Provider and Patient Burdens of Obtaining Oral Anticancer Medications

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More than 50 oral anticancer medications (OAMs) have been approved since 1998, making treatment possible and more convenient for many patients.[1,2] Unlike office-administered chemotherapy, which is covered as a medical benefit by insurance plans, OAMs are obtained through a patient's prescription coverage. Although providers anecdotally discuss the significant burden that is placed on them to help patients receive OAMs, there are few empirical data that describe the effort and time spent to obtain these drugs. Access to these data is complicated for multiple reasons. First, there is heterogeneity among prescription plans regarding the requirements for prior authorization for OAMs and the contracted specialty pharmacies to fill them. Second, cost sharing varies substantially based on insurance; for example, many Medicare patients will face very high co-pays for their initial drug fills as they enter the coverage gap.[3] Third, patient assistance programs (PAPs) may provide some relief, but accessing them can be time-consuming and complicated due to the applications involved, the availability of funds, and restrictions on eligibility.[3] The reasons described above are not clear to providers at the time of prescribing and the problems they present require significant staff effort to resolve. Given the multiple parties involved for each prescription (patient, prescriber, insurer, specialty pharmacy, industry, and foundation co-pay PAPs), quantifying this effort is challenging because the data are not readily available in data sets traditionally used for health services research, such as administrative claims data.

In an initial step to characterize the barriers to timely initiation of oral therapy, we describe our efforts obtaining on-label OAMs in the Genitourinary Medical Oncology clinic at Fox Chase Cancer Center in Philadelphia, Pennsylvania. Because of the multiple hand-offs among the different parties, we sought to granularly quantify and qualitatively describe the clinic staff's efforts to obtain OAMs. We focused on metastatic prostate and renal cell cancers, 2 diseases for which OAMs are frequently used.

ABSTRACT

Oral anticancer medications (OAMs) are frequently used to treat patients with cancer. Unlike intravenous chemotherapy, OAMs are covered by prescription drug plans. We examined barriers to initiation of OAMs in 116 patients with prostate or kidney cancer (149 unique prescriptions). We found that the median time from initial prescription to prior authorization was 3 days and the median time from initial prescription to patient receipt of drug was 12 days. Seventy-three percent of all prescriptions required 2 or more phone calls by clinic staff and 40% required 5 or more calls. Of 107 prescriptions with data available, 54% utilized financial assistance; these required significantly more phone calls (*P* = .0001) and led to a longer median time to drug obtainment (*P* = .003) compared with those that did not require financial assistance. In those prescriptions with both initial and final co-pay information available, the initial out-of-pocket mean and median co-pays were $1226.03 and $329.73, respectively, but these dropped to $124.57 and $25.00 after utilization of co-pay assistance programs, excluding those with a $0 final co-pay. These early observations suggest that a more efficient process for initiation of OAMs is needed.

METHODS

Clinical Setting

We conducted a retrospective review of prescriptions written for on-label recommended OAMs for advanced prostate cancer (abiraterone and enzalutamide) and renal cell carcinoma (sunitinib, pazopanib, axitinib, everolimus, and sorafenib). To identify patients, we accessed nurse-maintained clinic tracking logs for OAMs between August 1, 2014, and August 31, 2015. During the study period, 4 attending physicians, 2 advanced practice clinicians, and 3 registered nurses were involved in the care of these patients.

Data Source

The tracking sheets, which are maintained for all patients prescribed OAMs, are used by the clinic staff to organize data regarding patients' OAM prescriptions. Notes about phone calls, pharmacy and co-pay information, patient-specific notes, and other data are kept in these logs. In addition, we searched the electronic health records for incoming and outgoing telephone calls.

Data Elements and Measures

We collected information on demographics, insurance coverage, use of co-pay PAPs, and specialty pharmacy assignment. In addition, we measured the number of phone calls involving clinic staff required to obtain a drug and noted the reasons for phone calls. We also recorded the date the prescription was initiated, the date prior authorization was received (if applicable), and the date the drug was received or initiated by the patient. When available, any co-pay information was recorded. Time in days and number of calls were summarized by whether the patient received co-pay assistance. Differences were compared using Wilcoxon rank sum tests. This study was approved by Fox Chase Cancer Center's Institutional Review Board.

RESULTS

Prescription Characteristics

Of 116 patients examined, 56% had renal cell carcinoma and 44% had prostate cancer. The median age was 65 years (range, 27-88); 85%

TAKEAWAY POINTS

Oral anticancer medications (OAMs) are frequently used to treat patients with cancer. Unlike intravenous chemotherapy, OAMs are covered by prescription drug plans. We examined barriers to initiation of OAMs.

▸ We found that the median time from initial prescription to prior authorization was 3 days and the median time from initial prescription to patient receipt of drug was 12 days.

▸ Seventy-three percent of all prescriptions required 2 or more phone calls by clinic staff and 40% required 5 or more calls to facilitate prior authorizations, financial assistance, and drug acquisition.

▸ More than half (54%) of all prescriptions with data available were too expensive for the patient to afford and required the acquisition of financial assistance. In the end, most final co-pays were less than $100, but significant work was required by clinic staff in order to obtain financial assistance and lower patient co-pays.

TABLE. Patient Characteristics and Variables Involved in Obtaining OAMs[a]

	Prostate Carcinoma	Renal Cell Carcinoma	Total
Prescriptions, n (%)	54 (36)	95 (64)	149 (100)
Patient characteristics, n (%)			
Patients	51 (44)	65 (56)	116 (100)
Patients with prescription drug coverage	43 (83)	46 (72)	89 (77)
Patients without prescription drug coverage	0 (0)	3 (5)	3 (2)
Patients with unknown prescription drug coverage status	9 (17)	15 (23)	24 (21)
Prescription details			
Initial pharmacy transferred the OAM prescription to another pharmacy to be dispensed, n (%)			
Yes	18 (33)	29 (31)	47 (32)
No	36 (67)	66 (69)	102 (68)
Date of prescription to prior authorization approval interval[b]	44	68	112
Mean (range), days	6 (0-45)	5.6 (0-81)	6 (0-81)
Median, days	3.5	3	3
Date of prescription to prescription initiation interval[b]	54	93	147
Mean (range), days	16.8 (0-62)	13.2 (0-42)	14.5 (0-62)
Median, days	12.5	11	12

(continued)

were male, 89% were white, and 77% had prescription drug coverage. Of note, only 3 patients were known to not have prescription drug coverage, with status of the remainder (21%) being unknown. There were 149 unique prescriptions written during the study's time period. Four specialty pharmacies dispensed almost 70% of all prescriptions. For 32% of prescriptions, the initially contacted specialty pharmacy transferred the prescription to another pharmacy. The **Table** shows the results for prescription details, phone calls made, co-pays incurred, and financial assistance obtained for patients.

Time to Prior Authorization and Receipt of Medications

The median time from initial prescription to prior authorization was 3 calendar days (range, 0-81) and the median time from initial prescription to patient receipt of the drug was 12 days (range, 0-62). One hundred nine (73%) prescriptions required 2 or more phone calls and 60 (40%) required 5 or more calls to acquire prior authorization and/or financial assistance or to provide instructions to the patient. The **Figure** is an example of a typical patient's 16-day process to obtain an on-label OAM with 9 phone calls made by the nursing staff.

Co-Pay Information

Some financial information was available for 107 prescriptions (72%). Fifty-eight prescription fills had documentation of utilizing financial assistance: 8 qualified for a drug voucher or free limited supply and 50 qualified for a grant or co-pay card. Examining the 38 prescription fills with complete (initial and final) co-pay information, 2 prescriptions initially had a $0 co-pay. The remaining 36 initially had mean and median co-pays of $1226.03 and $329.73, respectively (range, $3.60-$6000.00). For final co-pays, 17 of the 38 prescriptions had a $0 co-pay, and the remaining 21 prescriptions had a mean and median co-pay of $124.57 and $25.00, respectively (range, $3.60-$1056.44). The Table contains all available co-pay information. Among those prescriptions with available co-pay information, those that required financial assistance took longer to obtain the drug (*P* = .003) and required more phone calls by clinic staff (*P* = .0001) than those that did not (**eAppendix Table** [eAppendix available at **ajmc.com**]).

DISCUSSION

In a genitourinary oncology patient cohort being treated by a subspecialized group of providers, we report on a substantial and unique barrier to timely initiation of OAMs—time and effort of clinical staff and patients—a challenge not present with the use of intravenous oncology drugs. Although all drugs were prescribed on-label, approximately 50% of calls involved
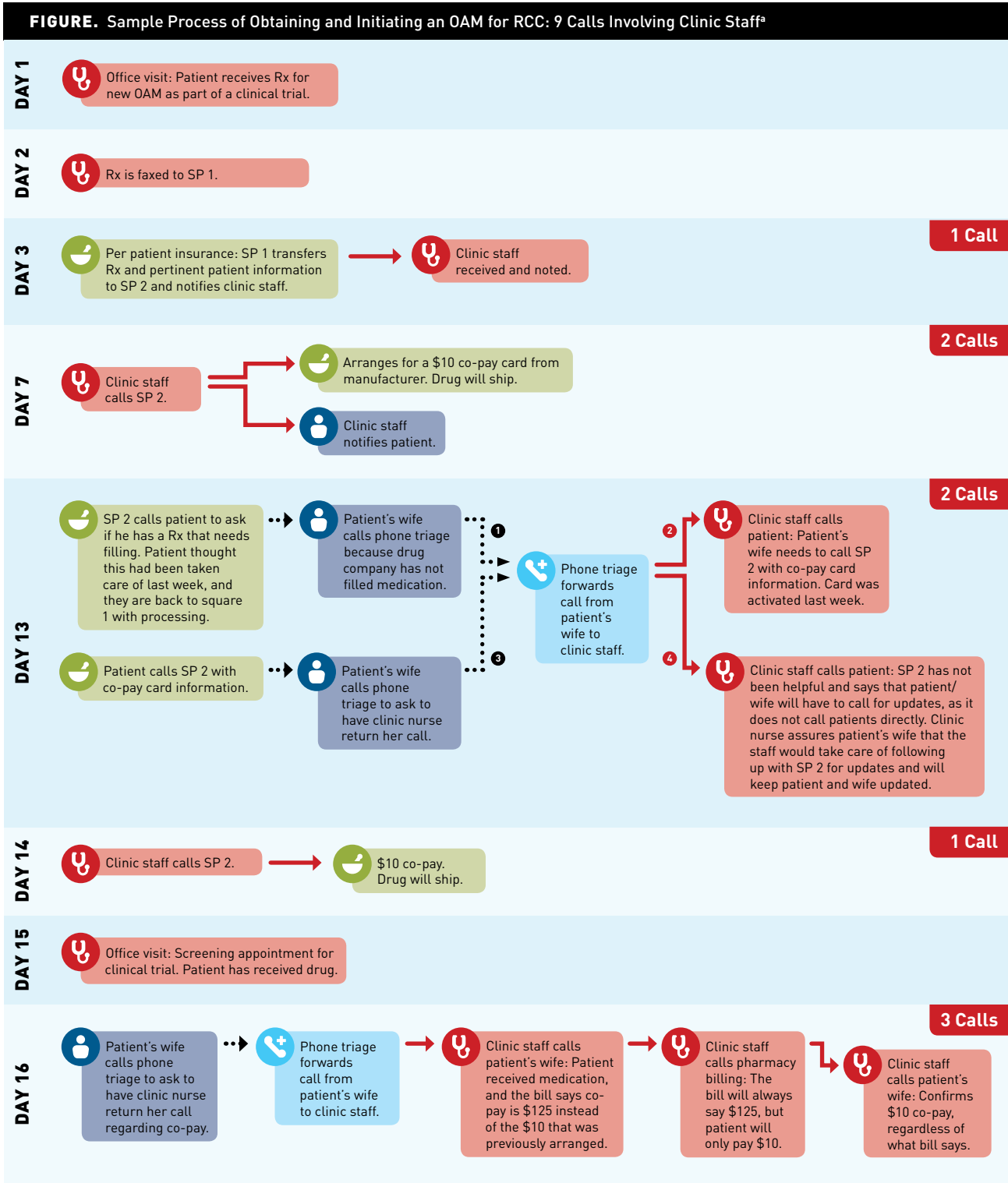
TABLE. *(Continued)* Patient Characteristics and Variables Involved in Obtaining OAMs[a]

	Prostate Carcinoma	Renal Cell Carcinoma	Total
Phone calls involving clinic staff			
Total number of phone calls (to and from clinic)	280	328	608
Average number of phone calls per patient	5.5	5	5.25
Mean (range) number of phone calls per prescription	5 (0-22)	3.5 (0-15)	4 (0-22)
0-1 calls, n (%)	8 (15)	32 (34)	40 (27)
2-4 calls, n (%)	18 (33)	31 (33)	49 (33)
≥5 calls, n (%)	28 (52)	32 (34)	60 (40)
Parties involved			
Pharmacy, n (%)	158 (56)	208 (63)	366 (60)
Patient/family, n (%)	83 (30)	100 (30)	183 (30)
Other, n (%)	39 (14)	20 (6)	59 (10)
Subject of call, n (%)			
Prior authorization	91 (33)	53 (16)	144 (24)
Insurance	54 (19)	87 (27)	141 (23)
Transferring prescription	16 (6)	20 (6)	36 (6)
Miscellaneous medication questions	79 (28)	127 (39)	206 (34)
Other	40 (14)	41 (13)	81 (13)
Co-pays and financial assistance			
Any financial data available[b]	45	62	107
Initial prescription co-pay per month[b]	25	31	56
$0, n (%)	1 (4)	2 (6)	3 (5)
$1-$100, n (%)	8 (32)	12 (39)	20 (36)
>$100, n (%)	16 (64)	17 (55)	33 (59)
Mean	$1679.22	$973.18	$1292.90
Median	$445.15	$150.00	$250.00
Range	$20.00-$9453.15	$3.60-$3729.81	$3.60-$9453.15
Assistance program used[b]	25	33	58
Final prescription co-pay per month[b]	32	44	76
$0, n (%)	18 (56)	19 (43)	37 (49)
$1-$100, n (%)	14 (44)	22 (50)	36 (47)
>$100, n (%)	0 (0)	3 (7)	3 (4)
Mean	$31.00	$109.40	$81.26
Median	$30.00	$25.00	$25.00
Range	$2.50-$75.00	$3.60-$1056.44	$2.50-$1056.44

OAM indicates oral anticancer medication.
[a]Unit of analysis is prescriptions. "Days" refer to calendar days, not business days. Co-pays reported are for a monthly supply. Mean, median, and range values for initial and final co-pays do not include prescriptions with $0 co-pay.
[b]Numbers in these rows are numbers of prescriptions with data available.

FIGURE. Sample Process of Obtaining and Initiating an OAM for RCC: 9 Calls Involving Clinic Staff[a]

DAY 1
Office visit: Patient receives Rx for new OAM as part of a clinical trial.

DAY 2
Rx is faxed to SP 1.

DAY 3 — 1 Call
Per patient insurance: SP 1 transfers Rx and pertinent patient information to SP 2 and notifies clinic staff.
→ Clinic staff received and noted.

DAY 7 — 2 Calls
Clinic staff calls SP 2.
→ Arranges for a $10 co-pay card from manufacturer. Drug will ship.
→ Clinic staff notifies patient.

DAY 13 — 2 Calls
SP 2 calls patient to ask if he has a Rx that needs filling. Patient thought this had been taken care of last week, and they are back to square 1 with processing.
••→ Patient's wife calls phone triage because drug company has not filled medication.
••→ ❶ ➤ Phone triage forwards call from patient's wife to clinic staff. ➤ ❷ Clinic staff calls patient: Patient's wife will have to call SP 2 with co-pay card information. Card was activated last week.

Patient calls SP 2 with co-pay card information.
••→ Patient's wife calls phone triage to ask to have clinic nurse return her call.
••→ ❸ ➤ ❹ Clinic staff calls patient: SP 2 has not been helpful and says that patient/ wife will have to call for updates, as it does not call patients directly. Clinic nurse assures patient's wife that the staff would take care of following up with SP 2 for updates and will keep patient and wife updated.

DAY 14 — 1 Call
Clinic staff calls SP 2.
→ $10 co-pay. Drug will ship.

DAY 15
Office visit: Screening appointment for clinical trial. Patient has received drug.

DAY 16 — 3 Calls
Patient's wife calls phone triage to ask to have clinic nurse return her call regarding co-pay.
••→ Phone triage forwards call from patient's wife to clinic staff.
→ Clinic staff calls patient's wife: Patient received medication, and the bill says co-pay is $125 instead of the $10 that was previously arranged.
→ Clinic staff calls pharmacy billing: The bill will always say $125, but patient will only pay $10.
→ Clinic staff calls patient's wife: Confirms $10 co-pay, regardless of what bill says.

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Calls initiated/actions taken by:

→ Calls involving clinic staff ••••➤ Other calls

Clinic staff   SP   Patient   Phone triage

OAM indicates oral anticancer medication; RCC, renal cell carcinoma; SP, specialty pharmacy.
[a]"Real-life" example of 48-year-old male patient with metastatic RCC and his path for obtaining a single OAM.

prior authorization and insurance barriers. With a median time of 12 days from prescription to receipt of drugs, many patients waited weeks to start their drugs for no reason other than the work required to obtain them. At a time when increasing value in healthcare is becoming a major focus of reform, the extra work and time imposed by this model creates waste and reduces value for all parties involved.[4]

We believe that these data provide, for the first time, empiric insight into the real-world experience that providers face when prescribing OAMs. We also provide initial evidence that the need to obtain financial assistance leads to a statistically, and potentially clinically, significant additional delay in obtaining OAMs. This has face validity as obtaining financial assistance entails administrative hurdles, including filling out applications, calling foundations, and obtaining patient financial documents, adding to the burden of both the patient and clinic staff. Thus, procedures to streamline the financial assistance process would be beneficial, although they would not eliminate the delay that persisted for patients who did not need financial assistance.

Our findings have implications for both clinical care and research. A delay of several weeks in prompt initiation of care may lead to clinical deterioration of patients as well as significant anxiety, although both of these outcomes need further prospective evaluation. The nursing logs and phone call records we reviewed documented confusing and frustrating efforts to navigate through prior authorizations and PAPs. A recent study by Zafar et al found that, as a whole, the industry-sponsored PAPs lacked transparency with regard to the eligibility criteria and actual financial benefit available to patients.[3] The authors concluded that "more work is needed in understanding how these programs affect practice patterns, outcomes, and the overall cost of cancer care." Our findings extend the discussion surrounding the many barriers to efficient obtainment of OAMs and the impact of the process on clinic staff and patients.

Although limited, our co-pay data also provide information regarding the importance of co-pay assistance programs in providing access to these treatments. Fifty-eight of the 107 prescriptions with co-pay data available utilized some type of financial assistance. Given the missing data, this likely understates the true need for co-pay assistance, which is particularly notable because 77% of our patient sample had prescription coverage. Of the remaining 23%, only 2% were known to not have prescription drug coverage and, therefore, no analysis based on whether one had or did not have drug coverage was possible. In contacting hotlines for various industry-sponsored assistance programs, Zafar et al found the average reported patient out-of-pocket co-pay to be $21, with a range of $0 to $75, consistent with our findings of 49% having $0 co-pay but the remaining 51% having a mean and median co-pay of $81 and $25, respectively. This highlights that cost control strategies imposed by payers, such as prior authorizations and cost sharing, were resource-intensive and diverted staff resources from patient care, and ultimately, very few patients had co-pays of more than

$100. Although co-pays were initially developed to discourage overuse of unnecessary care,[5] for OAMs they may instead serve as a barrier by requiring patients and staff to seek out co-pay assistance to access drugs.

Practice-level quality improvement projects to improve access to OAMs will need to account for the heterogeneity of patients' insurance coverage for treatments and should include adequate staff to address these issues. The scenario shown in the Figure is not uncommon and requires attentive and dedicated staff to ensure that information is accurately and efficiently transmitted among the involved parties. New research methods to address disparities in care will need to be developed to adjust for the use of PAPs and other resources that may not be apparent in claims data.

Limitations

Our study has several limitations. This was a retrospective analysis and the tracking sheets were not designed for prospective data collection. The staff may not have recorded all the phone calls, so we may have underestimated the number of phone calls made. We also did not collect information on faxes received or sent or the length of phone calls. The days reported were calendar days, not business days, which could account for some of the delays in prior authorization and drug obtainment. The source of the co-pay financial support was not recorded in all cases and could have come from manufacturers or patient support foundations. In addition, given the focus of our practice, we only evaluated on-label treatments for renal cell cancer and prostate cancer. However, the issues we identified were related to insurance characteristics, such as the need for prior authorization, rather than disease-specific issues, and thus we expect that these barriers would be relevant to patients treated on-label for other cancers in which OAMs are used (more than 60 OAMs are currently FDA-approved for patients with cancer). We would expect that patients receiving off-label treatments might have longer delays. Finally, we had a stable staff focusing on only 2 diseases. It is likely that practices focusing on a wider range of diseases or with a less experienced staff would have greater delays due to their lack of familiarity with disease-specific assistance programs or other clinical issues.

CONCLUSIONS

Processes to fill on-label prescriptions for OAMs are heterogeneous and involve multiple parties, which can lead to delays in treatment initiation. As payers and healthcare providers examine methods for quality improvement, they should consider improved processes to facilitate prompt initiation of OAMs. ∎

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eAppendix Table. Time and Phone Calls Required to Obtain Drugs for Patients, Depending on Whether Financial Assistance Was Required[a]

	Financial Assistance (58 Rx)	No Documented Financial Assistance (91 Rx)	P
Median (range) time from prescription to prior authorization (days)	3 (0-52)	3 (0-83)	.25
Median (range) time from prescription to drug obtainment (days)	15 (0-62)	10 (0-49)	.003
Mean (range) number of phone calls per prescription	3.2 (0-8)	2.0 (0-8)	.0001

[a]"Days" refer to calendar days, not business days. No initiation period was available for 1 individual for whom it took 83 days to receive a prior authorization, thus resulting in a smaller range.