

# Patient Out-of-Pocket Payments for Oral Oncolytics: Results From a 2009 US Claims Data Analysis

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According to the National Cancer Institute, approximately 11.4 million Americans with a history of cancer were alive in January 2006, and approximately 1,529,560 new cancer cases were expected to be diagnosed in 2010.<sup>1</sup> The National Institutes of Health estimates overall cost of cancer in 2010 at \$263.8 billion: \$102.8 billion for direct medical cost (total of all health expenditures), \$20.9 billion for indirect morbidity cost (cost of lost productivity because of illness), and \$140.1 billion for indirect mortality cost (cost of lost productivity because of premature death).<sup>1</sup> A study reported in the *Journal of the National Cancer Institute* determined that the associated direct cost of cancer care would increase by 27%, from \$125 billion in 2010 to \$158 billion in 2020, assuming constant incidence, survival, and costs; if cost of care increased annually by 2% in the initial year after diagnosis and in the last year of life, the projected 2020 cost would increase to \$173 billion, a 39% increase from 2010.<sup>2</sup>

Oral oncolytics are a relatively new addition to cancer treatment. Their benefits include ease of use and more flexibility and convenience for patients. Additionally, oral oncolytics may have different adverse effect profiles and therefore may be better tolerated.<sup>3</sup> Initial research into patient preferences and quality-of-life issues in treatment options indicate that patients do prefer oral to intravenous chemotherapy.<sup>3</sup>

Prescription drugs, although accounting for only 10% of total health care expenditures in the United States in 2009, have been one of the fastest-growing segments, and the cost of these drugs, including oral oncolytics, can vary widely.<sup>4</sup> The average wholesale price for temozolomide of \$1500 per course is consistent with the pricing of approved intravenous chemotherapies, such as vinorelbine and gemcitabine, and is less than the price of paclitaxel or docetaxel; however, it is more expensive than 2 other approved oral therapies for advanced breast cancer: capecitabine, which has a typical acquisition price of \$700 per 3-week course, and anastrozole, which can be acquired for \$200 per month.<sup>5</sup> Results from a US-based retrospective claims database study measuring the cost of oral sunitinib and sorafenib, 2 therapies for advanced renal cell carcinoma, showed mean total medical costs per patient per month of \$8213 and \$6998, respectively.<sup>6</sup> The range of oral oncolytic cost varies widely. More recently introduced novel targeted agents are on the higher end of historical prices.

For patients with cancer, initial concerns after a diagnosis usually focus on prognosis and treatment choices. Financial aspects are only a secondary concern.<sup>7</sup> The SUP-PORT study (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment)

**Objectives:** Oral oncolytics are an increasingly important treatment option for cancer. These agents often fall within the pharmacy benefit, with the potential for increased out-of-pocket (OOP) cost burden for patients. The purpose of this study was to evaluate patient OOP payments for oral oncolytic therapies in US managed care plans.

**Materials and Methods:** Patients aged  $\geq 18$  years who received 1 of 21 oral oncolytics were identified in 2009 US claims; the first oral therapy was the index therapy. OOP payments were calculated as the allowed amount (dollar amount a health plan allows for a therapy, including member liability) minus the paid amount (dollar amount paid by a health plan). Patient characteristics were provided, and per-claim OOP payments were evaluated for each of the 21 therapies in aggregate and stratified by payer type and index therapy.

**Results:** A total of 6094 patients who received at least 1 oral oncolytic therapy were identified. Mean age was 53 years; 54% were women; 77% had a commercial payer; prevalent cancer diagnoses included breast, colorectal, glioblastoma, and lung. Mean OOP payments were highest for dasatinib (\$527; median, \$36) and lowest for cyclophosphamide (\$15; median, \$10). Medicare Risk patients had higher mean OOP payments for most therapies compared with commercial, Medicaid, and self-insured patients.

**Conclusions:** Among 21 oral oncolytics, average OOP cost ranged from \$15 to  $>$ \$500. These results confirm previous findings showing OOP payments differing widely among oral oncolytic options. As cost for therapy becomes a greater part of treatment decisions, an understanding of patient OOP cost will be critical in informing choices.

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■ **Table 1.** Twenty-One Oral Oncolytic Therapies of Interest

Generic Name	
Altretamine	Lapatinib
Bexarotene	Lenalidomide
Capecitabine	Nilotinib
Cyclophosphamide	Sorafenib
Dasatinib	Sunitinib
Erlotinib	Temozolomide
Etoposide	Thalidomide
Everolimus	Topotecan
Gefitinib	Tretinoin
Imatinib	Vorinostat
Isotretinoin	

found that approximately 33% of families lost most or all of their savings after a cancer diagnosis.<sup>8</sup> Additionally, researchers at the National Cancer Institute, using data from the Centers for Disease Control and Prevention National Health Interview Survey, found that more than 1 million cancer survivors in the United States are foregoing necessary medical care because of the cost, with 7.8% foregoing general medical care and 9.9% going without prescription medication.<sup>9</sup> These cost concerns are great enough that the American Society of Clinical Oncology recently published guidance measures to assist patients with managing the cost of cancer care.<sup>10</sup>

With the increase in multitier formularies and other cost-control mechanisms, the growth in outpatient prescription drug spending decreased from 16% in 2000 to 8% in 2004; in contrast, the demand for specialty drugs continues to accelerate.<sup>11</sup> Recent reports have suggested that oral oncolytics account for approximately 25% of the current oncology pipeline.<sup>12</sup> As insurers contemplate a variety of payment and distribution strategies to control their use and cost, more patients are being placed at financial risk for higher OOP spending, which can result in patients not following or completing their cancer treatment plans.<sup>11</sup>

Currently, limited data are available on patient OOP cost for oral oncolytic therapies. The objective of this study was to evaluate claims-level data and to characterize patient OOP payments for 21 oral oncolytic therapies in aggregate and by payer type in a sample of >100 US managed care plans during calendar year 2009.

## MATERIALS AND METHODS

### Data Source

Anonymous patient-level data were obtained from the IMS LifeLink: Health Plan Claims Database (Watertown, Massa-

chusetts), which contains adjudicated medical and pharmaceutical claims for >100 health plans across the United States. The database includes inpatient and outpatient diagnoses (*International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM]* format) and procedures (*Current Procedural Terminology*, Fourth Edition, and Healthcare Common Procedure Coding System formats) as well as prescription records. It also includes demographic variables; product and payer types; provider specialty; charged, allowed, and paid amounts; and dates inclusive of plan enrollment. In compliance with the Health Insurance Portability and Accountability Act,<sup>13</sup> patient data used in the analysis were de-identified; therefore, this study was exempt from institutional review board review.

### Patient Selection

Health insurance claims were screened to identify all patients aged ≥18 years with at least 1 claim for 1 of 21 oral oncolytic therapies (Table 1) between January 1, 2009, and December 31, 2009; claims were identified by National Drug Code. The date of the first prescription for any of the oral oncolytics during this time period represented the index date for each patient. Patients were required to have continuous health plan enrollment from 6 months before through 6 months after the index date. Patients were classified as having one of 12 specific cancer types or as having other cancer. Cancer type was defined as the closest claim involving one of the 12 cancer diagnoses (identified using ICD-9-CM codes; Table 2) on the index date or within 90 days before or after the index therapy. If none of the 12 cancer types were identified, the nearest other cancer diagnosis was identified, and the patient was classified as having other cancer. Patients aged ≥65 years were included only if they were in a Medicare Risk (private Medicare) plan to ensure complete data collection (Medicare Part D data not available).

### Measures

The primary outcome of interest was the claim-level OOP cost for oral oncolytic therapies during calendar year 2009. OOP payment was calculated as the allowed amount (dollar amount a health plan contracted for a therapy, including member liability) minus the paid amount (dollar amount paid by the health plan for the therapy). Per-claim OOP payments were evaluated for each of the 21 oral oncolytic therapies in aggregate and by individual therapy using all available data during the year 2009. OOP payments also were stratified by payer type (commercial, Medicaid, Medicare Risk, self-insured, unknown). Patient-level demographics (age, sex, geographic region, health plan and payer types) and clinical characteristics (cancer type) were evaluated from data obtained on the index date or during the preindex period. Per-

■ **Table 2.** ICD-9-CM Diagnosis Codes for 12 Cancer Types and All Other Cancers

Cancer Type	ICD-9-CM Codes
Breast	174.x, 198.81, V10.3
Ovarian	183.xx
Lung	162.2-162.9, 163.x, 197.0, 231.2, 231.8, 231.9, V10.1, V10.11
Colorectal	153.x, 154.0, 154.1, 154.8, 197.5, 230.3, 230.4, V10.05, V10.06
Glioblastoma	191.x
Pancreatic	157.x, 230.9
Renal cell	189.0x, 189.1x, 198.0, 233.9, V10.52, V10.53
Gastroesophageal	150.x, 151.x, 197.8, 230.1, 230.2, V10.03, V10.04
Melanoma	172.x, V10.82
Nonmelanoma skin	173.x
Non-Hodgkin lymphoma	200.x, 202.x
Chronic lymphocytic leukemia	204.1x, 208.1x
All other	140-209, 230-239 (excluding codes for the 12 cancers of interest)

*ICD-9-CM indicates International Classification of Diseases, Ninth Revision, Clinical Modification.*

claim per-patient OOP cost, calculated for the index therapy on the index date and for corresponding index therapies identified during the 6-month follow-up period and summed across the time frame, were categorized by cost category (\$0, \$1 to \$50, \$51 to \$100, \$101 to \$500, and >\$500).

**Statistical Analyses**

Patient-level descriptive statistics were used to illustrate patient characteristics, including numbers and percentages for categorical variables and arithmetic means, medians, and standard deviations for continuous variables. OOP payments were reported as per claim averages (arithmetic means) and medians and by distribution of payment categories. Differences in OOP payments by payer type were calculated using parametric analysis of variance testing. All data management and analyses were conducted using SAS versions 8.2 and 9.1 (SAS Institute, Cary, North Carolina).

**RESULTS**

A total of 6094 patients with evidence of receiving at least 1 of 21 oral oncolytic therapies in 2009 were identified. Of those therapies identified in 2009, altretamine had the smallest number of claims (n = 24), whereas capecitabine had the largest sample (n = 7726). Demographics and clinical characteristics are presented in **Table 3**. The average age of the patient sample was 53 years, and 54% were women. Approximately 77% of the patients were enrolled in a health maintenance organization or preferred provider organization plan, and 77% were insured by a commercial payer. An evaluation of preindex neoplasms revealed that of the 12 cancers

specifically identified, breast cancer was the most commonly found cancer indication, followed by colorectal cancer, glioblastoma, and lung cancer.

**OOP Payments for Oral Oncolytic Therapies During Calendar Year 2009**

Among the oral oncolytic therapies with claims in 2009, cyclophosphamide (n = 996 claims) had the lowest OOP payment, averaging \$15, whereas dasatinib (n = 736 claims) had the highest average OOP cost at \$527 (**Table 4**). Median per-claim OOP payments in 2009 ranged from \$0 (altretamine, n = 24 claims; topotecan, n = 36 claims) to \$41 (bexarotene, n = 122 claims; vorinostat, n = 66 claims). Median OOP payments generally were lower among those therapies with a generic version available, with mean costs of \$31 (median, \$10) for those therapies with generics versus \$171 (median, \$26) for those therapies with no available generics. Among therapies with generic versions available, the percentage of the health plan–contracted amount comprising the OOP payment was largest for cyclophosphamide (12.5%, n = 996 claims) and smallest for topotecan (0.6%, n = 36 claims), with no other therapies >10%; among those therapies with no available generics, the percentage of the health plan–contracted amount comprising the OOP payment ranged from 2.7% (everolimus, n = 217 claims) to 9.9% (vorinostat, n = 66 claims).

We evaluated the proportion of patients with per claim OOP payments stratified into 5 categories: \$0, \$1 to \$50, \$51 to \$100, \$101 to \$500, and >\$500 (**Figure**); these data were examined in the aggregate population and stratified by 21 index oral oncolytic therapies. Among all patients in aggregate (N = 6094), 66% were paying, on average, ≤\$50 per claim.

■ **Table 3.** Demographics and Clinical Characteristics of Patients Receiving 1 of 21 Oral Oncolytic Agents (N = 6094)

Characteristic	No. of Patients	%
<b>Age, years</b>		
Mean	53.1	
SD	13.0	
Median	55	
<b>Sex</b>		
Female	3317	54.4
<b>Geographic region</b>		
Northeast	1719	28.2
Midwest	1569	25.7
South	1525	25.0
West	1281	21.0
<b>Health plan type</b>		
HMO	1190	19.5
Indemnity	127	2.1
POS	1062	17.4
PPO	3529	57.9
Unknown	186	3.1
<b>Payer type</b>		
Commercial	4712	77.3
Medicaid	82	1.3
Medicare Risk	551	9.0
Self-insured	630	10.3
Unknown	119	2.0
<b>Cancer type</b>		
Breast	832	13.7
Colorectal	675	11.1
Glioblastoma	589	9.7
Lung	348	5.7
Renal cell carcinoma	282	4.6
Gastroesophageal	159	2.6
Pancreatic	94	1.5
Melanoma	73	1.2
Ovarian	69	1.1
Nonmelanoma skin	36	0.6
Non-Hodgkin lymphoma	35	0.6
Chronic lymphocytic leukemia	0	0.0
Other cancer type	2902	47.6
Chronic myeloid leukemia (without mention of remission)	644	22.2
Multiple myeloma (without mention of remission)	595	20.5
Neoplasm of uncertain behavior of skin	440	15.2
Chronic myeloid leukemia (in remission)	102	3.5
Acute myeloid leukemia (without mention of remission)	67	2.3
Other cancer type	1054	36.3

HMO indicates health maintenance organization; POS, point of service; PPO, preferred provider organization; SD, standard deviation.

For each oral oncolytic therapy studied, at least 50% of patients had per claim OOP payments of \$0 to \$50; patients receiving index cyclophosphamide (94% of 237 patients) comprised the highest proportion of patients paying ≤\$50, likely because of the availability of generic formulations of this therapy. At the high end, 21% of all patients had significant OOP cost >\$100. Lenalidomide (n = 551 patients) had the highest proportion of patients in this category (30%), followed by everolimus (n = 17 patients) and thalidomide (n = 202 patients) at 29% each; conversely, eight therapies (al tretamine, bexarotene, cyclophosphamide, etoposide, gefitinib, isotretinoin, topotecan, tretinoin) had <20% of patients paying >\$100 OOP.

### OOP Payments for Oral Oncolytic Therapies in 2009 by Payer Type

For all therapies combined, patient OOP payments varied by payer type (commercial, Medicaid, Medicare Risk, self-insured, unknown; **Table 5**). Medicare Risk (private Medicare) plans had significantly higher OOP payment amounts ( $P < .001$ ) compared with those under other payers for most therapies. Medicare Risk plans, however, accounted for only 10% of total claims, with commercial payers covering the majority of oral oncolytic claims (77.2%).

## DISCUSSION

This retrospective study used a large multipayer US database to report OOP cost to patients receiving oral oncolytic therapy. Per claim OOP payments varied by therapy, from a low of \$15 to

## Patient Out-of-Pocket Payments for Oral Oncolytics

**Table 4.** 2009 Median and Average Per-Claim OOP Payments and Percentage of Contracted Amount for 21 Oral Oncolytic Therapies

Oral Oncolytic Therapy	No.	OOP Payment				Average OOP Payment as % of Contracted Amount
		Median (\$)	IQR	Average (\$)	SD	
<b>Therapies with no available generic versions</b>	31,509	26	50	171	652	4.6
Altretamine	24	0	59	38	51	7.8
Gefitinib	90	6	41	95	324	5.0
Everolimus	217	25	71	120	496	2.7
Capecitabine	7726	26	45	76	194	4.9
Erlotinib	2411	26	46	225	698	6.2
Nilotinib	302	26	72	292	991	5.0
Sorafenib	879	26	30	224	791	5.9
Imatinib	7455	26	40	154	611	3.6
Lapatinib	1154	26	41	157	559	5.4
Lenalidomide	3935	30	92	297	981	4.2
Temozolomide	3771	30	51	131	416	4.3
Thalidomide	1304	31	88	193	615	3.4
Sunitinib	1317	31	51	199	835	3.9
Dasatinib	736	36	101	527	1496	8.6
Vorinostat	66	41	53	453	1176	9.9
Bexarotene	122	41	67	156	581	3.6
<b>Therapies with available generic versions</b>	4129	10	12	31	130	9.1
Topotecan	36	0	31	27	47	0.6
Etoposide	266	10	11	31	83	5.0
Isotretinoin	2502	10	11	31	73	9.2
Cyclophosphamide	996	10	12	15	19	12.5
Tretinoin	329	10	26	89	399	2.3

IQR indicates interquartile range; OOP, out of pocket; SD, standard deviation.

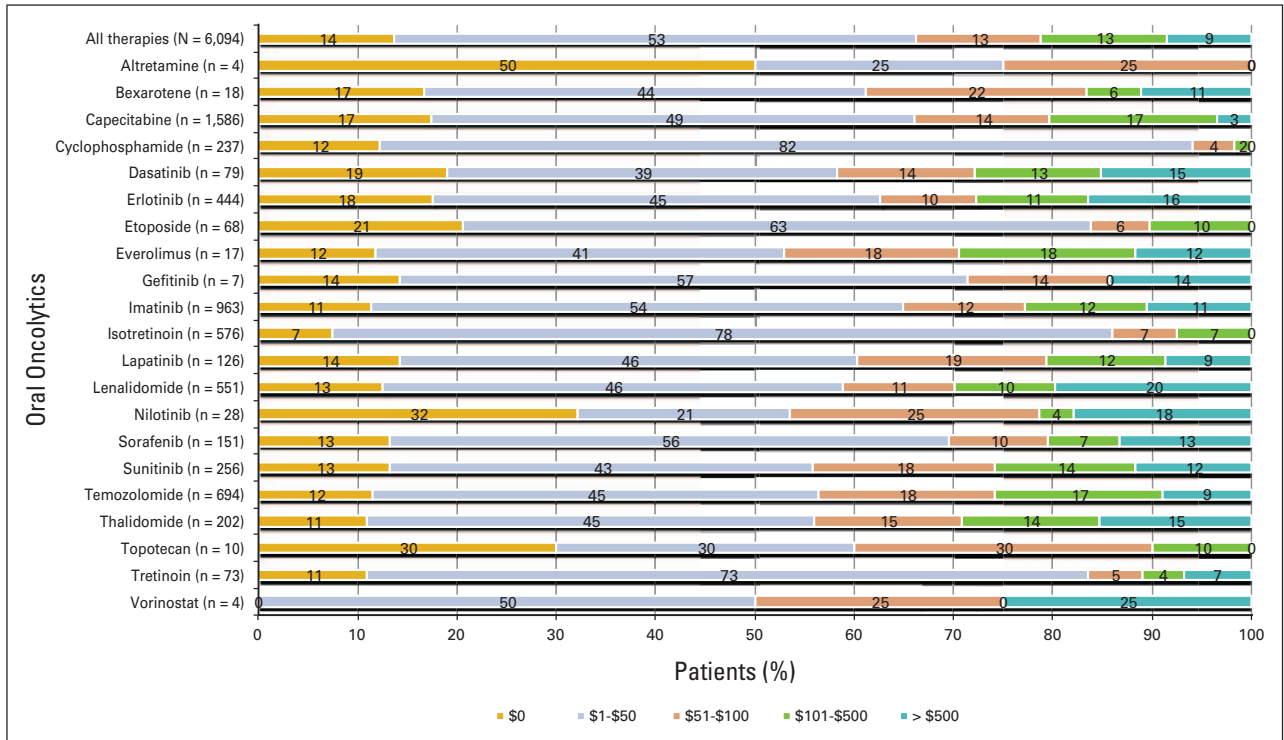
>\$500. Almost 70% of patients had per claim OOP payments ≤\$50, with approximately 20% with cost >\$100 per claim. Medicare Risk patients had higher OOP payments for most therapies compared with patients with commercial plans, Medicaid, and self-insurance. Patients paid ≥5% of the actual amount allowed by the health plan for more than half of the oral oncolytics under investigation.

Few studies have evaluated the patient burden for oral oncolytic therapies. Women with a recent breast cancer diagnosis were queried between October 1999 and November 2002 and asked to discuss the financial burden of cancer. Overall, patients incurred mean total OOP and lost-income costs of \$1455 per month (range, \$0 to \$15,700); 41% of these costs, or approximately \$597, were associated with direct medical cost. More than 40% of patients reported total monthly cost <\$500, and approximately 33% reported total monthly cost

between \$1000 and \$5000. The most commonly reported OOP expenditures were for medications (80%), transportation (78%), and physician visits (66%).<sup>14</sup> A second study of patients with cancer in 55 health plans offered by 15 large employers in 2003 and 2004 found that more than 10% of patients with cancer had an annual OOP cost exceeding \$18,585, and 5% had a yearly cost surpassing \$35,660.<sup>11</sup> More recent data on the financial burden for patients receiving oral oncolytic therapy, however, are not readily available.

Insurance design can play a role with regard to patient burden. With medical benefits covering physician-administered drugs and pharmacy benefits covering patient-administered drugs, the current insurance design can result in higher cost-sharing requirements for patients with cancer, making oral cancer therapies less affordable than traditional intravenous drugs. Pharmacy benefit plans may implement cost-con-

■ **Figure.** Distribution of 2009 Out-of-Pocket Payments for 21 Oral Oncolytic Agents



tainment mechanisms such as increased patient cost sharing through placement in higher copayment tiers.<sup>12</sup> Avalere Health (Washington, DC), along with the Community Oncology Alliance (Washington, DC), reviewed 2009 Medicare Part D plan formularies as well as those of select private payers with regard to coverage for 11 oral cancer therapies. Only 3 oral oncolytics (capecitabine, temozolomide, topotecan) had Medicare Part B coverage; the remaining 8 therapies (erlotinib, imatinib, lapatinib, lenalidomide, nilotinib, sorafenib, sunitinib, tamoxifen) were covered under Medicare Part D. Of these latter drugs, the most common formulary tier placement was the highest tier (generally tiers 3 to 5); here, patients pay a large portion of the drug cost OOP, with cost sharing typically a coinsurance requirement ranging from 25% to 55% of the drug cost. The use of lenalidomide for 12 months, for example, resulted in patient OOP cost of approximately \$8700.<sup>15</sup>

Our study found that the OOP cost to patients for oral oncolytic therapies varies widely. This is probably because of the availability of generic versions for about one quarter of the agents under investigation. Because this study evaluated only specific drug OOP cost, the actual financial burden to patients may be even greater once indirect and other medical service costs are included. For drug therapy alone, patients may be required to pay as much as \$500 depending on the oral therapy. As oral oncolytics increasingly become used as monotherapy

or in combination with chemotherapy for the treatment of advanced cancers, consideration of OOP cost becomes part of treatment decisions. For patients with advanced or metastatic disease with multiple lines of therapy, the integrated or total cost burden may be even greater and affect their treatment choices. It is likely that many patients would be unable to afford the cost and would have to seek alternative therapy options or discontinue treatment if financial help were unavailable, resulting in an increase in the rate of noncompliance among patients with cancer.

Compliance with oral oncolytics has long been an issue independent of the disproportionate cost burden, with rates of 16% to 48% not uncommonly reported.<sup>16</sup> A study by Lebovits et al<sup>17</sup> of patients with breast cancer treated with oral oncolytics found a noncompliance rate of 43%. Another study found the abandonment rate of newly initiated oral oncolytics to be 10%; claims with cost sharing >\$500 were 4 times more likely to be abandoned than claims with cost sharing ≤\$100, whereas patients with 5 or more prescription claims processed within the previous month had a 50% higher likelihood of abandonment than patients with no other prescription activity.<sup>12</sup> Traditional reasons for non-compliance include complex treatment protocols, agent toxicity, cost-sharing requirements, inadequate supervision or social support, dissatisfaction with care, inconvenience and inefficiency of the healthcare setting, and psychological issues

## Patient Out-of-Pocket Payments for Oral Oncolytics

■ **Table 5.** 2009 Per-Claim OOP Payments for 21 Oral Oncolytic Agents by Payer Type

Oral Oncolytic Therapy	Commercial		Medicaid		Medicare Risk		Self-Insured		Unknown		P <sup>a</sup>
	Total No. of Claims	Mean OOP Amount (\$)	Total No. of Claims	Mean OOP Amount (\$)	Total No. of Claims	Mean OOP Amount (\$)	Total No. of Claims	Mean OOP Amount (\$)	Total No. of Claims	Mean OOP Amount (\$)	
Altretamine	9	0	0	0	3	43	3	0	9	87	<.001
Bexarotene	89	34	0	0	25	618	8	80	0	0	<.001
Capecitabine	5692	70	90	42	1009	79	767	110	168	108	<.001
Cyclophosphamide	810	15	4	5	126	13	39	14	17	19	.626
Dasatinib	482	547	42	2	83	1207	106	134	23	42	<.001
Erlotinib	1657	118	48	2	352	847	319	133	35	223	<.001
Etoposide	211	16	1	1	41	86	8	20	5	231	<.001
Everolimus	176	87	0	0	11	879	30	32	0	0	<.001
Gefitinib	74	109	0	0	11	18	5	54	0	0	.661
Imatinib	6056	118	168	10	508	552	650	217	73	106	<.001
Isotretinoin	2192	31	44	8	24	9	194	39	48	27	.059
Lapatinib	963	129	22	18	53	866	91	64	25	222	<.001
Lenalidomide	2745	174	51	0	744	856	301	105	94	262	<.001
Nilotinib	196	273	0	0	60	549	46	35	0	0	.027
Sorafenib	725	174	26	13	43	1195	80	241	5	47	<.001
Sunitinib	1057	186	11	1	57	530	165	172	27	260	.037
Temozolomide	3123	119	20	22	144	270	407	166	77	200	<.001
Thalidomide	886	83	11	0	249	621	123	122	35	247	<.001
Topotecan	21	26	0	0	1	256	14	12	0	0	<.001
Tretinoin	294	82	0	0	3	16	30	166	2	23	.714
Vorinostat	50	436	0	0	9	239	6	988	1	21	.651

ANOVA indicates analysis of variance; OOP, out of pocket.  
<sup>a</sup>P values calculated using the parametric ANOVA test.

(eg, denial, depression).<sup>12,18,19</sup> As patients shoulder an even greater proportion of the cost burden of oral oncolytics, compliance may fall; for example, the intravenous and oral forms of temozolomide are priced similarly, with the only difference being patients' share of the cost, which is higher for the oral version.<sup>18</sup>

This claims study has several limitations. Because this analysis was focused on drug use primarily at the claim level and not at the patient level, we did not perform additional statistical analyses, such as multivariate regression models, to control for patient characteristics. Variations in OOP payments for oral drugs among more severely ill patients (eg, more advanced cancers) were not evaluated. However, we do not believe this would change the overall cost burden of oral oncolytic therapies, because drug prices or benefit designs do not vary by indication. Additionally, we were unable to evaluate OOP payments by cancer stage because of a lack of this information in the study database. We did not account for packaging or days supplied. We assumed there was a distribution of packaging (25 vs 100 mg package) represented

in the claims data, accounted for in computing the average per-claim cost. Finally, we were unable to evaluate dosing differences among patients.

The claims data set also did not include uninsured patients and those covered only by Medicare (Part D); therefore, we were unable to account for any variation in OOP cost among these patients. A recent study, however, found that Medicare patients pay significantly more OOP compared with commercially insured patients, with 46% of Medicare patients paying >\$500 for their first oral oncolytic claim, compared with only 11% of commercially insured patients.<sup>12</sup> Because Medicare Risk plans accounted for only 10% of the total claims in our study, these analyses are most generalizable to commercial plans. Additionally, patient OOP payments for infused oncolytic products, other therapies, other direct healthcare services, and indirect cost were not evaluated. This analysis describes the patient burden for oral therapies only and does not reflect the overall financial burden on patients, which may encompass these other direct and indirect services. As with all claims databases, we were unable to determine if the

oral therapies prescribed by the physician were taken as indicated on the prescription.

The claims data set does not include any information on ancillary prescription assistance, including rebate programs, and we have no insight into the proportion of patients who may be receiving this payment support. Finally, the database does not provide information on systemic factors that could affect care, including plan limits on medication use. Because of the large and diverse nature of the plans in the database, however, these factors should not have affected our study results.

In summary, OOP payments for oral oncolytics vary widely, with the average OOP cost ranging from \$15 to >\$500 among the 21 oral oncolytics studied. The present study can help inform patients and providers of relative cost sharing for oral oncolytics as they make treatment decisions. As payers continue to institute measures to control cost, the burden to pay for treatment will fall more heavily on the patient. From a health policy perspective, future studies will be important to understand how these health plan strategies affect not only treatment decisions and the ability of patients to continue oral oncolytics over time but also the impact on total health-care cost compared with infused therapies and other cancer treatment modalities.

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## REFERENCES

- American Cancer Society:** Cancer facts and figures 2010. <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-026238.pdf>
- Mariotto AB, Yabroff KR, Shao Y, et al:** Projections of the cost of cancer care in the United States: 2010-2020. *J Natl Cancer Inst* 103:1-12, 2011
- Liu G, Franssen E, Fitch MI, et al:** Patient preferences for oral versus intravenous palliative chemotherapy. *J Clin Oncol* 15:110-115, 1997
- Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group:** 2009 national health care expenditures data. <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>
- Hillner BE, Agarwala S, Middleton MR:** Post hoc economic analysis of temozolomide versus dacarbazine in the treatment of advanced metastatic melanoma. *J Clin Oncol* 18:1474-1480, 2000
- Duh MS, Dial E, Choueiri TK, et al:** Cost implications of IV versus oral anti-angiogenesis therapies in patients with advanced renal cell carcinoma: Retrospective claims database analysis. *Curr Med Res Opin* 25:2081-2090, 2009
- Brown ML, Lipscomb J, Snyder S:** The burden of illness of cancer: Economic cost and quality of life. *Annu Rev Public Health* 22:91-113, 2000
- Covinsky KE, Goldman L, Cook F, et al:** The impact of serious illness on patients' families: SUPPORT Investigators--Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. *JAMA* 272:1839-1844, 1994
- Weaver KE, Rowland JH, Bellizzi KM, et al:** Foregoing medical care because of costs: Assessing disparities in health care access among cancer survivors living in the United States. Presented at the Second American Association for Cancer Research Science of Cancer Health Disparities Conference, Carefree, AZ, February 3-6, 2009
- American Society of Clinical Oncology:** Managing the cost of cancer care: Practical guidance for patients and families. [http://www.cancer.net/patient/Diagnosis%20and%20Treatment/Managing%20the%20Cost%20of%20Cancer%20Care/Cost\\_of\\_Care\\_Booklet.pdf](http://www.cancer.net/patient/Diagnosis%20and%20Treatment/Managing%20the%20Cost%20of%20Cancer%20Care/Cost_of_Care_Booklet.pdf)
- Goldman DP, Joyce GF, Lawless G, et al:** Benefit design and specialty drug use. *Health Aff (Millwood)* 25:1319-1331, 2006
- Streeter SB, Schwartzberg L, Husain N, et al:** Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *Am J Manag Care* 17:SP38-SP44, 2011
- Health Insurance Portability and Accountability Act (HIPAA). Pub L No. 104-191, 110 Stat 1936 (2006) 1996
- Arozullah AM, Calhoun EA, Wolf M, et al:** The financial burden of cancer: Estimates from a study of insured women with breast cancer. *J Support Oncol* 2:271-278, 2004
- Bames L, Burich M, Haroldson B, et al:** Oral oncolytics/addressing the barriers to access and identifying areas for engagement. Washington, DC, Avalere Health, 2010. <http://www.avalerehealth.net/wm/show.php?c=&id=842>
- Levine AM, Richardson JL, Marks G, et al:** Compliance with oral drug therapy in patients with hematologic malignancy. *J Clin Oncol* 5:1469-1476, 1987
- Lebovits AH, Strain JJ, Schleifer SJ, et al:** Patient noncompliance with self-administered chemotherapy. *Cancer* 65:17-22, 1990
- Partridge AH, Avom J, Wang PS, et al:** Adherence to therapy with oral antineoplastic agents. *J Natl Cancer Inst* 94:652-661, 2002
- Ruddy K, Mayer E, Partridge A:** Patient adherence and persistence with oral anticancer treatment. *CA Cancer J Clin* 59:56-66, 2009 ■