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ORIGINAL RESEARCH

Utilization and Determinants of Anticancer Drugs Under China's National Drug Price Negotiation Policy

Bingbing Tuo[1], Haokai Zhao[2], Anxin Hu[2], Junnan Jiang[2]

[1]Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei Province, People's Republic of China; [2]School of Public Administration, Zhongnan University of Economics and Law, Wuhan, Hubei Province, People's Republic of China

Correspondence: Junnan Jiang, School of Public Administration, Zhongnan University of Economics and Law, No. 182, Nanhu Avenue, East Lake New Technology Development Zone, Wuhan City, Hubei Province, 430073, People's Republic of China, Email jiangjunnan@zuel.edu.cn

Purpose: The Chinese government began to take national drug price negotiation (NDPN) in 2016, aiming to enhance the accessibility and affordability of anticancer drugs. This study aims to assess the utilization and influence factors of anticancer drugs under NDPN policy in China.

Patients and Methods: Gastric cancer patients within chemotherapy were included. Independent variables were measured by age, gender, insurance type, total medical expenditure (THE), length of stay (LOS), drug-to-total-expense ratio (DTR). The primary outcomes were negotiated drugs usage, costs and treatment outcome. Two-part model was used to identify influence factors of anticancer drugs utilization. Propensity Score Matching (PSM) was employed to evaluate the impact of negotiated drug utilization on treatment outcomes among inpatients.

Results: The sample included 9868 gastric cancer patients from three cities. Outpatient patients demonstrated limited utilization of negotiated drugs (1.33%). Patients aged 61–75 (β=0.923, $P < 0.01$) and over 75 years (β=0.946, $P < 0.05$) were more likely to use negotiated drugs. Key factors influencing inpatient drug utilization included medical insurance type (β=−0.245, P<0.01), LOS (β=−0.122, P<0.001), and the DTR (=0.037, P<0.001). The use of negotiated drugs had no significant effect on treatment outcomes.

Conclusion: Their limited utilization of negotiated drugs for outpatients arises an urgent necessity for more comprehensive insurance coverage, and the no significant outcome effect dedicated the importance to rigorously validate the effectiveness of these drugs with abundant real-world evidence in the foreseeable future.

Keywords: national drug price negotiation, anticancer drugs, China

Introduction

Cancer has emerged as a preeminent global health concern, claiming a substantial number of lives annually. Recently published data indicate a staggering figure of over 19.3 million newly diagnosed and registered cancer cases worldwide.[1] The National Cancer Center (NCC) of China has reported a notable incidence of approximately 4,824,700 new cancer cases and 2,574,200 new cancer deaths occurred in China in 2022.[2] The exorbitant pricing of pharmaceuticals has emerged as a pivotal concern within oncological therapies.[3]

It is now widely recognized that efficacious negotiations on drug pricing have the potential to mitigate the escalation of costs associated with these treatments.[4] The Chinese government began to take national drug price negotiation (NDPN) in 2016.[5] As of January 2023, there were 430 kinds of negotiated drugs encompassed in the National Reimbursement Drug List (NRDL), which included hundreds of anti-cancer medicines. China has a huge population base and pharmaceutical market volume, and the entry of anticancer drugs into the NRDL will bring a significant increase in sales and profit returns, and also provide more real-world clinical data for the future innovation and research and development of enterprises,[6] the procedures of NDPN are detailed in Table S1.

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But do drug price negotiations actually increase sales significantly? Between the implementation of the new negotiations process in 2011 through the first quarter of 2019, the net negotiated prices averaged 23.6% below the manufacturers' list prices.[7] The statutory ceiling prices for negotiation would have reduced spending by $26.5 billion on these drugs.[8] The NDPN policy also improved the availability, utilization, and affordability of anticancer medicines in China.[9] The utilization of the medicines increased by 11.44 defined daily doses (DDDs) immediately.[10] Drug price negotiation also has extensive practice experience in Europe and the United States. In August 2022, the Inflation Reduction Act (IRA) was signed into law, allowing Medicare to negotiate the prices of a small number of medicines beginning in 2026.[11] The IRA limits the Centers for Medicare & Medicaid Services (CMS) to negotiating up to 20 high-spending drugs each year, which can only qualify after being on the market for at least 9 years (13 years for biologic products).[12] However, China has allowed innovative drugs launched in the same year to enter the scope of price negotiation, which undoubtedly expands the coverage of drugs under this reform. In Germany, the umbrella organization of sickness funds (GKV-SV) then negotiates a price with the manufacturer based on the Federal Joint Committee (GBA) assessment, and the prices charged by the manufacturer for its new drug in other European markets.[13] China's NDPN system is not as mature as Germany's innovative drug pricing mechanism, and it has not yet implemented a tiered classification of drugs based on pharmacoeconomic outcomes.

The research landscape regarding factors influencing access to anticancer medications is extensive,[14] particularly in low- and middle-income countries (LMICs). Several studies have revealed that private hospitals (71%) tend to have higher availability of anticancer drugs compared to public hospitals (43%), yet access to novel anticancer agents remains challenging in both sectors.[15,16] Another investigation observes that in countries such as India and Bangladesh, even generic anticancer drugs listed on the World Health Organization's Essential Medicines List (WHO EML) are unaffordable for patients due to high out-of-pocket expenses.[17] The cost and affordability of recently market-approved anticancer treatments have emerged as primary contributors to disparities in access to these medications.[18] Studies highlight pronounced inequalities in cancer treatment, which are primarily associated with limited coverage by public insurance schemes and exclusion from the EML.[19] Systematic evaluations of medication adherence to oral anticancer drugs have identified age,[20] gender,[21] out-of-pocket medical costs[22] and other socioeconomic status.[23]

Our study significantly contributes to the existing literature in three pivotal aspects. Firstly, distinct from prior works such as Cai[10] and Zhou,[6] which predominantly centered on the quantity of publicly disclosed drug purchases, our model introduces a novel dimension by incorporating patient-level drug utilization. The disparity between hospital procurement volumes and actual patient consumption underscores the importance of utilizing actual anticancer drug consumption data from both outpatient and inpatient settings for gastric cancer patients, as this better mirrors the policy's true impact. Secondly, we integrate an assessment of the therapeutic efficacy of negotiated drugs. Beyond mere analysis of immediate negotiated drug consumption, we delve into whether these innovative medications positively influence cancer patient outcomes. To this end, we meticulously evaluate the effects of negotiated drugs on treatment outcomes, while controlling for confounding factors from other covariates.

Material and Methods

Data Source

To analyze the impact of NDPN on the use of clinical anticancer drugs, this study sampled cities in three different provinces in China: Shanghai (east), Xi'an (west), and Shenyang (northeast). Random sampling of outpatient and inpatient patients with gastric cancer in tertiary hospitals was conducted from 2018 to 2020. We conducted drug usage and health expenditure data thorough Hospital Information System (HIS), sample inclusion and exclusion rules are set out in Table S2.

Variables

In this study, negotiated drugs related to gastric cancer treatment in NRDL at the end of 2018–2020 were used as a reference to determine whether patients used the negotiated drugs (Table S3). The expenditure of negotiated drugs was calculated by the total costs of negotiated drugs. Treatment outcomes, as assessed at the time of discharge for patients

with gastric cancer, are documented by physicians based on the entirety of the treatment process. These outcomes are categorized into four distinct groups: cure, improvement in condition, no improvement in condition, and death. One indicating cure and improvement, 0 encompassing both no improvement and death.

Independent variables comprised age, gender, insurance type (Urban Employee Basic Medical Insurance (UEBMI) and Urban and Rural Resident Basic Medical Insurance (URRBMI)), total medical expenditure (THE), length of stay (LOS), and the drug-to-total-expense ratio (DTR). THE, a comprehensive measure, encapsulates all expenses incurred by gastric cancer patients during chemotherapy, encompassing medication costs, bed charges, outpatient registration fees, and expenses related to radiological and biochemical examinations, among other miscellaneous items.[24] Prior to 2019, DTR served as a pivotal metric for evaluating the medical quality of tertiary hospitals, with an annual average benchmark not exceeding 45%. While this indicator has been subsequently surpassed in 2019 by a more extensive array of metrics that encompasses adjunctive medications, essential drugs, antibiotics, outpatient pharmaceutical expenditures, and inpatient drug costs, the DTR retains its relevance in the decision-making process for selecting anticancer medications.[25]

Data Analysis

A two-part model has been devised to address the constrained lower bound in their value range-dependent variables.[26] Drug consumption by patients results in a positive expenditure, whereas non-consumption yields a zero expenditure. This two-part model facilitates the modeling of the censoring mechanism (zeros) and the expenditure outcomes (nonzeros) through independent processes, thereby enabling the zeros and nonzeros to be governed by distinct probability distributions, akin to a specialized mixture model.[27] A probit model is employed to elucidate the decision to opt for negotiated drugs,[28] while linear regression is utilized to explain the magnitude of drug expenditures conditional on usage.

In the present study, Propensity Score Matching (PSM) methodology was utilized to rigorously assess the influence of negotiated drug utilization on therapeutic outcomes among hospitalized patients diagnosed with gastric cancer. The propensity score $e(X_i)$ is defined as the probability of an individual i receiving the treatment ($D_i = 1$) given their observed covariates X_i. It is typically estimated using a logistic regression model:

$$e(X_i) = \frac{1}{1 + exp(-(\beta_0 + \beta X_i))}$$

where β_0 are coefficients learned from the data. Individuals in the treatment group ($D_i = 1$) are matched with individuals in the control group ($D_i = 0$) who have similar propensity scores. This reduces selection bias by balancing the distribution of covariates X between the two groups, mimicking a randomized controlled trial. This approach entailed the meticulous pairing of individuals from a control cohort, comprising those who did not avail of negotiated drugs, with those in an experimental group, characterized by the utilization of such drugs. The pairing was based on the similarity of participants across a comprehensive set of covariates, ensuring a balanced comparison. The balance test before and after variable matching was shown in Table S4. Nearest neighbor matching, kernel matching, and radius matching were employed to estimate the Average Treatment Effect on the Treated (ATT), thereby providing a nuanced understanding of the causal impact of negotiated drug usage on patient outcomes.

Results

The study encompassed a sample of 9,419 outpatient patients and 449 inpatient patients. Within the outpatient cohort, 5,921 (62.86%) were male, and 8,409 (89.28%) resided in Shanghai. The mean medical expenditure for outpatient amounted to 149.86 yuan. Only 1.33% (n=125) of outpatient records indicated the use of negotiated drug, which is noted in Table 1. Among inpatients, 334 (74.39%) were male, and the highest proportion (40.31%) hailed from Shenyang. In both outpatient and inpatient settings, the age distribution of male gastric cancer patients was concentrated in the 60–75 years age groups. In outpatient patients, women accounted for 79.6% of those under 60 years of age (Figure 1). Similarly, the majority of outpatients (79.88%) and inpatients (83.30%) were covered by URRBMI, covers urban and rural residents in China, while the UEBMI provides medical insurance for employees. Comparatively, UEBMI offers higher welfare benefits. Therefore, it is not surprising that in our sample, the average medical expenses of inpatients covered by UEBMI were 30,725.53 yuan, significantly higher than those covered by URRBMI (25,041.6 yuan). Patients had an average LOS

Table 1 Characteristics of Gastric Cancer Patients

Variables	Category	Outpatients n (%)	Inpatients n (%)
Age, year		71.53±9.98[a]	68.70±9.39[a]
Gender	Male	5921 (62.86%)	334 (74.39%)
	Female	3498 (37.14%)	115 (25.61%)
Region	Shanghai	8409 (89.28%)	181 (40.31%)
	Shenyang	1010 (10.72%)	227 (50.56%)
	Xian	0 (0)	41 (9.13%)
Insurance type	UEBMI	1565 (16.62%)	71 (15.81%)
	URRBMI	7524 (79.88%)	374 (83.30)
	Without insurance	330 (3.50%)	4 (0.89%)
Total medical expenditure, CNY		149.86±784.55[a]	26358.57±268800.55[a]
LOS, days		-	7.28±4.72[a]
DTR, %		-	46.00±25.97
Negotiated drug	Yes	125 (1.33%)	182 (40.53%)
	No	9294 (98.67%)	267 (59.47%)
N		9419	449

Note: a is the Mean± Standard Deviation.
Abbreviations: UEBMI, Urban Employee Basic Medical Insurance; URRBMI, Urban and Rural Resident Basic Medical Insurance; CNY, Chinese Yuan, LOS, Length of Stay (LOS); DTR, Drug-to-total-expense ratio.

of 7.28±4.72 days, incurring a mean medical cost of 263,585.70±268,800.55 yuan, with 46.00% DTR (SD=25.97). 40.53% (n=182) of inpatients received treatment with negotiated drugs.

Age, sex, type of medical insurance and total outpatient cost all affect whether patients with malignant tumors use negotiated drugs in outpatient treatment (Table 2). Compared to patients less than 60, older adults aged 61–75 (β=0.923, $P < 0.01$) and over 75 years (β=0.946, $P < 0.05$) were more likely to use negotiated drugs. However, results from the linear regression model showed that among outpatient patients who used negotiated drugs, medical expenditure incurred by patients over 75 years (β=−1498.625, $P < 0.001$) was significantly lower than that of those under 60 years. Compared patients with UERMI, patients covered by URRBMI used less negotiated drugs (β=−0.932, $P < 0.001$). Patients with

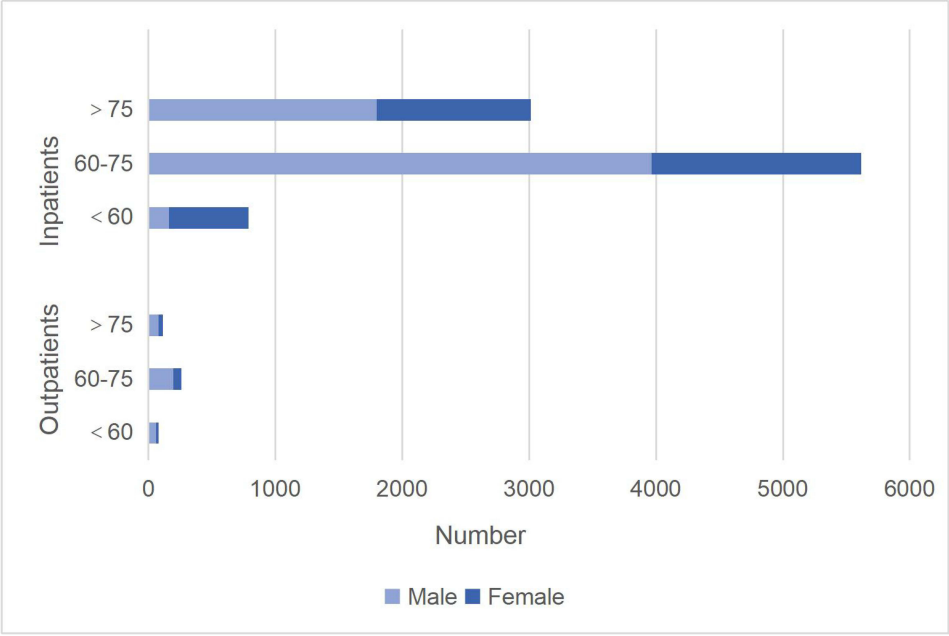

Figure 1 The age and gender distribution of outpatients and inpatients.

Table 2 Influence Factors of Outpatient Negotiated Drug Usage and Expenditure-Two Part Model

Variables	Category	Probit Regression		OLS Regression	
		Coef	SE	Coef	SE
Gender	Male	Ref	Ref	Ref	Ref
	Female	0.792*	0.315	474.197	523.013
Age	<60	Ref	Ref	Ref	Ref
	60–75	0.923**	0.273	−886.590	550.405
	>75	0.946*	0.392	−1498.625**	525.283
Insurance	UEBMI	Ref	Ref	Ref	Ref
	URRBMI	−0.932***	0.250	−692.023	391.164
	Without insurance	0.141	1.282	−726.760	521.453
Total outpatient expenditures (log)		2.322***	0.597	3901.391***	252.783

Notes: ***p < 0.01, **p < 0.05, *p < 0.1.
Abbreviations: Coef, Coefficient; OLS, Ordinary Least Squares; SE, Standard Error; UEBMI, Urban Employee Basic Medical Insurance; URRBMI, Urban and Rural Resident Basic Medical Insurance.

higher outpatient care costs were more likely to use negotiated drugs (β=2.322, P < 0.001). In addition, patients with higher outpatient medical expenses negotiated a larger amount of drug use (β=3901.391, P < 0.001).

The results in Table 3 show that age, gender, type of medical insurance, LOS and THE all affect whether patients use negotiated drugs in hospitalization. Compared with men, female patients were less likely to use negotiated drugs during hospitalization (β=−0.545, P < 0.05). Compared patients with UERMI, patients covered by URRBMI used less negotiated drugs (β=−0.245, P < 0.01). Patients with more hospital days were less likely to use negotiated drugs (β=−0.122, P < 0.001). Patients with higher DTR were more likely to use negotiated drugs (β=0.037, P < 0.001). The higher the proportion of drugs, the higher the amount of negotiated drugs (β=0.041, P < 0.01).

The matching results of propensity score showed that the use of negotiated drugs had no significant effect on the treatment outcome of hospitalized patients with malignant tumors, and the P-value was not significant at the level of 0.05. Different matching methods were used to verify the robustness of the study results (Table 4).

Table 3 Influence Factors of Inpatient Negotiated Drug Usage and Expenditure-Two Part Model

Variables	Category	Probit Regression		OLS Regression	
		Coe.f	SE	Coe.f	SE
Gender	Male	Ref	Ref	Ref	Ref
	Female	−0.545*	0.245	0.475	0.647
Age	<60	Ref	Ref	Ref	Ref
	61–75	−1.123*	0.536	1.752	0.587
	>75	−1.177	0.898	1.059	0.633
Insurance	UEBMI	Ref	Ref	Ref	Ref
	URRBMI	−0.245**	0.079	0.143	0.392
LOS		−0.122***	0.017	−0.130	0.045
THE	Q1	Ref	Ref	Ref	Ref
	Q2	0.379	0.716	0.809	0.286
	Q3	−0.242	0.216	0.787*	0.170
	Q4	0.552***	0.145	1.997*	0.220
DTR		0.037***	0.008	0.041**	0.003

Notes: ***p < 0.01, **p < 0.05, *p < 0.1.
Abbreviations: UEBMI, Urban Employee Basic Medical Insurance; URRBMI, Urban and Rural Resident Basic Medical Insurance.

Table 4 Effect of Negotiating Drug Use on Treatment Outcomes in Patients with Gastric Cancer – PSM Model

Propensity Score Matching (ATT)	Intervention Group	Control Group	Differences	t value
Nearest neighbor matching	0.831	0.857	−0.026	−0.35
Kernel Matching	0.831	0.861	−0.030	−0.50
Radius matching	0.740	0.750	−0.010	−0.10

Notes: (1) The standard error of the ATT (Average Treatment Effects on Treated) was computed utilizing a Bootstrap sampling approach with 500 replications.

Discussion

This study investigated the utilization of anticancer medicines after NRDLN policy based on data of gastric cancer patients in three sample cities. We found that compared with the high usage of negotiated anticancer drugs in inpatients, patients in outpatient rarely use such high-value drugs. Age, sex, type of insurance and medical costs have different effects on whether outpatient and inpatient drugs are used and the corresponding drug costs. In the short term, the use of negotiated drugs was not found to affect treatment outcomes in patients with gastric cancer.

We identified that the use of negotiated drugs in patients with gastric cancer during outpatient treatment is very limited, and there was a substantial difference in total costs between outpatient and inpatient care. Compared with hospital admissions, which receive higher reimbursement rates, outpatient visits usually mean high out-of-pocket costs.[29] Therefore, gastric cancer patients tend to allocate the use of innovative drugs (which account for a higher proportion of expenses) and other treatment items to inpatient care, while spending less during outpatient visits. Patients aged 61–75 and over 75 years were more likely to use negotiated drugs. Epidemiological literature shows that the incidence of gastric cancer in China increases with age,[30,31] this implies that the release of the national negotiated drug list benefits patient age groups with higher incidence risks.[32] However, as the "over 6" age group retires, they become more price-sensitive and have lower willingness to pay for new high-price drugs,[33] while working-age gastric cancer patients are willing to incur more medical expenditure for their health. Differentiated reimbursement policies force patients to choose more expensive cancer drugs in the hospital.

For inpatient treatment, working-age patients were more likely to taking negotiated anticancer drugs be compared with elders. It is easy to understand that working age patients who tend to have higher incomes and a stronger willingness to treat, have better access to health information and are able to track the latest drug negotiations published by the state.[34,35] As the LOS increases, the likelihood of hospitalized patients using negotiated drugs decreases, possibly for the longer LOS tend to mean higher medical costs, and hospitalized patients may reduce the use of costly negotiated drugs when medical expenditures are considered, while current research efforts tend to separately assess the utilization of anticancer medications and LOS among patients with malignant tumors.[36,37] Moreover, patients who had highest THE were more willing to take negotiate drugs. Those patients often possess a greater ability to pay, and the utilization of high-priced negotiated medications inevitably leads to an increase in THE, thereby forming a bidirectional influence. Patients taking national negotiated anticancer drugs also used adjuvant medications, including gastric and hepatic protectants, as well as traditional Chinese patent medicines. The DTR serves as an intriguing indicator, often employed by health regulatory authorities to monitor hospitals amidst the backdrop of drug abuse. Hospitalized patients with a higher DTR are more likely to utilize negotiated drugs, even after these drugs have undergone national drug negotiation processes, as their prices remain exorbitant, further elevating the DTR.

Notably, the utilization of negotiated drugs during outpatient and inpatient care is significantly influenced by the various types of medical insurance schemes. In our study, patients supported by UEBMI will pay more for inpatient treatment than those supported by URRBMI. Similar finding has been reported from Yin.[38] The disparity in insurance funding amount results in a significantly higher reimbursement ratio for UEBMI compared to URRBMI.[39] In respect to financial benefits, both insurance schemes emphasize cost-sharing mechanisms for enrollees, incorporating intricate

regulations pertaining to deductibles, copayments, and reimbursement ceilings. But the financial benefits conferred by UEBMI surpass those offered by URRBMI.[40]

After delving into a myriad of factors influencing the utilization of negotiated drugs, we intriguingly observe that there is no compelling evidence to suggest that the adoption of newly negotiated drugs leads to marked improvements in treatment outcomes. The majority of these negotiated drugs are recent market entrants, having been launched within the past two years. Despite the favorable pharmacoeconomic reports submitted, which attest to their efficacy, there remains a dearth of large-scale clinical utilization data. Furthermore, patients in the control group are often treated with first- or second-line conventional anticancer medications, resulting in a non-significant divergence in treatment outcomes within a short time-frame. The study conducted a Health Technology Assessment (HTA) on a subset of the drugs negotiated in 2019, revealing that more efficacious targeted anticancer drugs do not necessarily yield higher negotiation prices.[41] Study highlighted that the price of anticancer drugs does not necessarily reflect their therapeutic efficacy in Italy.[42]

In order to effectively facilitate the implementation of negotiated drug access, the Chinese government has established a "dual-channel" drug supply system encompassing medical institutions and retail pharmacies.[43] Regarding diseases undergoing payment reforms such as Diagnosis-Related Groups (DRGs), the weight of these diseases is promptly and reasonably adjusted based on the actual utilization of negotiated drugs.[44] We still aspire to further alleviate the economic burden of malignancy patients through means such as commercial medical insurance and medical assistance. Additionally, there is a need to collect clinical usage data, employing real-world evidence to dynamically conduct drug price negotiations.[45]

The present study is subject to the following potential limitations: Firstly, the measurement of treatment outcomes relies on the discharge status recorded in the hospital inpatient system, which has been noted to potentially introduce bias. Physicians tend to favor positive outcomes when filling in these records, while conditions such as mortality are often underestimated. Secondly, constrained by data collection limitations, our analysis focuses solely on the utilization of negotiated drugs among hospital patients in selected regions, neglecting the consumption patterns in designated retail pharmacies. While this component of consumption data may constitute a relatively small proportion, its exclusion nonetheless compromises the comprehensiveness of our data analysis. Thirdly, there is no outpatients from *Xi'an*, making the sample less representative, and the study timeframe (2018–2020) is likely too short to capture meaningful clinical outcomes in oncology. Consequently, this represents an area for further investigation in our subsequent research endeavors.

Conclusion

This study evaluated the utilization of negotiated drugs by gastric cancer patients during outpatient and inpatient treatments following the implementation of the national drug negotiation policy, along with the associated influencing factors. Our findings revealed that outpatient patients exhibited limited utilization of negotiated drugs due to constraints imposed by the modest reimbursement rates and ceiling limits of medical insurance. Factors such as the type of medical insurance, LOS, and DTR significantly influenced the use of drugs among inpatients. Notably, the short-term use of negotiated drugs did not demonstrate an impact on treatment outcomes, indicating the necessity of extending the follow-up period for cancer patients and improving clinical efficacy assessment indicators. Consequently, there is a pressing need for more comprehensive insurance coverage, such as increasing the reimbursement ratio for negotiated drugs in commercial insurance, and adopting more HTA studies based on real-world data as the basis for medical insurance payment standards, so as to jointly improve drug accessibility and affordability.

Ethics

Ethics approval for this study was obtained from Tongji hospital (Ethics project number: TJ-IRB20191219), and the data was obtained from the hospital with its permission and anonymized before export. To protect the privacy of the sample data, patient identification IDs and other identifying information are removed in data collection. All data involving human participants were in accordance with the 1964 Helsinki Declaration.

Author Contributions

Bingbing Tuo: Writing-review & editing, Visualization, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Haokai Zhao: Writing-review & editing, Methodology, Investigation, Formal analysis, Conceptualization. Anxin Hu: Writing-review & editing, Methodology, Investigation. Junnan Jiang: Writing-review & editing, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Funding acquisition, Data curation, Conceptualization.

All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflict of interest.

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