

BMJ Open Access to innovative anticancer medicines in China: a national survey on availability, price and affordability

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ABSTRACT

Objectives This study aimed to investigate the availability, price, and affordability of nationally negotiated innovative anticancer medicines in China.

Design Retrospective observational study based on data from a nationwide medical database.

Data sources/setting Quarterly data about the use of innovative anticancer medicines from 2020 to 2022 were collected from the Chinese Medicine Economic Information Network. This study covered 895 public general hospitals in 30 provincial administrative regions in China. Of the total hospitals, 299 (33.41%) were secondary and 596 (66.59%) were tertiary.

Main outcome measures The adjusted WHO and Health Action International methodology was used to calculate the availability and affordability of 33 nationally negotiated innovative anticancer medicines in the investigated hospitals. Price is expressed as the defined daily dose cost.

Results On average, the total availability of 33 innovative anticancer medicines increased annually from 2020 to 2022. The median availability of all investigated medicines in tertiary hospitals from 2020 to 2022 was 24.04%, 33.60% and 37.61%, respectively, while the indicators in secondary hospitals were 4.90%, 12.54% and 16.48%, respectively. The adjusted prices of the medicines newly put in Medicare (in March 2021) decreased noticeably, with the decline rate ranging from 39.98% to 82.45% in 2021 compared with those in 2020. Most generic brands were priced much lower than the originator brands. The affordability of anticancer medicines has improved year by year from 2020 to 2022. In comparison, rural residents had lower affordability than urban residents.

Conclusions The overall accessibility of 33 nationally negotiated innovative anticancer medicines improved from 2020 to 2022. However, the overall availability of most anticancer medicines in China remained at a low level (less than 50%). Further efforts should be made to sufficiently and equally benefit patients with cancer.

INTRODUCTION

Cancer is a major global health challenge, contributing to almost 10 million deaths annually in addition to an estimated 19.3 million new cases appearing in 2020.¹ In China, an estimated 4.57 million new cancer cases and 3 million cancer deaths occurred

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A threshold of 20% for household capacity to pay was used to define what is unaffordable, which seemed to be more suitable for assessing the affordability of innovative anticancer drugs.
- ⇒ The large sample size is allowed for the exploration of 895 hospitals in 30 province-level administrative regions of China.
- ⇒ Private hospitals and pharmacies were not considered in our study. Thus, the availability of innovative anticancer drugs in these institutions requires further research.

in 2020.² Population growth, increasing urbanisation and lifestyle changes are among the reasons for the high morbidity rate of cancer.³ To address the increased cancer risk, pharmaceutical companies have focused on the research and development of new anticancer medicines worldwide.⁴⁻⁶ Innovative anticancer medicines—such as protein kinase inhibitors and monoclonal antibodies—have been proven to improve the survival rates and patients' quality of life.^{7,8} These medicines play an important role in the treatment of advanced tumours, bringing hope to cancer patients who have a high mortality risk.⁹ However, due to patent protection and technological monopolies of innovative drugs, these much-needed treatments are priced so high that they pose a financial burden on those who need them worldwide.^{10,11}

The availability and affordability of anticancer drugs are major challenges in China. The prices of anticancer medicines are relatively high for Chinese patients, when considering their income.¹² Before 2015, the accessibility of innovative anticancer drugs in China was dim. Previous studies have reported that out of the 31 novel anticancer medicines approved in the the USA in 2010–2014, only 6 were approved in China, with an average delay of 5.5 years. In addition, only three innovative anticancer drugs were



independently developed in China during this period.¹³ In this regard, the Chinese government has implemented a series of policies to address these challenges—such as giving an approval for a 60 work days investigation of a new drug filing system, tariff exemptions on imported anticancer drugs and national drug price negotiations for innovative medicines. For innovative drugs with early clinical trial data that can likely predict the efficacy and clinical benefit of the drugs, the marketing authorisation might be granted before the completion of the confirmatory clinical trial through the conditional approval procedure, with all data comprehensively reviewed. These initiatives have substantially improved the availability, and reduced the cost, of some novel anticancer drugs in China.^{13 14} As of 30 April 2021, a total of 65 innovative anticancer drugs were marketed in China, including 51 (41.80%) innovative anticancer drugs launched in the USA and 14 novel anticancer drugs independently developed in China. The proportion of monoclonal drugs was the highest (46.15%), followed by the small molecule targeted drugs (44.58%) and the antibody–drug conjugates (15.38%).¹³ As of 1 September 2022, 32 innovative anticancer drugs had received conditional approval for marketing in China for 37 cancer indications.¹⁵ China has implemented seven rounds of national drug price negotiations since 2016 to introduce innovative and unaffordable medicines into the National Reimbursement Drug List (NRDL). Recently, Xia *et al* have comprehensively summarised the progress in national reimbursement negotiations in China and analysed the development of negotiated anticancer medicines from a variety of aspects.¹⁶ Each year, after negotiations between the National Healthcare Security Administration and drug companies, the average price discount for newly added drugs exceeds 50%.⁹ Since 2012, the national basic medical insurance coverage rate in China surpassed 95%, thus most patients could enjoy the treatment, as it is reimbursed by medical insurance. The procurement and sales processes for innovative anticancer drugs in China are shown in online supplemental figure 1. In December 2020, 221 drugs were included in the NRDL through national negotiations, 52 of which were anticancer drugs—including 23 protein kinase inhibitors, 10 monoclonal antibodies and some other anticancer drugs. According to the guidelines for cancer treatment in both China and the rest of the world in recent years, 3 of the 33 innovative anticancer drugs mentioned above are suitable for subsequent treatments following first-line failures (ie, fruquintinib, anlotinib and regorafenib), while the remaining 30 are used as monotherapy or in combination with other drugs for the first-line treatment of specific cancers, most of which are advanced cancers. With regard to nationally negotiated drugs, changes in the availability, affordability and clinical uses of anticancer drugs have been investigated in specific regions and provinces of China.^{8 9 17} However, there remains a lack of nationwide data concerning the accessibility of nationally negotiated innovative anticancer medicines across recent years.

The price, availability and affordability are the main criteria to measure whether patients can purchase a medicine at an affordable price.¹⁸ A standardised method was developed by the WHO and Health Action International (WHO/HAI) to assess the accessibility of essential medicines around the world.^{19–21} In recent years, the method has been adjusted, and the target medicines include not only essential medicines but also medicines that were originally not included in the standard surveys, such as rare disease medicines and anticancer medicines.^{7–9 22} In order to evaluate the access to innovative anticancer medicines in China, the availability and affordability of national negotiated innovative anticancer medicines were investigated nationwide through an adjusted WHO/HAI methodology, and the prices were expressed in defined daily dose (DDD) costs (DDDC).

METHODS

Data sources

The data were collected from the Chinese Medicine Economic Information Network (CMEI), one of the largest drug information service platforms, which covers more than 1500 public hospitals in China.^{14 23} The CMEI provides hospital information and drug procurement data for each hospital, including drug category, generic name, dose, brand name producer, procurement volume and procurement price.

Sample and data selection

There are 23 protein kinase inhibitors and 10 monoclonal antibodies for anticancer therapy in the National Negotiation catalogue section of the 2020 NRDL. Our study evaluated access to these 33 innovative anticancer medicines. The details of these anticancer drugs are listed in online supplemental table 1. The study covered 895 public general hospitals (accounting for approximately 2.5% of the total number of hospitals in China and approximately 7.5% of all public hospitals nationwide) in 30 province-level administrative regions in China. The hospitals are located in 10 eastern, 6 central, 11 western and 3 northeastern provinces. Of the total hospitals, 299 (33.41%) were secondary and 596 (66.59%) were tertiary. We collected the quarter, average availability, procurement volume and procurement price of each drug from 2020 to 2022 for tertiary and secondary hospitals.

Data analysis

Availability

In line with the WHO/HAI methodology and previous research, we defined drug availability as the proportion of hospitals in which a drug was available.^{7 24 25} We recorded whether the medicine was in stock at any time in the quarter (yes/no). This was calculated as the percentage of hospitals in which a drug was found among the investigated hospitals. The following criteria were used to describe the availability of the anticancer medicines¹⁸:

1. Absent: 0% of hospitals; the medicine was not found in any hospital surveyed.
2. Very low: <30% of hospitals; the medicine was very difficult to find.
3. Low: 30%–49% of hospitals; the medicine was available in a few hospitals surveyed.
4. Fairly high: 50%–80% of hospitals; the medicine was available in many hospitals surveyed.
5. High: >80% of hospitals; the medicine had acceptable availability.

Price

The price was expressed as DDDc, which refers to the cost per DDD of drugs. A higher DDDc value indicated that the medicine was more expensive. DDDc was calculated by dividing the total expenditure of a medicine by DDDs, whereas DDDs were calculated as the drug consumption volume divided by DDD. DDD information was obtained from the WHO Collaborating Center for Drug Statistics Methodology,²⁶ clinical application guidelines and drug package inserts. The DDD value for each medicine was consistent throughout the calculations. Expenditures were converted to US\$ using the average exchange rate of the year when the data were collected.

Affordability

According to WHO/HAI methodology, the affordability for patients was estimated using the minimum daily income of unskilled government workers by determining the daily income required to purchase the selected courses of treatment for common acute or chronic conditions. Generally, if the outcome was ≤ 1 , then it is said to be affordable.²⁵ Since the price of anticancer medicines was much higher than that of general medicines, this approach was considered inappropriate to assess the affordability of anticancer medicines. Thus, this study used the catastrophic medicine expenditure indicator to assess the affordability of anticancer medicines.^{22–27} When the medicine expenditure exceeded a certain proportion of the total household expenditure, it was considered that the family fell into ‘catastrophic expenditure’ due to the payment of medical expenses.²⁸ In recent years, the most widely used thresholds is 20%.^{7 18 27} In this study, the monthly expenditure was replaced by the monthly household income. When the medical expenses for a 30-day standard chemotherapy regimen did not exceed 20% of the monthly household income, the medicine was considered affordable. Given that each therapeutic scheme included a single medicine, the monthly cost of each medicine was calculated using the following equation:

The cost of an anticancer medicine per month = DDDc × 30 days.

Currently, 31 provincial administrative regions of China have included all the negotiated drugs in the Class B catalogue, but the reimbursement rates vary from place to place (ranging from about 50% to 85%).^{29 30} In our study, the reimbursement rate of investigated anticancer medicines was calculated at 65% according to an average of

the real percentages reimbursed in five cities distributed across five provinces with different economic development levels.²⁹ The investigated medicines required 100% out-of-pocket payment by patients before they were in NRDL. From 2020 to 2022, the median annual per capita disposable income of residents in China was US\$3993, US\$4646 and US\$4664, respectively. The median annual per capita disposable income of urban residents from 2020 to 2022 was US\$5854, US\$6743 and US\$6709, respectively, while the indicators for rural residents were US\$2204, US\$2620 and US\$2637, respectively.^{31–33} Household disposable income was calculated based on three persons per household.

Statistical analysis

SPSS (V.22.0) was used for data analysis. Descriptive statistics such as frequencies, percentages and means were used to present the data.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Availability

The availability of 33 innovative anticancer medicines is presented in online supplemental table 2 and figure 1. The availability rate for each year is the mean value of the availability for each quarter of the year, and the detailed data for each quarter are presented in online supplemental tables 3–5. On average, the total availability of the 33 innovative anticancer medicines has increased significantly from 2020 to 2022 (figure 1). The median availability of all investigated medicines in tertiary hospitals from 2020 to 2022 was 24.04%, 33.60% and 37.61%, respectively, while the indicators in secondary hospitals were 4.90%, 12.54% and 16.48%, respectively. The medicines which entered Medicare in March 2021 showed a huge increase in their availability from 2020 to 2021 (ranging from 393.96% to 5487.50%). By 2022, all four investigated drugs have had generic brands (GBs) in total. The overall availability of GBs showed an increasing trend, whereas that of the corresponding originator brands (OBs) showed a decreasing trend, except for lenvatinib. In 2022, a total of eight medicines had fairly high (50%–80%) availability, and the GBs of bevacizumab showed the highest availability (71.87%).

Price

As shown in table 1, the adjusted prices of the medicines newly added to Medicare (in March 2021) decreased noticeably in 2021 when compared with those of 2020. The decline rate of these medicines ranged from 39.98% to 82.45% (figure 2). As to the medicines that joined Medicare in other years, the declining rates of four medicines showed relatively large high decline rates in

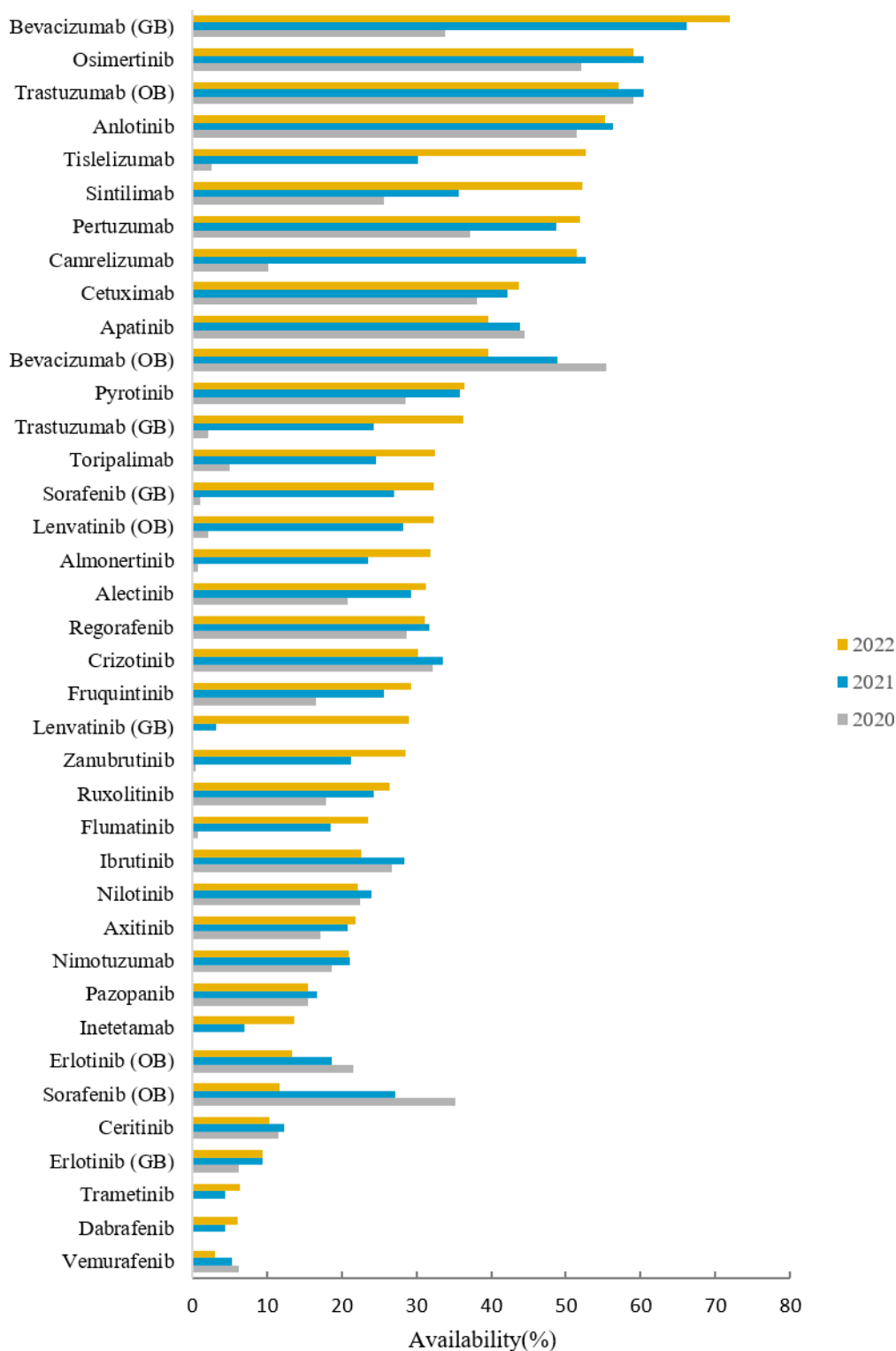


Figure 1 Availability of nationally negotiated innovative anticancer medicines in all investigated hospitals. GB, generic brand; OB, originator brand.

2021, including the GBs of sorafenib (58.62%) and the OBs of osimertinib (55.36%), anlotinib (23.64%) and vemurafenib (11.53%). However, price changes for the remaining drugs were relatively small. The prices of the vast majority of drugs decreased in 2022 compared with those in 2021. The medicines with larger price declines among GBs were lenvatinib (41.02%), erlotinib (35.10%)

and sorafenib (21.40%). For OBs, there were three medicines with significant price reductions in 2022, including sintilimab (63.44%), tislelizumab (37.57%) and pyrotinib (20.31%). During the study period, most GBs were much cheaper than the OBs. In addition, the differences in the exchange rate between the US\$ and the CNY in each year also had an impact on the comparison of prices

Table 1 DDDc of national negotiated innovative anticancer medicines in the investigated hospitals

Type	No.	Name	DDD (mg)	DDDc (US\$)		
				2020	2021	2022
OBs	1	Zanubrutinib	320	102.39	61.46	50.35
	2	Trametinib	2	127.99	57.41	55.36
	3	Dabrafenib	300	191.58	57.54	55.00
	4	Lenvatinib	12	243.57	52.57	48.17
	5	Flumatinib	600	76.55	29.36	29.01
	6	Almonertinib	110	148.07	54.52	52.33
	7	Tislelizumab	9.52	147.52	32.85	20.51
	8	Toripalimab	15	65.24	27.42	22.48
	9	Camrelizumab	14.29	205.03	35.97	31.14
	10	Inetetamab	20	NA	36.58	35.09
	11	Ruxolitinib	30	50.28	53.69	47.93
	12	Alectinib	1200	78.87	84.25	75.20
	13	Fruquintinib	3.75	42.09	47.20	43.56
	14	Pyrotinib	400	61.82	66.52	53.01
	15	Pertuzumab	20	34.12	36.57	35.07
	16	Sintilimab	9.52	39.10	41.51	15.18
	17	Vemurafenib	1920	129.86	114.88	106.50
	18	Osimertinib	80	73.87	32.97	27.65
	19	Anlotinib	8	45.41	34.68	29.69
	20	Crizotinib	500	64.62	71.09	68.13
	21	Ceritinib	450	59.88	65.75	60.66
	22	Pazopanib	800	90.15	99.20	95.15
	23	Axitinib	10	59.09	61.53	58.65
	24	Regorafenib	120	82.24	81.52	76.93
	25	Nilotinib	600	40.69	45.24	43.02
	26	Ibrutinib	420	81.48	79.88	75.37
	27	Cetuximab	62.5	115.39	117.84	108.23
	28	Erlotinib	150	11.57	12.57	11.90
	29	Sorafenib	800	36.78	58.86	56.40
	30	Apatinib	850	55.53	60.54	52.92
31	Bevacizumab	25	54.46	58.13	55.75	
32	Nimotuzumab	14.29	59.39	63.57	60.97	
33	Trastuzumab	20	36.23	38.76	37.17	
GBs	34	Lenvatinib	12	NA	38.75	22.85
	35	Erlotinib	150	10.30	11.02	7.15
	36	Sorafenib	800	38.57	15.96	12.54
	37	Bevacizumab	25	43.46	45.61	41.82
	38	Trastuzumab	20	32.63	34.81	33.31

DDD, defined daily dose; DDDc, DDD costs; GBs, generic brands; NA, not available; OBs, originator brands.

in different years (the average exchange rate of the US\$ against CNY in 2020, 2021 and 2022 was 6.90, 6.45 and 6.73, respectively). As the prices of drugs in the research

areas were set according to national negotiation standards, there was basically no difference in the prices of drugs from the same manufacturer and the same specification in the investigated hospitals. Within the same year, the lowest drug price for the same manufacturer and the same specification in different hospitals was less than 1.50%. However, the prices of generic drugs from different manufacturers vary greatly, with the lowest price of the same specifications being 25.20%–54.97% cheaper than the highest price in 2022.

Affordability

In 2020, the anticancer medicines absent from the NRDL were hardly afforded by those whose monthly expenses ranged from 196.08% to 732.03% of their household income (online supplemental table 6). However, the affordability of these medicines has significantly improved since they entered the NRDL in 2021 (figure 3). The affordability of the investigated drugs has increased annually from 2020 to 2022. Rural residents had lower affordability than urban residents. By 2022, there were eight affordable OBs and three affordable GBs for urban residents, whereas only one OBs and two GBs were affordable for rural residents. In addition, the affordability of all GBs was better than that of the corresponding OBs from 2020 to 2022.

Comprehensive analysis of medicine availability and affordability

A comprehensive analysis of medicine availability and affordability in all hospitals in 2022 is shown in figure 4. Figure 4 can be divided into four quadrants. The availability of all investigated medicines was less than 80% and only five medicines were found to be affordable. Both the OBs and GBs of erlotinib were affordable, but their availability was below 20%. Among the affordable medicines, only tislelizumab and sintilimab had availability rates greater than 50%. Most of the investigated innovative anticancer medicines were unaffordable and had low availability rates (less than 50%).

DISCUSSION

This is one of several nationwide empirical studies that provide evidence on the availability, price and affordability of negotiated innovative anticancer medicines in China. It provides up-to-date data and the findings can serve as a reference for policymakers to improve relevant policies. In this study, we found that, when compared with 2020, the overall availability and affordability of medicines newly included in Medicare (in March 2021) improved significantly in 2021. Three previous studies have demonstrated the positive effect of the national drug price policy on drug accessibility in China through interrupted time-series methods,^{8 14 34} two of which focused on anticancer drugs in the 2017 NRDL.^{8 14} Fang *et al* used the adjusted WHO/HAI methodology to calculate the price and availability of 15 innovative anticancer medicines included in

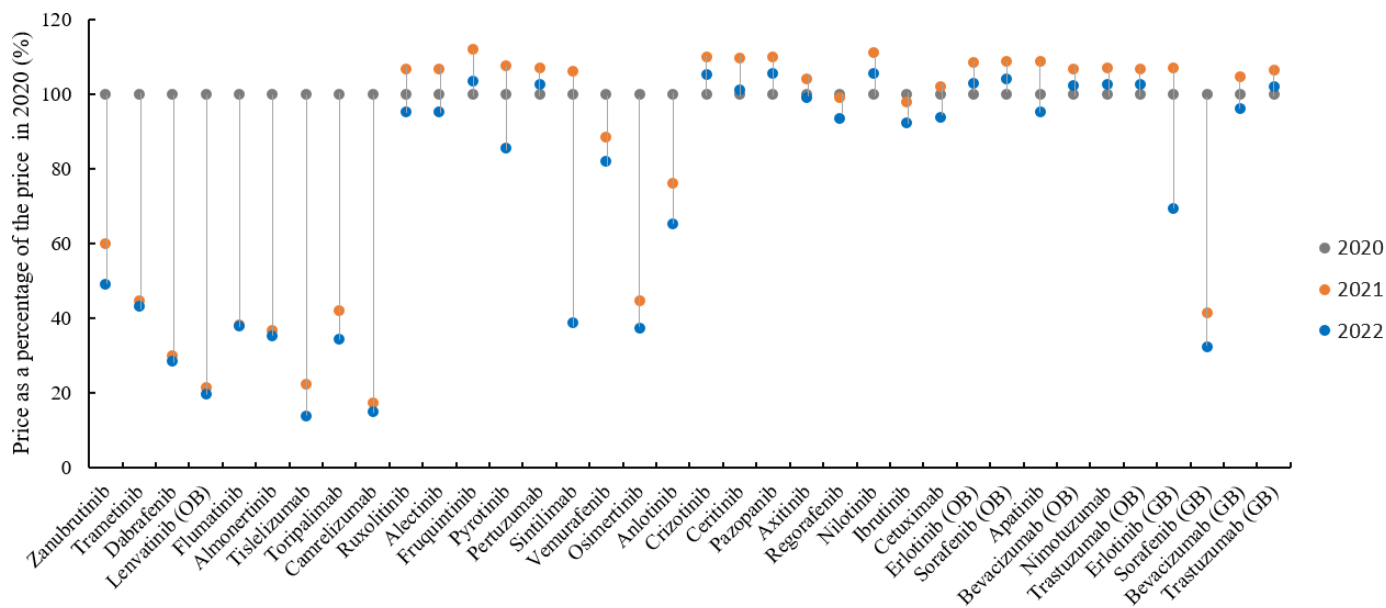


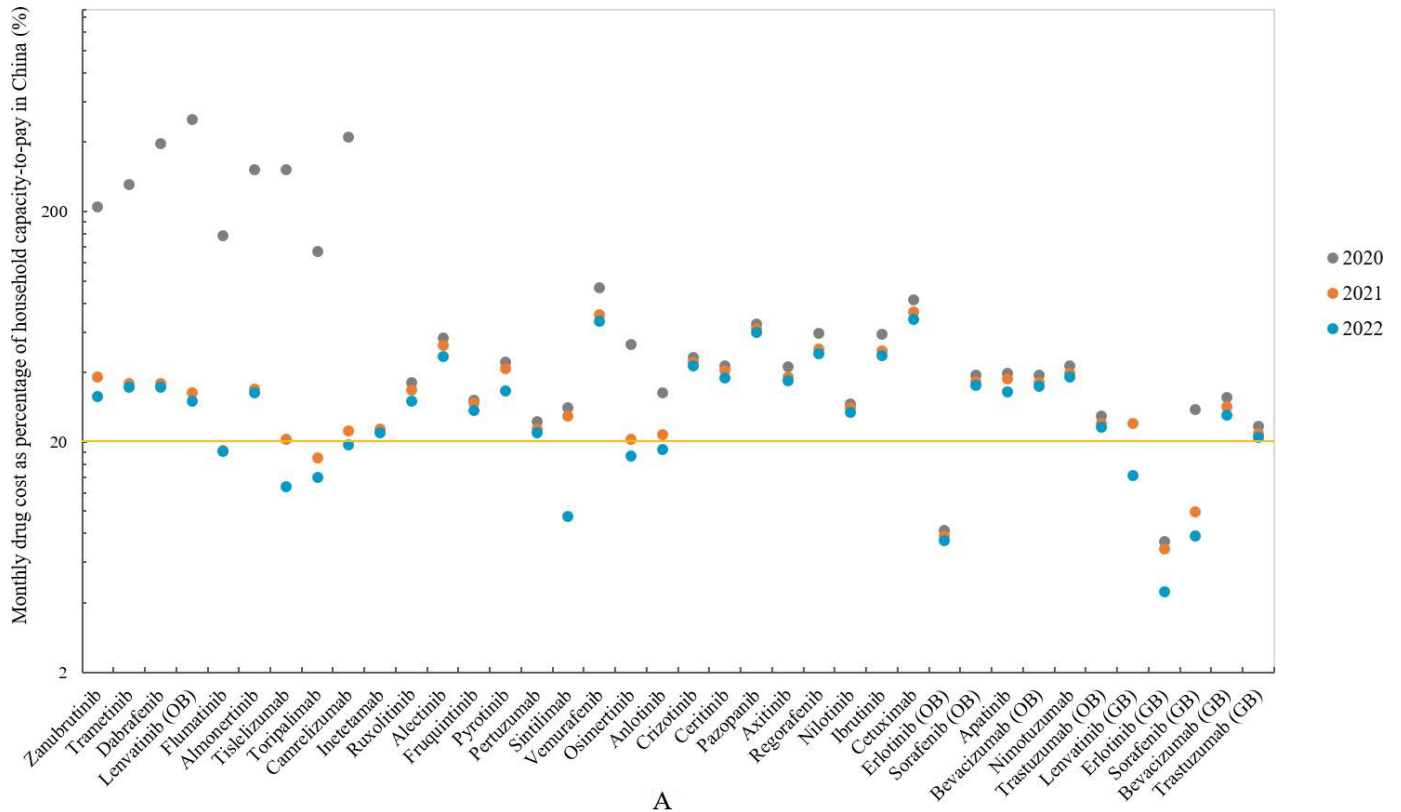
Figure 2 Price trends of investigated medicines from 2020 to 2022. GB, generic brand; OB, originator brand.

the NRDL in 20 tertiary hospitals and 6 secondary hospitals in Nanjing before and after policy implementation (from January 2016 to December 2018). They found that the price reduction rates of innovative anticancer medicines ranged between 34% and 65%, the mean availability rate was 27.44% and 47.33%, respectively, before and after policy implementation and the medicines became more affordable after policy implementation (0.06–1.90 times the per capita annual disposable income for urban patients and 0.13–4.46 times the per capita annual disposable income for rural patients).⁸ Zhu *et al* analysed the impact of the policy on the accessibility of 18 anticancer drugs (15 innovative anticancer medicines and 3 traditional Chinese medicines) in tertiary (72.83%) and secondary (21.17%) hospitals in China from 2015 to 2019. They found that the average annual availability of 15 innovative anticancer medicines increased from approximately 10.87% in 2015 to 33.86% in 2019. The average DDDc of these 15 medicines dropped from CNY 1406.49 (US\$225.81) in 2015 to CNY 401.87 (US\$58.25) in 2019, with a reduction of 23.88%.¹⁴ In our study, the average availability rate of six medicines in the 2017 NRDL (erlotinib, sorafenib, apatinib, bevacizumab, nimotuzumab and trastuzumab) from 2020 to 2022 was 39.04%, 36.66% and 30.40%, respectively. Their overall availability improved compared with that of the two previous studies. The DDDc of these six medicines dropped further in our research compared with the data at the end of 2019.¹⁴ In 2021, despite the increased availability of most of the innovative anticancer medicines, the overall availability of most anticancer medicines in China remained at a low level (<50%). This may be explained by the indications for drugs, distribution of diseases and purchasing policies for drugs in the investigated hospitals. There are many other types of commonly used anticancer drugs, in addition to innovative ones. Given the absence of relevant data regarding the availability of other anticancer

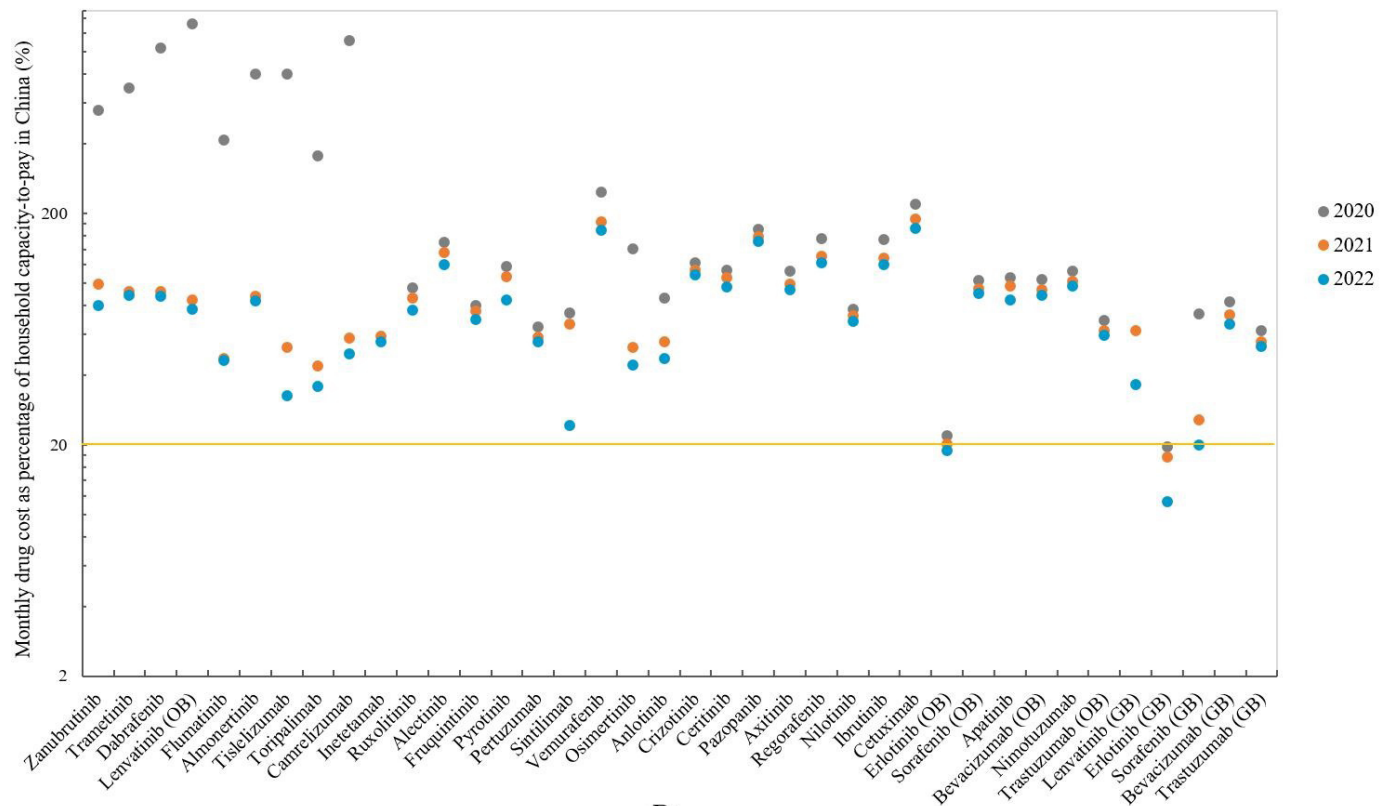
drugs in China during the survey period, we were unable to compare the availability of innovative anticancer drugs with other types of anticancer drugs.

Price declines often occur with higher usage, and an increase in the availability of investigational drugs may be closely related to the reduction in prices. Our study also found that patients had more opportunities to access the investigated anticancer medicines in tertiary general hospitals than in secondary hospitals during the study period. This could be attributed to the fact that patients in China are inclined to seek medical care in tertiary hospitals when confronted with serious illnesses, such as cancer. This phenomenon has also been reported in previous studies.^{8 14} The investigation period witnessed a heavy impact brought by the COVID-19 pandemic, and the availability of medicines was greatly affected during this time in many countries.^{35 36} The availability of innovative anticancer medicines could also be affected by the pandemic. In our study, the average availability of the investigated drugs showed an upward trend from the first quarter of 2020 to the third quarter of 2022, but it decreased by 3.76% in the fourth quarter of 2022 (online supplemental table 3). We speculate that this may be related to the impact of the COVID-19 epidemic in China during this period, as it coincided with the large-scale outbreak of the pandemic in China.

We found an instant decrease in DDDc among the most investigated drugs in 2021, especially among drugs that newly entered the NRDL. This was in line with recent studies reporting that the NRDL Negotiation Policy was the direct reason for the significant reduction in the average daily costs of anticancer drugs.^{37 38} Generic competition is widely acknowledged to be closely related to drug prices.³⁹ One of the generic drugs investigated in this study, lenvatinib, was launched in China in July 2021. Following its commercial release, the price of the originator product experienced a further decrease in



A



B

Figure 3 Monthly drug cost (30x DDDc) as percentage of household capacity to pay in China. (A) Monthly drug cost as percentage of household capacity to pay for urban residents. (B) Monthly drug cost as percentage of household capacity to pay for rural residents. DDDc, defined daily dose costs; GB, generic brand; OB, originator brand.

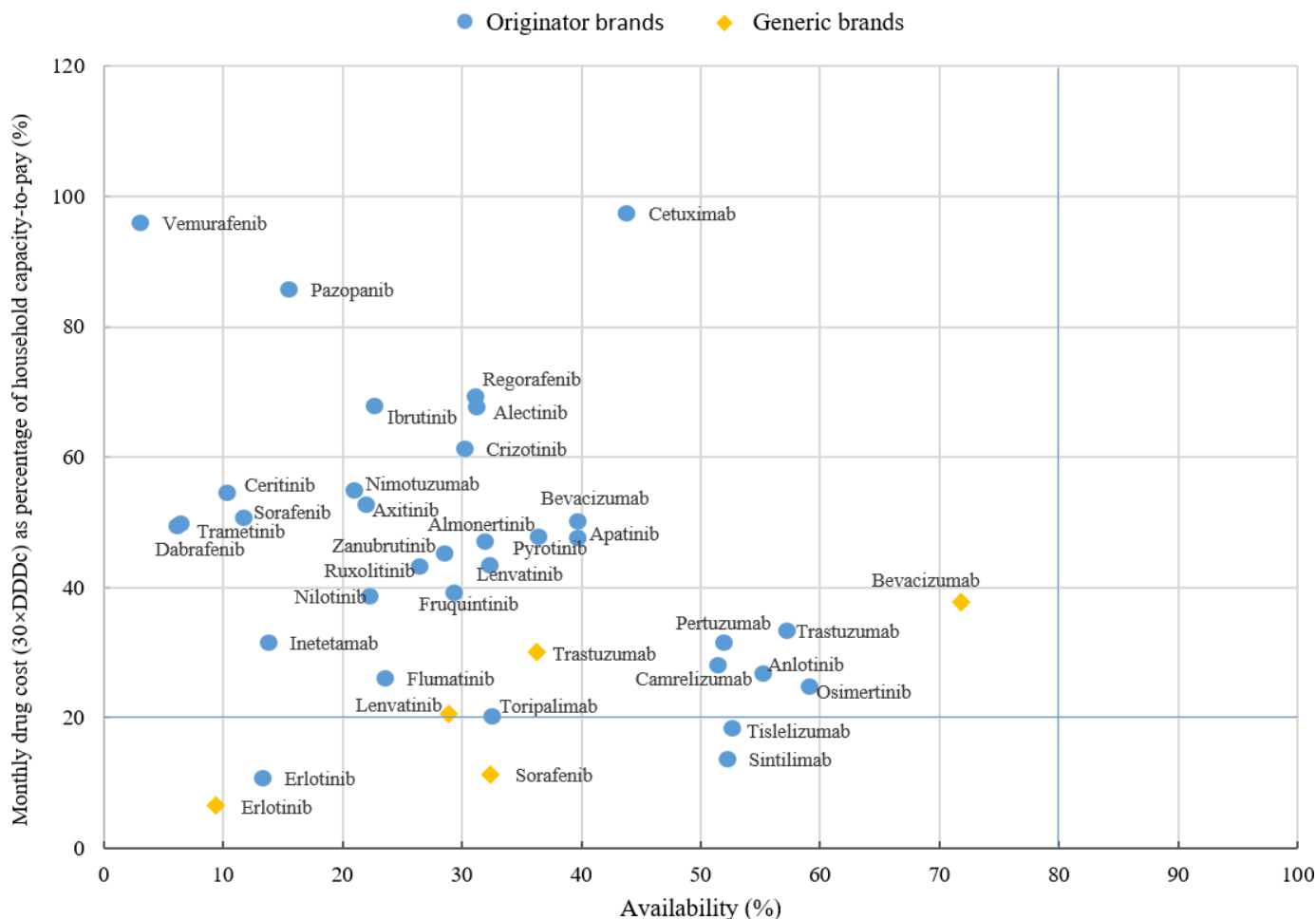


Figure 4 Comparative analysis of medicine availability and affordability in 2022 for all hospitals.

2022. This indicates that the introduction of generic drugs could have a certain promoting effect on reducing the price of originator products. The price of some investigated drugs saw a significant reduction during the study period, primarily attributed to renegotiation by the National Medical Insurance Administration, with the exception of the generic erlotinib, which was greatly reduced through national centralised procurement.

In 2021, the affordability of the investigated drugs was lifted with an increase in residents' disposable income and a drastic reduction in drug prices. However, according to the affordability evaluation criteria used in this study, the overall affordability of the investigated drugs was low, particularly for rural residents. Therefore, policies should be made to address the inequality in the affordability of anticancer medicines between urban and rural patients.⁸ In addition, the current study revealed that the OBs of all anticancer medicines were found to be less affordable than the lowest-priced generics.¹⁸ Recently, a small number of GBs of innovative anticancer medicines have been put on the market in China, which will play a positive role in reducing the price of similar drugs. To improve the affordability of innovative anticancer drugs, the government should adjust related policies to accelerate

the approval of low-cost and high-quality generic anticancer medicines.

However, this study has several limitations. The CMEI database provides information on the clinical use of anticancer drugs in Chinese hospitals and although describing the overall availability rate for a year is possible, it is not a direct substitute for information on real-time availability rates. Second, private hospitals and pharmacies were not considered, and the availability of innovative anticancer drugs in these institutions requires further research. Third, as the latest international reference price for medicines was not available, the prices of the investigated drugs were not compared at the international level. In order to show a general impression of the price level in China, we have set out the price information of four monoclonal antibodies in China and the the USA during the same period (online supplemental table 7) and relevant drug prices in Japan, Switzerland and Norway in 2024 (online supplemental table 8). It is indicated that the innovative anticancer medicines in China hold obvious advantages in price compared with those in the above countries. Fourth, the affordability in this study reflects the overall level in China, and the affordability for each individual patient cannot be accurately reflected

because of the differences in their dosage and treatment plans. In addition, the income level of residents and the reimbursement rate of anticancer drugs by basic medical insurance vary considerably among provinces. Therefore, the affordability of innovative anticancer drugs in different regions requires further comparative studies.

CONCLUSION

It was concluded that the overall accessibility of 33 nationally negotiated innovative anticancer medicines was improved year by year from 2020 to 2022. The mean availability of medicines was significantly higher in tertiary general hospitals than that in secondary general hospitals. Prices of the investigated drugs showed a downward trend, and the prices of GBs were lower than those of the corresponding OBs (approximately 10%–78% lower). However, the overall availability of most innovative anticancer medicines in China remained at a low level (<50%). In addition, the overall affordability of the investigated drugs is low, particularly among rural residents. Collaborative policy combinations are required to benefit more patients with cancer equally and sufficiently.

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Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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