



# IS THE LACK OF INCLUSION ON THE NATIONAL DRUG REIMBURSEMENT LIST THE END OF THE WORLD FOR HIGH VALUE DRUG ACCESS IN CHINA?

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## INTRODUCTION

- China further expanded universal health insurance in 2014 with 1,387 million citizens now eligible for Basic Medical Insurance (BMI) and a coverage rate of over 97%. The patients covered by BMI have access to drugs listed on the NDRL (National Drug Reimbursement List). However, inclusion criteria for listing on the NDRL are very strict and the list has not been revised since 2009. Therefore, understanding alternative strategies and approaches for listing on the Provincial Drug Reimbursement List (PDRL) is essential to optimizing market access.

## METHODOLOGY

- This analysis includes a review of secondary data of PDRL inclusion in six key provinces in China: Zhejiang, Jiangsu, Fujian, Shandong, Anhui and Jiangxi. It is supplemented with primary research with regional payers and payer-advising KOLs to assess the PDRL inclusion criteria as an alternative market access strategy to the NDRL.

## RESULTS

In contrast to the NDRL, the PDRLs are revised on a more regular basis and have less restrictive inclusion criteria.

- Provinces have more money to consider how to provide coverage for more drugs. For example, the provinces of Guangdong, Jiangsu, Zhejiang and Shandong have more funding and surplus of BMIs and accordingly they include more high value drugs (including oncology drugs) in their PDRL.
- Drugs going through price negotiation have higher chances to be granted reviews and reimbursement by PDRL.
- Provincial payers are more willing to consider the value proposition of products supported with strong health economics.
- MNCs can work with local payers to provide the appropriate local data. The most used local data is from the local insurance management center and EMR (Electronic Medical Record) from several hospitals in local area.

Interviews with stakeholders identified the importance of key value messages and HEOR/PE studies in decision making with the priority of identifying cost offsets and cost effective use of insurance funding.

*"When we review the new drug, we assume the efficacy and safety are reviewed by CFDA correctly with credibility. We only review the economics part. In the economics part, key value messages are important, as we're making value-based decisions." – local payer*

*"Review by payer advisors is crucial. As to economics assessment, I think the pricing is more important at present. However, as you know a lot of data companies and MNCs are building their own access to different data sets. I think in the future, when we have more solid data to support real world evidence related studies or research, the real world evidence will be more and more important." – local payer*

**FIGURE 1: THE INCLUSION STATUS OF HIGH-VALUE DRUGS BY INTERVIEWED PROVINCES IN 2014-2016**

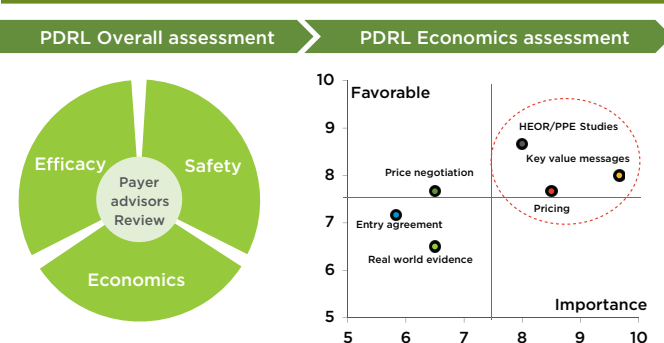
Province	Time	High value Drugs
Fujian	March, 2014	Included 15 fixed dose combinations into PDRL
Jiangsu	2015	Included Viread in NCMRS, Gleevec, Herceptin, Tasigna, Conmana and Iressa for critical disease reimbursement
Shandong	Jan, 2015	Over 20 drugs in total, including Gleevec, Iressa, Tarceva, Herceptin, Sutent, Conmana, Erbitux, Xalkori, Sprycel
Jiangxi	2015	5 drugs including Gleevec, Herceptin, Mabthera into critical disease reimbursement
Zhejiang	Jan, 2015	15 drugs in total, including Gleevec, Iressa, Tarceva, Herceptin, Mabthera, Sutent, Conmana, Erbitux, Tasigna, Sprycel, Avastin, Nexavar
Anhui	2011	Included more than 10 fixed dose combination into PDRL
	2016	Considering including Gleevec and other oncology products
Hunan	Jan, 2016	12 chemical drugs including Tasigna, Avastin, Tarceva, Herceptin, and 11 chemical drugs including Conmana, Tasigna, Tarceva, Sprycel, Iressa, Mabthera, Velcade, and Pulaile (Pemetrexed disodium for Injection), Dacogen's generic: Qingweike, two Gleevec's generics: Xinwei and Genike, and 5 biological medicines: Somatuline, Benefix, Avastin, Herceptin and Actemra.

**FIGURE 3: PAYER'S OPINIONS ON DIFFERENT WAYS TO SUBSTANTIATE VALUE**

	Budget impact	Disease burden	HEOR/PE	Probability for success
<b>Budget impact</b>	<ul style="list-style-type: none"> <li>Direct for payers to understand the budget impact after new drug inclusion</li> </ul>	<ul style="list-style-type: none"> <li>Payers have less power to negotiate price if the result strongly indicates the advantage of inclusion</li> </ul>		<ul style="list-style-type: none"> <li>The result of budget impact gives Payers a direct view to understand the budget impact after new drug inclusion, probability for success is high</li> </ul>
<b>Disease burden</b>	<ul style="list-style-type: none"> <li>MNCs can work with provincial payers to provide the appropriate local data</li> </ul>	<ul style="list-style-type: none"> <li>Need to define clinical pathway, hard to clean the data</li> <li>Longer time</li> </ul>		<ul style="list-style-type: none"> <li>If the results from control arm can't convince payers, probability for success may be low</li> </ul>
<b>HEOR/PE</b>	<ul style="list-style-type: none"> <li>MNCs can design the prospective study to better present the drug's value proposition</li> </ul>	<ul style="list-style-type: none"> <li>Hard to find the local relevant data and even harder to obtain the permission to use it</li> <li>Lack of professionals to conduct the study</li> <li>More cost</li> </ul>		<ul style="list-style-type: none"> <li>Payers prefer this study for high-value drugs</li> </ul>

Provincial payers are cautious about how they allocate their drug budget and seek to implement value-based decision-making taking into consideration efficacy, effectiveness, safety and not surprisingly, price. Local healthcare stakeholders are eager for Health Economics And Outcomes Research(HEOR) and pharmaco-economic (PE) studies for economics assessment.

**FIGURE 2: IMPORTANT CRITERIA FOR PDRL INCLUSION ASSESSMENT**



Source: Payer interviews from Zhejiang, Jiangsu, Fujian, Shandong, Anhui and Jiangxi

**FIGURE 4: KOL'S OPINIONS ON DIFFERENT WAYS TO SUBSTANTIATE VALUE**

	Budget impact	Disease burden	HEOR/PE
<b>Budget impact</b>	<ul style="list-style-type: none"> <li>Payers or head of hospitals like to see budget impact study result</li> </ul>	<ul style="list-style-type: none"> <li>It's intuitive to see how much patients will spend</li> </ul>	<ul style="list-style-type: none"> <li>The study result could help to explain to patients the value of the drug long term</li> </ul>
<b>Disease burden</b>	<ul style="list-style-type: none"> <li>Does not provide insight into clinical decisions</li> </ul>	<ul style="list-style-type: none"> <li>Sample size is too small, can't represent all</li> </ul>	<ul style="list-style-type: none"> <li>Hard to evaluate oncology drugs' value</li> </ul>

Source: Payer and KOL interviews from Zhejiang, Jiangsu, Fujian, Shandong, Anhui and Jiangxi

## CONCLUSIONS

- Given the current environment, healthcare stakeholders are eager for PE studies that support and lend credibility to value-based decision-making
- While NDRL remains an elusive goal for access, PDRL inclusion may be a more realistic alternative with the probability for success enhanced by providing locally-relevant pharmaco-economic studies completed in conjunction with local authorities and KOLs