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Low rates of primary medication nonadherence in patients prescribed oral oncology agents across health system specialty pharmacies

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Plain language summary

This study found that most patients (89%) who received cancer medication to take at home from a health system specialty pharmacy start treatment. The most common reason for not starting was because of the patient's own decision not to start.

Implications for managed care pharmacy

Rates of primary medication nonadherence as high as 30% have been reported in previous studies of patients starting oral oncolytics. With the increasing number of cancer treatments moving toward patient-administered oral therapies, it is important to understand reasons behind primary medication nonadherence and how the health system specialty pharmacy model is uniquely positioned to positively impact these rates. This study proves that patients are most likely to initiate treatment when managed by health system specialty pharmacies.

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ABSTRACT

BACKGROUND: New oral oncology medications bring novel challenges when patients are initiating treatment. Rates of primary medication nonadherence (PMN), the rate at which a medication is prescribed but not obtained, of up to 30% have been reported for oral oncology medications. More research is needed to identify causes and develop strategies for health system specialty pharmacies (HSSPs) to improve cancer treatment initiation rates.

OBJECTIVE: To evaluate the rate and reasons for PMN to specialty oral oncology medications in an HSSP setting.

METHODS: We performed a multisite retrospective cohort study across 7 HSSP sites. Patients were included if they had an orally self-administered oncology medication referral generated by the health system of the affiliated specialty pharmacy between May 1, 2020, and July 31, 2020. Data collected at each site using pharmacy

software and the electronic health record were deidentified and aggregated for analysis. After identifying unfilled referrals within a 60-day fill window, a retrospective chart review was performed to identify final referral outcomes and reasons for unfilled referrals. Referral outcomes were categorized as unknown fill outcomes (because of being referred to another fulfillment method or if received for benefits investigation only), filled by the HSSP, or not filled. The primary outcome was PMN for each PMN-eligible referral and secondary outcomes included reason for PMN and time to fill. The final PMN rate was calculated by dividing the number of unfilled referrals by total referrals with a known fill outcome.

RESULTS: Of 3,891 referrals, 947 were PMN eligible, representing patients with a median age of 65 years (interquartile range = 55-73), near equal distribution between male and female (53% vs 47%), and most commonly with Medicare pharmacy coverage (48%). The most referred medication was capecitabine (14%), and the most common diagnosis was prostate cancer (14%). Among PMN-eligible referrals, 346 (37%) had an unknown fill outcome. Of the 601 referrals with known fill outcome, 69 referrals were true instances of PMN, yielding the final PMN rate of 11%. Most referrals were filled by the HSSP (56%). Patient decision was the most common reason for not filling (25%; 17/69 PMN cases). The median time to fill after initial referral was 5 days (interquartile range = 2-10).

CONCLUSIONS: HSSPs have a high percentage of patient initiation of new oral oncology medication treatments in a timely manner. More research is needed to understand patient reasons for deciding not to start therapy and to improve patient-centered cancer treatment planning decisions.

The landscape of cancer care is shifting from traditional provider-administered chemotherapy infusions to self-administered oral cancer therapies. Oral cancer therapy development has been up trending steadily, making up about 25%-35% of the new oncology drug pipeline.[1] The growing use of oral therapies provides logistical advantages, such as decreased travel time to infusion centers and ease of administration, but also reveals unique challenges such as increased patient involvement in coordination of care, high out-of-pocket costs, and insurance mandates on the filling pharmacy. Manufacturer distribution restrictions and payer networking limitations can also contribute to a cumbersome medication access process for patients who must navigate the insurance approval process, navigate the financial-assistance enrollment, and then identify the pharmacy that is in both the manufacturer distribution network and the insurer's network. In an already complex health care system, these challenges become barriers to care and increase the risk for primary and secondary nonadherence, which is associated with poor health outcomes and increased health care costs.[2,3]

Understanding primary medication nonadherence (PMN), defined as the rate of a new prescription being issued but not filled within an acceptable time, is an important step in addressing barriers to medication initiation. Currently there are limited data on PMN rates to oral oncology medications. A recent analysis of Medicare Part D beneficiaries found that 30% of prescriptions for anticancer drugs went unfilled.[4] A single-center study at a health system specialty pharmacy (HSSP) revealed a low PMN rate of 4%, indicating that this model may improve oncology treatment initiation. However, because of the single site nature of the study, a relatively small sample size, and limited ability to evaluate risk factors for PMN, there is a continued need for studies to explore rates of PMN in oncology and how different patient care models impact PMN rates.[2]

Integration with providers, clinics, and other services within the health system enables HSSPs to often overcome common barriers to access while meeting the needs of manufacturers and payers.[5-17] HSSPs have also demonstrated the ability to ensure patients can afford high-cost specialty therapies, which may be a particularly pressing concern for cancer treatments as most patients are Medicare beneficiaries that do not qualify for manufacturer assistance.[6,9,12,18-22] By collaborating with other health system services, such as social workers and financial advisors, HSSPs provide comprehensive care that ensures patients can access, afford, and initiate specialty medications in a timely manner.[23]

The aim of this study was to evaluate the rate of PMN to specialty oral oncology medications in patients referred to HSSPs. These data are needed to provide insight into potential challenges patients face when obtaining treatment and the impact of the growing HSSP model of specialty care.

Methods

DESIGN AND POPULATION

A retrospective, multisite cohort study was performed at 7 geographically diverse HSSPs across the United States. Patients were included if they had a referral for an included oncology medication generated within the health system and sent to the HSSP between May 1, 2020, and July 31, 2020. A referral was defined as a prescribing provider communicating an intention to treat, including a prescription sent to the specialty pharmacy or a communication from a prescriber to a pharmacy team member recommending treatment initiation. For the purpose of this study, we

defined a "fill" as an oral oncology prescription medication dispensed to the patient. Patients were excluded if the medication was prescribed by a nonhealth system provider or non-oncology provider, or for a non-oncology disease. The study was approved by all participating sites' individual institutional review boards.

DATA SOURCES AND COLLECTION

Data were retrospectively collected by each site using the site's electronic health record (EHR), pharmacy fulfillment software, or specialty patient management software. Data from each site were input into a shared centralized, password-protected, Health Insurance Portability and Accountability Act (HIPAA)–compliant data entry system (Research Electronic Data Capture [REDCap]).[24,25]

OUTCOMES AND ANALYSIS

The primary outcome was PMN for referrals with a known fill outcome. Prescriptions eligible for PMN assessment included all referrals meeting inclusion criteria after excluding referrals for the following reasons: (1) Previous referral event (prescribing) or prescription fill in the last 180 calendar days (lookback window) from the index prescription. (2) Duplicate referral for an included oncology medication within 30 days of the referral. If there were 2 referrals for an included oncology medication within 30 days of each other with no corresponding fill or cancellation event, the first referral was considered the PMN-eligible referral. If 2 referrals for an included oncology medication were received on the same day, the study site investigator determined which medication to include as the index prescription. (3) Transferred to external pharmacy.

The initial PMN calculation using pharmacy claims was defined as a lack of a fill event of the prescribed medication or its therapeutic equivalent within a 60-day fill window. A fill event occurred at the time of prescription sale. Therapeutic equivalence was defined as any oncology specialty medication on a list of self-administered oncology medications developed and reviewed by the study team of specialty pharmacists. The time to fill was calculated as the number of days from receipt of a referral to the prescription being sold.

After an initial PMN calculation using pharmacy claims, sites completed a chart review of the referrals classified as PMN eligible without a fill event in the fill window to determine the reasons for not being filled. The outcomes of some referrals remained unknown. An unknown outcome was most commonly due to insurance restrictions in which the HSSP was not able to fill the medication. Another reason for an unknown outcome was the referral was not intended to be filled, such as a referral for benefits investigation purposes only. Referrals in which the outcome was unknown, or the referral was not intended to be filled, were defined as "unknown fill outcomes." Unfilled referrals in which the outcome was able to be determined after chart review were defined as "true PMN." All referrals were classified as unknown fill outcome, true PMN, and not PMN. Reasons for true PMN were identified via EHR documentation regarding the referral outcome.

The final PMN rate for the sample was calculated by dividing the total number of referrals that did not have a fill event by the number of referrals sent to the HSSP during the study time period, excluding those with an unknown fill outcome.

Secondary outcomes included time to fill, reasons for unknown fill outcome, and reasons for true PMN among unfilled referrals.

Results

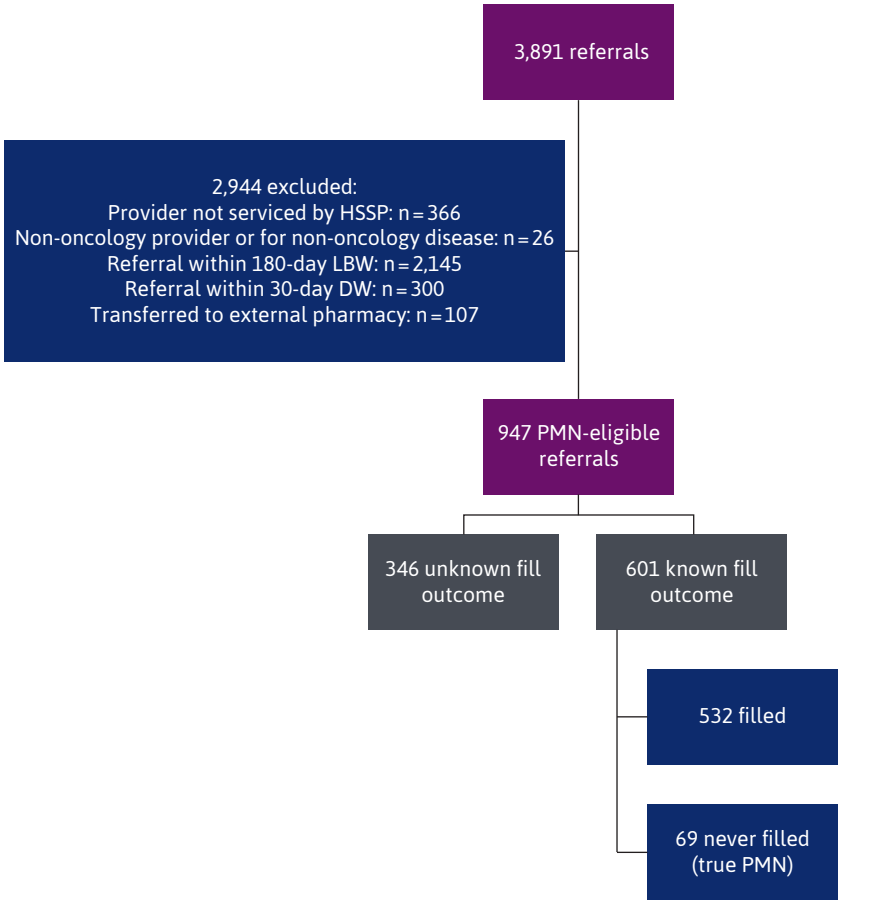
There were 3,891 referrals for oral oncology medications sent to participating HSSPs during the study period. Referrals were deemed non-PMN eligible for the following reasons: referral by a provider not serviced by the HSSP (n = 366), referral by non-oncology provider or for non-oncology disease (n = 26), previous referral or prescription fill in the previous 180 days (n = 2,145), duplicate referral within 30 days of the first referral (n = 300), and transferred to external pharmacy (n = 107) (Figure 1).

Each referral in the 947 PMN-eligible referrals represented a unique patient. Patients were a median age of 65 years (interquartile range = 55-73) and approximately half were male (52.6%), with pharmacy coverage mostly from Medicare (47.6%) and commercial (35.7%) payers (Table 1). The top 3 treatment indications based on National Comprehensive Cancer Network (NCCN) guidelines were cancers of the prostate (14.1%), breast (11.2%), and central nervous system (8.2%) (Supplementary Table 1, available in online article). The top 3 medications, based on referrals, were capecitabine (14.1%), temozolomide (7.3%), and venetoclax (7.3%) (Supplementary Table 2) (Table 1).

Based on initial PMN calculation using pharmacy claims, more than half of PMN-eligible referrals were dispensed through the HSSP (n = 532, 56.2%). The median time for the HSSPs to dispense after the initial referral was 5 days (interquartile range = 2-10) (Figure 2).

Following chart review, 346 (37%) referrals had an unknown fill outcome because of being triaged externally, with reasons that include: rerouted to external pharmacies (n = 194), filled by the manufacturer patient-assistance program (n = 98), referred to the specialty pharmacy for insurance coverage and benefits investigation only (n = 51),

FIGURE 1 Referral Attrition



There were 947 PMN-eligible referrals after the initial exclusion criteria was applied. Using pharmacy claims data, 532 referrals were filled and 415 referrals were unfilled. The chart review of the 415 unfilled referrals revealed that 69 were truly never filled and 346 had an unknown fill outcome.

DW = duplicate window; HSSP = health system specialty pharmacy; LBW = lookback window; PMN = primary medication nonadherence.

filled inpatient (n = 2), and filled through clinical trial (n = 1). Patients with an unknown fill outcome were removed from the final PMN calculation, leaving 601 referrals with a known fill outcome for the final PMN calculation. The final PMN rate was 11% (69 referrals never filled/601 referrals with known fill outcome). Reasons for PMN included patient decision (25%), medication not approved by insurance (13%), intentional delays based on provider/patient request (13%), medication changed (12%), clinical decline (12%), death (12%), no longer appropriate (7%), or unaffordable copay (7%) (Table 2).

Discussion

Patients with referrals sent to an HSSP for oral oncology medications had a low rate of PMN. After review of unfilled referrals, the true PMN rate was 11%. Patient decision was the most common reason for PMN (25%). A systematic review of PMN studies summarized reasons for PMN into 5 broad categories: patient factors (eg, demographics, beliefs, health conditions), medication factors (eg, drug regimen, polypharmacy, complex dosing), health care provider factors (eg, patient-physician relationship), health care system factors (eg, electronic prescribing, access to health care), and socioeconomic factors (eg, financial hardship, income level).[26] Many of these factors are common features of oral anticancer drugs that can affect PMN.[20,26] The HSSP model provides services to reduce the impact of these factors and by association, PMN. The American Society of Health-System Pharmacists defined an HSSP as "an integrated advanced practice model that incorporates specialty medication-use management across the continuum of care."[27] Hallmark attributes of an HSSP are access to the EHR and close collaboration with prescribing providers. HSSP pharmacists, therefore, are often involved in medication selection and pretreatment patient education that can ensure patients are prescribed the most appropriate treatment option and are aware of potential medication benefits and risks and monitoring requirements. The short time to medication access seen in the population of patients that filled medication at an HSSP aligns with previous research demonstrating that HSSP integration leads to fast specialty medication access.[5,7-17,28] The least common reasons for PMN was unaffordable copay or that the treatment was no longer appropriate. HSSP team members help patients obtain access to the treatment through prior authorizations and/or financial assistance obtained through foundations or manufacturer programs. Financial assistance is often needed if denied access via payer, if resulting copays are unaffordable, or if patients are uninsured. These services are described as the

TABLE 1 Patient and Site Characteristics

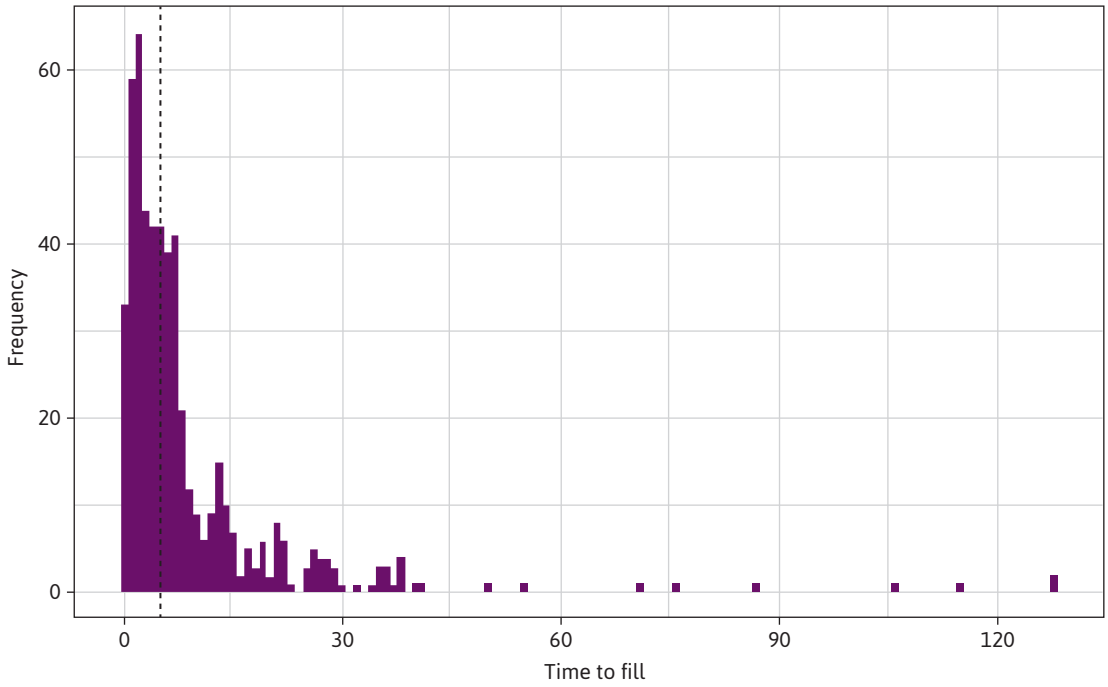
Characteristic	Filled (not PMN), n = 532	True PMN, n = 69	Unknown, n = 346	Overall, N = 947
Site, n (%)				
1	82 (15.4)	14 (20.3)	137 (39.6)	233 (24.6)
2	95 (17.9)	5 (7.25)	2 (0.58)	102 (10.8)
3	145 (27.3)	27 (39.1)	161 (46.5)	333 (35.2)
4	38 (7.1)	5 (7.3)	21 (6.07)	64 (6.8)
5	19 (3.6)	2 (2.9)	8 (2.3)	29 (3.1)
6	63 (11.8)	6 (8.7)	7 (2.0)	76 (8.0)
7	90 (16.9)	10 (14.5)	10 (2.9)	110 (11.6)
Age				
Mean (SD)	63.0 (14.7)	63.4 (15.2)	61.9 (13.9)	62.7 (14.4)
Median (IQR)	65.0 (55.0-73.0)	67.0 (56.0-73.0)	63.0 (54.0-71.0)	65.0 (55.0-73.0)
Range	12.0-89.0	14.0-89.0	23.0-94.0	12.0-94.0
Sex, n (%)				
Male	277 (52.1)	37 (53.6)	184 (53.2)	498 (52.6)
Female	255 (47.9)	32 (46.4)	162 (46.8)	449 (47.4)
Insurance type, n (%)				
Medicare	281 (52.8)	37 (53.6)	133 (38.4)	451 (47.6)
Medicaid	78 (14.7)	7 (10.1)	32 (9.3)	117 (12.4)
Tricare	5 (0.9)	0 (0)	3 (0.9)	8 (0.8)
Commercial	153 (28.8)	23 (33.3)	162 (46.8)	338 (35.7)
None	5 (0.9)	2 (2.9)	16 (4.6)	23 (2.4)
Other	10 (1.9)	0 (0)	0 (0)	10 (1.1)
Referral filled within 30-day window?, n (%)				
Not filled	11 (2.1)	69 (100.0)	346 (100.0)	426 (45.0)
Filled	521 (97.9)	0 (0)	0 (0)	521 (55.0)

IQR = interquartile range; PMN = primary medication nonadherence.

role of HSSP pharmacists in a recent literature review and help to mitigate socioeconomic reasons such as income or employment.[23] Although the long-term clinical impact of HSSPs is continuing to be demonstrated and published, the value and efficiency of HSSPs in terms of expediting and fostering medication access and limiting factors that impact PMN are clearly beneficial to patients.

The PMN measure developed by the Pharmacy Quality Alliance was originally limited to a subset of chronic medication classes (treatments for hypertension, diabetes, chronic obstructive pulmonary disease, hyperlipidemia, and asthma).[29] The quality measure has been used more broadly for depression and osteoporosis, and there is interest in its use to demonstrate quality in specialty pharmacy because of the unique characteristics of oral oncology specialty medications.[30] However, the utility and applicability of the currently Pharmacy Quality Alliance–recommended PMN calculation in the use of oral anticancer drugs is limited without further study. The current study found a PMN rate of 11% for prescriptions sent to an HSSP, but required additional data from the EHR to appropriately describe PMN in this population and identified a high rate of misidentified PMN. Although many patients did not obtain the medication from the HSSP, further review indicated that most patients

FIGURE 2 Time to Referral Fill



Of the referrals that were filled based on pharmacy claims (n = 531), the median time to fill was 5 days (interquartile range = 2-10), with 95.3% filling within 30 days of a referral.

TABLE 2 Reasons for PMN

Reason for PMN	n = 69, n (%)
Patient decision	17 (24.6)
Not approved on insurance	9 (13.0)
Intentional delay based on provider/ patient request	9 (13.0)
Medication changed	8 (11.6)
Clinical decline	8 (11.6)
Death	8 (11.6)
No longer appropriate because of new or pending clinical data	5 (7.3)
Unaffordable copay	5 (7.3)

PMN = primary medication nonadherence.

may have received a medication dose or fill from an alternate source. Based solely on claims data, the rate of PMN is likely overrepresented because of medication factors that are not accounted for, such as prescription transfer and use of manufacturer patient-assistance programs. Of the referrals that were unfilled based on pharmacy claims in our study, 47% (194/415 unfilled referrals) were rerouted to an external specialty pharmacy, similar to the 40% transfer rate described by Wang et al.[31] Increasing HSSP manufacturer and payer network access could mitigate the loss of relevant clinical data and patient follow up. However, the shortcoming of claims data to provide true insight into the patient journey because of network restrictions limits the applicability of the PMN quality measure in an oncology patient population when calculated at the pharmacy-dispensing level.

Though there was a low rate of true PMN, some of the reasons identified may provide opportunities for intervention and identify areas for HSSPs to improve. Patient decision accounted for one-fourth of all cases. Based on the reason for the patient's decision to not initiate treatment, health care providers, such as pharmacists, can intervene. For example, if the concern was potential side effects, then pharmacists can provide further education on what to expect, how to prevent, and how to manage side effects if they do occur. By understanding and addressing the patient's concern prior to treatment initiation, this could encourage primary

medication adherence. Even after the pharmacist provides education and expectations regarding treatment, the decision to start treatment is ultimately up to the patient and may be out of the control of the HSSP team. Patients do have the right to forgo treatment and decide what is best for them based on risks and benefits, particularly when considering anticancer medications that may be prescribed near the end of life. Another potential opportunity for intervention is unaffordable copay or lack of insurance. Despite HSSPs providing extensive financial-assistance services, including enrollment in manufacturer copay cards and patient-assistance programs, there may be limiting factors, such as payer type, payer approval, patient cost sharing responsibilities, and the amount and availability of financial-assistance funding. Although these circumstances may be outside of the control of HSSPs, better benefits design or availability of assistance could help mitigate the potential financial restrictions that may result in PMN.

Other reasons for PMN may not be avoidable. For example, the medication, or an acceptable alternative, may no longer be clinically appropriate for the patient, potentially because of the availability of new clinical information resulting after a referral, such as genetic testing. If a patient has advanced illness and has failed multiple treatment options, the decision may be to stop therapy and pursue palliative care alone. Therefore, a PMN rate of 0%, particularly in an oncology population, should likely not be a target for specialty pharmacies, rather minimizing avoidable reasons for PMN and promoting timely treatment initiation.

LIMITATIONS

This study is not without limitation. Despite being a multisite study with 7 HSSPs, the sample size was limited, and a short retrospective time frame was used for referral inclusion (May to July 2020). Because this was a multisite study, the data collection from multiple different electronic medical record systems and pharmacy dispensing software had to be collected individually and combined together. Although the 7 HSSPs provide similar levels of service in terms of medication access, financial assistance, and patient education, the workflow of each site may provide the opportunity for data, such as referrals that were rerouted, to be falsely low. PMN rates could vary throughout the year, particularly at the beginning of the year because of insurance deductibles and increased need for financial assistance. Almost half of all referrals had to be transferred to an external site resulting in an unknown outcome, making it difficult to capture the true rate of PMN at prescriptions filled outside of HSSPs. Because this accounts for many prescriptions filled, there could be additional barriers to care that were not identified and the true rate of PMN could be misrepresented. Additional studies are needed to further identify the true rate of PMN, not just at HSSPs, but at external sites as well. Reasons for PMN were reliant on EHR documentation, which may have been incomplete.

Conclusions

This multisite retrospective cohort study at HSSPs identified a PMN rate of 11% in patients who were newly prescribed oral oncology medications, which is much lower than the recently reported rate of 30% across Medicare beneficiaries. Results suggest that the personalized patient care provided by HSSPs through close collaboration with prescribers and team members dedicated to working on insurance approvals and financial-assistance options likely affects PMN rates. The current study demonstrates that HSSP teams play a key role in reducing rates of PMN and are an integral part of the oncology care team. The most common reason for PMN was patient decision, and future studies are needed to identify specific factors that contribute to a patient's decisions not to start therapy, as well as ways the HSSP team can address their concerns. By identifying reasons for PMN, HSSPs can address potential obstacles to care, improve patient outcomes, and work with insurance companies, manufacturers, and external pharmacies to reduce the rate of PMN when appropriate.

DISCLOSURES

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