Expedited Regulatory Pathways and Reimbursement Decisions for Innovative Cancer Drugs in China

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Background & Aim

As the interval between market authorisation and reimbursement assessment in China has shortened, regulatory and reimbursement decisions increasingly rely on similar clinical evidence. Whether expedited regulatory designations confer advantages during reimbursement decision-making remains unclear.

Methods

Study population: Cancer drug indications entering NRDL negotiations for the first time (2017–2024).

Included: Eligible cancer drug indications only.

Excluded: Traditional Chinese medicines, generic drugs, supportive care therapies, and expanded indications of already listed drugs.

Statistical Analysis: Univariable analyses and multivariable logistic regression.

Outcome: Reimbursement status.

Main predictor: Expedited review status.

Covariates: Application year, company type, tumour type, innovation status, OS/PFS benefit, pivotal phase III trial support, line of therapy, and monthly treatment cost.

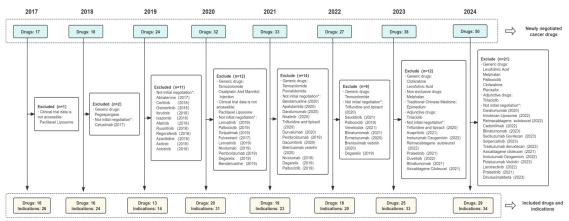

Fig. 1: Flowchart of target cancer drugs and indications selection.

Results

Characteristics

A total of 205 indications involving 156 anticancer drugs were included, of which 137 were reimbursed in the NRDL and 68 were not.

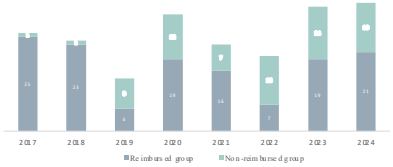

Fig 2. Reimbursement Outcomes of Anticancer Drugs in NRDL Negotiations, 2017–2024

Indications were mainly concentrated in lung cancer, lymphoma, and breast cancer. Lung cancer had the highest number of indications (48, 23.41%), with 35 included in the NRDL (listing rate: 72.9%), followed by lymphoma (31 indications) and breast cancer (23 indications).

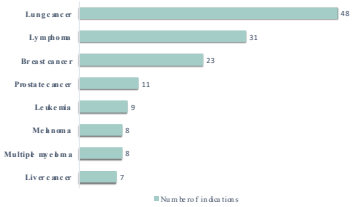

Fig 3. Distribution of Anticancer Drug Indications by Cancer Type (Top 8)

Among the 205 indications included in the analysis, 117 (57.1%) received priority review designation, 63 (30.7%) were approved under conditional approval, and 15 (7.3%) were designated as breakthrough therapies.

Conditional approval showed a statistically significant difference between reimbursed and non-reimbursed groups.

Table 1. Distribution of Expedited Review Pathways by Reimbursement Status

	All indications (n=205)	Reimbursed indications (n=137)	Non-reimbursed indications (n=68)	P value
Priority review				0.093
Yes	117(57.07)	72(52.94)	45(65.22)	
No	88(42.93)	64(47.06)	24(34.78)	
Conditional approval				0.013
Yes	63(30.73)	34(25.00)	29(42.03)	
No	142(69.27)	102(75.00)	40(57.97)	
Breakthrough therapy				0.268
Yes	15(7.32)	8(5.88)	7(10.14)	
No	190(92.68)	128(94.12)	62(89.86)	

Multivariable Logistic Regression

No significant association between overall expedited regulatory designation and NRDL inclusion. However, conditionally approved drugs were less likely to be reimbursed. Indications with OS or PFS benefit in pivotal trials were more likely to be reimbursed, whereas higher monthly treatment cost was associated with a lower likelihood of inclusion.

Table 2. Selected Results from the Multivariable Logistic Regression for Any Expedited Review Pathway (Model 1)

	OR (95% CI)	P value
Through any expedited review pathway		
No	Reference	..
Yes	1.50(0.53-4.29)	0.446
Trial phase		
Not III phase	Reference	..
III phase	0.13(0.26-0.61)	0.010
Line of therapy		
First-line therapy	Reference	..
Second-line and later therapy	0.39(0.15-0.99)	0.047
Other*	11.58(1.56-86.24)	0.017
OS or PFS improvement		
No	Reference	..
Yes	4.38(1.02-18.84)	0.047
Monthly costs (pre negotiation)	0.41(0.25-0.68)	0.001

Table 3. Selected Results from the Multivariable Logistic Regression for Specific Expedited Review Pathways (Model 2)

	OR (95% CI)	P value
Priority review		
No	Reference	..
Yes	2.34(0.79-7.84)	0.169
Conditional Approval		
No	Reference	..
Yes	0.32(0.09-1.11)	0.072
Breakthrough Therapy		
No	Reference	..
Yes	1.67(0.35-8)	0.521

Conclusion

Based on the available evidence, expedited regulatory designation did not appear to be independently associated with reimbursement decisions for innovative cancer drugs in China. Reimbursement decisions were more closely aligned with demonstrated clinical benefit and treatment cost.

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