

Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions

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Objective: To calculate the abandonment rate of oral oncolytic medications and identify factors that may affect likelihood of abandonment.

Study Design: Cross-sectional cohort study using administrative claims data.

Methods: We analyzed a nationally representative pharmacy claims database and identified 10,508 patients with Medicare and commercial insurance for whom oral oncolytic therapy was initiated between 2007 and 2009. We calculated the abandonment rate for the initial claim, in which abandonment was defined as reversal of an adjudicated pharmacy claim without a subsequent paid claim for any oncolytic (oral or intravenous) within the ensuing 90 days. We assessed likelihood of abandonment using bivariate and multivariate logistic regression analyses including patient demographics, plan type, drug type, cost sharing, and concurrent prescription activity.

Results: The abandonment rate of newly initiated oral oncolytics was 10.0%. Unadjusted bivariate analyses found that high cost sharing, increased prescription activity, lower income, and Medicare coverage were associated with a higher abandonment rate ($P < .05$). In the logistic regression model, claims with cost sharing greater than \$500 were 4 times more likely to be abandoned than claims with cost sharing of \$100 or less (odds ratio [OR], 4.46; $P < .001$). Patients with 5 or more prescription claims processed within in the previous month had 50% higher likelihood of abandonment than patients with no other prescription activity (OR, 1.50; $P < .001$).

Conclusion: Abandonment of newly prescribed oral oncolytic therapy is not uncommon, and the likelihood increases for patients enrolled in plans with pharmacy benefit designs that require high cost sharing. Increased concurrent prescription activity was also associated with a higher abandonment rate. These factors should be taken into account when considering likely adherence to cancer therapy.

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Patients diagnosed with cancer require timely access to appropriate treatments to achieve optimal outcomes. Until recently, drug therapy for patients with cancer consisted of intravenous (IV) infused treatment. Oncolytic medications that can be administered orally are a relatively new addition to cancer treatment and provide patients with the benefits of ease of use and convenience.¹ Utilization of oral oncolytics is expected to increase.² Recent reports have suggested they account for approximately 25% of the current oncology pipeline.³

Because of costs associated with these newer oral oncolytic agents, pharmacy benefit plans may implement cost-containment mechanisms such as increased patient cost sharing through placement in higher co-payment tiers. The degree to which increased cost sharing influences access to and utilization of oral oncolytics may be an important factor affecting patient adherence to prescribed cancer therapy.

Traditional adherence studies of oncology medication track patient utilization longitudinally by assessing refill rate, self-reported compliance with prescribed therapies, continuous dose observations, pill counting, and administrative claims analysis.^{1,4} Studies of nonadherence have found that barriers to appropriate care include cost-sharing requirements, agent toxicity, patient- and disease-related factors, social issues, and financial status.^{1,2,4}

The purpose of our study was to assess abandonment of newly initiated oral oncolytics. Specifically, we were interested in examining patients who had been prescribed oral oncolytic therapy, submitted prescriptions for their first oral oncology medications to pharmacies, and then reversed claims after adjudication (ie, initial approval of claim). If patients did not follow up with a subsequent oncolytic agent, we noted their reversed claim as an abandoned prescription.

Our objective was to calculate reversal and abandonment rates of newly initiated oral oncolytic medications using an approach similar to those found in the literature.⁵⁻⁷ Building on previous research, we investigated the degree to which abandonment is affected by patient and plan characteristics, specifically cost-sharing requirements, patient income, concurrent prescription activity, and insurance type.

METHODS

We acquired administrative claims data from the Wolters Klu-

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wer Dynamic Claims Lifecycle Database, a source of nationally representative pharmacy utilization data, for 20,607 patients for whom at least 1 pharmacy claim was adjudicated for 1 of the oral oncolytic agents included in our study between January 1, 2007, and June 30, 2009. The data set included pharmacy claims and demographic data for all patients as well as medical claims for a subpopulation of patients. We studied patients using capecitabine, imatinib, sorafenib, lenalidomide, sunitinib, erlotinib, temozolomide, and lapatinib. These agents represented widely available oral oncolytic agents at the time of our analyses. We then identified a subset of adjudicated oral oncolytic claims between May 1, 2007, and March 31, 2009 (defined as the index period) to determine if a patient had newly initiated therapy with a study drug. For each claim, we looked back 120 days in the patient's claim history from first adjudication of an oral oncolytic claim during the index period to exclude patients with previous oral or IV oncolytic treatment. To confirm that the data set included prescription data for each patient both before and after the newly initiated oral oncolytic, we restricted the sample to those patients who had at least 1 claim for any type of medication at least 120 or more days before and at least 90 days or more after the first oral oncolytic claim, a methodology employed to assess patient eligibility during the observation period.^{8,9}

To calculate the portion of newly initiated oral oncolytics that were ultimately abandoned, we defined adjudication status of the oral oncolytic as paid, reversed with follow-up, or abandoned. Patients with claims defined as reversed with follow-up had a successfully paid IV or oral oncolytic claim within 90 days after submission date of the reversed newly initiated oncolytic. Patients with claims defined as abandoned had reversed the newly initiated oncolytic but did not have a paid oncolytic claim within 90 days of submission date of the reversed claim.

We required the sample to include only patients insured by a non-Medicare commercial or Medicare plan, including prescription drug plans and Medicare Advantage Prescription Drug plans. We also restricted the sample to claims with complete patient- and claim-level data for all variables utilized in the regression model.

To conduct bivariate and multivariate analyses, we identified patient-level characteristics such as age (≤ 40 , 41 to 65, 66 to 80, or ≥ 81 years), sex, and geographic region (Northeast, South, Midwest, or West). A variable for annual patient income was included in the data set and categorized as less than \$40,000, between \$40,000 and \$75,000, or more than \$75,000. Cost-sharing amounts were collected for each

Take-Away Points

Oral oncolytic therapy is an increasingly important aspect of cancer care, and adherence to treatment is critical to deriving benefit.

- Our study found that 10% of patients abandoned their anticancer medicine, and another quarter had some delay in initiating another oncolytic.
- Pharmacy plan design (cost-sharing amount) and complexity of patients' drug therapy (prescription activity) are significant drivers of abandonment of oral oncolytic agents.
- As the structure of Medicare Part D and commercial plans is modified and health reform initiatives evolve, policy makers and stakeholders should be aware of the impact of benefit structure on adherence and access to vital oncology therapy.

paid and reversed claim and were grouped into the following categories: \$0 to \$100, \$101 to \$150, \$151 to \$200, \$201 to \$250, \$251 to \$350, \$351 to \$500, or more than \$500. We also created a variable to measure concurrent prescription activity for each patient based on the number of claims processed within 30 days before the submission date of the newly initiated oral oncolytic. The prescription activity variable was defined as follows: no claims, 1 claim, 2 to 3 claims, 4 to 5 claims, or more than 5 claims. Variables were created to control for the specific oral oncolytic agent that the patient was prescribed.

χ^2 analyses were conducted to compare abandonment rates across the independent variables previously described. A logistic regression model was constructed using abandonment status (0 = no, 1 = yes) within 90 days after the initially adjudicated oral oncolytic claim as the dependent variable. Covariates included all independent variables described to identify significant predictor variables ($P < .05$). Odds ratios and 95% confidence intervals [CIs] were calculated for all predictors in the model using selected references for comparison.

RESULTS

Of the initial 20,607 patients in the data set, we identified 10,508 patients who met the final inclusion criteria for our study. Sixty-seven percent of the claims were adjudicated and paid for by the patient and/or pharmacy benefit plan, whereas 33% of claims were reversed. Of the total number of reversed claims, 23% of patients followed up with another oncolytic agent within 90 days. The remaining 10% of patients had no follow-up and thus abandoned the oral oncolytic agent. A sensitivity test to extend the follow-up window from 90 to 120 days did not significantly affect the portion of claims defined as abandoned.

Table 1 provides demographics and plan characteristics for patients included in our study. Approximately half of the patients in our sample were younger than 65 years. Patients were slightly more likely to be female, more likely to have an income between \$40,000 and \$75,000, and most commonly

■ **Table 1.** Adjudication Status of Newly Initiated Oral Oncolytic Claims

Patient Characteristic	Adjudication Status					
	Total		Paid or Reversed With Follow-Up		Abandoned	
	No.	%	No.	%	No.	%
Total patients	10,508	100.0	9455	90.0	1053	10.0
Age, years^a						
0-40	302	2.9	272	90.1	30	9.9
41-65	5109	48.6	4672	91.5	437	8.6
66-80	3837	36.5	3419	89.1	418	10.9
>81	1260	12.0	1092	86.7	168	13.3
Sex						
Female	5548	52.8	5009	90.3	539	9.7
Male	4960	47.2	4446	89.6	514	10.4
Annual household income^a						
<\$40,000	2721	25.9	2410	88.6	311	11.4
\$40,000-\$75,000	4038	38.4	3626	89.8	412	10.2
>\$75,000	3749	35.7	3419	91.2	330	8.8
Geographic region						
Midwest	2355	22.4	2105	89.4	250	10.6
Northeast	2764	26.3	2479	89.7	285	10.3
South	3692	35.1	3343	90.6	349	9.5
West	1697	16.1	1528	90.0	169	10.0
Patient cost-sharing amount^a						
\$0-\$100	7638	72.7	7147	93.6	491	6.4
\$101-\$150	271	2.6	242	89.3	29	10.7
\$151-\$200	258	2.5	234	90.7	24	9.3
\$201-\$250	123	1.2	108	87.8	15	12.2
\$251-\$350	291	2.8	256	88.0	35	12.0
\$351-\$500	200	1.9	168	84.0	32	16.0
>\$500	1727	16.4	1300	75.3	427	24.7
Insurance type^a						
Medicare	1737	16.5	1467	84.5	270	15.5
Commercial	8771	83.5	7988	91.1	783	8.9
Prescription activity, No. of claims^a						
0	3049	29.0	2775	91.0	274	9.0
1	1318	12.5	1207	91.6	111	8.4
2-3	2168	20.6	1947	89.8	221	10.2
4-5	1550	14.8	1383	89.2	167	10.8
>5	2423	23.1	2143	88.4	280	11.6
Study drug^a						
Capecitabine	3758	35.8	3527	93.9	231	6.2
Imatinib	1380	13.1	1194	86.5	186	13.5
Sorafenib	460	4.4	335	72.8	125	27.2
Lenalidomide	1038	9.9	960	92.5	78	7.5
Sunitinib	569	5.4	501	88.1	68	12.0
Erlotinib	2022	19.2	1763	87.2	259	12.8
Temozolomide	1060	10.1	982	92.6	78	7.4
Lapatinib	221	2.1	193	87.3	28	12.7

^a χ^2 ; $P < .05$.

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■ **Table 2.** Results of Logistic Regression of Likelihood of Abandonment of Newly Initiated Oral Oncolytic Claims

Independent Variable	Odds Ratio	95% CI	P
Age group, years (reference, 0-40)			
41-65	0.82	0.55 to 1.23	.346
66-80	0.71	0.47 to 1.07	.102
>81	0.80	0.52 to 1.23	.313
Sex (reference, female)			
Male	0.99	0.86 to 1.14	.899
Annual household income (reference, >\$75,000)			
<\$40,000	1.19	0.99 to 1.41	.058
\$40,000-\$75,000	1.13	0.96 to 1.32	.142
Geographic region (reference, Midwest)			
Northeast	1.15	0.95 to 1.38	.157
South	0.91	0.76 to 1.08	.279
West	1.01	0.81 to 1.25	.937
Patient cost-sharing amount (reference, \$0-\$100)			
\$101-\$150	1.84	1.23 to 2.75	.003
\$151-\$200	1.51	0.97 to 2.34	.066
\$201-\$250	2.30	1.31 to 4.04	.004
\$251-\$350	2.31	1.59 to 3.36	<.001
\$351-\$500	3.28	2.20 to 4.88	<.001
>\$500	4.46	3.80 to 5.22	<.001
Prescription activity, No. of claims (reference, 0)			
1	1.02	0.80 to 1.30	.870
2-3	1.26	1.03 to 1.53	.023
4-5	1.27	1.02 to 1.57	.029
>5	1.50	1.24 to 1.81	<.001
Study drug (reference, capecitabine)			
Imatinib	2.09	1.68 to 2.60	<.001
Sorafenib	4.87	3.74 to 6.34	<.001
Lenalidomide	1.04	0.79 to 1.38	.759
Sunitinib	1.63	1.21 to 2.21	.001
Erlotinib	1.47	1.20 to 1.81	<.001
Temozolomide	1.11	0.85 to 1.47	.445
Lapatinib	2.15	1.39 to 3.33	.001

CI indicates confidence interval.
Pseudo $R^2 = 0.0922$.

from the South. Most patients were insured by a commercial plan.

Bivariate analyses comparing the combination of paid claims and reversed claims with follow-up versus abandoned claims indicated significant differences across age groups and rate of abandonment. Thirteen percent of patients older than 80 years abandoned their first oral oncolytic compared with 10% of patients 40 years or younger ($P < .05$). Insurance sta-

tus was also a significant variable, with abandonment rates of 16% for Medicare claims versus 9% for commercial insurance claims ($P < .05$).

Lower annual household income was associated with higher abandonment rates. Patients with incomes of less than \$40,000 per year had an abandonment rate of 11%, decreasing to 10% for incomes between \$40,000 and \$75,000 and 9% for incomes above \$75,000 ($P < .05$).

■ **Table 3.** Distribution of Cost-Sharing Amounts for Newly Initiated Oral Oncolytic Claims by Insurance Type

Cost-Sharing Requirement	Commercial Insurance		Medicare		Total	
	No.	%	No.	%	No.	%
\$0-\$100	7027	80.1	611	35.2	7638	72.7
\$101-\$150	217	2.5	54	3.1	271	2.6
\$151-\$200	162	1.9	96	5.5	258	2.5
\$201-\$250	90	1.0	33	1.9	123	1.2
\$251-\$350	192	2.2	99	5.7	291	2.8
\$351-\$500	146	1.7	54	3.1	200	1.9
>\$500	937	10.7	790	45.5	1727	1.4
Total	8771		1737		10,508	

Twenty-three percent of patients submitted more than 5 claims for nononcolytic medications within the previous month of initiating the oral oncolytic, whereas 29% of patients had no concurrent prescription activity. Prescription activity was significantly associated with increased abandonment rates. Patients with more than 5 claims in the previous month had an abandonment rate of 12% compared with 9% for patients with no claims in the previous month ($P < .05$).

Seventy-three percent of newly initiated oncolytics had a cost-sharing amount of \$100 or less, although 16% required an out-of-pocket cost of more than \$500. For reference, median cost-sharing amount in the sample for all patients was \$30. The abandonment rate increased with cost-sharing amount. Claims with cost sharing above \$500 had the highest abandonment rate (25%) compared with an abandonment rate of 6% for claims with cost sharing of \$100 or less ($P < .05$).

Among the 8 oral oncolytics in our study, capecitabine accounted for more than one-third of the sample. Imatinib, lenalidomide, erlotinib, and temozolomide were also commonly used medications. The unadjusted abandonment rate for each oral oncolytic agent varied greatly.

After controlling for multiple factors in the logistic regression model, we found that patients experiencing higher cost-sharing amounts were significantly more likely to abandon the oral oncolytic agent, compared with patients with the lowest cost-sharing amount (Table 2). Claims with cost sharing over \$500 had more than 4 times the likelihood of abandonment versus claims with cost sharing of \$100 or less ($P < .05$). Patients with between 2 and 5 prescription claims and patients with more than 5 claims in the previous month had a 26% and 50% higher likelihood to abandon the oral oncolytic agent, respectively, versus those patients with no concurrent prescription activity ($P < .05$). A sensitivity analysis in which we calculated the prescription activity variable with only paid

claims (not including reversals) produced similar regression results.

In the multivariate logistic regression, age and annual income (which showed significant bivariate relationships with abandonment) were no longer significant predictors once we controlled for other factors. In addition, patients with incomes less than \$40,000 were 20% more likely to abandon versus patients with incomes greater than \$75,000 ($P = .058$).

We completed a subanalysis to explore the distribution of cost-sharing amounts by insurance type (Table 3). Eighty percent of commercially insured patients paid \$100 or less out of pocket for the first oral oncolytic claim, compared with 35% of Medicare patients. Only 11% of commercially insured patients paid more than \$500 versus 46% of Medicare patients. A χ^2 test confirmed that Medicare patients pay significantly more out of pocket than commercially insured patients ($P < .001$).

To estimate the impact of insurance plan type on abandonment rates while controlling for other factors, we constructed an additional logistic regression model as part of this subanalysis. This model included the same covariates as our logistic regression model, with the addition of an insurance-type variable (commercial vs Medicare). We also restricted the sample to claims submitted in calendar year 2008 and added a variable to designate calendar quarter of submission to control for the impact of the Medicare coverage gap. The results of this analysis confirmed relationships found in the main regression analysis. Cost-sharing amount continued to be a significant predictor of the likelihood of abandoning the newly initiated oral oncolytic. Insurance type was not a significant predictor of abandonment, perhaps because of the strong relationship between cost sharing and insurance type. We also found that abandonment rates were significantly higher between April and December than in the first quarter of the year ($P < .05$).

DISCUSSION

This research provides new insight into factors that affect the abandonment rate of oral oncolytic medications at pharmacies. We found that 1 in 10 patients abandoned their first prescription for an oral oncolytic agent, a rate similar to those reported for specialty medications to treat rheumatoid arthritis and multiple sclerosis and higher than those for other oral chronic medication classes (eg, antihypertensives, antipsychotics, and antidepressants).^{5,6} We found that almost a quarter of patients reversed their newly initiated oral oncolytic and subsequently followed up with another oncolytic prescription, potentially causing an unnecessary delay in treatment. Approximately two-thirds of patients successfully paid for their first oral oncolytic claim on initiation of the medication.

Out-of-pocket costs played a significant role with regard to the likelihood that a patient would abandon the first fill of the oral oncolytic agent. One in 4 patients filling prescriptions with cost-sharing amounts over \$500 abandoned the prescription and did not follow up with another oncology medication within 90 days. Cost sharing was also highly correlated with insurance type. Patients enrolled in Medicare plans, including prescription drug plans and Medicare Advantage Prescription Drug plans, had higher cost sharing than those insured by commercial insurance plans.

Although the relationship between cost sharing and abandonment rate has been previously investigated and presented elsewhere, we identified other factors that also significantly increased likelihood of abandonment.⁷ Patients with higher concurrent prescription activity were more likely to abandon their first oral oncolytic claim at the pharmacy. Lower annual household income was also associated with higher abandonment rates, although this relationship was not statistically significant after controlling for other factors.

Differences in abandonment rates across oncolytic agents may be related to specific cancer diagnoses for reasons unrelated to factors in our analysis. Further research that integrates additional clinical data elements derived from administrative or medical records may more appropriately assess differences across oral oncolytic agents.

Our study had limitations. It is possible that some patients whom we characterized as abandoning their oral oncolytic claim actually followed up with an IV oncolytic. The data set we used for this study included pharmacy benefit claims for oral medications and some IV medications. Some IV medications are instead processed through the patient's medical benefit plan, although these claims were not available for all patients in our sample. We conducted a post hoc exploratory analysis to assess the portion of claims that may have been mischaracterized as abandoned by utilizing pharmacy claims in

our analysis without incorporating medical claims. We found that our results would not change significantly if we were to include medical claims for the limited number of patients in our sample. However, future research would benefit from large cohorts created by combining medical and pharmacy claims data to allow for additional follow-up of IV-administered drugs as well as controls for cancer diagnosis and comorbidity. In addition, the method we employed to ensure available pharmacy data for each patient based on the existence of claim activity outside the observation period may have led to underestimation of the actual rate of abandonment.

Finally, we did not have access to information that would identify patients who abandoned a claim for an oral oncolytic but might have accessed medication through a manufacturer's patient assistance program (PAP) or copayment assistance program. Availability of PAP programs is not consistent across manufacturers. Those manufacturers that have established PAP programs employ a variety of eligibility requirements, but a majority base eligibility on income and/or lack of insurance coverage.¹⁰ It is not clear what percentage of the Medicare and commercially insured patients in our sample abandoned their newly initiated oral oncolytic at the pharmacy and followed up with a prescription from a PAP. We are not aware of an observational database that would include PAP utilization for such patients.

Oral oncolytic therapy is an increasingly available and important aspect of cancer care, and adherence to treatment is critical to deriving benefit.^{11,12} Our study found that 10% of patients abandoned their anticancer medicine, and another quarter had some delay in initiating another oncolytic. Moreover, factors related to pharmacy plan design, cost-sharing amount, and patients' concurrent prescription activity were significant drivers for patients to abandon their oral oncolytic agents. Pharmacy benefit plans with cost sharing in the form of a coinsurance payment may require hundreds of dollars in patient out-of-pocket spending, thus increasing the likelihood of abandonment.

A number of major changes to Medicare and commercial healthcare insurance coverage will be driven by the Affordable Care Act of 2010.¹³ As the structure of Medicare Part D and commercial plans are modified and health reform initiatives evolve, policy makers and stakeholders should be aware of the impact of benefit structure on adherence and access to vital oncology therapy. The results of this study highlight the importance of identifying strategies to minimize the impact of high cost-sharing requirements in prescription drug plans so that they do not pose a barrier to access to newer oral therapies for patients diagnosed with cancer, thereby denying patients the potential benefits of these effective agents.

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