

Targeting Financial Toxicity in Oncology Specialty Pharmacy at a Large Tertiary Academic Medical Center

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ABSTRACT

BACKGROUND: Patients with cancer often face financial toxicity. They may face financial distress because of high out-of-pocket costs that in turn can result in delays in treatment, treatment abandonment, and higher overall costs of care, all of which can have a negative effect on patient care. A specialty pharmacy practice model can play a role in decreasing financial toxicity.

OBJECTIVE: To evaluate the patient out-of-pocket costs after enrollment in manufacturer patient assistance programs, copay cards, and foundation grants by an oncology specialty pharmacy at University of Chicago Medicine (UCM).

METHODS: For this quality improvement project, a retrospective analysis of prescription claims from January 2017 to June 2017 was performed. The primary outcomes included the number of patients enrolled in manufacturer patient assistance programs, copay cards, and foundation grants, along with the total dollars applied to pharmacy claims. The secondary outcome was the average days to approval of a foundation grant. Inclusion criteria for this quality improvement project included prescriptions filled at UCM Specialty Pharmacy in the 6-month time frame for an oncology indication. Exclusion criteria were prescriptions that were not filled at UCM Specialty Pharmacy due to out-of-network insurance and prescriptions that were part of a patient assistance program where the medication was directly shipped from the manufacturer.

RESULTS: In the 6-month time frame, 75 patients received financial assistance, with a total cost savings of \$314,857. Financial assistance was most frequently applied to the following medications: peg-filgrastim, dasatinib, abiraterone, filgrastim and filgrastim-sndz, palbociclib, venetoclax, and ruxolitinib. The cost savings of these interventions ranged between \$5 and \$13,138 per prescription claim. The average days from date of insurance approval to date of financial grant approval was 1.2 days.

CONCLUSIONS: This project demonstrates the importance of an oncology specialty pharmacy team in ensuring timely approval of a foundation grant and reducing financial toxicity, which can play a major role in access to therapy.

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What is already known about this subject

- Since patients diagnosed with cancer are living longer, there has been a shift towards requiring long-term oral anticancer medication and supportive care management.
- The costs of oral anticancer and supportive care medications are increasing, leading to financial toxicity for patients.
- Financial assistance programs may help decrease high costs and improve medication access.

What this study adds

- This project presents an oncology specialty pharmacy practice model and its role in decreasing financial toxicity.
- This project discusses the effect of the use of financial assistance programs, such as copay cards, foundation grants, and manufacturer patient assistance programs.
- This project demonstrates how pharmacists and pharmacy technicians can provide ongoing support to patients by ensuring access and affordability with financial assistance programs.

There is an emotional, physical, and financial burden that oncology patients are unexpectedly faced with once they are diagnosed with cancer. According to a 2017 study by Narang and Nicholas, who evaluated out-of-pocket costs for patients with cancer, study participants had a mean annual out-of-pocket cost of \$3,737, which equaled 11.4% of annual household income.¹ The term “financial toxicity” has been coined in the literature and first gained traction in 2011.^{2,3} This concept is not fully understood, but Carrera et al. (2018) defined a patient’s financial toxicity as the culmination of objective financial burden and subjective financial distress.⁴ Patients with a cancer diagnosis are 2 and a half times more likely than those without cancer to file bankruptcy.⁵

Barriers to accessing OAMs include obtaining prior authorization, lack of time and familiarity, and costs.⁶ In June 2017, The American Society of Clinical Oncology released a statement regarding the affordability of cancer drugs and called for oncology care providers to provide a standardized approach on drug pricing and reimbursement.⁷ Pharmacists are key stakeholders who can decrease the financial toxicity for oncology patients and provide potential solutions to this problem by enrolling patients in financial assistance programs, such as manufacturer patient assistance programs, copay cards, and foundation grants.

The University of Chicago Medicine (UCM) is a large tertiary academic medical center located in Chicago, IL, which includes the Comprehensive Cancer Center. The Comprehensive Care Center was established in 1973 and is a National Cancer Institute-designated cancer center. The UCM Specialty Pharmacy is integrated into the health system, with the provision of medication management services for patients with chronic conditions as its goal.

The UCM Specialty Pharmacy implemented its oncology specialty pharmacy services in August 2016. This service is supported by 3 pharmacists and 2 ambulatory medication access coordinators. The pharmacists are clinical pharmacy specialists who typically have 1-2 years of residency training and are board certified. These pharmacists are integrated into the outpatient clinics and serve as an extension of the provider team. With each referral, pharmacists perform a clinical review for efficacy, provide medication and disease state education, manage patient adherence, consult with physicians, and provide access to care on a 24/7 basis through a specialty pharmacist on-call program. An ambulatory medication access coordinator is a highly trained certified pharmacy technician who performs benefits investigation, obtains prior authorizations, enrolls patients in financial assistance programs, and performs ongoing refill management. The UCM Specialty Pharmacy is accredited by the Accreditation Commission for Health Care and the Utilization Review Accreditation Commission.

Methods

Study Design and Data Collection

This quality improvement project was a retrospective analysis of prescription claims data. The project received a determination of quality improvement status. Since it was not human subject research, this project was not reviewed by the Institutional Review Board.

Data was collected and managed using Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN), an electronic data capture tool hosted at UCM.⁸ REDCap is a secure, web-based application designed to support data capture for research studies and provides (a) an intuitive interface for validated data entry; (b) audit trails for tracking data manipulation and export procedures; (c) automated export procedures for seamless data downloads to common statistical packages; and (5) procedures for importing data from external sources.

Prescription claims data were retrieved from the pharmacy dispensing software ScriptPro (ScriptPro, Mission, KS). The data consisted of patients who filled at least 1 oncology specialty prescription between January 1, 2017, and June 30, 2017. Patient profiles and *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis codes were reviewed to ensure prescription use for an oncology indication. Relevant ICD-10-CM codes can be found in Table 1. The claims data included primary and secondary payers, which were categorized as third-party payers (Medicare, Medicaid, and commercial) or financial assistance.

Financial assistance plans were further categorized as manufacturer patient assistance programs, foundation grants, and trial and copay cards. Manufacturer patient assistance programs are programs supported by pharmaceutical companies that

TABLE 1 List of Oncology ICD-10-CM Code Categories

Category	Code
Malignant neoplasm of other and unspecified parts of tongue	C02
Malignant neoplasm of other and unspecified parts of mouth	C06
Malignant neuroendocrine tumors	C7A
Malignant neoplasm of esophagus	C15
Malignant neoplasm of stomach	C16
Malignant neoplasm of colon	C18
Malignant neoplasm of rectosigmoid junction	C19
Malignant neoplasm of anus and anal canal	C21
Malignant neoplasm of liver and intrahepatic bile ducts	C22
Malignant neoplasm of gallbladder	C23
Malignant neoplasm of body of pancreas	C25
Malignant neoplasm of bronchus and lung	C34
Malignant neoplasm of other connective and soft tissue	C49
Malignant neoplasm of breast	C50
Malignant neoplasm of unspecified ovary	C56
Malignant neoplasm of prostate	C61
Malignant neoplasm of kidney, except renal pelvis	C64
Malignant neoplasm of brain	C71
Malignant neoplasm of thyroid gland	C73
Nonfollicular lymphoma	C83
Mature T/NK-cell lymphomas	C84
Other specified and unspecified types of non-Hodgkin lymphoma	C85
Malignant immunoproliferative diseases and certain other B-cell lymphomas	C88
Multiple myeloma and malignant plasma cell neoplasms	C90
Lymphoid leukemia	C91
Myeloid leukemia	C92
Benign neuroendocrine tumors	D3A
Chronic myeloproliferative disease	D47

ICD-10-CM = *International Classification of Diseases, Tenth Revision, Clinical Modification*.

provide medications at no cost to financially qualifying patients. Foundation grants are nonprofit organizations that provide financial assistance to fill gaps in coverage and help cover costs for prescription copays, health insurance premiums, and travel costs. Copay cards are used by patients with commercial insurance who have high out-of-pocket costs. The manufacturer patient assistance programs and foundation grants that were assessed included, but were not limited to, the following: Novartis, Johnson and Johnson, Health Well Foundation, Patient Access Network Foundation, and Good Days.

Inclusion criteria for this quality improvement project were prescriptions filled at UCM Specialty Pharmacy in the 6-month time frame for an oncology indication. Prescriptions were excluded if there were no oncology indications, were not filled at UCM Specialty Pharmacy due to out-of-network prescription insurance, and were part of a patient assistance program where the medication was directly shipped from the manufacturer. Prescriptions were also excluded if the financial assistance was

approved before January 2017, even if benefits were used during this time frame.

Statistical Analysis

The primary outcomes included the number of patients who were enrolled in financial assistance and the total cost savings in dollars. The secondary outcome was the average days to foundation grant approval. The days to foundation grant approval was defined as the number of days between the date of the paid pharmacy test claim and the date of foundation grant approval. Descriptive analytics were performed. All analyses were performed using STATA software, version 11.0 (StataCorp, College Station, TX).

Results

There were 233 patients who filled at least 1 specialty pharmacy prescription at UCM Specialty Pharmacy. Of these patients, 75 were enrolled in financial assistance. In the 6-month time frame, the total patient cost savings was \$314,857. The total number of claims for financial assistance was 153 claims. Financial assistance was most frequently applied to peg-filgrastim, dasatinib, abiraterone, filgrastim and filgrastim-sndz, palbociclib, venetoclax, and ruxolitinib. The cost savings of each intervention ranged from \$5 to \$13,138 for the 75 patients who received financial assistance. The highest out-of-pocket cost was \$4,240. The average days to financial grant approval were 1.2 average days.

Manufacturer Patient Assistance Programs

The total number of claims for manufacturer patient assistance programs was 25 claims. The total patient cost savings for manufacturer patient assistance programs was \$216,037. The total patient cost savings per claim was \$8,642. The total unique patients enrolled in manufacturer patient assistance programs was 14 patients. The total cost savings per unique patient was \$15,431. The overall mean patient cost savings per claim was \$8,642 for manufacturer patient assistance programs.

Copay Cards

The total number of claims for copay cards was 65 claims. The total patient cost savings for copay cards was \$41,416. The total number of unique patients was 41 patients. The total cost savings per unique patient was \$1,010. The overall mean cost savings per claim was \$637 for copay cards, with an average reduction of 88% on out-of-pocket costs for patients.

Foundation Grants

The total number of claims for foundation grants was 63 claims. The total patient cost savings for foundation grants was \$57,404. The total number of unique patients enrolled in copay cards was 20 patients. The total patient cost savings was per unique patient was \$2,870. The overall mean costs savings

per claim was \$911 for foundation grants, with an average reduction of 99.9% on out-of-pocket costs for patients.

Table 2 shows the total dollars applied to pharmacy claims by enrollment in manufacturer patient assistance programs, copay cards, and foundation grants.

Discussion

Financial assistance programs, including copay cards, foundation grants, and manufacturer patient assistance programs, can decrease costs of OAMs. Similar studies have found that these types of financial assistance programs can play a role in reducing out-of-pocket expenses for prescriptions drugs and OAMs.⁹⁻¹² Mitchell et al. (2018) performed a similar study that evaluated the number of oncology patients receiving patient assistance programs for OAMs and the retail value of the assistance.¹³ This study found that 10.6% of patients obtained a patient assistance program for an oral cancer medication, where our quality improvement project showed 18.6% of patients received a patient assistance program. The enrollment rate for patient assistance programs is likely an underestimate because patients who received the patient assistance program medication shipment directly from the manufacturer were not included.

The high cost burden of OAMs puts patients at risk for financial toxicity and creates barriers to obtaining life-saving and supportive oncology treatments. Patients who have high out-of-pocket costs are more likely to discontinue cancer therapy.^{14,15} Doshi et al. (2018) found that patient out-of-pocket costs between \$100 and \$500 were associated with a 32% therapy abandonment rate.¹⁶ This quality improvement project demonstrates how specialty pharmacists and pharmacy technicians integrated within a health system can perform benefits investigations, assess patient out-of-pocket responsibility, and enroll patients in such programs to alleviate the high cost burden of OAMs and prevent therapy abandonment. Pharmacists and technicians provide ongoing support to patients by ensuring access and affordability during the course of therapy.

Limitations

There are limitations to this quality improvement project. The full scope of UCM Oncology Specialty Pharmacy's effect is limited by the time frame of the quality improvement project, exclusion criteria, and internal barriers. This quality improvement initiative was performed at a large, tertiary academic medical center, with the resources of an integrated, dedicated pharmacy service. The results may not be generalizable to smaller, community hospitals. The 6-month time frame does not account for all patients enrolled in financial assistance since implementation of the specialty pharmacy program. Patients were excluded if they used financial assistance that was awarded before January 2017, which may underrepresent total dollars of financial assistance.

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TABLE 2 Total Dollars Applied to Pharmacy Claims by Enrollment in Manufacturer Patient Assistance Programs, Copay Cards, and Foundation Grants

Manufacturer patient assistance programs							
	Claims, n	Mean ± SD, \$	Median, \$	Range, \$	Total, \$		
Dasatinib	6	11,322 ± 4,448	12,414	2,244-13,138	67,934		
Abiraterone	13	9,301 ± 212	9,360	8,595-9,360	120,915		
Filgrastim and filgrastim-sndz	5	3,646 ± 311	3,939	2,843-3,570	15,360		
Ribociclib	1	11,828	11,828	11,828	11,828		
Total	25	8,642 ± 3,616	9,359	2,244-11,828	216,037		
Copay cards							
	Claims, n	Mean ± SD	Median, \$	Range, \$	Total, \$	Average Out-of-Pocket Cost Before Enrollment	Average Percentage Saved After Enrollment
Peg-filgrastim	18	782 ± 1,000	125	30-3,120	14,076	782	100
Dasatinib	3	117 ± 29	101	100-151	351	117	100
Filgrastim and filgrastim-sndz	7	926 ± 1,401	100	50-2,976	6,486	926	100
Venetoclax	6	76	76	76	456	101	75
Everolimus	4	239 ± 279	100	100-657	957	239	100
Afatinib	4	5	5	5	20	30	17
Lapatinib	4	667 ± 730	667	35-1,304	2,670	680	99
Imatinib	3	703 ± 495	700	210-1,200	2,110	2,186	66
Ruxolitinib	2	423 ± 527	423	50-796	846	448	81
Ibrutinib	2	1,089 ± 229	1,089	926-1,251	2,177	1,098	99
Palbociclib	2	3,692 ± 993	3,692	2,990-4,395	7,385	3,702	99
Rucaparib	2	40 ± 14	40	30-50	80	40	100
Eltrombopag	2	35	35	35	70	60	58
Enzalutamide	1	231	231	231	231	251	92
Erlotinib	1	3,326	3,326	3,326	3,326	3,351	99
Pazopanib	1	75	75	75	75	100	75
Ribociclib	1	30	30	30	30	30	100
Midostaurin	1	40	40	40	40	50	80
Nilotinib	1	30	30	30	30	40	75
Total	65	637 ± 1,029	100	5-4,395	41,416	709	88
Foundation grants							
Palbociclib	12	1,115 ± 1,028	552	547-3,022	13,379	1,115	100
Dasatinib	8	352 ± 282	399	60-613	2,816	365	100
Ruxolitinib	6	978 ± 987	588	555-2,995	5,870	978	100
Enzalutamide	6	706 ± 917	500	60-2,529	4,235	706	100
Erlotinib	5	393	393	393	1,965	398	99
Cabozantinib	5	1,136 ± 871	756	720-2,696	5,683	1,136	100
Pazopanib	4	1,752 ± 1,393	1,730	547-3,004	7,011	1,752	100
Vismodegib	4	1,142 ± 1,187	548	548-2,923	4,568	1,142	100
Venetoclax	3	742 ± 1,048	154	120-1,952	2,226	742	100
Abiraterone	3	456 ± 21	468	432-468	1,369	456	100
Sorafenib	3	1,349 ± 1,609	420	420-3,206	4,046	1,349	100
Filgrastim and filgrastim-sndz	2	1,996 ± 1,699	1,996	794-3,197	3,991	1,996	100
Ibrutinib	2	123 ± 88	123	60-185	245	123	100
Total	63	911 ± 962	549	60-3,206	57,404	913	99.9

SD = standard deviation.

The quality improvement project excluded patients with out-of-network insurance and those who received medications directly from the manufacturer as part of patient assistance programs. The UCM Oncology Specialty Pharmacy helps all patients receive financial assistance even if they have out-of-

network insurance, so this project underestimated the total cost savings provided to the patient population.

The authors were unable to calculate average percentage saved after enrollment in manufacturer patient assistance programs. Patients are typically enrolled in patient assistance

programs if they have high copays or are denied coverage by insurance. For these prescriptions, data were not available for what the copay would have been before enrollment in a free drug program. Finally, internal barriers include financial assistance enrollment time frame based on prompt responsiveness from patients.

Conclusions

This quality improvement project revealed how vital an oncology specialty pharmacy team is in reducing patient financial burden and improving access to medications. Through financial interventions made by the UCM Oncology Specialty Pharmacy, 1 in 3 patients was enrolled in a financial assistance program, with cost savings ranging from \$5 to over \$13,000 per prescription claim. The UCM Oncology Specialty Pharmacy team improved access to copay cards, foundation grants, and patient assistance programs, mitigating financial barriers to treatment initiation and continuation.

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DISCLOSURES

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