

BMJ Open Differences in reimbursement listing of anticancer therapies in China: an observational study

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ABSTRACT

Objective Access to highly priced anticancer medications usually requires insurance coverage. A first step towards coverage of such medications is their inclusion in reimbursement lists. We assessed listing for reimbursement in China between 2009 and 2018 of anticancer medications on the WHO's Essential Medicines List.

Setting and study design Using publicly available data, we assessed which anticancer medications listed in the 20th WHO Model List of Essential Medicines (EML) were included in China's National Reimbursement Drug List (NRDL). For five targeted anticancer medications on the WHO EML, we also assessed inclusion in the 31 Chinese Provincial Reimbursement Drug Lists (PRDLs). Logistic regression was used to test whether inclusion of targeted anticancer medications was associated with provincial economic levels.

Primary outcome measures Inclusion of five targeted anticancer medications in the NRDL and PRDLs before and after 2017.

Results The 2017 NRDL included all anticancer medications on the WHO EML (except for one not approved in China at the time), and by 2018, all 31 PRDLs listed the targeted anticancer medications except for nilotinib; four provinces had covered all five targeted medications before the 2017 NRDL coverage mandate. Provincial economic level and regional incidence of specific cancers seemed unrelated to the inclusion of five targeted anticancer medications in PRDLs.

Conclusion Our findings suggest that by including medications in the national and provincial reimbursement lists, China has taken an important first step in promoting access to targeted anticancer medications. Further research is needed to determine whether inclusion in PRDLs improved the availability, appropriate use and affordability of highly priced targeted anticancer medications in China.

INTRODUCTION

New anticancer medications have significantly changed the treatment of cancers in the last two decades.¹ However, new therapies, especially targeted anticancer medications, are expensive and often unaffordable, limiting patients' options for cancer treatment.^{2–3} Aiming to satisfy the priority healthcare needs

Strengths and limitations of this study

- This study is the first to examine listing status on China's National Reimbursement Drug List (NRDL) and 31 Provincial Reimbursement Drug Lists (PRDLs) from 2009 to 2018 of 51 anticancer medicines listed on the WHO Essential Medicines List (EML) in 2017.
- Specifically, we assessed provincial listing for reimbursement of the five targeted anticancer medicines included in the 20th WHO EML.
- We also compared provincial listing status with provincial economic level and incidence of cancer types targeted by the five therapies.
- Listing for reimbursement is an important first step in expanding access to targeted anticancer medicines; future research should determine whether inclusion in PRDLs improved availability of or access to anticancer medications in China.

of the population, the WHO has proposed the concept of essential medicines and published its Model List of Essential Medicines (EML).⁴ The EML is a guide for governments to develop their own medicines lists to meet the needs of patients in their health systems; since insurance coverage is a prerequisite for access to highly priced anticancer medications, insurance reimbursement lists ideally include medicines deemed essential for quality cancer care.

Considering public health need, medication effectiveness and safety, the WHO has included several new, highly priced anticancer therapies in the EML.^{5,6} In 2017, the 20th version of WHO EML listed 51 anticancer medications, including 5 expensive targeted anticancer medications.

With increasing incidence and mortality, cancer has been the leading cause of death in China since 2010.^{7,8} To promote access to care in general, including access to cancer care and anticancer medications, China has, since 2009, implemented Basic Medical Insurance (BMI).⁹ The BMI, which by the end of 2018 had enrolled more than 94% of

Chinese citizens,¹⁰ consists of three main health insurance schemes: the Urban Employee Basic Medical Insurance (UEBMI) for urban and retired employees, the Urban Resident Basic Medical Insurance (URBMI) for urban residents and the New Rural Cooperative Medical Scheme (NRCMS) for rural residents.¹¹ Due to the widely differing coverage policies of provincial and municipal insurance systems in China, reimbursement rates differ widely by geographic area, system and population. Overall, the reimbursement rates of UEBMI are higher than URBMI rates, and the NRCMS has the lowest reimbursement rates.⁹ To provide better financial protection for the Chinese population, China's new medical reform in 2009 proposed to integrate URBMI and NRCMS into Urban and Rural Resident Medical Insurance (URRMI),¹² although not all provinces had finished the integration by the end of 2018.⁹

The National Reimbursement Drug List (NRDL) is the guiding standard for BMI funds to pay for medications, and NRDL listing is an important step towards increasing access to expensive medications.¹³ Provinces are required to implement the most recent NRDL or issue their Provincial Reimbursement Drug List (PRDL) with limited modifications of the NRDL—provinces can delete, add or substitute up to 15% of the NRDL's medications¹⁴—to accommodate differences in economic development, insurance funding pools and reimbursement rates. Thus, reimbursement requirements for anticancer medications may differ across provinces and could lead to inequities in anticancer medication coverage. We assessed which anticancer medications listed on the 2017 WHO EML were included in the 2017 NRDL. Further, we analysed the variation in listing on PRDLs of five targeted anticancer medications across provinces in the last decade (2009–2018).

METHOD

We first compared the 2017 WHO EML with China's 2017 NRDL to assess overlap in listed anticancer medications. Then we selected the five targeted antineoplastic medications included in the 2017 WHO EML (trastuzumab, rituximab, imatinib, dasatinib and nilotinib) to investigate whether and when these medications were listed in the 31 PRDLs.

Data were collected from websites of the WHO,¹⁵ the Ministry of Human Resources and Social Security of the People's Republic of China,^{14 16} the State Medical Insurance Administration,¹⁷ the Center for Drug Evaluation of the National Medical Products Administration (NMPA),¹⁸ provincial Human Resources and Social Security Bureaus and provincial Health and Family Planning Commissions (see online supplementary appendix 1). We evaluated PRDLs in effect between 1 January 2009 and 31 October 2018. All data were separately checked by two researchers, and the inclusion dates in each provincial list of the five targeted medications confirmed in publicly available data.

We used logistic regression to test whether the inclusion of targeted anticancer medications in provincial lists was associated with provincial economic levels before 2017. The independent variable is the rank of 2017 provincial per capita Gross Domestic Product (GDP) provided by the China Health Statistical Yearbook 2018.¹⁰ Statistical analysis was performed using the statistical software Stata/MP V.14.0 (Revision 02 April 2015), StataCorp.

Patient and public involvement

No patients or members of the public were involved in this study.

RESULTS

Listing of anticancer medications in the NRDL

The 2017 NRDL was issued in February 2017 and updated following two rounds of government drug price negotiations in July 2017 and October 2018. Compared with the most recent 2009 NRDL, the 2017 and updated NRDL added 50 new anticancer medications and comprised 196 unique (by international non-proprietary name) anticancer medications in the following categories: traditional cytotoxic chemotherapy (n=73 unique international non-proprietary names), targeted anticancer medications (n=31, details in online supplementary appendix 2), other antineoplastic medications (n=49) and Chinese traditional medications (19 antineoplastic medications and 24 auxiliary antineoplastic medications). All but one (bendamustine, which had not been approved by the NMPA in 2017) of the 51 antineoplastic medications listed on the 2017 WHO EML were listed on the 2017 NRDL (see online supplementary appendix 3).

The five targeted anticancer medications added to the WHO EML in 2015 and 2017 were first approved by the NMPA between 2000 and 2011. All five medications were included in the 2017 NRDL and its updated versions (July 2017 and October 2018) following price negotiations (table 1).

Listing of targeted anticancer medications on PRDLs

By 31 October 2018, all PRDLs had been updated following publication of the 2017 NRDL, and all targeted anticancer medications except nilotinib were listed on 16 PRDLs (figure 1B). Twenty provinces had included at least one targeted anticancer medication on at least one insurance system's list before 2017 (figure 1A).

Variation across provincial listing of targeted anticancer medications before 2017

Table 2 illustrates the characteristics of provinces and the listing of targeted anticancer medications by different provincial insurance schemes. Before 2017, 11 provinces had no reimbursement lists listing any of the five medications, while four provinces covered all five medications (figure 1A). Interestingly, these provinces ranked low in per capita GDP. By contrast, none of the top three municipalities in terms of per capita GDP (Beijing, Shanghai

Table 1 NMPA authorisation, WHO EML and NRDL listing of five targeted anticancer medications

| Targeted anticancer medications | Year of WHO-EML inclusion | Year of NMPA approval | Year of NMPA generic approval | Year.months of NRDL listing |
|---------------------------------|---------------------------|-----------------------|-------------------------------|-----------------------------|
| Rituximab | 2015 | 2000 | NA | 2017.7 |
| Trastuzumab | 2015 | 2002 | NA | 2017.7 |
| Imatinib | 2015 | 2002 | 2013 | 2017.2 |
| Dasatinib | 2017 | 2011 | 2013 | 2017.2 |
| Nilotinib | 2017 | 2009 | NA | 2018.10 |

EML, Model List of Essential Medicines; NMPA, National Medical Products Administration; NRDL, National Reimbursement Drug List.

and Tianjin) included any of the five targeted anticancer medications in their PRDLs before 2017. Inclusion of the five targeted medications was not statistically related to provincial per capita GDP rank ($r=0.05$, $p=0.216$).

Prior to 2017, listing decisions were not always aligned with cancer risk. In terms of disease burden and mortality,¹⁹ provinces in the Southwest region with the lowest incidence and mortality of breast cancer did not include trastuzumab in their reimbursement lists. In the Northeastern region (three provinces) with the highest incidence of breast cancer, only Liaoning Province included trastuzumab in its PRDL in 2016. Similarly, for lymphoma, two provinces (of three) in the Southern region with the highest lymphoma incidence and mortality included rituximab, while three provinces (of five) in the Northwest region with the lowest incidence also listed rituximab. In the Southern region with the highest incidence and mortality of leukaemia, only one province (of three) covered the three indicated tyrosine kinase inhibitors.

In terms of insurance type, most provinces began to incorporate targeted anticancer medications into their BMI or urban insurance system reimbursement lists after 2010. For example, 13 of 14 provinces listed rituximab in their BMI and 1/14 in the combined UEBMI and URBMI

reimbursement list. Only four provinces included any targeted anticancer medications in their NRCMS reimbursement lists before 2017: Inner Mongolia Autonomous Region, Hebei, Fujian and Guizhou.

DISCUSSION

The national and provincial Chinese governments seek to provide safe, affordable and effective healthcare to all citizens by 2020 by increasing health insurance coverage and establishing a national essential drug programme.²⁰ Our findings document that since the 2009 NRDL, the national and provincial governments have increasingly added anticancer medications, including new targeted anticancer medications, to their reimbursement lists.

We found that all 51 WHO EML-listed essential anticancer medicines (except for one that was not yet approved in China) were listed in the NRDL. Compared with previous studies of WHO-EML listed anticancer medications listed in national EMLs of 135 countries²¹ and those of countries in South-East Asia,²² the number of anticancer medications listed on China's NRDL exceeds the world average. Listing for reimbursement is a prerequisite, but not sufficient, for expanding economically equitable access to these expensive treatments.²³ Interestingly,

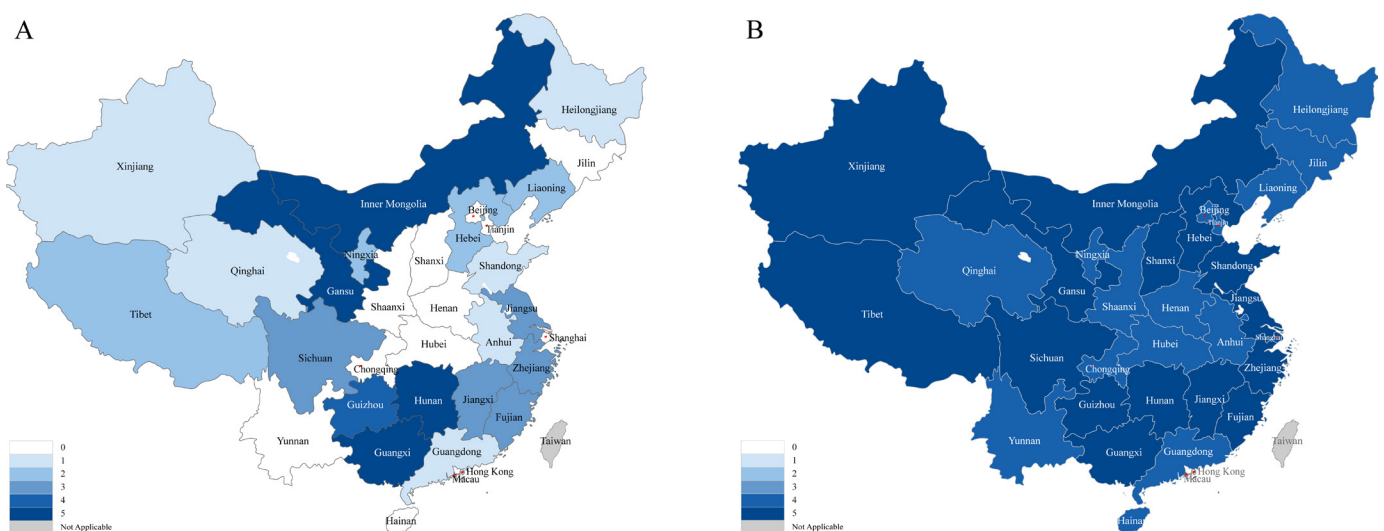


Figure 1 (A) Inclusion of five targeted anticancer medications in PRDLs of at least one insurance system before 2017. (B) Inclusion of five targeted anticancer medications in PRDLs after 2017. PRDL, Provincial Reimbursement Drug List.



Table 2 Year of inclusion of five essential targeted antineoplastic medications in PRDLs by insurance type prior to 2017

| Geographic areas | Provinces | Ranking of 2017 per capita GDP | Female breast cancer | | | Leukaemia | | | Incidence (mortality) rates of cancer (1/10 ⁵) | | | | |
|------------------|----------------|--------------------------------|----------------------|-----------|----------|-----------|-----------|-----------|--|----------|-----------|--|--|
| | | | Trastuzumab | Rituximab | Lymphoma | Imatinib | Dasatinib | Nilotinib | Female breast | Lymphoma | Leukaemia | | |
| North | Beijing* | 1 | | | | | | | | | | | |
| | Tianjin* | 3 | | | | | | | | | | | |
| | Inner Mongolia | 9 | 2015 | 2015 | 2015 | 2014 | 2015 | 2014 | 2015 | 2014 | 2015 | | |
| | Hebei | 17 | | | | 2016 | | 2013 | | | | | |
| | Shanxi | 27 | | | | | | | | | | | |
| Northeast | Jilin | 13 | | | | | | | | | | | |
| | Liaoning | 14 | 2016 | | | | 2016 | | | | | | |
| | Heilongjiang | 25 | | 2010 | | | | | | | | | |
| East | Shanghai* | 2 | | | | | | | | | | | |
| | Jiangsu | 4 | 2013 | | | | 2013 | | | | | | |
| | Zhejiang | 5 | 2015 | 2015 | | | 2015 | | | | | | |
| | Fujian | 6 | | | | | 2010 | 2013 | 2013 | | | | |
| | Shandong | 8 | | 2010 | | | | | | | | | |
| | Jiangxi | 20 | 2014 | 2010 | 2010 | | 2014 | | | | | | |
| Central | Anhui | 24 | | 2010 | | | | | | | | | |
| | Hubei | 11 | | | | | | | | | | | |
| | Human | 16 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | | |
| | Henan | 19 | | | | | | | | | | | |
| South | Guangdong | 7 | | | | | | | | | | | |
| | Hainan | 18 | | | | | | | | | | | |
| | Guangxi | 26 | 2010 | 2010 | 2010 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | | |
| Southwest | Chongqing* | 10 | | | | | | | | | | | |
| | Sichuan | 22 | | | | | 2015 | 2015 | 2015 | 2015 | | | |
| | Tibet | 28 | | 2010 | | | 2010 | | | | | | |
| | Guizhou | 29 | | 2010 | | | 2014 | 2016 | 2016 | 2016 | | | |
| | | | | | | | | | | | | | |

Continued

Table 2 Continued

| Geographic areas | Provinces | Ranking of 2017 per capita GDP | Female breast cancer | | | | Incidence (mortality) rates of cancer (1/10 ⁵) | | | | | | | | |
|------------------|--|--------------------------------|----------------------|-----------|----------|-----------|--|------------|-----------|-----------|------|------|------|------|------|
| | | | Trastuzumab | Rituximab | Lymphoma | Leukaemia | Female breast | Lymphoma | Leukaemia | Leukaemia | | | | | |
| Northwest | Yunnan | 30 | | | | | | | | | | | | | |
| | Shaanxi | 12 | | | | | | | | | | | | | |
| | Ningxia | 15 | | | | | | | | | | | | | |
| | Xinjiang | 21 | | | | | | | | | | | | | |
| | Qinghai | 23 | | | | | | | | | | | | | |
| All areas | Gansu | 31 | 2016 | 2010 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 | 2016 |
| | Total | | 8 | 14 | 15 | 7 | 9 | 28.2 (6.3) | 4.1 (2.3) | 5 (2.9) | | | | | |
| | BMI (Basic Medical Insurance) | | | | | | | | | | | | | | |
| | UEBMI&URBMI (Urban Employee Basic Medical Insurance and Urban Residence Basic Medical Insurance) | | | | | | | | | | | | | | |
| | URRMI (Urban and Rural Resident Medical Insurance) | | | | | | | | | | | | | | |
| | NRCMS (New Rural Cooperative Medical Scheme) | | | | | | | | | | | | | | |

Note * Four municipalities. Incidence rates of female breast cancer, lymphoma and leukaemia in 2014 are provided by Chen *et al* (2018). Per capita GDP in 2017 are provided by China Health Statistical Yearbook 2018.

Bold entries indicates geographic areas with the highest incidence (mortality) rates of cancer GDP, Gross Domestic Product; PRDL, Provincial Reimbursement Drug List.



neither provincial wealth nor regional cancer morbidity appear to have been highly correlated with inclusion of targeted anticancer medications on PRDLs prior to 2017. Indeed, several economically disadvantaged provinces included all five expensive targeted medications while none of the three most economically developed municipalities incorporated any into their PRDLs.

There are two possible explanations for these observations. First, since implementation of insurance benefits is coordinated at the municipal level, provincial medical insurance listing does not signify a budgetary commitment for allocating funds; at the provincial level, the PRDL is a guiding document. At the municipal level, however, listing would require a commensurate budget allocation. That is, for economically developed municipalities (eg, Beijing, Shanghai, Tianjin), listing would require budget allocation and might result in unexpected budget impact. Second, in underdeveloped areas, due to the high out-of-pocket (OOP) copayments, listed medications may be still unaffordable, even with insurance coverage.^{24 25} In underdeveloped areas, few patients can afford expensive targeted anticancer medications; therefore, expected impact on local medical insurance funds following listing for reimbursement could be limited. Similarly, due to the NRCMS's higher copayments compared with the UEBMI and URBMI,²⁶ the costs of targeted medications would be too high for most rural villagers to afford, even with insurance coverage.^{24 27} The true effect on affordable access of listing expensive medications on reimbursement lists is thus unknown, especially for NRCMS enrollees and those in underdeveloped provinces.

LIMITATION OF THIS STUDY

There are several limitations of our study. First, all information we used in this study was captured from government websites, and they might not provide complete information. However, two independent investigators separately collected and double checked the information, and the inclusion time of the five targeted medications were cross-checked against information in social media. Second, due to the limited availability of provincial cancer incidence and mortality data, we could not statistically analyse the relation between inclusion of targeted anticancer medication and provincial cancer incidence or mortality. Third, as the NRDL is only a guide for BMI funding, listing in the NRDL and PRDLs may not mean actual reimbursement. Further research will be needed to evaluate whether inclusion in PRDLs has improved access to the listed anticancer medications in China.

CONCLUSION

Our findings suggest that by including medications in the national and provincial reimbursement lists, China has taken an important first step in promoting access to targeted anticancer medications. Further research is needed to understand whether inclusion in

reimbursement lists has promoted the availability, appropriate use and affordability of highly priced targeted anticancer medications.

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Patient consent for publication Not required.

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