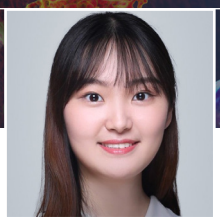
China's NRDL 2022 Update: Spotlight on Rare Disease

Part 3 of 3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Chloe Wang, Katherine Leong & Cherry Moldovan | PRECISIONadvisors

In part 3 of the NRDL 2022 update series, PRECISIONadvisors' Chloe Wang, Katherine Leong and Cherry Moldovan discuss key trends and strategic considerations for multinational companies, with a deep dive into rare disease.

Seven rare disease products entered the NRDL 2022 for the first time, all via negotiations, with a lower average inclusion rate and higher price cut than overall (Table 1).

- Notably, the negotiated price of Roche's Evrysdi was 94% lower than its launch price (Case Study A).
- Furthermore, with a trend of increasing competition in the rare disease space, access is likely to become even more challenging for future entrants, allowing payers to lever higher price pressure (Case Study B).

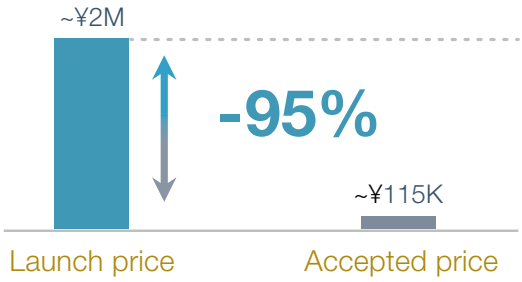
Product	Indication
Takhzyro (lanadelumab)	HAE
Evrysdi (risdiplam)	SMA
Uplizna (inebilizumab)	AQP4-IgG+ NMOSD
Kesimpta (ofatumumab)	RMS
Tecfidera (dimethyl fumarate)	RMS
Teglutik (riluzole)	ALS
Rui Ni Er (treprostinil)	PAH
Inclusion rate:	37% (rare disease) vs. 56% (overall)
Average price cut:	68% (rare disease) vs. 60% (overall)

Table 1: Overview of Rare Disease Entrants in NRDL 2022

Case Study A: Price Cuts for Evrysdi in SMA

- Evrysdi is the second SMA drug included in the NRDL, following inclusion of Biogen's Spinraza from last year.
- The entrance of Spinraza also came with a dramatic price cut of 95% from its launch price.

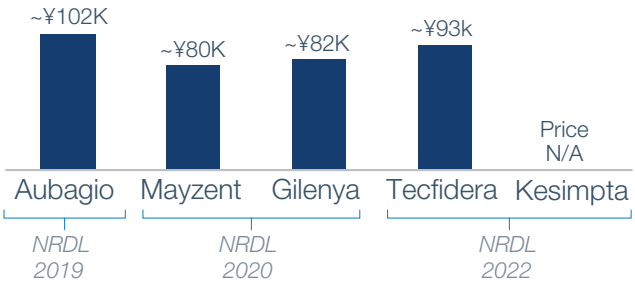
Annual Prices of Erysidi (CNY)



Case Study B: Competition in MS

- With the entrance of Novartis's Kesimpta and Biogen's Tecfidera, NRDL now covers 5 disease-modifying treatments for MS.[1]
- Products included subsequent to Aubagio all had a negotiated price below that of Aubagio, ranging from CNY 80K-93K.[2]

Annual Prices of NRDL-Included MS Products (CNY)



Considerations and Conclusions

Although the Chinese government has shown commitment to expand patient access to rare disease treatments (eg, introducing priority regulatory priority review and increasing years of market exclusivity), NRDL listing trends suggest that a challenging access environment still remains. Pharmaceutical companies should weigh the benefits of broad access against the expected price decrease alongside risk of non-inclusion, especially for products in ultra-rare indications with very small target populations. Alternative access channels such as commercial health insurance and rare disease funds should be considered to provide patient access, giving their flexibility to balance on more favourable price points.

1 Fampyra (fampridine) is an MS product covered by the NRDL, but is a symptomatic treatment for improving walking in MS patients with walking disability

2 Prices shown refer to year 1 prices (accounting for loading doses); price for Mayzent was calculated based on dosage for CYP2C9 *1*1/*1*2/*2*2 patients

Abbreviations: ALS, amyotrophic lateral sclerosis; AQP4-IgG+ NMOSD, anti-aquaporin-4 immunoglobulin G seropositive neuromyelitis optica spectrum disorders; ATMPs, advanced therapy medicinal products; CNY, Chinese Yuan/renminbi; HAE, hereditary angioedema; MS, multiple sclerosis; NRDL, National Reimbursement Drug List; PAH, pulmonary arterial hypertension; RMS, relapsing multiple sclerosis; SMA, spinal muscular atrophy

For any questions in relation to the NRDL updates or China access more generally, please don't hesitate to **reach out to our China Centre of Excellence**:

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