HPR11

Oncolytic Therapies in China: Laying the Groundwork for a Successful Launch

Clarivate Consulting Services

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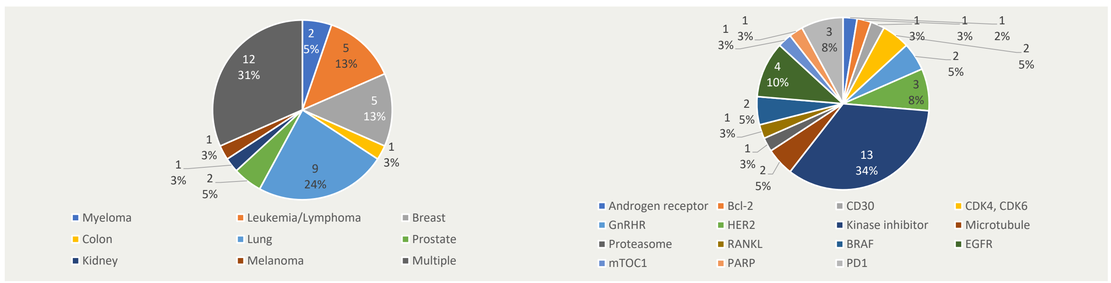
Introduction

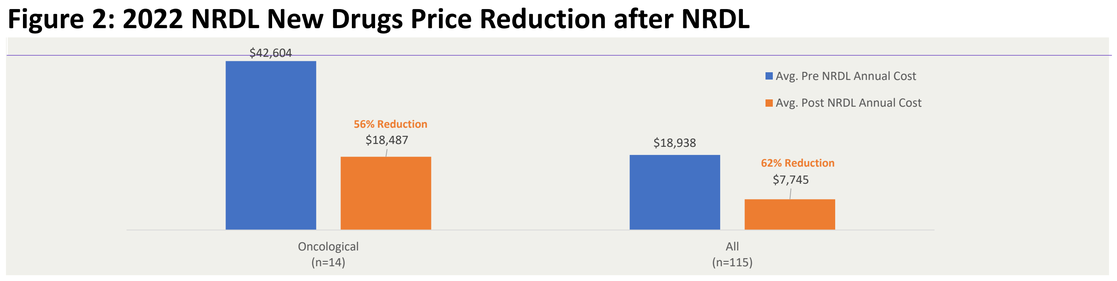
Every year, China updates the National Reimbursement Drug List (NRDL) to reflect the current drug reimbursement options available for patients[1]. In the year 2022, a total of 111 new medications were incorporated into this list, including 23 drugs specifically designed for the treatment of various types of cancer[2]. Among the oncology drugs currently covered by the NRDL, lung cancer drugs make up the largest proportion at 24%, followed closely by leukemia/lymphoma drugs and breast cancer drugs, each constituting 13% of the list. Regarding targeted oncology drugs, the four most prominent categories are kinase inhibitors, EGFR inhibitors, PD1 inhibitors, and HER2 inhibitors, making up 34%, 10%, 3%, and 3% of the list, respectively.

Figure 1: 2022 NRDL Oncology Drugs by Indications and Targets



Medications included in the NRDL experience significant price decreases. For each year between 2018 and 2022, average price reductions were 56.7%, 60.7%, 50.6%, 61.7%, and 60.1%[3]. Imported drugs, for the most part, reached their lowest global prices during this period. Newly added cancer drugs in 2022, experienced an average price reduction of 56%. Even so, successful NRDL inclusion frequently correlates with higher likelihood of commercialization success. For example, four PD-1 drugs, Tislelizumab, Sintilimab, Camrelizumab, and Toripalimab, which were enrolled into NRDL in 2019 or 2020, underwent varying levels of increases in sales. Tislelizumab, branded as BAI ZE AN, achieved its peak sales among the four PD-1 drugs in 2022[4] and held the largest market share in H1 2023[5].

Figure 2: 2022 NRDL New Drugs Price Reduction after NRDL



Objectives

This study aims to determine the overall reimbursement landscape and market access implications for oncology products in China. Additionally, the study provides suggestions for positioning oncology drug launches given the frequency of updates in the NRDL to be more inclusive of innovative western oncolytic medicine that can be accessed within China. This study will also help form access strategies for oncolytic products based on examples.

Methods

Through secondary research, we looked at new policy changes (updates directly from the Chinese Government). Additional qualitative research included interviews-with industry experts who are experienced with new product launches and market access in China. Lastly, we analyzed the NRDL inclusion data from the National Healthcare Security Administration and performed quantitative analysis from 2017 to 2022 regarding the price changes pre- and post- NRDL negotiation of oncology products.

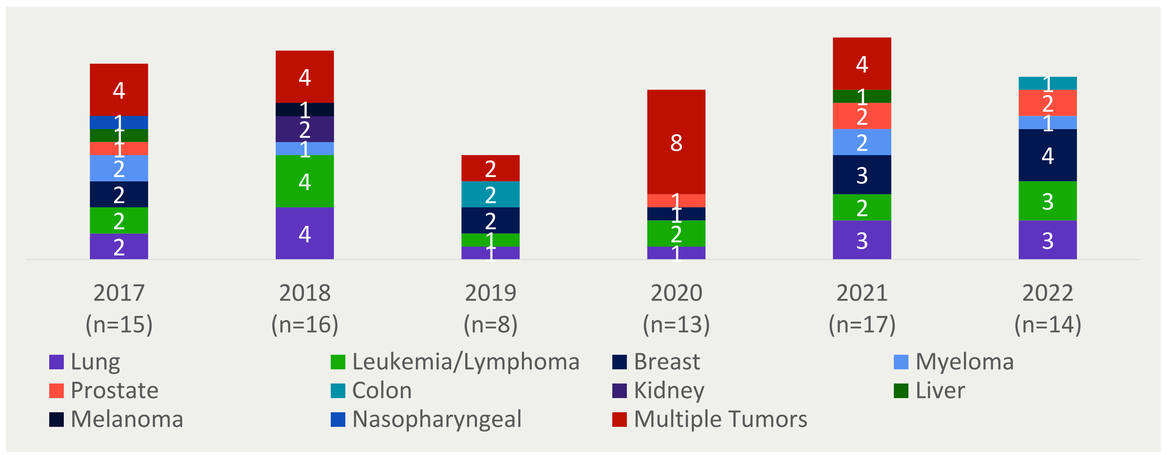
Results

Since 2017, 14 new oncology drugs were added to NRDL each year, on average, or 83 oncolytic therapies in total.

Focused Cancer Types in NRDL

Oncolytic Therapies that have been successfully included in NRDL are concentrated in several major cancer types. **Lung cancer, breast cancer, and leukemia/lymphoma constitute over half of all NRDL oncological inclusions, which are also the top 1, 5, and 8 most prevalent cancer types in China[1].** In contrast, cancers of the gastrointestinal tract account for approximately 40% of total cancer cases in China[6], yet only 22% of NRDL-included drugs since 2017 solely target these tumors. 27% of NRDL-included oncological drugs since 2017 have multiple indications, including chemotherapies such as multikinase inhibitors and agents targeting microtubules and mTOR pathway, as well as targeted biologics for PD-1/PD-L1 and HER2. **This expansion of indications of the agents targeting well-established oncological targets in China mimics what has happened in other major markets.** Meanwhile, 55% of agents with multiple indications (12 out of 22) are still included in NRDL as of this paper's publication, while only 43% of agents with a single indication are still included.

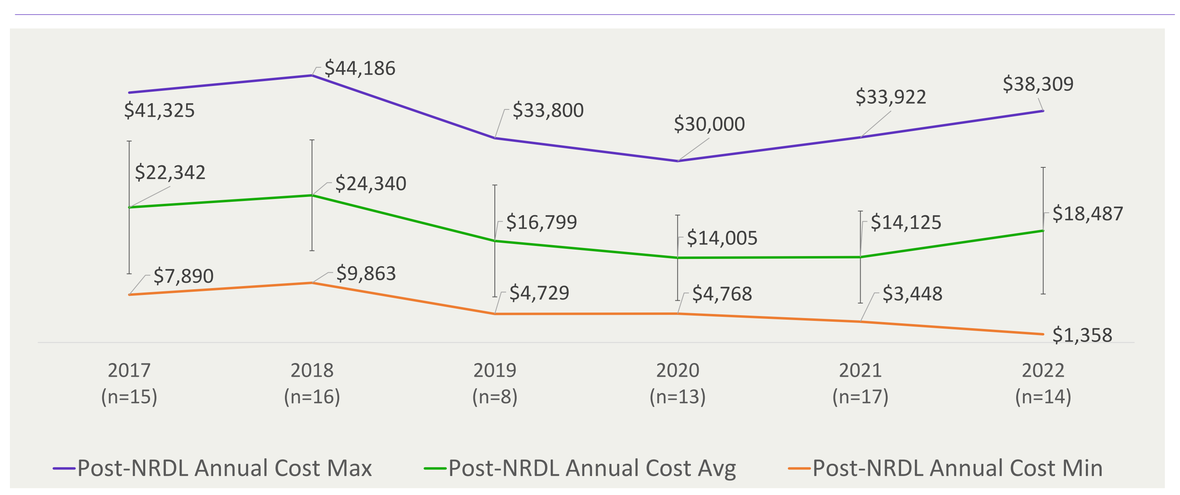
Figure 4: NRDL New Oncolytic Therapies by Year and Tumor Type



Post-NRDL Prices of New Oncolytic Therapies

Prices of new oncological agents post NRDL inclusion have been decreasing since 2017. The average annual treatment cost was $21.2k between 2017-2019, dropping to $15.5k in 2020-2022. Although it is unclear if the average annual treatment cost will continue to decrease, this result partially reflects that the **NHSA has a higher threshold of willingness to pay (WTP) for new NRDL candidates because an increasing number of oncolytic drugs are covered, reimbursed, and have become widely available to Chinese people**. Meanwhile, the maximum and minimum annual post-NRDL costs of new oncological agents have become increasingly divergent in recent years. The delta between the maximum and minimum annual post-NRDL costs of new agents was $25.2k in 2020 and grew to $37.0k (46% increase) in 2022. **This may reflect that NHSA is aiming to achieve a higher reduction in new agents for existing targets or with well-established MoAs.**

Figure 5: Post-NRDL Annual Costs of New Oncolytic Therapies by Year



Conclusion

China has established a mature and systematic national coverage and reimbursement process, and the policy-shaping opportunities are closed for major changes to the current system. The established system has made the process predictable, stable, and relatively more transparent compared with the pharmaceutical market in the pre-NRDL negotiation period. **(For more details on the NRDL process, please refer to the Clarivate 2022 ISPOR Poster: China Drug Market Changes: How to Navigate the Future of Reimbursement in China)**

However, **smaller adjustments are ongoing, for example, a recent adjustment to require contract renewal for existing drugs**. According to the new adjustment, manufacturers could submit materials for negotiating planned indication expansion and estimated price adjustment to the NHSA. This new adjustment enables manufacturers to better estimate future pricing erosion with more capability to manage risks for a product's full life-cycle management.

Additionally, **the increasing gap between post-NRDL minimum and maximum price (Figure 5) demonstrates a varying level of WTP from the NHSA**. On one hand, the NHSA has a higher WTP for new products that are first-in-class and able to address unmet needs; for example, as a MET inhibitor for treating metastatic non-small cell lung cancer, Savolitinib has negotiated a relatively higher price with the NHSA. On the other hand, for oncolytic products in a competitive space, the NHSA has lowered WTP since there are products already covered, and they have a higher threshold of including more products.

Successful planning and implementation of new product launch strategies in China requires an in-depth and agile understanding of these policy adjustments. Additionally, understanding the key elements of price setting in the NRDL process will enable companies to adopt a cautious pricing strategy with a long-term vision as well as a full lifecycle strategy for new products, seizing the opportunity at hand.

References

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