison groups at the start of the Model (averaging 9 on a 10-point scale), and ratings did not change over time. The composites that patients rated somewhat lower (i.e., had the most room for improvement) were shared decision making, enabling patient self-management, and symptom management. The patient survey also asks respondents if they were bothered by symptoms from their cancer or cancer treatment, including pain, energy level, emotional problems, nausea, breathing, coughing, constipation, and neuropathy. As described earlier, OCM had no meaningful impact on any of these eight symptoms.

> OCM practices receive regular Feedback Reports from CMS, including their composite scores on the survey.

composite, and implemented changes they hoped would improve these scores.

#### Insights from the Field

To improve patient care experiences, one practice established "shared decision making appointments" where a nurse navigator joins a patient and his/her oncologist to discuss treatment options. The navigators document each option presented to the patient and the decision reached jointly by the patient and the oncologist. This document is scanned into patients' charts and printed for patients to take home.



A few practices we visited described gaining actionable insight from the patient survey scores.

#### 8.2. Are OCM Practices Improving Pain And Depression Management?

Many cancer patients experience pain and depression while undergoing treatment, and evidence suggests that attention to pain and depression can improve health outcomes and survival.<sup>58</sup> More than 16 percent of cancer patients experience major depression, and another 22 percent experience more minor depression.<sup>59</sup> Depression may affect the ability to tolerate treatment, health care use, and cost of care. Additionally, more than half of cancer patients require treatment for pain.<sup>60</sup> Clinical guidelines recommend screening cancer patients for pain, but strategies to address pain can be inadequate.<sup>61</sup> OCM practices that consistently screen patients for depression and pain, and effectively manage these important symptoms, may help reduce overall health care use and Medicare spending while improving quality of care. In addition, one element of the required OCM Care Plan is attention to patients' psychosocial needs (including depression).

### Screening for pain and depression became more frequent and systematic at the OCM practices we visited, due to OCM.

Most of the practices we visited throughout the evaluation systematically screen patients for depression, and all screen patients for pain. Those that screen for depression told us that they began this screening to meet OCM reporting requirements. Even practices that previously screened for pain and depression told us that the screening is more frequent and systematic because of

OCM, for example, using standardized forms. Only a few practices told us that they had well-developed screening practices in place prior to OCM, and had made no changes.

The majority of practices screen for depression every six months, but several found this difficult to operationalize, and instead screen at each office visit, or on other occasions (e.g., at start of treatment, after hospital discharge). Half of the practices we visited in Model Year 3 screen only Medicare FFS beneficiaries for depression; others screen all

#### **Insights from the Field**

"We used to react to patients—we didn't ask about depression or nutrition. [The patient] had to tell us. Now the [screening] forms are picking up on more issues."

Oncologist at a Large Practice

patients, either because staff found it easier to implement universal screenings, or because screening all patients is viewed as a best practice. Patients who screen positive for depression are referred to social workers, to other mental health resources (e.g., community psychiatrists), or to their oncologist for prescription of antidepressants. Practices that screen for pain generally do so at every visit.

Several practices separately screen for distress and psychosocial needs (transportation, social support, nutrition needs, etc.). Most practices that screen for psychosocial needs do so at every visit, while a few do so at each care transition, or every six months. Beneficiaries with social services needs are referred to social workers and/or community resources.

Some practices raised concerns related to frequent screenings. For example, some oncologists worry that screening for pain creates an expectation of treatment, even when pain is not cancer-related. In addition, some practices are concerned about not having enough social support resources available in the community to address the psychosocial needs identified through screenings.

<sup>&</sup>lt;sup>58</sup> Reyes CC, Anderson KO, Gonzalez CE, et al. (2019). Depression and survival outcomes after emergency department cancer pain visits BMJ Supportive & Palliative Care. 9:e36.

<sup>&</sup>lt;sup>59</sup> Management of Depression in Patients With Cancer: A Clinical Practice Guideline Madeline Li, Erin B. Kennedy, Nelson Byrne, Caroline Gérin-Lajoie, Mark R. Katz, Homa Keshavarz, Scott Sellick, and Esther Green. *Journal of Oncology Practice* 2016 12:8, 747-756

<sup>&</sup>lt;sup>60</sup> Halpern, M. T., de Moor, J. S., & Yabroff, K. R. (2019). Is cancer pain associated with employment and cost concerns for individuals with cancer? *Journal of Clinical Oncology*. 37:31\_suppl, 94-94

<sup>&</sup>lt;sup>61</sup> Ibid.

### *OCM* survey respondents reported improvement in their cancer care team asking about emotional problems, but no improvement in addressing those needs.

Our patient survey asks about the assistance patients receive from their cancer care teams to deal with emotional problems. The first step in addressing emotional problems is discussing whether such problems are present. In the baseline survey, 53.4 percent of OCM survey respondents reported that they had discussed emotional problems with their cancer care team in the previous year, and this increased to 58.3 percent in the survey wave that took place during Model Year Three (roughly PP5). This 4.8 percentage point improvement was statistically significant (p<0.01) (Exhibit 33). A much larger proportion of respondents with higher-risk episodes reported that they had discussed emotional problems with their cancer care team in the previous year, and there was a 4.6 percentage point improvement from the baseline to PP5 (p<0.01). After identifying patients who have emotional problems, the next step is addressing their needs. Among survey respondents who reported that they did have emotional problems, there was no improvement in cancer care teams addressing these needs. In the PP5 survey, 74 percent of those reporting emotional problems reported that their cancer care team tried to help them deal with emotional problems, essentially the same as in the baseline survey.

### There was no change over time in OCM survey respondents reporting that their practices discussed and addressed pain.

In the baseline survey, 71 percent of OCM survey respondents reported that they discussed pain with their cancer care team, and 94 percent of those who had pain said that their cancer care team tried to help them deal with it. These rates remained stable in the PP5 survey. Among survey respondents with higher-risk episodes, a larger proportion of respondents reported that their cancer care teams talked about pain and tried to help them deal with pain (those with lower-risk episodes had little pain and less need for assistance), and there was no change from baseline to PP5.

#### Exhibit 33: OCM Practices Improved in Patient-Reported Discussions About Emotional Problems, but Still Have Opportunity To Improve

| Patient Survey Measures (Coded As Yes/No)   | Baseline<br>Survey<br>(4/2016–9/2016) | Year Three<br>Survey<br>(10/2018–<br>3/2019) | Linear<br>Time<br>Trend | Mean Difference,<br>Baseline to the<br>Most Recent<br>Survey Wave |
|---|---------------------------------------|--|-------------------------|---|
| All Survey Respondents  |                                       |  |                         |   |
| Talked about pain with cancer therapy team  | 70.8%                                 | 70.5%  | 0.0%                    | -0.3%   |
| Among patients with pain, cancer therapy team tried to help deal with pain                                | 93.6%                                 | 93.2%  | 0.0%                    | -0.3%   |
| Talked about emotional problems with cancer therapy team  | 53.4%                                 | 58.3%  | 0.4%***                 | 4.8%***   |
| Among patients with emotional problems, cancer therapy team tried to help deal with emotional problems    | 74.9%                                 | 73.9%  | -0.1%                   | -1.0%   |
| Survey Respondents with Higher-Risk Episodes†   |                                       |  |                         |   |
| Talked about pain with cancer therapy team  | 76.7%                                 | 76.6%  | 0.0%                    | -0.1%   |
| Among patients with pain, cancer therapy team tried to help deal with pain                                | 95.4%                                 | 95.6%  | 0.0%                    | 0.2%  |
| Talked about emotional problems with cancer therapy team  | 58.8%                                 | 63.4%  | 0.4%**                  | 4.6%**  |
| Among patients with emotional problems, cancer therapy<br>team tried to help deal with emotional problems | 76.7%                                 | 76.3%  | -0.1%                   | -0.4%   |

Asterisks denote statistically significant impact estimates at \*p<0.10, \*\*p<0.05, and \*\*\*p<0.01.

Source: OCM Patient Survey, Baseline-wave12; OCM patients only. Survey responses were collected in April 2016–March 2019. Notes: Estimates were weighted for sampling and nonresponse and adjusted for age, gender, education, health status, mental health,

respondent, dual eligibility, race, number of hierarchical condition category flags, cancer type, month of episode period, radiation, surgery, and practice characteristics. Weights and risk adjustment were applied using logistic regression.

†Excludes lower-risk episodes (hormone-only treatment for breast or prostate cancer), because those respondents reported very low levels of pain and emotional problems.

# *Practices self-reported high pain assessment and management rates, and lower (but improving) rates of depression screening and follow-up plans.*

OCM practices submit quality measures to CMS for each PP. Among these practice-reported measures are pain management and depression screening with follow-up plans as needed.<sup>62</sup> From PP2 through PP5<sup>63</sup> the mean practice-reported performance rate for depression screening and management increased from 57.2 to 70.3, a 13.1 percentage point change (p<0.05) (**Exhibit 34**). This improvement across PPs was initially driven by small and medium-sized practices (those with fewer than 20 oncologists); larger practices with 20 or more oncologists caught up with smaller practices by PP5. The mean practice-reported performance rate for pain assessment and management also improved, by 9.4 percentage points between PP2 and PP5, from 77.2 to 86.6 (p<0.05). In no PP did practice-reported ratings differ based on practice characteristics.

### Exhibit 34: OCM Practices Reported Improvements in Pain Screening and Management, and Depression Screening and Follow-up

| Quality Massura                         | Average Performance Rate Across All OCM Practices |       |       |       |  |  |  |  |
|---|---|-------|-------|-------|--|--|--|--|
| Quality Measure                         | PP2   | PP 3  | PP 4  | PP5   |  |  |  |  |
| Pain assessment and management          | 77.2  | 80.8* | 83.6* | 86.6* |  |  |  |  |
| Depression screening and follow-up plan | 57.2  | 64.5* | 64.8* | 70.3* |  |  |  |  |

Source: OCM quality measure data reported to CMS by participating practices.

**Notes:** N=166 OCM practices. \*Indicates that the mean performance rate was significantly greater than the mean performance rate in PP2 (p<0.05). PP: performance period.

<sup>&</sup>lt;sup>62</sup> The practice-reported quality measures contribute to CMS's calculation of an AQS for each practice, in each PP. Payments are adjusted downward for practices that fail to reach an AQS threshold set by CMS.

<sup>&</sup>lt;sup>63</sup> Performance rates from the practice-reported data were not available for the baseline period or for PP1.

### 9. Is OCM Improving Palliative Care and Care at the End of Life, Or Reducing Utilitizion or Medicare Payments at the End of Life?

OCM includes several elements that are intended to improve End of Life (EOL) care.

- First, OCM requires Care Plans for every patient that document shared decision making and Advance Care Planning (ACP). The goal of this is to encourage oncologists to discuss preferences and planning with beneficiaries, especially those who have advanced disease.
- Second, OCM practices' PBP is adjusted for quality, and CMS incorporates five quality measures into an Aggregated Quality Score (AQS). One of these measures is the share of dying beneficiaries who enter hospice care more than two days prior to death—in time to benefit from the services hospices offer.
- Third, OCM practices receive regular CMS Feedback Reports that include several measures of EOL care.

To understand whether these requirements, incentives, and information are effective in improving EOL care, we discussed ACP, palliative care, and hospice care during case studies. We also measured the impact of OCM on use of services in the last days of life, and we surveyed the family members of deceased cancer patients to understand their perceptions of the care beneficiaries received in the last weeks of life.

#### **Key Findings**

- Nearly all the practices we visited made changes to improve Advance Care Planning (ACP). More than
  half also told us they now offer new or enhanced palliative care services as a result of OCM, and are
  working on more and earlier referral to hospice care.
- However, based on claims analyses, OCM had no impact on use of hospice care, duration, or timing.
- OCM led to a small relative reduction in hospitalizations during deceased patients' last weeks of life, and a corresponding decrease in Part A payments during deceased cancer patients' last episodes.
- OCM had no impact on family-reported experiences of EOL care.

#### 9.1. Is OCM Improving Advance Care Planning?



The practices we visited have implemented a variety of new ACP activities, including the following:

- Ensuring that beneficiaries receive ACP documents like the *Five Wishes*<sup>64</sup> or health care proxy forms early, at the first chemotherapy visit or soon after
- Adding advance directive forms to an education binder and having an APP schedule ACP visits with interested beneficiaries

#### **Insights from the Field**

One OCM practice assigned nurse practitioners to encourage ACP, and told us they experienced a 75 percent increase in rates of completed ACP documentation. Another practice reported an increase of more than 30 percent in completed advance directives after assigning a social worker to have focused discussions with OCM patients on advance care planning.

<sup>&</sup>lt;sup>64</sup> <u>https://fivewishes.org/</u>

- Assigning social workers, advance practice providers (APPs), nurse navigators, and care coordinators to have ACP discussions with patients and their families
- Dedicating MEOS funds to cover the staff responsible for ACP visits

#### 9.2. Is OCM Improving Palliative Care?

Half of the practices we visited offer new or enhanced palliative care services as a result of OCM. Some hired palliative care specialists, or are contracting with outside providers to bring palliative care into the practice. Other strategies practices adopted to expand palliative care, often explicitly due to OCM, include the following:

- Training non-specialists in palliative care, to enhance the general palliative care knowledge of all clinicians in the practice
- Creating standard guidelines for symptom management
- Developing automatic triggers for referral to palliative care (e.g., all patients with stage IV cancer)
- Implementing palliative care home visits, or telehealth visits, for patients who cannot easily travel to the clinic

In practices that added more palliative care services, and also in many of those that did not, leaders described ongoing challenges in providing palliative services. These include inability to recruit palliative care clinicians to fill staff vacancies, concerns about inadequate insurance reimbursement to cover the salaries of palliative care clinicians, and the need for culturally competent palliative care clinicians.

9.3. Is OCM improving care or referral to hospice care at the end of life?

When patients are terminally ill and further intensive treatment may reduce quality of life, holistic care shifts to prioritizing pain

#### Insights from the Field

Palliative care team members in two practices reported that speaking to patients and family members in their native language increases trust and willingness to discuss sensitive topics like advancing illness and treatment futility. Also, addressing culturespecific barriers on topics like opioid use helps overcome myths.

In a practice that started a new palliative care team because of OCM, clinicians are multilingual and patients are assigned to care teams based on language and country of origin. This supports culturally competent discussions about advance care planning and EOL preferences.

management and symptom palliation. Extensive prior research indicates that timely hospice care referral, avoiding medical interventions in the last month of life, and death outside the hospital reflect better quality of care, and higher satisfaction as perceived by family members and caregivers.<sup>65,66,67,68,69,70</sup>

<sup>70</sup> Wright AA, Zhang B, Ray A, Mack JW, et al. Associations between end-of-life discussions, patient mental health, medical care near death, and caregiver bereavement adjustment. *JAMA* 2008;300(14):1665–1673.

<sup>&</sup>lt;sup>65</sup> Ersek M, Miller SC, Wagner TH, Thorpe JM, et al. Association between aggressive care and bereaved families' evaluation of end of life care for veterans with non-small cell lung cancer who died in Veterans Affairs facilities. *Cancer* 2017;123(16):3186–3194.

<sup>&</sup>lt;sup>66</sup> Kris AE, Cherlin EJ, Prigerson H, et al. Length of hospice enrollment and subsequent depression in family caregivers: 13-month follow-up study. *American Journal of Geriatric Psychiatry* 2006;14(3):264–269.

<sup>&</sup>lt;sup>67</sup> Wright AA, Keating NL, Ayanian JZ, et al. Family perspectives on aggressive cancer care near the end of life. *JAMA* 2016;315(3):284–292.

<sup>&</sup>lt;sup>68</sup> Wright AA, Keating NL, Balboni TA, et al. Place of death: correlations with quality of life of patients with cancer and predictors of bereaved caregivers' mental health. *Journal of Clinical Oncology* 2010;28(29):4457– 4464.

<sup>&</sup>lt;sup>69</sup> Wright AA, Zhang B, Keating NL, et al. Associations between palliative chemotherapy and adult cancer patients' end of life care and place of death: prospective cohort study. *BMJ* 2014;348:g1219.

Eliminating ineffective, unnecessary, and often costly treatments at the end of life improves life quality and also reduces Medicare payments.

Most of the practices we visited in Model Year 3 told us they implemented changes to promote more and earlier referrals to hospice care, and that these changes were due to OCM. These initiatives included: having hospice care professionals provide on-site training for practice staff; sharing individualized metrics with practice oncologists (e.g., ICU admissions in the last 30 days of life, hospice care referrals in the last three days of life) to encourage earlier referrals; and assigning specific staff—usually not oncologists—to make hospice care referrals.

While most practices did not specifically mention hospice care referrals in the context of reducing Medicare payments, one practice saw the direct alignment between earlier hospice care and earning a PBP. That practice assigned care coordinators to discuss hospice care with patients, and gave medical assistants the task of making the actual referrals and completing necessary paperwork to support timely transitions to hospice care. Two other practices noticed in the CMS Feedback Reports that they had unusually high rates of hospital admissions in the last month of life, and realized that many patients were dying in the hospital without benefit of hospice care. These two practices worked with their local hospital and hospice care status, without the stress of being moved to a different unit or facility. While this strategy benefits patients in the last day or two of life (as well as increasing the practice's hospice care use rate and reducing Medicare payments), earlier hospice care referral could have allowed the same patient to benefit from several days or weeks of hospice services, and might have avoided the final hospitalization.

Leaders in the practices we visited described ongoing challenges in improving early referral to hospice care, and greater use of hospice care, including the following:

- Patient and family discomfort in discussing EOL care
- Oncologists' uneasiness initiating discussions with patients about transitioning from curative or disease-modifying treatment to comfort-focused care
- Inadequate processes for triggering EOL discussions and hospice care referrals
- Lack of professionally trained clinicians certified in palliative or EOL care
- A shortage of culturally similar clinicians to discuss EOL care with immigrant and minority patients
- Patient populations that have a cultural resistance to hospice care

Several also spoke about the tendency of some oncologists to continue suggesting new lines of treatment to patients who are unlikely to benefit, and how hard it can be to reorient oncologists who view treatment cessation as a "failure."

#### **OCM** led to reduced hospitalizations during deceased beneficiaries' last weeks of life.<sup>71</sup>



The efforts practices described to improve care at the end of life had a small impact on ACH hospitalizations in the last month of life. ACH hospitalizations decreased by 1.1 percentage points for deceased OCM beneficiaries relative to comparisons ( $p\leq0.05$ ); this is equivalent to be available of the last 20 days of life for 1 out of every 100 deceased OCM beneficiaries (see

avoiding hospitalization in the last 30 days of life for 1 out of every 100 deceased OCM beneficiaries (see **Exhibit 35**).

OCM had no impact on outpatient ED use (two or more visits) in the last two weeks of life, or use of Part B (infused) chemotherapy in the last two weeks of life.

<sup>&</sup>lt;sup>71</sup> Most claims-based EOL results are at the patient level and not the episode level, because death is a person event, not an episode event.

|  |         | ber of<br>ciaries | ОСМ              |              | СОМР             |              | Cumulative Impact Estimates Through<br>PP5 |            |            |                   |  |
|--|---------|-------------------|------------------|--------------|------------------|--------------|--|------------|------------|-------------------|--|
| Measure  | ОСМ     | СОМР              | Baseline<br>Mean | Int.<br>Mean | Baseline<br>Mean | Int.<br>Mean | DID<br>Percent-<br>age<br>Point<br>Impact  | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| High-Intensity Care                                  |         |                   |                  |              |                  |              |  |            |            |                   |  |
| Part B chemo-<br>therapy in last<br>14 days of life  | 121,699 | 134,403           | 10.0%            | 8.9%         | 9.7%             | 8.6%         | 0.0%                                       | -0.3%      | 0.4%       | 0.4%              |  |
| Any<br>hospitalization<br>in last 30 days<br>of life | 121,699 | 134,403           | 53.5%            | 52.2%        | 53.7%            | 53.5%        | -1.1%**                                    | -1.9%      | -0.4%      | -2.1%             |  |
| ED use (2+<br>visits) in last 30<br>days of life     | 121,699 | 134,403           | 15.1%            | 15.5%        | 15.8%            | 16.7%        | -0.5%                                      | -1.1%      | 0.1%       | -3.4%             |  |

#### Exhibit 35: OCM Led to Fewer Hospitalizations at the End of Life

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01. COMP: comparison group.

Source: Medicare claims 2014–2019.

**Notes:** Means and DID impact estimates are regression-adjusted. DID: difference-in-differences. ED: emergency department. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit.

One of the five quality measures that CMS uses to adjust PBP is entry to hospice care more than two days prior to death. Despite this focus, OCM had no impact on use, duration, or timing of hospice care (Exhibit 36).

### Exhibit 36: Among Beneficiaries Who Died, There Was No OCM Impact on Use of Hospice Care, Duration, or Timing

| Number of<br>Episodes   |         |         | ОСМ              |              | СОМР             |              | Cumulative Impact Estimates<br>Through PP5 |            |            |                   |
|---|---------|---------|------------------|--------------|------------------|--------------|--|------------|------------|-------------------|
| Measure   | ОСМ     | СОМР    | Baseline<br>Mean | Int.<br>Mean | Baseline<br>Mean | Int.<br>Mean | DID<br>Percent<br>-age<br>Point<br>Impact  | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |
| Never used<br>hospice care                                      | 121,699 | 134,403 | 32.4%            | 30.5%        | 33.7%            | 32.4%        | -0.5%                                      | -1.3%      | 0.2%       | -1.7%             |
| Hospice stay of<br>3–180 days and<br>dying with<br>hospice care | 121,699 | 134,403 | 58.5%            | 59.8%        | 59.8%            | 58.0%        | 0.5%                                       | -0.4%      | 1.4%       | 0.8%              |
| Hospice stay of<br>1–2 days and<br>dying with<br>hospice care   | 121,699 | 134,403 | 7.4%             | 7.8%         | 7.2%             | 7.6%         | 0.0%                                       | -0.5%      | 0.5%       | -0.1%             |

Source: Medicare administrative data 2014–2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. UCL: upper confidence limit. Means and DID impact estimates are regression-adjusted.

Our patient survey asks family members about the experiences of care for the patient in the last month of life.

#### OCM had no impact on most measures of family-reported experiences of EOL care.

OCM had no overall impact on patients' care experiences at the end of life. The experiences of patients who died after a higher-risk episodes are especially relevant, because their cause of death was likely cancer (while many patients who died after a lower-risk episodes probably had a non-cancer cause of death). For this higher-risk group, the only measure where OCM had a significant impact was on whether clinicians always explained things clearly and in a way that the patient could understand. For family members of patients who died after a higher-risk episode, there were no differences between OCM and comparisons on the 16 other EOL care questions on the survey.

#### 9.4. Is OCM Reducing Medicare Payments Near the End of Life?

As shown in **Exhibit 37**, OCM led to a relative decline in hospitalizations during deceased beneficiaries' last month of life. Avoiding hospital care may also reduce Part A costs during dying beneficiaries' final cancer episodes.

### During deceased beneficiaries' last cancer episodes, Part A payments increased slightly less for OCM than for comparisons, but there was no significant OCM impact on TEP.

We identified beneficiaries who died during an episode, or within 90 days thereafter, and assessed Medicare payments during that last final episode. Among OCM beneficiaries who died, Part A payments decreased during their last episode relative to comparison beneficiaries who died. In our previous annual report for PP1–PP3, we found that TEP (without MEOS) during the patient's last episode decreased for deceased OCM patients, relative to comparisons, by \$672 (a 1.8 percent reduction from the OCM baseline mean of \$37,158; p $\leq$ 0.05). The DID estimate for PP1–5 was \$539, and no longer statistically significant. For PP1–5, the average Part A payments during the last episode decreased by \$440 relative to comparisons, a 2.4 percent reduction from the OCM baseline mean of \$18,530 (p $\leq$ 0.05). This is consistent with the reduction in hospitalizations noted above. OCM had no impact on TEP (without MEOS), or on Medicare Part B or D payments, during deceased beneficiaries' last episodes (**Exhibit 37**).

| Measure                     | Number of<br>Episodes |         | ОСМ              |              | СОМР             |              | Cumulative Impact Estimates<br>Through PP5 |            |            |                   |  |
|-----------------------------|-----------------------|---------|------------------|--------------|------------------|--------------|--|------------|------------|-------------------|--|
| weasure                     | ОСМ                   | COMP    | Baseline<br>Mean | Int.<br>Mean | Baseline<br>Mean | Int.<br>Mean | DID<br>Impact                              | 90%<br>LCL | 90%<br>UCL | Percent<br>Change |  |
| TEP                         | 121,699               | 134,403 | \$37,501         | \$45,686     | \$37,963         | \$46,687     | -\$539                                     | -\$1,118   | \$39       | -1.4%             |  |
| Part A<br>payments          | 121,699               | 134,403 | \$18,530         | \$19,413     | \$18,764         | \$20,087     | -\$440**                                   | -\$809     | -\$71      | -2.4%             |  |
| Part B payments             | 121,699               | 134,403 | \$16,224         | \$22,134     | \$16,482         | \$22,433     | -\$41                                      | -\$424     | \$342      | -0.3%             |  |
| Part D<br>payments          | 91,000                | 102,278 | \$3,563          | \$5,460      | \$3,558          | \$5,496      | -\$41                                      | -\$208     | \$125      | -1.2%             |  |
| Part B<br>chemo<br>payments | 121,699               | 134,403 | \$5,648          | \$9,791      | \$5,716          | \$9,734      | \$125                                      | -\$144     | \$394      | 2.2%              |  |

#### Exhibit 37: OCM Led to a Relative Reduction in Part A Payments for Dying OCM Beneficiaries' Last Episodes

Asterisks denote statistically significant impact estimates at \*p≤0.10, \*\*p≤0.05, \*\*\*p≤0.01.

Source: Medicare claims 2014-2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. PP: performance period. TEP: total episode payments. UCL: upper confidence limit. Means and DID impact estimates are regression-adjusted.

### 10. Is OCM Affecting Survival?

We assessed the impact of OCM on survival for beneficiaries with several types of higher-risk cancer. It is possible that OCM could improve survival if practices prevent complications and adverse events, or if OCM increases the likelihood of receiving effective treatments or improves adherence to treatment regimens, although some of these benefits could take years to accrue. Alternatively, OCM could potentially have a negative impact on survival if incentives lead practices to stint on care.

#### Key Finding

OCM had no impact on survival time through 18 months.

We sought to examine survival for beneficiaries who were likely being treated for newly diagnosed or newly recurrent/progressive cancer. We therefore identified beneficiaries with OCM-defined cancer episodes who had no episode in the prior 12 months. We measured survival at the beneficiary level from the start of that index episode through 18 months. Beneficiaries were assigned to OCM or comparison practices based on that index episode.<sup>72</sup>

We computed restricted mean survival time (RMST)<sup>73,74,75</sup> through 18 months for beneficiaries assigned to OCM and comparison practices, and compared this across the baseline and intervention periods. This analysis included all beneficiaries with seven types of cancer that have high prevalence and at least moderately high mortality (acute leukemia, high-risk breast cancer, chronic leukemia, colorectal cancer, lung cancer, lymphoma, pancreatic cancer). We examined survival overall, adjusting for cancer type (in addition to other covariates), and separately for each of the seven cancer types, since the individual cancer types have very different survival probabilities. We did not examine survival for low-risk breast cancer or low-intensity prostate cancer because almost all of these beneficiaries survived for at least 18 months.

Survival differences of 30 days or less are not generally considered to be clinically significant (for example, in randomized clinical trials of new drugs). We therefore considered survival among beneficiaries in OCM and comparison practices to be clinically equivalent if the DID point estimate and 90 percent confidence limits for the OCM group are within +/-30 days of the 18-month RMST for the comparison group. Details about this analyses are provided in **Appendix D**.

<sup>&</sup>lt;sup>72</sup> Beneficiaries could have more than one beneficiary-episode if they had another 12-month period with no chemotherapy (97.9 percent of beneficiaries had a single episode); models account for clustering at the practice level.

<sup>&</sup>lt;sup>73</sup> Pak K, Uno H, Kim DH, Tian L, Kane RC, Takeuchi M, Fu H, Claggett B, Wei L-J. Interpretability of cancer clinical trial results using restricted mean survival time as an alternative to the hazard ratio. *JAMA Oncol* 2017; 3(12): 1692-1696.

<sup>&</sup>lt;sup>74</sup> Uno H, Wittes J, Fu H, Solomon SD, Clagget B, Tian L, Cai T, Pfeffer MA, Evans SR, Wei L-J. Alternatives to hazard ratios for comparing the efficacy or safety of therapies in noninferiority studies. *Ann Intern Med* 2015; 163: 127-34.

<sup>&</sup>lt;sup>75</sup> Uno H, Schrag D, Kim DH, Tang D, Tian L, Rugo HS, Wei L-J. Assessing clinical equivalence in oncology biosimilar trials with time to event outcomes. *JNCI Cancer Spectrum* 2019; 3(4): pkz058

#### OCM had no impact on survival time through 18 months.

OCM had no impact on survival time through 18 months for all seven cancer types combined (DID impact estimate = -2.2 days, 90 percent CL= -4.6, 0.3 days) (Exhibit 38). There also was no clinically meaningful difference in survival for any of the seven individual types of cancer (see Appendix D for stratified analyses).

|  | # of Beneficiaries |         | ОСМ                        |                        | CON                        | ΛP                     | Impact Estimate |                      |                      |
|--|--------------------|---------|----------------------------|------------------------|----------------------------|------------------------|-----------------|----------------------|----------------------|
|  | ОСМ                | СОМР    | Baseline<br>RMST<br>(days) | Int.<br>RSMT<br>(days) | Baseline<br>RMST<br>(days) | Int.<br>RSMT<br>(days) | DID<br>(days)   | 90%<br>UCL<br>(days) | 90%<br>LCL<br>(days) |
| All 7 cancers<br>RMST through 18<br>months | 116,233            | 125,186 | 427.9                      | 433.5                  | 430.4                      | 438.2                  | -2.2            | -4.6                 | 0.3                  |

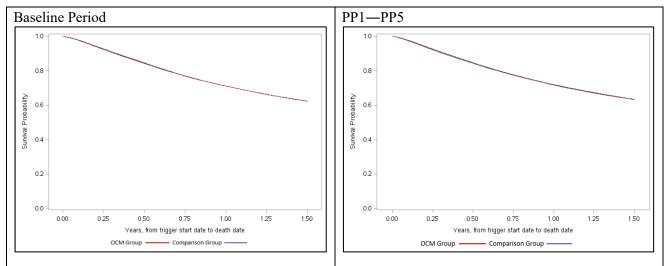
#### Exhibit 38: OCM Had No Impact on Restricted Mean Survival Time Through 18 Months

Source: Medicare claims 2014-2019.

**Notes:** COMP: comparison group. DID: difference-in-differences. Int.: intervention period. LCL: lower confidence limit. OCM: OCM intervention group. RMST: restricted mean survival time. UCL: upper confidence limit.

Survival curves for beneficiaries in the OCM and comparison groups are shown in **Exhibit 39** (baseline period and PP1–PP5). The curves show that 100 percent of beneficiaries are surviving at time zero and the proportion surviving decreases over time. Survival curves by cancer type are included in **Appendix D**.





Source: Medicare claims 2014–2019. Baseline N=41,834 OCM and 45,522 comparison beneficiaries; PP1-5 N=74,398 OCM and 79,664 comparison beneficiaries. PP: performance period.

Medicare claims lack information about cancer disease stage, and stage is strongly associated with survival. If the mix of metastatic and non-metastatic (advanced-stage versus early-stage) cancers changed differently over time for OCM and comparison beneficiaries, such changes could affect differential survival in the two groups. We previously developed clinical algorithms to identify beneficiaries with metastatic and non-metastatic colorectal cancer, which has an accuracy of more than 80 percent. We repeated survival analyses for beneficiaries with colorectal cancer stratified by non-metastatic versus metastatic cancer. OCM had no statistically significant or clinically meaningful impact on survival for beneficiaries with metastatic or non-metastatic colorectal cancer (details are in **Appendix D**).

### 11. Is OCM Having Differential Impacts Based on Beneficiary Demographics?

Disparities persist in cancer diagnosis and access to cancer treatment in the United States.<sup>76</sup> OCM's enhanced oncology services and incentives, especially patient navigation, Care Plans, and attention to symptom management, may support vulnerable populations, such as minority beneficiaries who are most affected by disparities in access and care.

We evaluated episode payments for subgroups of beneficiaries based on the following race/ethnic groups: non-Hispanic White, non-Hispanic Black Hispanic, and other race.<sup>77</sup> About 82 percent of all episodes in the intervention period were for White beneficiaries, 9 percent for Black beneficiaries, and Hispanic and other-race beneficiaries each made up between 4 and 5 percent of episodes. We also assessed whether OCM led to differential changes in patient-reported care experiences for White, Black, and Hispanic survey respondents.

Finally, we assessed the OCM impact on outpatient ED use and unplanned 30-day readmissions, to understand whether reductions in payments were achieved at the expense of worsening quality for racial/ethnic subgroups.

#### **Key Findings**

- OCM reduced TEP for White beneficiaries, but not for Black or Hispanic beneficiaries.
- OCM may have led to more unplanned readmissions for Black beneficiaries.

# OCM reduced TEP for White beneficiaries, relative to comparisons, but had no impact on TEP for Black or Hispanic beneficiaries.



Through PP5, OCM reduced TEP by \$256 (p<0.05) for White beneficiaries, but had no statistically significant impact on TEP for Black or Hispanic beneficiaries (**Appendix B**). The reduction in TEP for White beneficiaries was significant for PP3, PP4, and PP5, ranging from \$340 (p<0.05) to \$435 (p<0.05). In some PPs the impacts were greater in Part B, while in other PPs Part A was a driver, and there were no consistent patterns.

# OCM may have led to a less of a decline in unplanned readmissions for Black beneficiaries, but had no impact on outpatient ED visits.

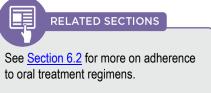
30-day unplanned readmissions declined slightly for all race/ethnicity subgroups, in both OCM and comparison episodes. However, 30-day unplanned readmissions declined less for Black beneficiaries with OCM episodes than for Black beneficiaries with comparison episodes, by 90 unplanned readmissions per 10,000 episodes (p<0.1), representing a 7.5 percent relative increase from the mean OCM baseline value. This lesser decline during Black beneficiaries' episodes was mainly in PP4 and PP5. OCM had no impact on 30-day unplanned readmissions among White or Hispanic beneficiaries. OCM had no impact on number of outpatient ED visits for any of the race/ethnicity subgroups.

<sup>&</sup>lt;sup>76</sup> American Cancer Society. Cancer Disparities: a Chartbook; 2018. Retrieved from Fight Cancer: http://www.fightcancer.org/disparitieschartbook.

<sup>&</sup>lt;sup>77</sup> Beneficiary race is defined according to the Research Triangle Institute race algorithm. The "Other" category includes Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries, as well as beneficiaries with multiple races reported or no race reported.

# *OCM led to modest improvements in adherence to CML and prostate cancer drugs among Black beneficiaries.*

If patients are educated about their treatment, their symptoms are well-managed, and any financial barriers are addressed, they may be better able to adhere to oral drug treatment regimens. As described earlier, OCM led to modest improvements in adherence to CML and prostate cancer drugs during episodes for Black patients.



# OCM led to slightly worsening patient-reported care experiences for Hispanic survey respondents, but not for White or Black respondents.

OCM led to little change in care experiences for White or Black survey respondents, but experiences worsened slightly over time for Hispanic respondents due to OCM. For White respondents, there was a small statistically significant improvement in the composite score for patient self-management (0.1 on a10-point scale), and the same was true for Black respondents. There were no other statistically significant changes due to OCM for any other survey composites or for overall satisfaction with cancer care. In contrast, OCM led to small but significant declines in patient-reported care experiences for Hispanic respondents on all survey composites (except symptom management), ranging from -0.5 (on a scale of 0–10) for the access to care composite to -1.0 for the affective communication composite. OCM also led to a small decline of 0.4 in Hispanic respondents' overall satisfaction with cancer care. (See **Appendix C**).

### 12. Are OCM Practices Aligning Physician Compensation and Performance Feedback with OCM Quality Incentives?

CMS adjusts PBP based on whether a practice meets quality targets, as summarized in an aggregate quality score (AQS).<sup>78</sup> Providing physicians with feedback and benchmarking about quality of care may help to encourage improvement. Practices can also use physician compensation strategies to reward highquality care.<sup>79, 80</sup> Both performance feedback and financial incentives may encourage physician engagement and behavior change,<sup>81</sup> which in turn may help a practice meet quality goals and score well on the AQS.

We surveyed leaders in OCM practices to understand the feedback they provide to physicians, and how they compensate physicians. We used the AQS assigned by CMS to each OCM practice for each PP, to understand whether low scores contributed to lower PBP.

#### **Key Findings**

- OCM practices increased performance feedback to physicians.
- Most practices did not share OCM revenue with physicians, and financial rewards for performance were modest.
- Most OCM practices either were not eligible for a PBP (if average Medicare payments exceeded the average Target Price for their OCM episodes or if they did not submit practice reported quality measures) or did not achieve the quality threshold to receive a full PBP.

### **Performance Feedback**

#### OCM practices increased performance feedback to physicians after OCM began.



Ninety-eight percent of active OCM practices responded to a leadership survey we conducted during the first year of OCM (Wave 1) and again at the end of Model Year Three (Wave 2). According to survey respondents, the proportion of practices that provided performance feedback to their physicians increased between these two survey waves. In the first year of OCM,

89 percent of practices routinely provided feedback to physicians on at least one of the following: patient-

- 79 Petersen LA, Simpson K, Pietz K, et al. Effects of Individual Physician-Level and Practice-Level Financial Incentives on Hypertension Care: A Randomized Trial. JAMA. 2013;310(10):1042-1050.
- 80 Navathe AS, Sen AP, Rosenthal MB, Pearl RM, Ubel PA, Emanuel EJ, Volpp KG. New Strategies for Aligning Physicians With Health System Incentives. The American Journal of Managed Care. 2016 Sep.
- 81 Bonner SE, Sprinkle GB. The effects of monetary incentives on effort and task performance: theories, evidence, and a framework for research. Accounting, Organizations and Society. 2002 May 1;27(4-5):303-45.

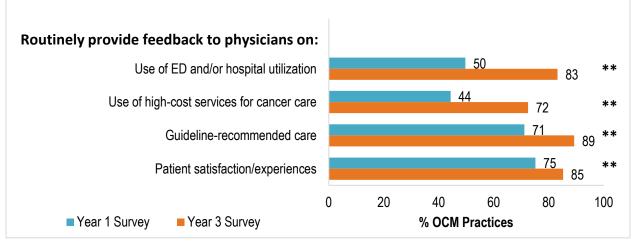
<sup>78</sup> The measures included in the AQS changed somewhat during the first three years of OCM. The AQS measure for PP5 was based on two claims-based measures (ED visit rate, rate of hospice entry more than two days before death), two practice-reported measures (depression-screening and practice-reported pain screening management), and patient-reported care experience. The proportion of patients with all-cause hospital admissions was also used in calculating the AQS prior to PP5. In each PP, the AQS is calculated as a weighted average of points achieved for the quality measures. For each PP, points for claims-based measures were awarded based on how a practice's achievement compared to quintiles of the national distribution at baseline; points for the patient survey measure were awarded based on how a practice's achievement compared to distributions of all OCM practices early in the model; and points for practice-reported measures were awarded based on full reporting to CMS (pay-for-reporting). More information is available at: https://innovation.cms.gov/files/x/ocm-cancercodelists.pdf

#### ARE OCM PRACTICES ALIGNING PHYSICIAN COMPENSATION AND PERFORMANCE FEEDBACK WITH OCM QUALITY INCENTIVES?

reported care experiences; adherence to guideline-recommended care; ED visits and hospitalizations; and use of high-cost therapies, imaging, or other technologies for cancer care. In the third year of OCM, 99 percent of practices provided feedback to physicians on at least one of these four measures, and 55 percent provided performance feedback to physicians on all four of these measures.

The largest increases in feedback provided to physicians were on measures of ED/hospital use, and use of high-cost cancer services (**Exhibit 40**). These two measures reflect opportunities to reduce Medicare payments. ED and hospital use are also among the quality measures included in the AQS.





\*\*p<0.05.

Source: OCM Evaluation Practice Leader Survey (Year One: October 2016–February 2017; Year Three: May–June 2019). Notes: N=150 OCM practices responding to the performance measure question in both waves of the Practice Leader Survey. ED: emergency

department.

Nearly 75 percent of practices routinely benchmarked the performance of physicians in the group against each other, or against external benchmarks from other practices or national standards. For example, academic medical centers participating in OCM often benchmarked physician performance against that of other academic practices. Benchmarking changed little over time.

### **Physician Compensation**

OCM offers participating practices two new streams of revenue: MEOS payments and PBPs. Sharing some of this revenue with physicians is a strategy that practices might choose to pursue, to enhance physician engagement, compensate for additional tasks/responsibilities, and incentivize efficient high-value treatment patterns.

### Most practices did not share OCM revenue with physicians, but did offer bonuses for performance.

In the Year Three survey we asked whether practices share OCM revenue with physicians. Nearly 70 percent of practice administrators responding to our survey reported that physicians receive no additional compensation from OCM revenue. Thirty-one percent reported that they share some OCM revenue with physicians: 18 percent share some of the revenue from both MEOS payments and PBPs, 4 percent share only a portion of the MEOS revenue, and 9 percent share only a portion of the PBP revenue. Additionally, 29 percent of independent practices share revenue from both MEOS and PBP with physicians, but this is true for only 6 percent of practices owned by a hospital or health system (p<0.05).

How OCM practices compensate physicians may influence how physicians respond to OCM. In the Model Year Three survey, over 70 percent of OCM practices reported offering physicians bonuses. These

#### ARE OCM PRACTICES ALIGNING PHYSICIAN COMPENSATION AND PERFORMANCE FEEDBACK WITH OCM QUALITY INCENTIVES?

bonuses could incentivize physicians to excel in areas that contribute to the AQS, such as patient care experiences and quality of care. Over 30 percent of responding practices offered physician bonuses based on patient care experiences, and these bonuses averaged 6.3 percent of base salary. Nearly half (47.3 percent) offered bonuses based on quality of care, and these bonuses averaged 9.6 percent of base salary (Exhibit 41).

Exhibit 41: Many OCM Practices Offered Physicians Bonuses for Performance on Quality and Other Factors

| Physician Bonuses Based On  | Percent of<br>Responding Practices<br>That Offer a Bonus | Average Bonus as<br>Proportion of Base Salary,<br>Among Practices That<br>Offer a Bonus |
|---|--|---|
| Patient experiences   | 30.8   | 6.3   |
| Quality of care   | 47.3   | 9.6   |
| Service to practice (e.g., administration, service on committees) | 43.2   | 8.8   |
| Other factors   | 56.8   | 25.5  |

Source: OCM Evaluation Practice Leader Survey (Model Year Three: May–June 2019).

Notes: N=173 OCM practices. However, five survey respondents did not answer questions about base compensation, and 27 respondents did not answer questions about bonus compensation.

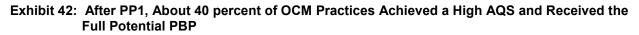
#### Aggregate Quality Scores (AQSs)

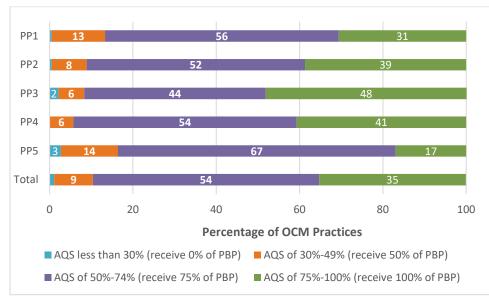
Most OCM practices informed physicians about their performance on quality and use measures, and some offered financial rewards for high quality of care. These strategies could help practices improve quality and achieve a high AQS.

## Almost all OCM practices eligible for a PBP achieved a sufficient AQS to receive a PBP. Most did not achieve the AQS threshold to receive the full potential PBP.

OCM practices must report quality data to qualify for a PBP, and then must meet both cost and quality thresholds to receive a PBP. In each PP, among those practices that qualified for a PBP, almost all received one. In each PP about 40 percent of practices achieved the full potential PBP by scoring at least 75 percent on their AQS; in PP3 nearly half reached that AQS threshold (Exhibit 42). There were no statistically significant differences in AQS based on practice size, ownership, or physician specialty mix, and there was no pattern of improvement over time. This is consistent with other results in this report showing no overall improvement on any of the individual OCM quality measures (pain management, patient-reported care experience, hospice care use and timing, ED visits, hospitalizations).

#### ARE OCM PRACTICES ALIGNING PHYSICIAN COMPENSATION AND PERFORMANCE FEEDBACK WITH OCM QUALITY INCENTIVES?





#### Source: OCM Quality Measures Data.

**Notes:** This exhibit includes OCM practices that were eligible for a PBP in each PP based on meeting episode payment targets, and the proportion that had the PBP reduced due to insufficient AQS. AQS: Aggregate Quality Score. PBP: performance-based payment. PP: performance period.

### **13.** Does OCM Have Unintended Consequences?

We explored several potential unintended consequences of OCM, some of which were also described in earlier sections of this report. All are assembled here to illuminate any patterns.

#### **Key Findings**

- OCM did not inhibit the use of specific types of chemotherapy, or access to new treatments.
- There is no evidence of "gaming": OCM practices did not trigger episodes with a single chemotherapy treatment, and did not alter case mix to favor lower-cost patients or avoid higher-cost patients.
- OCM is not increasing beneficiary cost-sharing or out-of-pocket spending.

# 13.1.OCM is not inhibiting the use of specific types of chemotherapy, or access to new treatments.

Some types of cancer treatment, including immunotherapy, are extremely expensive. Limiting the use of costly treatments, even slightly, could reduce TEP and help OCM practices qualify for a PBP. This could be done by limiting the number or type of costly chemotherapy drugs, or by substituting less-costly drugs.

OCM did not affect the use of novel therapies or immunotherapies and did not change the setting in which chemotherapy was delivered (e.g., Part B drugs administered in a clinic versus Part D drugs dispensed at a pharmacy). Changes over time were similar for OCM and comparison episodes overall, and by cancer type (**Appendix B and Appendix D**).

# 13.2. There is no evidence of OCM practices attracting or avoiding certain types of beneficiaries.

TEP varies both across and within cancer types. For example, TEP is generally higher in episodes for metastatic colorectal cancer than among episodes for localized cancer, but both types of episodes are assigned to the same OCM episode type. TEP can also be higher when beneficiaries have multiple comorbidities, and costs of care vary by beneficiary demographic characteristics. OCM practices could deliberately change their case mix by avoiding patients who are likely to have high-cost episodes (i.e., those with metastatic disease), or by deliberately avoiding patients with multiple comorbidities or other characteristics that tend to increase costs of care. We found no evidence of OCM practices trying to avoid taking on higher-cost patients.

### We found no evidence that OCM practices were altering case-mix by avoiding or attracting certain types of beneficiaries.

Changes in the share of episodes for beneficiaries with different demographic characteristics (e.g., age, gender, race dual eligibility, and mean hierarchical condition category risk score) were similar for OCM and comparison episodes, and consistent with national trends (**Appendix B**).

# OCM had no impact on the proportion of colorectal cancer episodes for beneficiaries with (imputed) metastatic versus non-metastatic colorectal cancer—no sign of preferential selection of patients with early-stage disease.

We used a clinical stage classification algorithm (described elsewhere)<sup>82</sup> to identify beneficiaries receiving chemotherapy for presumed metastatic (stage IV) colorectal cancer. We focused on colorectal cancer because the algorithm had good sensitivity, specificity, and accuracy when discriminating between metastatic and non-metastatic cancer, as validated with data reported by OCM practices (classification accuracy of approximately 80 percent <sup>83</sup> (see **Appendix D** for additional details).

The stage classification algorithm suggests that about 70 percent of colorectal cancer episodes in OCM and comparison practices were for treatment of metastatic disease before OCM began, and the same was true during the intervention period (**Appendix D**). The proportion of colorectal cancer episodes for presumed metastatic disease remained relatively stable over time, and OCM had no statistically significant impact.

### **OCM** may be leading to behavior designed to trigger more episodes for beneficiaries with low-risk breast cancer.

The mix of cancer episodes changed similarly among OCM and comparison episodes between the baseline and intervention periods, with the exception of low-risk breast cancer. The proportion of low-risk breast cancer episodes increased slightly among OCM episodes, but decreased among comparison episodes (**Appendix B**). However, the rate of new<sup>84</sup> low-risk breast cancer *beneficiaries* being treated by OCM practices over time was nearly identical to the rate for comparison practices. This suggests that OCM practices were bringing low-risk breast cancer patients in for more-frequent E&M visits, relative to comparison practices, and initiating more episodes for them, possibly to allow MEOS billing for the additional episodes.

#### **Insights from the Field**

A few practices we visited started asking breast cancer patients to come in for office visits at least twice each year (rather than once) specifically to trigger a second sixmonth OCM episode for which the practices then submitted bills for MEOS payments. One of these practices also limits Part D prescription refills to 30 days (rather than the previous 60 days), again to ensure that more OCM episodes are triggered for purposes of MEOS billing.

### 13.3.OCM is not leading to episodes triggered by a single day of chemotherapy.

A potential unintended consequence of an episode payment model such as OCM is the possibility of practices increasing the number of episodes, but then delivering less care or less chemotherapy after an episode begins. Unethical and fraudulent practices could attempt to game the model, for example by trying a single chemotherapy infusion to see how well a patient tolerates it, before deciding against further treatment, but then billing for a full six months of MEOS payments even if no further chemotherapy was given. Or practices might give one more (likely unnecessary) infusion after a beneficiary has completed a standard chemotherapy regimen, in order to trigger another episode and bill for another six months of MEOS payments. (If done solely for this purpose, with no potential benefit to the patient, such gaming behavior would constitute fraud.) This type of gaming would require that

<sup>&</sup>lt;sup>82</sup> Brooks GA, Bergquist S, Landrum MB, Rose S, Keating NL. Classifying lung cancer stage from health care claims: A comparison of multiple analytic approaches. JCO Clin Informatics 2019. *JCO Clin Cancer Inform* 2019:3:1–19.

<sup>&</sup>lt;sup>83</sup> Accuracy = [number of correct assessments] / [number of all assessments].

<sup>&</sup>lt;sup>84</sup> A low-risk breast cancer beneficiary was classified as "new" in a given PP in the baseline or intervention period if she had had her first episode in that PP, with no low-risk breast cancer episode in a prior PP.

practices track episode start and end dates closely, and that oncologists time infusions accordingly, which would likely be challenging to implement.

We evaluated whether OCM practices had more episodes with "minimal chemotherapy" than comparison practices, and whether this pattern was changing over time. We defined minimal chemotherapy as receipt of only one day of chemotherapy treatment (the minimum necessary to trigger an episode), versus two or more days of chemotherapy. We focused on higher-risk episodes triggered by Part B chemotherapy. We identified the date of the triggering chemotherapy infusion, and then counted the number of days of chemotherapy during the episode, categorizing each episode as one day versus two or more days.

## *OCM* practices are not initiating more episodes with a single (possibly unnecessary) day of chemotherapy.

OCM had no effect on the proportion of episodes for which beneficiaries received a single day of chemotherapy versus two or more days (**Appendix D**). This indicates that OCM has not led practices to initiate new episodes with a single (possibly unnecessary) chemotherapy infusion/injection.

#### 13.4.OCM is not increasing beneficiary cost-sharing or OOP spending.

OCM had no overall impact on beneficiary cost-sharing for Part A, B, and D services combined. OCM also had no impact on OOP spending reported by respondents to our survey.

### 14. Conclusions

This report presents evaluation findings through the fifth of 11 PPs for OCM. The practices we visited during PP4 and PP5 told us that they had largely finished hiring staff and implementing new care processes in response to OCM. We therefore believe that the Model was mature in this time period, and impacts should now be apparent.

TEP increased from about \$28,500 before OCM to about \$33,200 during PPs 1–5. TEP in OCM episodes increased by \$297 (1 percent) less than in comparison episodes. During higher-risk episodes, which made up about two-thirds of all episodes and averaged about \$46,500, payments rose by \$503 less in OCM episodes than in comparisons. Treatment during higher-risk episodes often involves many costly components (e.g., surgery, radiation therapy, advanced imaging, and costly drugs), some of which may be amenable to reductions. The payment reductions for higher-risk episodes were partially offset, however, by increased payments for lower-risk episodes. For lower-risk episodes, which made up about one-third of all episodes and averaged about \$7,500, payments increased by \$151 more for OCM episodes than for comparisons. Treatment during lower-risk episodes manly involves long-term hormonal therapy with periodic prescription refills or infrequent injections, and there may be fewer opportunities to reduce Medicare payments.

When MEOS and PBP are factored into the calculations, along with these changes in episodes payments, the bottom line was net losses for Medicare of \$65M to \$100M in each of the first four PPs. Medicare losses in PP4 were greater than in period two or three, in part because more practices qualified for PBP in period four, and those payments were larger than in prior periods.

The relative episode payment reductions due to OCM were greatest in Part B, especially for four types of higher-risk episodes (high-risk breast cancer, lung cancer, colorectal cancer, and lymphoma), where the Part B payment reductions were more than enough to cover MEOS payments. Despite the fact that Part B payments for chemotherapy drugs averaged \$7,677 per OCM episode at baseline, and increased to more than \$10,000 (out of the total \$33,200), few practices told us about specific efforts to reduce costs of chemotherapy, and OCM had no significant overall impact on Part B payments for chemotherapy drugs. Rather, OCM practices focused on more-value-based use of costly supportive care drugs, a subset of Part B drugs, which are given to manage symptoms from chemotherapy toxicity. Part B supportive care drugs averaged \$2,215 per OCM episode at baseline, and increased by \$150 less than in comparison episodes.

Every practice we visited described their efforts to avert ED visits and hospitalizations, by enhancing access to same-day urgent care, improving rapid response to patients' phone calls, and using proactive outreach to high-risk patients. Despite these efforts, OCM had no impact on ED visits or hospitalizations overall. OCM also had no meaningful impact on ED visits or hospitalizations due to chemotherapy toxicity. It is possible that most ED visits and hospitalizations for cancer patients cannot be avoided. It is also possible that additional contact with patients between office visits averted some ED visits, and also identified situations that led to additional ED visits. Lastly, it is quite possible that medical oncologists in both OCM and comparison practices were focusing on reducing unnecessary ED and hospital use in response to other pressures (e.g., Medicare's readmission reduction program, ACO contracting, other insurer initiatives). Any reductions in OCM episodes would need to exceed those in the comparison group in order to be judged an impact of the Model. For example, hospitalizations declined among both OCM and comparison of the Model. For example, hospitalizations declined among both OCM and comparison episodes, yielding no OCM impact.

OCM practices focused on advance care planning to ensure that cancer patients' EOL wishes are known and documented, and they hired more palliative care specialists. These investments helped OCM practices modestly reduce hospitalizations in the last month of life, by 1 percent. This is equivalent to avoiding a hospitalization in the last month of life for 1 out of every 100 deceased OCM beneficiaries, and benefits patients who avoid the disruption and stress of hospital (and ICU) care. This relative reduction in hospitalizations also contributed to reduced Part A payments during dying patients' last episodes. However, despite quality measures and CMS Feedback Reports emphasizing earlier use of hospice care, OCM had no impact on the use or timing of hospice care.

### Acronyms

| ABIM  | The American Board of Internal Medicine  |
|-------|--|
| ACH   | Acute Care Hospital                      |
| ACO   | Accountable Care Organization            |
| ACP   | Advance Care Planning; Advance Care Plan |
| AHRF  | Area Health Resources Files              |
| AMC   | Academic medical center                  |
| APM   | Alternative Payment Model                |
| APP   | Advanced Practice Provider               |
| AQS   | Aggregate Quality Score                  |
| ASCO  | American Society of Clinical Oncology    |
| ASTRO | American Society for Radiation Oncology  |
| CME   | Common Medicare Environment              |
| CML   | Chronic Myelogenous Leukemia             |
| CMS   | Centers for Medicare & Medicaid Services |
| CNS   | Central Nervous System                   |
| CPC   | Comprehensive Primary Care               |
| CQI   | Continuous Quality Improvement           |
| DID   | Difference-In-Differences                |
| DRG   | Diagnosis-Related Group                  |
| E&M   | Evaluation and Management                |
| ED    | Emergency Department                     |
| EHR   | Electronic Health Record                 |
| EOL   | End-Of-Life                              |
| ESRD  | End-Stage Renal Disease                  |
| FDA   | U.S. Food and Drug Administration        |
| FFS   | Fee-For-Service                          |
| GCFS  | Granulocyte Colony Stimulating Factor    |
| GDC   | Gross Drug Cost                          |
| HCC   | Hierarchical Condition Category          |
| HHA   | Home Health Agency                       |
| НМО   | Health Maintenance Organization          |
|       |  |

### ACRONYMS

| HPSA  | Health Professional Shortage Area             |
|-------|---|
| ICU   | Intensive Care Unit                           |
| IDR   | Integrated Data Repository                    |
| IMRT  | Intensity Modulated Radiation Therapy         |
| IP    | Inpatient                                     |
| ITT   | Intent-To-Treat                               |
| LCL   | Lower Confidence Limit                        |
| MDM   | Master Data Management                        |
| MDS   | Myelodysplastic Syndrome                      |
| MEOS  | Monthly Enhanced Oncology Service             |
| MIPS  | Merit-Based Incentive Payment System          |
| MSSP  | Medicare Shared Savings Program               |
| NCCN  | National Comprehensive Cancer Network         |
| NK1   | Neurokinin-1                                  |
| NP/PA | Nurse Practitioner/Physician Assistant        |
| NPI   | National Provider Identifier                  |
| OCM   | Oncology Care Model                           |
| OIP   | Other Inpatient Hospitalization               |
| OLS   | Ordinary Least Squares                        |
| OOP   | Out-of-Pocket                                 |
| PAC   | Post-Acute Care                               |
| PBP   | Performance-Based Payment                     |
| PDC   | Proportion of Days Covered                    |
| PDE   | Prescription Drug Event                       |
| POLST | Physician Order for Life-Sustaining Treatment |
| РР    | Performance Period                            |
| PSM   | Propensity Score Matching                     |
| РТР   | Practice Transformation Plan                  |
| QOPI  | Quality Oncology Practice Initiative          |
| QPP   | Quality Payment Program                       |
| RMST  | Restricted Mean Survival Time                 |
| TEP   | Total Episode Payment                         |
| TIN   | Taxpayer Identification Number                |
| TKI   | Tyrosine Kinase Inhibitors                    |
|       |   |

### ACRONYMS

| UCL  | Upper Confidence Limit             |
|------|------------------------------------|
| VEGF | Vascular Endothelial Growth Factor |
| VRDC | Virtual Research Data Center       |

### Glossary

| 340B Drug Pricing<br>Program           | The 340B Program provides discounts on outpatient drugs to certain safety net health providers, including Title X agencies. Outpatient prescription drugs, over-the-counter drugs (with a prescription), and physician-administered drugs are eligible for these discounts, whereas vaccines and inpatient drugs are not covered.   |
|--|---|
| Accountable Care<br>Organization (ACO) | An <u>ACO</u> is a group of doctors, hospitals, and other health care providers that<br>come together voluntarily to give coordinated high-quality care to their<br>Medicare patients. When an ACO succeeds both in delivering high-quality<br>care and in spending health care dollars more wisely, the ACO will share in<br>the savings it achieves for the Medicare program. |
| Adjuvant therapy                       | Additional cancer treatment given after surgery to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy. Neo-adjuvant therapy is given before surgery, usually to shrink the tumor or make it more accessible.   |
| Advance care planning                  | A conversation between a physician (or other qualified health care<br>professional) and a patient to discuss the patient's wishes regarding their<br>medical treatment, if they should become unable to communicate. This<br>discussion may or may not include completing relevant legal forms, such as<br>health care proxies or advance directives.                           |
| Advanced Alternative<br>Payment Model  | A subset of Alternative Payment Models (APMs) that let physician practices<br>earn payments for taking on down-side risk related to patient outcomes.<br>Practices that participate in an Advanced APM are eligible for up to a 5<br>percent incentive payment beginning in 2019, and are excluded from the<br>MIPS reporting requirements and payment adjustment.              |
| Advanced-practice<br>provider          | Medical professionals other than physicians who are authorized to prescribe medications, such as physician assistants and nurse practitioners.  |
| Alternative Payment<br>Model (APM)     | A payment approach that rewards providers or practices with incentive payments for providing high-quality and cost-efficient care.  |
| Antiemetic                             | Medication to prevent or reduce nausea and vomiting.  |
| Baseline period                        | The analytic time period during which outcomes are assessed prior the implementation of OCM, covering episodes that initiate July 1, 2014 to January 1, 2016.   |

| Biosimilar drug                        | A biological drug that is very much like another biological drug (called the reference drug) that has already been approved by the U.S. Food and Drug Administration (FDA). Biosimilar drugs and reference drugs are made from living organisms but they may be made in different ways and of slightly different substances. To be called biosimilar, a biological drug must be shown to be as safe as, work as well as, and work in the same way as its reference drug. It must also be used in the same way, at the same dose, and for the same condition as the reference drug. Biosimilar drugs must be approved by FDA, and may cost less than the reference drugs.   |
|--|--|
| Cancer bundle                          | The cancer bundle represents the primary cancer a beneficiary has during their episode. An episode is assigned a cancer type using the plurality of diagnoses on E&M services in the carrier file that occurred during the episode, per OCM program rules. The 21 reconciliation-eligible cancer types in the original OCM methodology are then expanded to 24, with breast cancer divided into low- versus high-risk, prostate cancer divided into low- versus high-risk, and bladder cancer divided into low- versus high-risk. The 25 <sup>th</sup> bundle is for all non-reconciliation eligible cancer types combined.  |
| Cancer bundle mix                      | The proportion of the different types of patients' cancers being treated by a given practice or observed within a given group of episodes.   |
| Care coordination/Care<br>coordinators | Care coordination involves deliberately organizing care activities and sharing<br>information among all of the participants involved in a patient's care, to<br>ensure the safe, appropriate, and effective delivery of health care services.<br>The individuals who coordinate care may be called care coordinators or nurse<br>navigators.   |
| Care Plan                              | Practices participating in OCM are required to document a Care Plan for<br>every OCM patient that includes 13 components as outlined by the Institute of<br>Medicine. The OCM Care Plan should include: 1) patient information (e.g.,<br>name, date of birth, medication list, allergies); 2) diagnosis, including specific<br>tissue information, relevant biomarkers, and stage; 3) prognosis; 4) treatment<br>goals; 5) initial plan for treatment and proposed duration, including surgeries<br>and radiation therapy; 6) expected response to treatment; 7) treatment benefits<br>and harms; 8) information on quality of life and patient's likely experience<br>with treatment; 9) who will take responsibility for specific aspects of a<br>patient's care; 10) advance care plans, including advance directives and other<br>legal documents; 11) estimated total and OOP costs of treatment; 12) a plan<br>for addressing a patient's psychosocial health needs, including psychological,<br>vocational, disability, legal, and financial concerns, and; 13) a survivorship<br>plan. |
| Chemotherapy (chemo)                   | For OCM purposes, CMS defines chemotherapy as systemic therapies<br>including cytotoxic chemotherapy, hormonal therapy, biologic therapy,<br>immunotherapy, and combinations of these therapies.   |

| Clinical decision support<br>(CDS)      | Provides clinicians, staff, patients, or other individuals with knowledge and<br>person-specific information, intelligently filtered or presented at appropriate<br>times, to support treatment decisions. CDS encompasses a variety of tools<br>including computerized alerts and reminders to care providers and patients,<br>clinical guidelines, condition-specific order sets, focused patient data reports<br>and summaries, documentation templates, diagnostic support, and<br>contextually relevant reference information.   |
|---|---|
| Clinical guidelines                     | Systematically developed statements to assist practitioner and patient decisions about appropriate treatment in specific clinical circumstances. Guidelines contain recommendations based on evidence from a rigorous systematic review and synthesis of the published medical literature, and define the role of specific diagnostic and treatment modalities in the diagnosis and management of patients. A clinical guideline may be broad, with several acceptable treatment regimens considered as compliant with the guideline. While clinical guidelines identify and describe generally recommended courses of treatment, they are not presented as a substitute for the advice of a physician or other knowledgeable health care professional or provider. |
| Coinsurance                             | The patient's share of costs of a covered health care service, calculated as a percentage. For example, a patient may pay 20 percent for a lab test or 80 percent for a prescribed medication that is not listed on their insurance plan's approved medication list.  |
| Comparison practice                     | A non-OCM oncology practice (identified by its TIN) selected to be in the evaluation comparison group. The evaluation team found selected comparison practices to be statistically similar to participating OCM practice(s) according to propensity score matching methods.   |
| Continuous Quality<br>Improvement (CQI) | As part of participation in OCM, practices are expected to track performance<br>against selected clinical quality measures, set future goals, and monitor the<br>effects of changes made. Strategies to improve quality might include data<br>reviews of metrics related to quality of care, utilization, or patient experience,<br>with or without a formal model of quality improvement in the practice.  |
| Copay/copayment                         | A fixed amount or percentage that a patient pays for a covered health service.<br>For example, a patient may need to pay \$20 to visit a doctor, or for a<br>prescription.  |
| Cost-sharing                            | What a patient pays for medical services covered by their health insurance.<br>Typical cost-sharing includes deductible, copayment, coinsurance, and<br>premium.  |
| Deductible                              | The amount a patient must spend for health care services that the patient's plan covers, before their health insurance begins to pay. For example, if a patient's deductible is \$1,000, their plan will not pay anything until they have met the \$1,000 deductible for covered health care services.  |
| Diagnosis-related group (DRG)           | A patient classification system that standardizes prospective payment to<br>hospitals based on a patient's specific diagnoses and treatments. In general, a<br>DRG payment covers all charges associated with a hospitalization from the<br>time of admission to discharge.   |

| Difference-in-Differences<br>(DID) | A statistical technique that quantifies the impact of an intervention by<br>comparing changes in outcomes of treatment cases (i.e., OCM episodes) to<br>changes in outcomes in a matched comparison group (i.e., comparison<br>episodes), from before to after Model implementation.   |
|------------------------------------|--|
| Dual eligible                      | A beneficiary who is enrolled in Medicare and also receiving full or partial Medicaid benefits.  |
| Electronic health record<br>(EHR)  | A longitudinal electronic record of patient health information generated by<br>one or more encounters in any care delivery setting. Included in this<br>information are patient demographics, progress notes, problems, medications,<br>vital signs, past medical history, immunizations, laboratory data, and<br>radiology reports. Also commonly referred to as electronic medical record<br>(EMR).  |
| Emetic                             | An agent that induces vomiting.  |
| Emetogenic                         | Causing nausea and vomiting.   |
| Enhanced oncology<br>services      | OCM practices are required to make the following enhanced services<br>available to beneficiaries with traditional Medicare insurance: 24/7 patient<br>access to an appropriate clinician who has real-time access to patient's<br>medical records; 2) core functions of patient navigation; 3) a documented<br>Care Plan that contains the 13 components recommended by the Institute of<br>Medicine; and 4) therapies consistent with nationally recognized clinical<br>guidelines (and explain deviations).  |
| Episodes (for OCM)                 | A six-month period of care that is triggered by receipt of chemotherapy with<br>at least one cancer-related E&M service occurring within six months of the<br>initial chemotherapy. Episodes initiate upon the date of service for an initial<br>Part B chemotherapy drug claim with a corresponding cancer diagnosis on the<br>claim, or upon the fill date for an initial Part D chemotherapy drug claim with<br>a corresponding Part B claim for cancer on the date of, or in the 59 days<br>preceding, the drug claim. If treatment continues for a beneficiary after the<br>six-month episode, a new episode begins when the episode criteria are met<br>again (i.e., a Part B chemotherapy infusion or Part D chemotherapy<br>prescription within 59 days after a Part B claim for cancer, followed by a<br>cancer E&M within six months). |
| Evaluation and<br>Management (E&M) | The billing code for a specific type of patient visit with a physician or<br>advanced practice provider, which includes at minimum the following<br>components: 1) history; 2) examination; and 3) medical decision making. An<br>E&M service with a cancer diagnosis on the same claim line on a carrier<br>claim is required to identify an OCM episode as well as assign the cancer<br>bundle to the episode.   |
| Evidence-based care                | Evidence-based care incorporates three fundamental components: 1) individual clinical expertise; 2) best external evidence; and 3) patient values and expectations. Also referred to as evidence-based practice.   |
| Fee-for-Service (FFS)              | A method in which doctors and other health care providers are paid for each<br>service performed. Examples of services include tests and office visits.<br>Traditional Medicare is also referred to as FFS Medicare insurance.   |
|                                    |  |

| Fractions                                  | The full dose of radiation is usually delivered in separate sessions, called fractions. This allows healthy cells to recover between treatments. In Medicare, a separate claim is submitted for each fraction/session.   |
|--|--|
| Generic drugs                              | Generic drugs are copies of brand-name drugs that have exactly the same<br>dosage, intended use, effects, side effects, route of administration, risks,<br>safety, and strength as the original drug. Their pharmacological effects are<br>exactly the same as those of their brand-name counterparts.   |
| Gross drug costs (GDC)                     | Total spending for the prescription claim, including payments from Medicare, supplemental insurance, and beneficiary payments.   |
| Growth factors                             | Proteins that help the body produce white blood cells. They are also called<br>hematopoietic, meaning blood-forming, colony-stimulating factors (CSFs).<br>White blood cells help fight infection and can be destroyed during some types<br>of cancer treatment. Growth factors can be administered to cancer patients, to<br>prevent neutropenia and infection. |
| Gynecologic oncology                       | The diagnosis and treatment of cancers located on a woman's reproductive organs (e.g., ovarian cancer).  |
| Health system or integrated health system  | An organization that includes at least one hospital, and at least one group of<br>physicians who are connected with each other and with the hospital through<br>common ownership or joint management, and combine their activities to<br>deliver comprehensive health care services.   |
| Health care proxy                          | A legally designated person who will express a patient's wishes and make<br>health care decisions for them if they are unable to speak for themselves.   |
| Hematology-oncology                        | The diagnosis, treatment, and prevention of blood diseases and blood cancers, such as leukemia, lymphoma, and myeloma.   |
| Hierarchical condition<br>categories (HCC) | CMS HCC flags are used to calculate risk scores that adjusts capitation<br>payments to Medicare Advantage health care plans for the health expenditure<br>risk of their enrollees. HCC scores use clinical diagnoses and comorbidities<br>(i.e., severity of illness) from the previous year to predict costs in the coming<br>year.                             |
|  | <u>Source</u> : Evaluation of the CMS-HCC Risk Adjustment Model Final Report,<br>available at: <u>https://www.cms.gov/Medicare/Health-</u><br><u>Plans/MedicareAdvtgSpecRateStats/downloads/Evaluation_Risk_Adj_Model</u><br>_2011.pdf   |
| Higher-risk episodes                       | Includes 22 of the 25 defined cancer bundles, and excludes the following: low-risk breast cancer, low-intensity prostate cancer, and low-risk bladder cancer.  |
| Hold-out period                            | The six-month time period prior to the implementation of OCM during which<br>the evaluation does not include episodes in order to prevent overlap between<br>baseline and intervention episodes.   |
| Home health care                           | Medical care provided in a patient's home. Home health care can include<br>skilled nursing care, physical therapy, occupational therapy, intravenous drug<br>therapy, and non-medical home aide services.  |

| Hormone therapy                              | A type of therapy that adds, blocks, or removes hormones. Hormones can<br>cause certain cancers (such as prostate and breast cancer) to grow. To slow or<br>stop the growth of cancer, synthetic hormones or other drugs may be given to<br>block the body's natural hormones. Also called endocrine therapy, hormonal<br>therapy, and hormone treatment.  |
|--|--|
| Hospice care                                 | End-of-life care provided by a team of health care professionals and<br>volunteers. The goal of hospice care is to help people who are dying have<br>peace, comfort, and dignity. Hospice care is covered by Medicare when a<br>patient is terminally ill and expected to live for six months or less. Patients<br>must stop active treatment for their terminal condition to receive Medicare-<br>covered hospice services. Hospice care can take place at home, at a hospice<br>center, in a hospital, or in a skilled nursing facility. |
| Hospital readmission                         | An admission to an acute care hospital within 30 days of discharge from an acute care hospital.  |
| Hospital utilization measures                | Hospital utilization measures include measures of inpatient care such as hospitalizations and length of stay (i.e., Medicare covered inpatient days per episode).  |
| Imaging                                      | A type of test that makes detailed pictures of areas inside the body. Imaging tests use different forms of energy, such as x-rays (high-energy radiation), ultrasound (high-energy sound waves), radio waves, and radioactive substances to help diagnose or treat cancer, and to monitor for cancer recurrence. Examples of imaging tests are computed tomography (CT), ultrasonography, magnetic resonance imaging (MRI), and nuclear medicine tests.  |
| Immunotherapy                                | A type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer.   |
| Infusion                                     | Treatment in which fluids, including drugs, are given through a needle or tube inserted into a vein, and travel through the blood. Also called intravenous infusion.   |
| Inpatient care                               | Inpatient care is medical treatment administered to a patient who has been formally admitted to a hospital or other health care facility.  |
| Intensity modulated radiation therapy (IMRT) | A type of three-dimensional radiation therapy that uses computer-generated<br>images to show the size and shape of a tumor. Thin beams of radiation of<br>different intensities are aimed at the tumor from many angles. This type of<br>radiation therapy reduces the damage to healthy tissue near the tumor.  |
| Intent-to-Treat (ITT)                        | A method for analyzing results in a prospective study where all participants<br>are included in the statistical analysis and analyzed according to the group<br>they were originally assigned (intervention or comparison), regardless of what<br>treatment (if any) they received. In the OCM evaluation, ITT analysis<br>includes all originally participating practices, including those that terminate<br>participation.   |
| Intervention period                          | The analytic time period during which outcomes are assessed while the OCM intervention is in effect. For this report, the intervention period covers episodes that initiate in PP1, PP2, and PP3.  |

| Intravenous chemotherapy                       | Treatment in which anticancer drugs are given through a needle or tube inserted into a vein, and travel through the blood to kill cancer cells in the body.   |
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| Long-term care (LTC)                           | A variety of services designed to meet a person's health or personal care<br>needs when they can no longer perform everyday activities on their own. LTC<br>is provided in different places by different caregivers, depending on a<br>person's needs. It can be provided at home by unpaid family members and<br>friends, or in a facility such as a nursing home.   |
| Lower-risk episodes                            | Includes low-risk breast cancer, low-intensity prostate cancer, and low-risk bladder cancer.  |
| Lumpectomy                                     | Excision of a breast tumor with a limited amount of associated tissue.  |
| Malignant                                      | Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.  |
| Mastectomy                                     | Surgery to remove part or all of the breast.  |
| Medical homes                                  | An approach to the delivery of primary care that is: 1) patient centered; 2) comprehensive; 3) coordinated; 4) accessible; and 5) committed to quality and safety.  |
| Medical oncology                               | The diagnosis and treatment of cancer using chemotherapy, hormonal therapy, biological therapy, and targeted therapy. A medical oncologist often is the main health care provider while a person is undergoing treatment for cancer. A medical oncologist also gives supportive care and may coordinate treatment given by other specialists.   |
| Medicare Advantage                             | A type of Medicare health plan offered by a private company that contracts<br>with Medicare. Medicare Advantage plans include: Health Maintenance<br>Organizations, Preferred Provider Organizations, Private FFS Plans, Special<br>Needs Plans, and Medicare Medical Savings Account Plans.  |
| Medicare beneficiary                           | A person enrolled in Medicare insurance, whether traditional Medicare or a Medicare Advantage plan.   |
| Merit-based Incentive<br>Payment System (MIPS) | CMS operates a quality payment incentive program, referred to as the QPP, which rewards value and outcomes in one of two ways: MIPS and Advanced APMs. Performance is measured in four areas: 1) quality; 2) improvement activities; 3) promoting interoperability of electronic health information; and 4) cost. All eligible clinicians were required to participate in MIPS starting in 2017 or be subject to a negative 4 percent payment adjustment on Medicare Part B reimbursements starting in 2019. Those who participate in an Advanced APM are eligible to receive up to a 5 percent bonus adjustment. |
| Metastasis                                     | The spread of cancer cells from the place where they first formed to another<br>part of the body. The new metastatic tumor is the same type of cancer as the<br>primary tumor.  |

| Monthly Enhanced<br>Oncology Service<br>(MEOS) payment | Payment intended to support care redesign and enhanced oncology services (see definition for enhanced oncology services). MEOS and PBPs are the financial incentives in OCM. OCM practices may bill Medicare a \$160 per beneficiary fee for each month of a six-month episode, unless the beneficiary enters hospice care or dies. MEOS payments billed for beneficiaries who do not meet all episode eligibility criteria (e.g., those who switch to Medicare Advantage during the episode) will be recouped since no episode will be identified for these beneficiaries. |
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| Multi-modal treatment                                  | Therapy that combines more than one method of treatment. This can include<br>any combination of surgery, chemotherapy/immunotherapy, and radiation<br>therapy. Also called combination therapy and multimodality therapy.   |
| Multi-specialty practice                               | Includes physicians certified in different specialties, for example, oncologists, cardiologists, surgeons, and pediatricians.   |
| National Comprehensive<br>Cancer Network (NCCN)        | A not-for-profit alliance of leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care. NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system, promotes the importance of CQI, and creates/updates clinical practice guidelines for cancer care.   |
| National provider<br>identifier (NPI)                  | A unique identification number assigned to health care providers in the United<br>States, used for administrative and financial transactions, such as submitting<br>claims to Medicare for payment of services rendered to Medicare<br>beneficiaries.   |
| National Quality Forum<br>(NQF)                        | A not-for-profit, nonpartisan, membership-based organization that endorses<br>quality measures. NQF-endorsed measures are considered the gold standard<br>for health care measurement in the United States. Most OCM measures are<br>NQF endorsed.  |
| Neoplasm   | An abnormal mass of tissue that results when cells divide more than they should or do not die when they should. Neoplasms may be benign (not cancer), or malignant (cancer). Also called tumor.   |
| Neutropenia  | A condition in which there is a lower-than-normal number of neutrophils (a type of white blood cell) in the blood. Neutrophils are made in the bone marrow. People who have neutropenia have a higher risk of getting serious infections.   |
| Non-Reconciliation<br>Eligible Cancer                  | Types of cancer identified by CMS to be rare. OCM episodes for these cancer types are not included in PBPs, although practices may submit claims for MEOS payment during treatment episodes for these types of cancer.  |

| Novel therapies              | Novel therapies are treatments newly approved by the Food and Drug<br>Administration (FDA) for treatment of cancer. In OCM, performance-based<br>payments are adjusted for novel therapies, which are often more costly than<br>alternative therapies. Use of the novel therapy must be consistent with the<br>FDA-approved indications. Most new oncology drugs/indications are<br>considered "novel" for two years after FDA approval for that specific<br>indication. Payment adjustment is based on the percentage of each practice's<br>average episode expenditures for novel therapies, compared to the average<br>percentage for practices that are not participating in OCM. |
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| OCM Data Registry            | CMS requires practices participating in OCM to enter information about each<br>patient's anatomic disease staging, and other clinically relevant data into a<br>data registry (e.g., molecular mutations that enable the use of targeted<br>therapies). In addition, practices must report quality measurement data for the<br>purposes of calculating PBPs and for measuring practice quality<br>improvement.  |
| OCM practice                 | An oncology practice that is participating in the Oncology Care Model. OCM practices comprise the evaluation treatment group.   |
| Oncologist                   | A physician who treats cancer and provides medical care for people with cancer.   |
| Oncology                     | A branch of medicine that specializes in the diagnosis and treatment of cancer.   |
| Oral chemotherapy            | Treatment with drugs given by mouth to kill cancer cells or stop them from dividing.  |
| Out-of-pocket (OOP)<br>costs | Expenses for medical care that are not reimbursed by insurance and are the responsibility of the patient. OOP costs include deductibles, coinsurance, and copayments for covered services, and all costs for services that are not covered by insurance.  |
| Outpatient care              | Care provided to a patient who has not been admitted to a hospital or other inpatient facility.   |
| Palliative care              | Palliative care addresses symptoms of disease and treatment, to improve the quality of life of patients and their families facing life-threatening illness. Palliative care aims to prevent or relieve pain and other suffering, whether physical, psychosocial, or spiritual.  |
| Part A                       | Medicare Part A is insurance coverage for inpatient care in a hospital, skilled<br>nursing facility, inpatient rehabilitation facility, or long term care hospital, as<br>well as hospice care and home health care.  |
| Part B                       | Medicare Part B is insurance coverage for outpatient/medical care, including medically necessary physician and other professional services and therapies, preventive services, and professionally administered prescription drugs such as chemotherapy infusions.   |
| Part D                       | Medicare Part D is optional insurance coverage to help Medicare beneficiaries<br>pay for self-administered prescription drugs. Medicare Part D plans are<br>offered by private insurance companies.   |

| Pathways software<br>programs                                | Pathways software programs provide clinical decision support that guides<br>physicians about which treatment regimen to select for a patient, based on<br>clinical guidelines about the most efficacious or the best-value treatment<br>option (for example, when more than one drug is equally efficacious, with<br>equivalent toxicity risk, but they have different costs). Pathways software<br>programs are sold by vendors, and can be incorporated into or separate from a<br>practice's EHR.  |
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| Patient navigator  | A health professional who focuses on the patient's needs. The navigator helps<br>guide the patient through the health care system and works to overcome<br>obstacles that are in the way of the patient receiving the care and treatment<br>they require.   |
| Performance period (PP)                                      | OCM episodes are organized into six-month performance periods. At each participating practice, all episodes that begin during a performance period are reconciled together. For example, Performance Period One (PP1) includes OCM-defined six-month treatment episodes that began between July 1, 2016, and January 1, 2017, the last of which ended by June 30, 2017.   |
| Performance-based<br>payment (PBP)                           | A practice participating in OCM may be eligible to receive a proportion of reductions in Medicare episode payments as compared with its historic benchmarks (less a discount retained by CMS). The PBP is calculated retrospectively for each PP, based on the practice's reductions in Medicare payments below a target price, adjusted for quality. The combination of these PBPs, along with monthly per-patient payments for enhanced oncology services (the MEOS payment) form the financial and quality incentives in OCM.  |
| Physician Order for Life-<br>Sustaining Treatment<br>(POLST) | Medical orders that travel with a patient, to be used when they have become<br>seriously ill or frail, and toward the end of life. A POLST form is completed<br>by a physician after discussing with a patient the diagnosis, prognosis, and<br>likely outcomes, and the patient's individual goals and preferences. It gives<br>medical orders to emergency personnel about which treatments the patient<br>does and does not wish to undergo. A doctor (sometimes physician assistant<br>or nurse practitioner, depending on the state) must sign the POLST form for it<br>to be valid. |
| Post-acute care (PAC)  | Includes rehabilitation or palliative services that beneficiaries receive after, or<br>in some cases instead of, hospital care. Depending on the intensity of care the<br>patient requires, PAC may be provided in a skilled nursing facility or in a<br>patient's home by a home health agency.  |
| Practice   | Physician group or business entity that provides cancer care to patients,<br>defined for OCM purposes by the unique TIN that the physicians use to<br>submit claims for Medicare payment. Practices can be independently owned,<br>health-system/hospital owned, or part of an academic medical center.   |
| Practice transformation<br>plans (PTP)                       | CMS asks participating OCM practices to submit annual PTPs. These are<br>structured self-assessments of their practice transformation activities during<br>the prior year, and their plans for the future.  |

| Prognosis                        | The likely outcome or course of a disease; the chance of recovery or recurrence. A cancer prognosis may indicate the likelihood of cure, or the anticipated life expectancy when cure is not possible.   |
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| Propensity score matching        | Propensity score matching is used to select a comparison group that is<br>statistically similar to an intervention/treatment group. Propensity scores can<br>be used to reduce or eliminate selection bias_in observational studies by<br>balancing observed covariates (the characteristics of participants' practices,<br>markets and attributed episodes) between treatment and comparison groups.<br>The goal is to approximate a random experiment, eliminating many of the<br>problems that come with observational data analysis. |
| Prophylactic                     | A preventive measure. A medication or treatment designed to prevent a disease or other outcome from occurring.   |
| Proton beam radiation<br>therapy | A type of radiation therapy that uses streams of protons (tiny particles with a positive charge) to kill tumor cells while reducing radiation damage to healthy tissue near a tumor. It is used to treat cancers of the head and neck and organs such as the brain, eye, lung, spine, and prostate. Proton beam radiation is different from x-ray radiation therapy.   |
| Quality Payment Program<br>(QPP) | The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to operate the Medicare QPP. There are two ways clinicians can participate in the QPP: MIPS or Advanced APMs. (See previous definitions.)  |
| Radiation oncology               | One of the three primary specialties in oncology, the other two being surgical<br>and medical oncology, involved in the treatment of cancer. Radiation can be<br>given as a curative modality, either alone or in combination with surgery<br>and/or chemotherapy. It may also be palliative, to relieve symptoms (e.g.,<br>pain from bone metastases) in patients with incurable cancer.  |
| Radiation therapy                | The use of high-energy radiation from x-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells or shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy) or from radioactive material placed in the body near cancer cells (internal radiation therapy or brachytherapy). Also called irradiation and radiotherapy.  |
| Regimen                          | A treatment plan that specifies the drug, dosage, schedule, and duration of treatment. A treatment regimen for a specific patient may include chemotherapy drugs as well as supportive therapy drugs such as white cell growth factors or antiemetics.   |
| Shared decision making           | A process in which clinicians and patients work together to make decisions<br>and select tests, treatments, and Care Plans based on clinical evidence that<br>balances risks and expected outcomes with patient preferences and values.  |
| Office-Based Physician<br>File   | This proprietary data source of physician data contains information about<br>every practice site in the United States where care is provided by medical<br>professionals. It includes the ownership, size, address, and list of individual<br>providers operating at the practice site, along with their health and hospital<br>affiliations.  |

| Skilled nursing facility<br>(SNF)       | An inpatient nursing facility where skilled nursing is provided by medical professionals. Medicare Part A covers up to 100 days of care in a SNF each benefit period.   |
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| Stage                                   | Cancer staging is usually based on the size of the tumor, whether lymph nodes contain cancer, and whether the cancer has spread from the original site to other parts of the body. Higher stages indicate larger, or more broadly spread cancer in the body and usually a poorer prognosis.   |
| Supportive therapy                      | Medications that are used to ameliorate chemotherapy-related side effects that<br>may occur during cancer treatments. Common types of supportive therapies<br>include anti-nausea medications, blood cell growth factors, and bone-<br>stabilizing medications.   |
| Surgical oncology                       | Surgical oncology is one of the three primary specialties in the treatment of cancer and involves the use of surgery to remove cancerous tumors. Surgery can be used by itself or with other (adjuvant) treatments, such as chemotherapy and radiation.   |
| Survivorship plan                       | A detailed plan given to a patient after successful treatment ends, that contains<br>a summary of the patient's treatment, along with recommendations for follow-<br>up care. In cancer, the survivorship plan is based on the type of cancer and the<br>treatment the patient received. A survivorship care plan may include<br>schedules for physical exams and medical tests to (also called surveillance) to<br>detect if the cancer has recurred or spread to other parts of the body. This<br>follow-up care and surveillance usually continues for several years. A<br>survivorship plan may also include information to help meet the emotional,<br>social, legal, and financial needs of the patient, such as referrals to specialists<br>and recommendations for a healthy lifestyle. |
| Taxpayer identification<br>number (TIN) | CMS uses IRS-assigned TINs to identify hospitals, physicians, and others that<br>submit claims for payment, for services delivered to Medicare beneficiaries.<br>The TIN is the same as the Federal Employer ID Number (FEIN) or Employer<br>Identification Number (EIN). In OCM, all providers in a practice must submit<br>claims for their services under one unified TIN.   |
| Total episode payment<br>(TEP)          | The total gross Medicare Part A, B and D payment for all cancer and non-<br>cancer care for a patient during a six-month OCM-defined episode. Part A<br>and B payments are standardized to remove geographic differences in labor<br>costs and to exclude payments to providers that support larger Medicare<br>program goals such as disproportionate share payments. Part D payments are<br>not standardized and are calculated as the sum of low income cost-sharing and<br>reinsurance. TEP does not include MEOS payments.   |
| Toxicity                                | The extent to which treatment is poisonous or harmful, or causes side effects.  |
| Triage                                  | The sorting of patients according to the urgency of their need for care. Triage<br>can be provided over the phone, to assess whether a patient should come into<br>the clinic or visit an emergency room.   |

| Two-sided risk             | Participating OCM practices may voluntarily adopt two-sided risk, in which<br>Medicare payments above the target are recouped by CMS. Accepting two-<br>sided risk meets the QPP's criteria for being an Advanced APM. Practices<br>will be required to move to two-sided risk (or their participation will be<br>terminated) if, as of the initial reconciliation of the fourth performance period<br>(estimated fall 2019), they have not yet achieved a PBP for at least one of the<br>first four performance periods. Practices that have achieved a PBP in one of<br>the first four performance periods may choose to stay in the model under one-<br>sided risk. |
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| Value-based payment models | Payment models that reward health care providers with incentive payments<br>for the quality of care they provide to patients. These models are part of<br>CMS's larger quality strategy to reform how health care is delivered and paid<br>for.  |