

Health Care Resource Utilization, Quality Metrics, and Costs of Bladder Cancer Within the Oncology Care Model

Heidi S. Wirtz, PharmD, PhD; Zsolt Hepp, PharmD, MSc; Simrun Grewal, PhD; Phoebe Wright, PharmD, MSc; Rupali Fuldeore, MSc; Samantha Tomicki, MPH; Jared Hirsch, MSc; Gabriela Dieguez, MSc; and L. Johnetta Blakely, MD

Bladder cancer (BC) is the sixth most common cancer in the United States, with 83,730 new cases and 17,200 deaths in 2021.^{1,2} Although the 5-year survival rate for BC overall is 77.1%, it is only 6.4% for metastatic disease.²

Before 2016, the therapeutic management of BC had remained largely unchanged for more than 30 years, with treatment for non–muscle-invasive BC consisting of transurethral resection of bladder tumor with or without intravesical chemotherapy (eg, mitomycin) or immunotherapy (bacille Calmette-Guérin [BCG]), whereas treatment for muscle-invasive, advanced, or metastatic disease was dominated by radical cystectomy and systemic therapy or immunotherapy.^{3,4} The most prominent histological subtype of BC is urothelial cancer (UC), accounting for more than 90% of cases of BC.⁵ Historically, patients with locally advanced or metastatic UC (LA/mUC) have been treated with cisplatin-based chemotherapy. However, because BC primarily affects individuals 70 years and older, a considerable proportion of patients were ineligible for cisplatin-based chemotherapy because of characteristics such as poor performance status and age-related comorbidities.⁴ Patients with LA/mUC who are ineligible for cisplatin are treated with carboplatin-based regimens, but with limited effectiveness.⁴

Many new treatment options for BC have been approved by the FDA since 2016. With the introduction of immunotherapies targeting PD-1 or PD-L1, including pembrolizumab, avelumab, and nivolumab,⁶⁻⁹ the treatment landscape for BC, particularly LA/mUC, is considered to be especially dynamic and evolving.⁶⁻¹⁰ Since 2019, further novel therapies have been approved in the second- and third-line setting of LA/mUC, including enfortumab vedotin, sacituzumab govitecan, and erdafitinib.¹¹⁻¹⁴

In 2016, the CMS Innovation Center introduced the Oncology Care Model (OCM), an alternative service delivery and payment model, to explore new mechanisms and payment and delivery structures, with the aim of delivering lower-cost and higher-quality oncology care to Medicare beneficiaries.¹⁵ The OCM was a 6-year model to test innovative payment strategies that promote high-quality and high-value care by oncology practices voluntarily participating in the model.^{16,17} The OCM was centered on 6-month episodes

ABSTRACT

OBJECTIVES: New and emerging therapies have significantly changed the bladder cancer (BC) treatment landscape and can potentially affect spending and patient care in CMS' Oncology Care Model (OCM), a service delivery and payment model for voluntarily participating practices. The objectives of this analysis were to estimate health care resource utilization (HCRU) and benchmark spending per OCM episode of BC, and to model spending drivers and quality metrics.

STUDY DESIGN: Retrospective cohort study.

METHODS: A retrospective cohort study was conducted of OCM episodes triggered by receipt of anticancer therapy among Medicare beneficiaries from 2016 to 2018. Based on this, an average performance estimation was conducted to assess the impact of hypothetical changes in novel therapy use by OCM practices.

RESULTS: BC accounted for approximately 3% (n = 60,099) of identified OCM episodes. Relative to low-risk episodes, high-risk episodes were associated with greater HCRU and worse OCM quality metrics. Mean spending per high-risk episode was \$37,857 (low-risk episode: \$9204), with \$11,051 spent on systemic therapies and \$7158 on inpatient services. In the estimation, high- and low-risk BC exceeded the spending target by 1.7% and 9.4%, respectively. This did not affect payments to practices and no retrospective payments were necessary.

CONCLUSIONS: As 3% of OCM episodes were attributed to BC, with only one-third classified as high-risk, controlling expenditure on novel therapies for advanced BC is unlikely to affect overall practice performance. The average performance estimation further emphasized the minimal impact that novel therapy spending in high-risk BC has on OCM payments to practices.

Am J Manag Care. 2023;29(5):In Press

of care triggered by receipt of anticancer therapy. During each episode, practices were reimbursed on a fee-for-service (FFS) basis, which was derived from the mean expenditures determined for each cancer diagnosis group. The OCM also had a 2-part payment approach: the Monthly Enhanced Oncology Service (MEOS) payment and the potential performance-based payment (PBP). Monthly MEOS payments of \$160 per beneficiary were paid to practices for enhanced services and care coordination, whereas potential PBPs incentivized practices to lower cost of care relative to a risk-adjusted target amount and to improve care quality.^{15,18} A benchmark episode expenditure at the end of each episode was determined based on historical data and was adjusted for novel therapy use (to partially compensate practices with higher-than-average novel therapy use) and patient-specific risk factors. A discount, depending on risk-sharing arrangement, was then applied to the benchmark episode expenditure to determine a target price. Practices could choose between a 1-sided risk-sharing arrangement (no additional payment from the practice to CMS when actual episode expenditures are higher than spending target) and a 2-sided arrangement (in which the practice is eligible for higher PBPs but is required to pay expenditures above spending target). Additional retrospective PBPs were made biannually, based on performance periods.^{16,19} The OCM was discontinued in December 2021, with payments ending in June 2022 for remaining episodes. It is anticipated to be replaced by a new episode-based alternative payment model, Oncology Care First (OCF). The OCF model will potentially include a shift from FFS reimbursement to capitation, improved PBP methodology, and an expansion of eligible beneficiaries.²⁰

A recent review of alternative US payment and care delivery models in cancer care, such as the OCM, identified a lack of outcome reporting and therefore limited evidence to evaluate the efficiency and impact of these models.¹⁸ Given the dynamic BC treatment landscape and the potential impact of novel therapies on outcomes and costs, it is important to understand current practices and spending in BC management as a benchmark within the OCM alternative payment model.

The primary objective of this analysis was to estimate health care resource utilization (HCRU) and benchmark spending per OCM episode (overall, and high- and low-risk episodes) of BC, as well as spending drivers and quality metrics within practices modeled as though they are participating in the OCM. New and emerging therapies will affect spending and patient care in this payment model; we therefore aimed to contextualize the historical experience of BC among all OCM cancer types to lay a foundation and to gain an understanding of how the changing landscape may impact this benchmark. This foundational work will improve the

TAKEAWAY POINTS

In the Oncology Care Model (OCM), high-risk episodes of bladder cancer (BC), 40% of which were metastatic BC, had higher health care resource utilization and costs, and lower quality performance, compared with low-risk episodes. Overall, less than 3% of OCM episodes were attributed to BC, and only one-third of BC episodes were classified as high risk. Therefore, controlling expenditure on novel therapies in BC episodes is unlikely to affect overall performance for practices participating in the OCM. An average performance estimation further emphasized the minimal impact that novel therapy spending in high-risk BC has on OCM payments to practices.

- ▶ The treatment landscape of BC is highly dynamic, and novel therapies offer an opportunity to optimize BC management and improve quality of care, particularly for high-risk episodes.
- ▶ The OCM is an example of an alternative payment model in oncology and can serve to inform other initiatives in this space. The forthcoming new and distinct Oncology Care First (OCF) model will build on lessons learned.
- ▶ Further studies should evaluate long-term OCM practice performance, accounting for the impact of emerging therapies on outcomes and costs over time, and continue to evaluate outcomes following implementation of the OCF model.

understanding of managing patients with BC in OCM practices and alternative payment models and of how BC fits into the overall experience of an OCM practice.

METHODS

Study Design

A retrospective cohort study was conducted among Medicare FFS beneficiaries with BC who qualified for an OCM 6-month episode of care based on the CMS OCM guidelines; these approximated episodes were triggered by receipt of cancer therapy. An average performance estimation was conducted using the results of the claims data analysis to assess how practices may perform differently based on their characteristics (eg, practice type, risk-sharing arrangement, utilization of medical and drug services, novel therapy uptake).

Study Population

The study population was derived from Medicare 100% Research Identifiable Files administrative claims data (with linked parts A [hospital insurance, including inpatient care, nursing facilities, hospice care, and home health care],²¹ B [medical insurance, including outpatient care, medical supplies, and preventive services],²² and D [prescription drug coverage]²³) from January 1, 2016, through December 31, 2018. These were the most recent CMS claims data available at the time of study conduct. The episodes were constructed following CMS OCM methodologies: An episode starts with an identifying trigger event in the claims data that indicates provision of cancer therapy for any cancer diagnosis. A cancer type was assigned to each episode to identify BC episodes specifically. The period for the trigger events eligible for inclusion in the analysis was between July 1, 2016, and June 30, 2018, to ensure a 6-month baseline period and up to 6 months of postindex follow-up. BC episodes were stratified by risk based on OCM definition. Low-risk BC was defined by receipt of BCG and/or mitomycin without any other cancer therapy; these are therapies used for patients with

non–muscle invasive BC only. High-risk BC was defined by receipt of cancer therapy other than BCG or mitomycin.

Inclusion criteria were aligned with CMS methodology for the OCM program. We required patients to (1) have a Part B or D cancer therapy trigger event (index date) with cancer diagnosis between July 1, 2016, and June 30, 2018; (2) have been enrolled in both parts A and B for the entire OCM episode (6 months or until death); (3) have Medicare as their primary payer; (4) have at least 1 qualifying evaluation and management visit during the episode; and (5) have 6 months' enrollment preindex and post index (or death).

CMS OCM methodology did not require a 6-month baseline period when considering episodes. New episodes could not be triggered while a 6-month episode was already ongoing. Patients covered under Medicare Advantage or any other group health program, or patients receiving Medicare benefits for end-stage renal disease, were excluded.

Among patients with a potential OCM triggering event, those with a diagnosis code for metastatic BC (*International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] codes C77.XX, C78.XX, C79.XX*) were described in an exploratory analysis. In its framework, CMS OCM does not specifically consider metastatic BC—only high- and low-risk BC.

Outcomes

The outcomes of interest are the following:

1. HCRU (including hospitalizations and intensive care unit [ICU] stays, lengths of stay, emergency department [ED] visits, cancer therapy use, and adverse events [AEs]).
2. OCM quality metrics (including metrics affecting payments for performance periods 1 through 4 in the CMS OCM [2016–2018]; proportion of episodes with all-cause hospital admissions within the 6-month episode; proportion of episodes with all-cause ED visits or observation stays that did not result in a hospital admission within the 6-month episode; proportion of episodes with hospice for 3 days or more, among patients who died within the 6-month episode; and proportion of patients who died during the episode).
3. Costs (including total cost per episode, inpatient services, outpatient services, cancer therapies, physician services, other Part B drugs, other Part D drugs, hospice care, and other services [eg, home health or skilled nursing facility]).

Statistical Analysis

Descriptive data summaries are reported, such as means, CIs, frequencies, and percentages.

Average Performance Estimation

An average performance estimation was conducted based on input values for hypothetical OCM practices to assess how practices performed differently from one another. The model was based on practice characteristics (eg, practice type, risk-sharing arrangement,

utilization of medical and drug services, and uptake of parts B and D novel therapies); proportion of patients with high- or low-risk BC; and the change in HCRU or Part B novel cancer therapy costs among patients with high-risk BC. Input values for the average performance estimation were derived from the retrospective cohort study and included practice-specific inputs, BC inputs, and OCM high-risk BC inputs. The default setting was an average integrated delivery network with a 1-sided risk-sharing arrangement (**eAppendix Table 1** [eAppendix available at [ajmc.com](https://www.ajmc.com)]).

Separate analyses testing different scenarios were conducted to assess the impact of no increase vs a 25% increase in spending on novel therapy in high-risk BC under a 1-sided and a 2-sided risk arrangement. The 1-sided risk arrangement assumed no reduction in utilization of medical and drug services, whereas in the 2-sided scenario, a 10% reduction in utilization of medical and drug services was assumed.

RESULTS

Study Population

Of the approximately 2.2 million OCM episodes identified for all cancer types among approximately 1 million Medicare beneficiaries, 60,099 (2.7%) were BC episodes. Our study cohort consisted of 43,621 BC episodes among 33,497 beneficiaries with BC, with 31.0% of the BC episodes identified as high risk (**eAppendix Figure 1**). Relative to patients who experienced low-risk episodes, high-risk episodes included a higher proportion of metastatic cases (40% vs 2%), based on post index episodes.

Across BC episodes, patients were predominantly White (92%) and male (77%), and they had a mean age of 76.6 years (**Table 1**). Relative to patients who experienced low-risk episodes, those with high-risk BC episodes had a higher comorbidity burden at baseline (mean Charlson Comorbidity Index score, 7.4 vs 4.3; 68% vs 35% of patients had 5 or more comorbidities). Hypertension, dyslipidemia, and coronary artery disease/atherosclerosis were the most commonly reported comorbid conditions across BC episodes.

HCRU and Quality Metrics per 6-Month OCM BC Episodes

Low-risk episodes of BC had a mean of 0.2 hospital admissions per episode, a mean length of stay of 4.9 days, 1% BC surgery rate, 2% mortality rate, and 5% of hospitalizations with ICU stays; 24% of episodes required ED visits. Among OCM quality metrics, low-risk episodes were associated with 15% of inpatient admissions and 20% of ED visits without inpatient admissions. The most common AEs reported during low-risk episodes were anemia and fatigue (**Table 2**).

High-risk episodes of BC had a mean of 0.7 hospital admissions per episode, a mean length of stay of 5.9 days, 7% BC surgery rate, 17% mortality rate, and 17% of hospitalizations with ICU stays; 47% of episodes required ED visits. Among OCM quality metrics, high-risk episodes were associated with 42% of inpatient admissions and 37% of ED visits without inpatient admissions. The most common AEs reported during high-risk episodes were also anemia and fatigue (**Table 2**).

Costs per Episode

Mean (SD) spending per high-risk BC episode was \$37,857 (\$30,433), with \$11,051 spent on cancer therapies and \$7158 on inpatient services. For low-risk BC episodes, the mean (SD) spending per episode was \$9204 (\$13,508), with \$683 spent on cancer therapies and \$2081 on inpatient services (Figure).

Episodes with metastatic BC had higher total costs (\$47,478), as well as higher component costs, with \$14,141 per episode spent on cancer therapies and \$10,531 on inpatient services. However, based on CMS classification, metastatic BC episodes are grouped as high risk along with other, nonmetastatic, or locally advanced episodes.

Average Performance Estimation

The average performance estimation resulted in 2116 total OCM episodes for all cancers in a 6-month period, with 28 (1.3%) high-risk BC episodes and 31 (1.5%) low-risk BC episodes (Table 3). The mean spend was \$32,043 per OCM episode across cancers, with a total 6-month episode spending of \$67.8 million. The mean spend was \$35,310 per high-risk and \$9263 per low-risk BC episode, which marginally exceeds OCM performance period spending targets of \$34,712 (high-risk BC) and \$8391 (low-risk BC). Although high-risk BC exceeded the 6-month spending target by 1.7% and low-risk BC by 9.4% in the average performance estimation, this does not affect the PBP because the performance estimation assumed a 1-sided risk-sharing arrangement with zero downside risk for OCM recoupment. In this scenario, the retrospective PBP from CMS was \$0. Trends in spending per episode by service type were similar to those observed in the retrospective analysis (eAppendix Figure 2).

Scenario Analysis

In the separate scenario analysis comparing a 0% vs 25% increase in novel therapy drug spending for OCM high-risk BC episodes under a 1-sided risk arrangement, a 25% increase in spending resulted in no change of the PBP (eAppendix Table 2).

In the scenario analysis under a 2-sided risk arrangement, for a 0% vs 25% increase in novel therapy drug spending, there was an overall incremental gain for practices on all OCM expenditures of only 0.1%, or \$23, per OCM episode (eAppendix Table 3).

DISCUSSION

In our analysis, BC accounted for approximately 3% of all OCM 6-month episodes, and one-third of OCM BC episodes among Medicare beneficiaries were classified as high risk. High-risk OCM episodes of BC—which involved individuals receiving systemic therapies, 40% of whom had metastatic BC—had higher HCRU and costs, and lower-quality performance, than low-risk episodes.

High-risk BC episodes were characterized by more advanced disease, exhibited by the high proportion of patients with metastatic disease, which indicates that high-risk episodes are primarily assigned to patients with muscle-invasive BC and LA/mUC. Novel therapies offer a significant opportunity to optimize BC management and

TABLE 1. Demographic and Clinical Characteristics

Characteristic	Total	High risk	Low risk
Number of episodes	43,621	13,533	30,088
Age in years, mean (SD)	76.6	76.8	76.5
Age, n (%)			
< 65 years	1197 (3)	475 (4)	722 (2)
65–74 years	17,062 (39)	5005 (37)	12,057 (40)
75–84 years	18,222 (42)	5566 (41)	12,656 (42)
≥ 85 years	7140 (16)	2487 (18)	4653 (15)
Male, n (%)	33,790 (77)	10,137 (75)	23,653 (79)
Low income, n (%)	3062 (7)	1196 (9)	1866 (6)
Race/ethnicity, n (%)			
White	40,012 (92)	12,246 (90)	27,766 (92)
Black	1836 (4)	696 (5)	1140 (4)
Other*	1773 (4)	591 (4)	1182 (4)
Geography, n (%)			
Northeast	12,337 (28)	3485 (26)	8852 (29)
South	15,614 (36)	4966 (37)	10,648 (35)
Midwest	8989 (21)	3045 (23)	5944 (20)
West	6679 (15)	2036 (15)	4643 (15)
Charlson Comorbidity Index score, mean (SD)	5.2 (3.38)	7.4 (4.01)	4.3 (2.49)
Number of comorbidities, n (%)			
≤ 2	9757 (22)	1560 (12)	8171 (27)
3–4	14,192 (33)	2807 (21)	11,385 (38)
≥ 5	19,672 (45)	9140 (68)	10,532 (35)
Common comorbidities, n (%)			
Hypertension	29,507 (68)	9550 (71)	19,957 (66)
Dyslipidemia	24,986 (57)	7662 (57)	17,324 (58)
CAD/atherosclerosis	14,960 (34)	5002 (37)	9958 (33)
Chronic kidney disease	12,669 (29)	5839 (43)	6830 (23)
Diabetes	12,572 (29)	3817 (28)	8755 (29)
Osteoarthritis	9266 (21)	3086 (23)	6180 (21)
Anemia	7519 (17)	3966 (29)	3553 (12)
Heart failure	4271 (10)	1601 (12)	2670 (9)

CAD, coronary artery disease.

*Other includes Asian, Hispanic, American Indian/Alaska Native, and other (≤2% each).

improve quality of care, particularly for high-risk episodes, where we demonstrated that costs of inpatient services were highest.²⁴

The cost impact to the OCM for introducing or increasing novel therapy use in BC episodes is low. Because low-risk episodes can include only BCG and mitomycin therapy, all novel anti-BC treatments will trigger high-risk episodes. Controlling expenditures on novel therapies in BC episodes is unlikely to affect overall episode spending for participating practices, because the novel therapy adjustment is calculated at the overall practice level for all cancers, not by cancer type. The low volume of BC episodes (~3%) across all cancers also makes the managing of high-risk BC, which represents a subset of this already small patient population, unlikely to affect overall

CLINICAL

TABLE 2. HCRU and Quality Measures Associated With OCM BC Episodes^a

Measure	Total	High risk	Low risk	
Number of BC episodes	43,621	13,433	30,088	
Inpatient admissions	Number of inpatient admissions per episode, mean (SD)	0.4 (0.8)	0.7 (1.1)	0.2 (0.6)
	Length of stay per admission, days, mean (SD)	5.5 (6.2)	5.9 (8.7)	4.9 (4.3)
	Admissions with ICU care, %	9 (0.1)	17 (0.3)	5 (0.1)
Mortality	Episodes with surgery, %	3 (0.1)	7 (0.2)	1 (0.1)
	Patient died during the episode, %	6 (0.1)	17 (0.3)	2 (0.1)
	Patient died within 30 days after episode end, %	7 (0.1)	20 (0.3)	2 (0.1)
ED care	Patient died within 90 days after episode end, days	9 (0.1)	24 (0.4)	3 (0.1)
	Episodes with any ED care, %	31 (0.2)	47 (0.4)	24 (0.2)
OCM quality measures	Episodes with an all-cause inpatient admission, %	23 (0.2)	42 (0.4)	15 (0.2)
	Episodes with an ED admission or observation stay not followed by an inpatient admission, %	26 (0.2)	37 (0.4)	20 (0.2)
Cancer therapies	Episodes with hospice for 3 days or more, among patients who died, %	46 (0.2)	50 (0.4)	26 (0.3)
	Episodes with platinum-based chemotherapy, %	—	33 (0.4)	—
	Episodes with non-platinum-based chemotherapy, %	—	76 (0.4)	—
Adverse events, ^b %	Episodes with PD-1/PD-L1 inhibitor, %	—	19 (0.3)	—
	Nausea/vomiting	8 (0.1)	19 (0.3)	3 (0.1)
	Diarrhea	4 (0.1)	7 (0.2)	2 (0.1)
	Fatigue	17 (0.2)	30 (0.4)	11 (0.2)
	Abdominal pain	12 (0.2)	18 (0.3)	9 (0.2)
	Anemia	20 (0.2)	41 (0.4)	11 (0.2)
	Neuropathy	4 (0.1)	6 (0.2)	3 (0.1)
	Neutropenia	4 (0.1)	14 (0.3)	0 (0)
	Thrombocytopenia	1 (0.1)	3 (0.1)	1 (0)
Hyperglycemia	10 (0.1)	11 (0.3)	10 (0.2)	

BC, bladder cancer; ED, emergency department; HCRU, health care resource utilization; ICU, intensive care unit; OCM, Oncology Care Model.

^aData are represented as mean (SD) unless otherwise noted.

^bDefined as part of the OCM Quality Metrics.

performance. Similarly, although low-risk BC makes up the majority of the BC episodes, the mean cost of a low-risk BC episode is only one-third of the mean OCM episode. Together with the overall low volume of BC episodes among all cancer episodes, this means that low-risk BC is also unlikely to be a suitable target for cost containment.

In addition to the retrospective analysis, an average performance estimation was conducted to explore potential differences in OCM practice characteristics. In the average performance estimation, a 1-sided risk arrangement was assumed in the default scenario, which does not result in an additional payment from the practice to CMS when actual expenditures are above spending target. In a 2-sided risk arrangement, the practice is eligible for higher PBPs, and recoupment payments to CMS are due when expenditures are above target. The exceeded novel therapy drug spending targets observed in the 1-sided risk arrangement do not affect the PBP to practices; the 2-sided risk arrangement showed that exceeding novel therapy

drug spending targets by 25% had a negligible effect, with an impact of only 0.1% on overall costs. This emphasizes the minimal impact that controlling novel therapy spending in high-risk BC has on OCM PBPs.

The costs observed in this retrospective analysis and average performance estimation for high-risk episodes of BC were consistent with costs reported in a retrospective analysis of patients diagnosed with LA/mUC who were identified using the 100% sample of the Medicare FFS Research Identifiable Files.²⁵ In that analysis, patients incurred mean costs of \$7153 per member per month (ie, an estimated \$42,918 over 6 months) among LA/mUC treated with PD-1/PD-L1 inhibitors.²⁵ Given the highly dynamic treatment landscape for BC, particularly the evolution of immunotherapies, this further confirms a clinically relevant economic benchmark for treatment costs for metastatic BC.

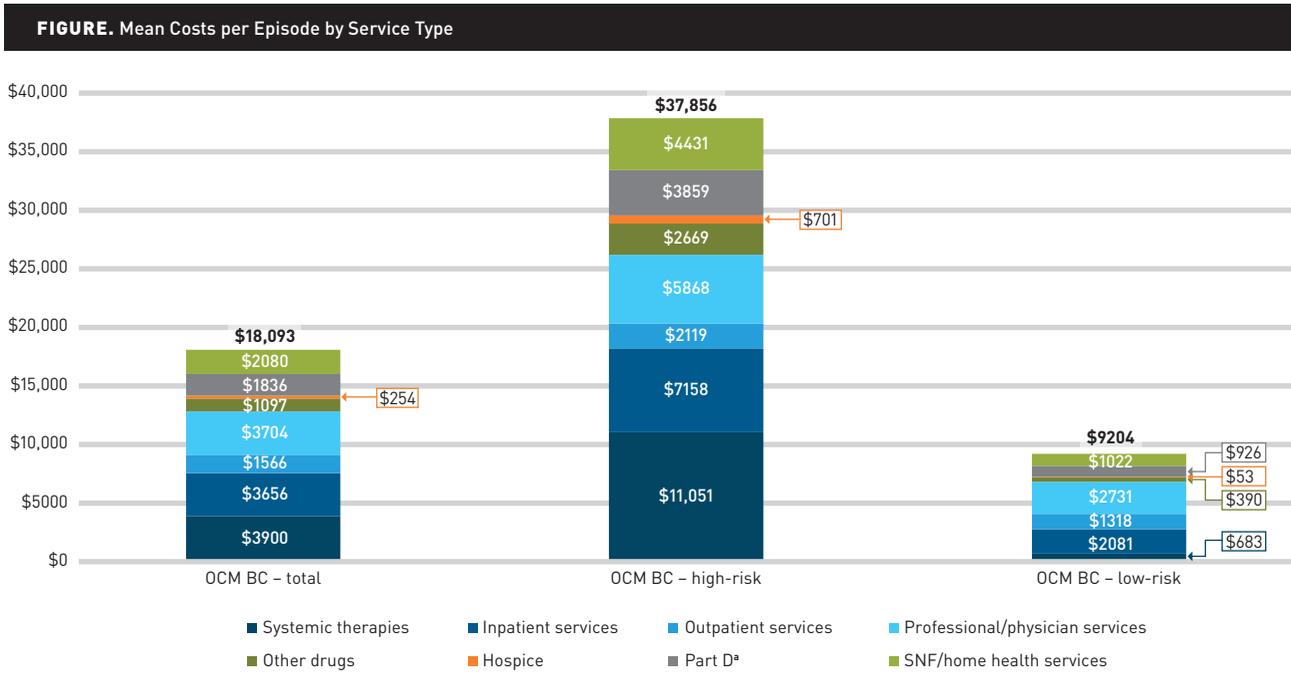
Limitations

This study has some limitations. The most recent available administrative claims data were for 2016 to 2018 at the time of analysis, before the introduction of the latest novel therapies for BC since 2019 (including enfortumab vedotin, sacituzumab govitecan, and erdafitinib¹¹⁻¹⁴), which further highlights the dynamic treatment landscape of BC. Outcome metrics and study conclusions do not reflect other changes that occurred after the study period (eg, benefit coverage changes, additional approved drugs, changes to standard of care). However, the average performance estimation explored changes beyond the study period, and even

an increase in novel therapy spending by as much as 25% did not affect the overall conclusion. Although a 25% increase was selected as the likely upper limit of increased spending on novel therapies, other percentage increases (such as 30%) would have a similarly negligible effect on overall costs. Furthermore, Medicare FFS claims data have inherent limitations (eg, cancer-specific clinical factors such as anatomical cancer stage, histology, biomarkers, or molecular mutations are not captured and cannot be adjusted for). Additionally, classification of metastatic episodes was based on ICD-10-CM codes, representing potential for misclassification and/or undercoding.

CONCLUSIONS

High-risk OCM episodes of BC, 40% of which included patients with metastatic BC, had higher HCRU and costs and lower-quality performance than low-risk episodes. Novel therapies offer an



BC, bladder cancer; OCM, Oncology Care Model; SNF, skilled nursing facility.

*Part D is an optional federal government program to help outpatient Medicare beneficiaries pay for self-administered prescription drugs.

TABLE 3. Summary Performance for the Average Integrated Delivery Network With a 1-Sided Risk-Sharing Arrangement

	OCM high-risk BC ^a	OCM low-risk BC ^a	OCM episodes other than BC	All OCM episodes
OCM performance period experience				
Number of episodes	28	31	2057	2116
Percent of episodes	1.3%	1.5%	97.2%	100%
Mean spending per episode	\$35,310	\$9263	\$32,341	\$32,043
A: Total 6-month episode spending	\$988,689	\$287,163	\$66,526,317	\$67,802,170
OCM performance period target^b				
Spending target per episode	\$34,712	\$8391	\$31,712	\$31,410
B: Total 6-month spending target	\$971,933	\$260,113	\$65,231,088	\$66,463,134
Novel therapy adjustment^c				
D: Practice % of total spending on novel therapies				26.61%
E: Benchmark % of total spending on novel therapies				27.43%
F: Revenue from novel therapy adjustment MAX[0, [B * (D - E) * 80%]]	\$0	\$0	\$0	\$0
OCM practice performance after novel therapy adjustment				
G: 6-month spending target with novel therapy adjustment [B + F]	\$971,933	\$260,113	\$65,231,088	\$66,463,134
Estimated gain (+) / loss (-) per OCM episode	-\$598	-\$873	-\$630	-\$633
H: Estimated gain (+) / loss (-) on all OCM episodes [G - A]	-\$16,756	-\$27,050	-\$1,295,230	-\$1,339,036
Estimated gain (+) / loss (-) as % of total OCM expenditures [H / A]	-1.7%	-9.4%	-1.9%	-2.0%
Payment from CMS to practice or payment from practice to CMS on 2-sided risk ^d				\$0

BC, bladder cancer; BCG, bacille Calmette-Guérin; OCM, Oncology Care Model.

^aEpisodes are assigned a high-risk designation if at least 1 cancer therapy received during the episode is not BCG and/or mitomycin. Episodes are assigned a low-risk designation if all cancer therapy received during the episode is either BCG and/or mitomycin.

^bOCM performance period target ignores the impact of the OCM risk adjustment.

^cNovel therapies, based on the CMS novel therapy list prior to 2019, included pembrolizumab, avelumab, durvalumab, nivolumab, and atezolizumab. Therapies are considered novel for 2 years after launch.

^dIncorporates risk arrangement, stop-loss/gain, and performance multiplier.

opportunity to optimize BC management and improve quality of care, particularly for high-risk episodes.^{24,26,27} Given that less than 3% of all OCM cancer episodes were attributed to BC, and that only one-third of these were classified as high risk, controlling expenditures on novel therapies in BC episodes is unlikely to affect overall performance for practices participating in the OCM.

The OCM is an example of an alternative payment model in oncology and can serve to inform other initiatives in this space. The OCF model would be a new and distinct model, building on lessons learned. Further studies should evaluate long-term OCM practice performance, accounting for the impact of emerging therapies on outcomes and costs over time, and following implementation of the forthcoming OCF model. ■

Acknowledgments

Medical writing support was provided by Vanessa Gross, of Curo (a division of Envision Pharma Group), and funded by Seagen Inc.

Author Affiliations: Seagen Inc (HSW, ZH, SG, PW), Bothell, WA; Astellas Pharma Inc (RF), Northbrook, IL; Milliman Inc (ST, JH, GD), New York, NY; Tennessee Oncology (LJB), Hermitage, TN.

Source of Funding: Seagen Inc and Astellas Pharma Inc.

Author Disclosures: Dr Wirtz is an employee of Seagen Inc, which provided funding for this manuscript, and owns stock in Seagen, Amgen Inc, and Teva Pharmaceutical Industries Ltd. Mr Hepp, Dr Grewal, and Dr Wright are employees of Seagen and hold stock/stock options in Seagen. Ms Fuldeore is an employee of Astellas Inc, which provided funding for this manuscript. Ms Tomicki, Mr Hirsch, and Ms Dieguez are employees of Milliman Inc, which received funding from Seagen and Astellas Pharma Inc in connection with this research. Dr Blakely received funding from Seagen and Astellas Pharma Inc in connection with this research.

Authorship Information: Concept and design (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); acquisition of data (ZH, SG, PW, RF, ST, JH, GD, LJB); analysis and interpretation of data (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); drafting of the manuscript (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); critical revision of the manuscript for important intellectual content (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); statistical analysis (ST, JH, GD); provision of patients or study materials (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); obtaining funding (HSW, ZH, SG, PW, RF); administrative, technical, or logistic support (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB); and supervision (HSW, ZH, SG, PW, RF, ST, JH, GD, LJB).

Address Correspondence to: Heidi S. Wirtz, PharmD, PhD, Seagen Inc, 21717 30th Dr SE, Bothell, WA 98021. Email: hwirtz@seagen.com.

REFERENCES

1. Saginala K, Barsouk A, Aluru JS, Rawla P, Padala SA, Barsouk A. Epidemiology of bladder cancer. *Med Sci (Basel)*. 2020;9(1):15. doi:10.3390/medsci8010015
2. Cancer stat facts: bladder cancer. National Cancer Institute Surveillance, Epidemiology, and End Results Program. Accessed December 1, 2021. <https://seer.cancer.gov/statfacts/html/ur1nb.html>
3. Hanna KS. Updates and novel treatments in urothelial carcinoma. *J Oncol Pharm Pract*. 2019;25(3):648-656. doi:10.1177/1078155218805141

4. Patel VG, Oh WK, Galsky MD. Treatment of muscle-invasive and advanced bladder cancer in 2020. *CA Cancer J Clin*. 2020;70(5):404-423. doi:10.3322/caac.21631
5. Wong MCS, Fung FDH, Leung C, Cheung WWL, Goggins WB, Ng CF. The global epidemiology of bladder cancer: a jointpoint regression analysis of its incidence and mortality trends and projection. *Sci Rep*. 2018;8(1):1129. doi:10.1038/s41598-018-19199-z
6. Han Y, Liu D, Li L. PD-1/PD-L1 pathway: current researches in cancer. *Am J Cancer Res*. 2020;10(3):727-742.
7. Flaig TW, Spiess PE, Agarwal N, et al. Bladder cancer, version 3.2020, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2020;18(3):329-354. doi:10.6004/jnccn.2020.0011
8. Atezolizumab's indication in previously treated metastatic bladder cancer is withdrawn. The ASCO Post. Updated March 31, 2021. Accessed September 22, 2021. <https://ascopost.com/news/march-2021/atezolizumab-s-indication-in-previously-treated-metastatic-bladder-cancer-is-withdrawn/>
9. Slatter H. AstraZeneca withdraws durvalumab indication for previously treated locally advanced or metastatic bladder cancer. *CancerNetwork*. February 22, 2021. Accessed September 22, 2021. <https://www.cancernetwork.com/view/astrazeneca-withdraws-durvalumab-indication-for-previously-treated-locally-advanced-or-metastatic-bladder-cancer>
10. Andreev-Drakhlin AY, Egoryan G, Shah AY, Msaouel P, Alhalabi O, Gao J. The evolving treatment landscape of advanced urothelial carcinoma. *Curr Opin Oncol*. 2021;33(3):221-230. doi:10.1097/CCO.0000000000000722
11. FDA grants accelerated approval to sacituzumab govitecan for advanced urothelial cancer. FDA. April 13, 2021. Accessed July 30, 2021. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sacituzumab-govitecan-advanced-urothelial-cancer>
12. FDA grants accelerated approval to enfortumab vedotin- ejfv for metastatic urothelial cancer. FDA. December 19, 2019. Accessed July 30, 2021. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-enfortumab-vedotin-ejfv-metastatic-urothelial-cancer>
13. FDA grants regular approval to enfortumab vedotin- ejfv for locally advanced or metastatic urothelial cancer. FDA. July 9, 2021. Accessed July 30, 2021. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-regular-approval-enfortumab-vedotin-ejfv-locally-advanced-or-metastatic-urothelial-cancer>
14. FDA grants accelerated approval to erdafitinib for metastatic urothelial carcinoma. FDA. April 12, 2019. Accessed July 30, 2021. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-erdafitinib-metastatic-urothelial-carcinoma>
15. Oncology Care Model. CMS. Updated November 18, 2022. Accessed February 2, 2023. <https://innovation.cms.gov/innovation-models/oncology-care>
16. Clough JD, Kamal AH. Oncology Care Model: short- and long-term considerations in the context of broader payment reform. *J Oncol Pract*. 2015;11(4):319-321. doi:10.1200/JOP.2015.005777
17. Walker B, Frytak J, Hayes J, Neubauer M, Robert N, Wilfong L. Evaluation of practice patterns among oncologists participating in the Oncology Care Model. *JAMA Netw Open*. 2020;3(5):e205165. doi:10.1001/jamanetworkopen.2020.5165
18. Aviki EM, Schleicher SM, Mullangi S. The Oncology Care Model and other value-based payment models in cancer care. *JAMA Oncol*. 2019;5(3):298-299. doi:10.1001/jamaoncol.2018.5735
19. Kline RM, Muldoon LD, Schumacher HK, et al. Design challenges of an episode-based payment model in oncology: the Centers for Medicare & Medicaid Services Oncology Care Model. *J Oncol Pract*. 2017;13(7):e632-e645. doi:10.1200/JOP.2016.015834
20. Young G, Schleicher SM, Dickson NR, Lyss AJ. Insights from the Oncology Care First proposal—where we've been and where we're going in value-based care. *JCO Oncol Pract*. 2020;16(4):151-153. doi:10.1200/JOP.20.00015
21. Costs: Part A (hospital insurance) costs. Medicare.gov. Accessed July 21, 2022. <https://www.medicare.gov/basics/costs/medicare-costs>
22. Costs: Part B (medical insurance) costs. Medicare.gov. Accessed June 21, 2022. <https://www.medicare.gov/basics/costs/medicare-costs>
23. What Medicare Part D drug plans cover. Medicare.gov. Accessed July 21, 2022. <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover>
24. Peng M, Xiao D, Bu Y, et al. Novel combination therapies for the treatment of bladder cancer. *Front Oncol*. 2020;10(3163):539527. doi:10.3389/fonc.2020.539527
25. Morgans AK, Hepp Z, Shah SN, et al. Real-world burden of illness and unmet need in locally advanced or metastatic urothelial carcinoma following discontinuation of PD-1/L1 inhibitor therapy: a Medicare claims database analysis. *Urol Oncol*. 2021;39(10):733.e1-733.e10. doi:10.1016/j.urolonc.2021.05.001
26. Bellmunt J. Treatment of metastatic urothelial cancer of the bladder and urinary tract. UpToDate. Updated January 9, 2023. Accessed February 2, 2023. <https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract>
27. Bellmunt J, de Wit R, Vaughn DJ, et al; KEYNOTE-045 Investigators. Pembrolizumab as second-line therapy for advanced urothelial carcinoma. *N Engl J Med*. 2017;376(11):1015-1026. doi:10.1056/NEJMoa1613683

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eAppendix Table 1. Average Performance Estimation Inputs

	OCM episode inputs	Impact on the model	Option selected in the model (default setting)^a	Source
Practice inputs	Type of practice	Determines the underlying data populating the model. This affects the proportion of episodes attributed to each cancer type as well as the average spending and target price per episode	Average IDN	100% RIF data. Contains Parts A, B, and D* data for 100% of Medicare FFS beneficiaries
	Risk-sharing arrangement	CMS applies a 4% discount for one-sided risk-sharing arrangements and a 2.75% discount for two-sided risk-sharing arrangements. One-sided risk sharing does not result in an additional payment from the practice to CMS when actual expenditures are above spending target. In a two-sided risk arrangement, the practice is eligible for higher PBPs.	One-sided: 4.00%	OCM PBP methodology
	Reduction in utilization of medical and drug services	Practices must improve healthcare spending relative to their experience to achieve a	Moderate: 5% reduction	Reductions in all services are illustrative

		PBP from CMS. This selection allows the user to reduce the spending of all medical and drug services within the episodes		
	Uptake of novel therapies relative to national use for episodes of all cancer types	An uptake of novel therapies by a practice can trigger a novel-therapy adjustment to the target price per episode across all cancer types	Average: 100.0%	“Average” is calculated from episodes created in Medicare RIF claims files. “Very high” is 1.25-times average, “High” is 1.1-times average, and “Low” is one-half of average
BC inputs	Proportion of episodes identified as OCM high-risk BC	The user can change the proportion of high-risk BC episodes within the practice	Average: 1.3%	“Average” is calculated from episodes created in Medicare RIF claims files. “High” is twice the average and “Low” is one-half of average
	Proportion of episodes identified as OCM low-risk BC	The user can change the proportion of low-risk BC episodes within the practice	Average: 1.5%	“Average” is calculated from episodes created in Medicare RIF claims files. “High” is twice the average and “Low” is one-half of average
OCM high-risk BC inputs	Reduction in all services other than cancer therapy for OCM high-risk BC episodes	The user can reduce the non-cancer therapy spending for high-risk BC episodes within the patient population	No reduction	Reductions in all services other than cancer therapy drug utilization are illustrative

	Change in Part B novel cancer drug spending from OCM high-risk BC episodes	The user can increase the Part B novel cancer therapy spending for high-risk BC episodes within the patient population	No increase	Changes in Part B novel-therapy drug utilization are illustrative
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^aAverage IDN with a one-sided risk-sharing arrangement.

^bPart A covers hospital insurance, including inpatient care, nursing facilities, hospice care, and home healthcare²; Part B covers medical insurance, including outpatient care, medical supplies, and preventative services³; Part D covers prescription drugs⁴.

Abbreviations: BC, bladder cancer; CMS, Center for Medicare & Medicaid Services; FFS, fee-for-service; IDN, Integrated Delivery Network; OCM, Oncology Care Model; PBP, performance-based payment; RIF, Research Identifiable File.

eAppendix Table 2. Summary Performance for Average Integrated Delivery Network With a One-Sided Risk-Sharing Arrangement – 25% Increase in Novel-Therapy Drug Spending vs No Increase

	(A) One-sided risk agreement: base case		(B) 25% increase in novel-therapy spending for high-risk BC		(C) Comparison (B)–(A)	
	OCM high-risk BC^a	All OCM episodes	OCM high-risk BC^a	All OCM episodes	OCM high-risk BC^a	All OCM episodes
OCM performance period experience						
Number of episodes	28	2,116	28	2,116	0	0
Mean spending per episode	\$37,118	\$33,679	\$39,021	\$33,704	\$1,903	\$25
% of episodes with novel-therapy utilization	21.4%	16.7%	21.4%	16.7%	0.0%	0.0%
A – Total 6-month episode spending	\$1,039,311	\$71,263,791	\$1,092,581	\$71,317,062	\$53,270	\$53,270
OCM performance period target^b						
Spending target per episode	\$34,712	\$31,410	\$34,712	\$31,410	\$0	\$0
B – Total 6-month spending target	\$971,933	\$66,463,134	\$971,933	\$66,463,134	\$0	\$0
OCM practice performance – before novel-therapy adjustment						
Gain (+) / loss (–) per episode	–\$2,406	–\$2,269	–\$4,309	–\$2,294	–\$1,903	–\$25
C – Total gain (+) / loss (–) for all episodes [B–A]	–\$67,377	–\$4,800,657	–\$120,648	–\$4,853,928	–\$53,270	–\$53,270
Gain (+) / loss (–) as % of total spending	–6.5%	–6.7%	–11.0%	–6.8%	–4.6%	–0.1%
Novel-therapy adjustment						
D – Practice % of total spending on novel therapies		26.7%		26.7%		0.1%
E – Benchmark % of total spending on novel therapies		27.4%		27.4%		0.0%
F – Revenue from novel-therapy adjustment MAX(0,[B * [D–E] * 80%])	\$0	\$0	\$0	\$0	\$0	\$0
OCM practice performance – after novel-therapy adjustment						

G – 6-month spending target with novel-therapy adjustment [B+F]	\$971,933	\$66,463,134	\$971,933	\$66,463,134	\$0	\$0
Estimated gain (+) / loss (-) per OCM episode	-\$2,406	-\$2,269	-\$4,309	-\$2,294	-\$1,903	-\$25
H – Estimated gain (+) / loss (-) on all OCM episodes [G-A]	-\$67,377	-\$4,800,657	-\$120,648	-\$4,853,928	-\$53,270	-\$53,270
Estimated gain (+) / loss (-) as % of total OCM expenditures [H/A]	-6.5%	-6.7%	-11.0%	-6.8%	-4.6%	-0.1%
Performance-based payment ^c		\$0		\$0		\$0
<p>^aEpisodes are assigned a high-risk designation if >1 cancer therapy received during the episode is not BCG and/or mitomycin. Episodes are assigned a low-risk designation if all cancer therapy received during the episode is either BCG and/or mitomycin.</p> <p>^bOCM performance period target ignores the impact of the OCM risk adjustment.</p> <p>^cReflects payments from CMS to the oncology practice for meeting cost savings and outcomes criteria under OCM rules. The performance-based payment incorporates risk arrangement, stop-loss/gain, and performance multiplier.</p> <p>Abbreviations: BC, bladder cancer; BCG, Bacillus Calmette-Guerin; CMS, Center for Medicare & Medicaid Services; OCM, Oncology Care Model.</p>						

eAppendix Table 3. Summary Performance for Average Integrated Delivery Network With a Two-sided Risk-Sharing Arrangement – 25% Increase in Novel-Therapy Drug Spending vs No Increase

	(A) Two-sided risk agreement: base case		(B) 25% increase in novel-therapy spending for high-risk BC		(C) Comparison (B)–(A)	
	OCM high-risk BC ^a	All OCM episodes	OCM high-risk BC ^a	All OCM episodes	OCM high-risk BC ^a	All OCM episodes
OCM performance period experience						
Number of episodes	28	2,116	28	2,116	0	0
Mean spending per episode	\$33,502	\$30,407	\$35,215	\$30,429	\$1,712	\$23
% of episodes with novel-therapy utilization	21.40%	16.70%	21.40%	16.70%	0.00%	0.00%
A – Total 6-month episode spending	\$938,068	\$64,340,548	\$986,011	\$64,388,491	\$47,943	\$47,943
OCM performance period target^b						
Spending target per episode	\$35,164	\$31,819	\$35,164	\$31,819	\$0	\$0
B – Total 6-month spending target	\$984,589	\$67,328,539	\$984,589	\$67,328,539	\$0	\$0
OCM practice performance – before novel-therapy adjustment						
Gain (+) / loss (–) per episode	\$1,661	\$1,412	–\$51	\$1,389	–\$1,712	–\$23
C – Total gain (+) / loss (–) for all episodes [B–A]	\$46,521	\$2,987,991	–\$1,422	\$2,940,048	–\$47,943	–\$47,943
Gain (+) / loss (–) as % of total spending	5.00%	4.60%	–0.10%	4.60%	–5.10%	0.00%
Novel-therapy adjustment						
D – Practice % of total spending on novel therapies		26.6%		26.6%		0.1%
E – Benchmark % of total spending on novel therapies		27.4%		27.4%		0.0%
F – Revenue from novel-therapy adjustment MAX(0,[B * [D–E] * 80%])	\$0	\$0	\$0	\$0	\$0	\$0
OCM practice performance – after novel-therapy adjustment						
G – 6-month spending target with novel-therapy adjustment [B+F]	\$984,589	\$67,328,539	\$984,589	\$67,328,539	\$0	\$0

Estimated gain (+) / loss (-) per OCM episode	\$1,661	\$1,412	-\$51	\$1,389	-\$1,712	-\$23
H – Estimated gain (+) / loss (-) on all OCM episodes [G–A]	\$46,521	\$2,987,991	-\$1,422	\$2,940,048	-\$47,943	-\$47,943
Estimated gain (+) / loss (-) as % of total OCM expenditures [H/A]	5.00%	4.60%	-0.10%	4.60%	-5.10%	0.00%
Performance-based payment ^c		\$2,987,991		\$2,940,048		-\$47,943

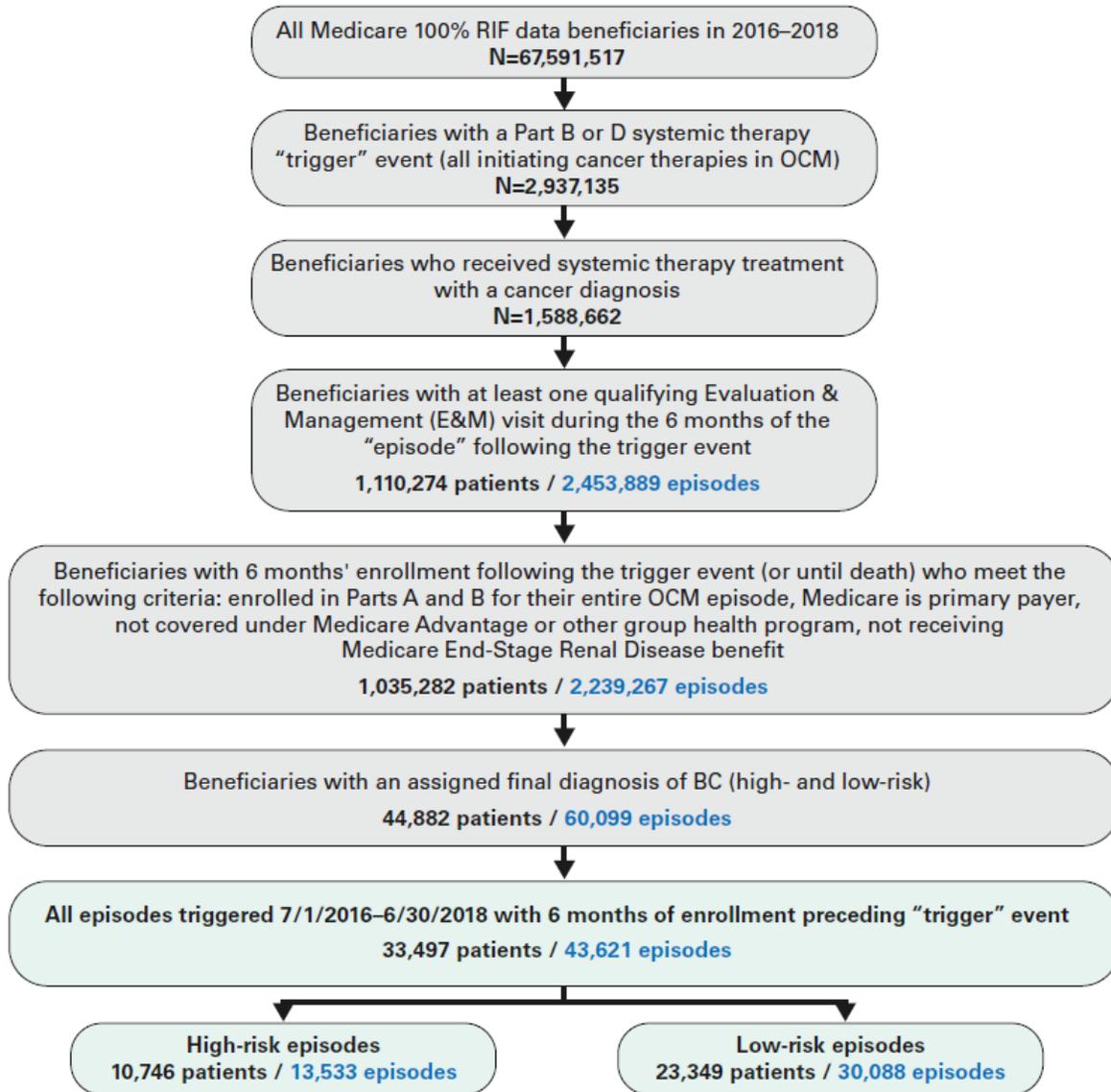
^aEpisodes are assigned a high-risk designation if >1 cancer therapy received during the episode is not BCG and/or mitomycin. Episodes are assigned a low-risk designation if all cancer therapy received during the episode is either BCG and/or mitomycin.

^bOCM performance period target ignores the impact of the OCM risk adjustment.

^cReflects payments from CMS to the oncology practice for meeting cost savings and outcomes criteria under OCM rules. The performance-based payment incorporates risk arrangement, stop-loss/gain, and performance multiplier. A negative value indicates payments from the oncology practice to CMS under two-sided risk arrangements.

Abbreviations: BC, bladder cancer; BCG, Bacillus Calmette-Guerin; CMS, Center for Medicare & Medicaid Services; OCM, Oncology Care Model.

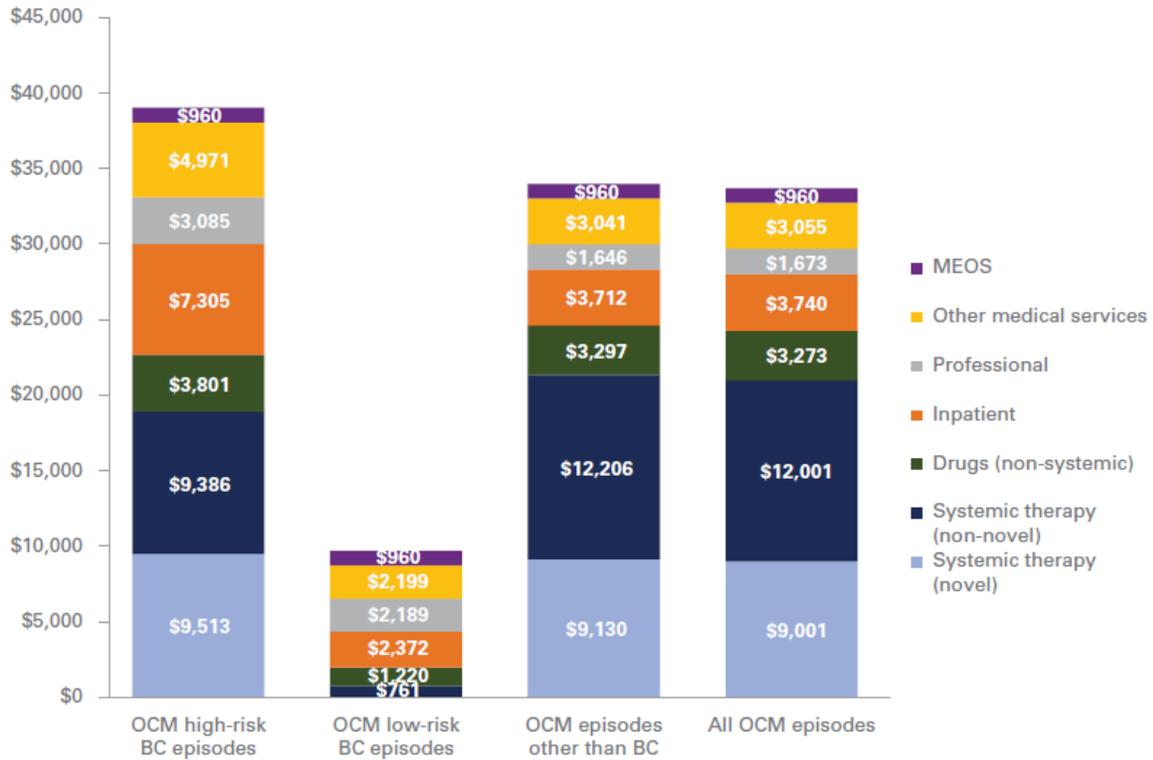
eAppendix Figure 1. OCM Cancer Episode Analysis: Patient Waterfall



Abbreviation: BC, bladder cancer; OCM, Oncology Care Model.

Note: Medicare Part A covers hospital insurance, including inpatient care, nursing facilities, hospice care, and home healthcare²; Part B covers medical insurance, including outpatient care, medical supplies, and preventative services³; Part D covers prescription drugs⁴.

eAppendix Figure 2. OCM Episode Spending by Service Type



Abbreviations: BC, bladder cancer; MEOS, Monthly Enhanced Oncology Service; OCM, Oncology Care Model.