

CHINA 2021 NRDL OVERVIEW

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China 2021 NRDL

67 New Additions at Average 62% Price Reduction

PRICENTRIC BRIEF:

- The National Healthcare Security Administration (NHSA) of China has published the 2021 National Reimbursement Drug List (NRDL), which takes effect on January 1, 2022
- The 2021 NRDL includes a total of 2,869 drug varieties – 1,486 western medicines and 1,374 traditional Chinese medicines (TCMs) – with 74 new listings covering 21 clinical groups; specifically, 20 drugs are for chronic diseases, 18 for cancer, and the rest for hepatitis C and HIV, rare diseases, and COVID-19, among other disease areas
- Sixty-seven drugs were included through negotiations that resulted in an average price reduction of 61.71% – Of these, 27 medicines come from western drugmakers, with Johnson & Johnson seeing four additions to the list: Darzalex (daratumumab), Erleada (apalutamide), and two indications for Stelara (ustekinumab)

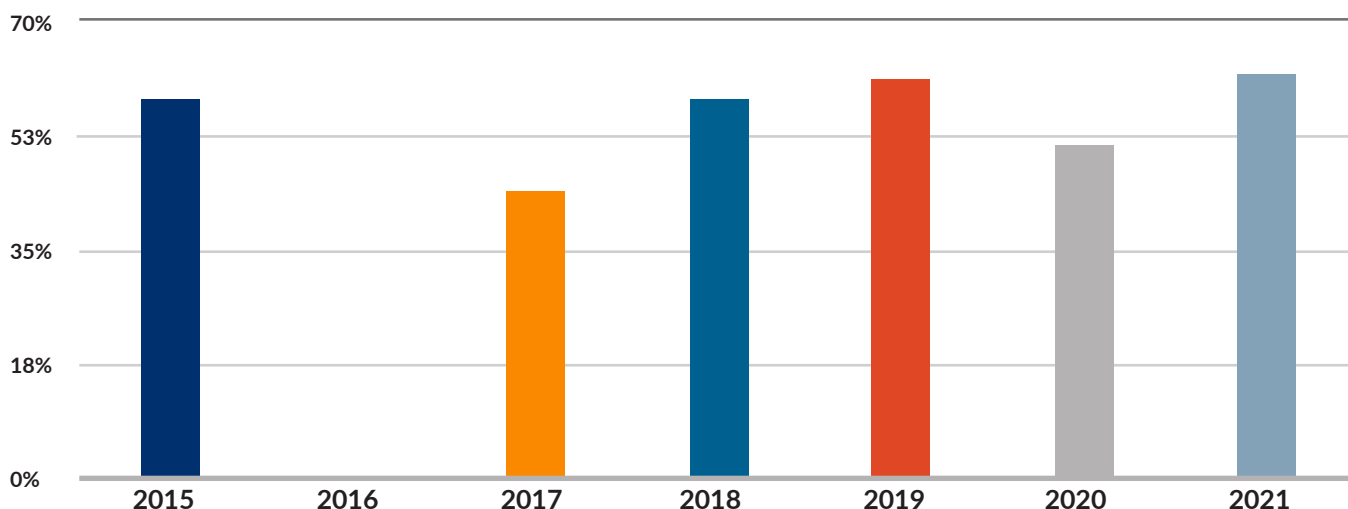
THE DETAILS

BEIJING, China – The National Healthcare Security Administration (NHSA) of China has published the 2021 National Reimbursement Drug List (NRDL), which takes effect on January 1, 2022.

The relevant notices from NHSA can be found [here](#) and [here](#).

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NRDL | Average Price Reductions Achieved Through Negotiation (%)





67 Drugs Make NRDL Debut

Sixty-seven new drugs (or indications for already-listed products) were included through negotiations that resulted in an average price reduction of 61.71%. Of these, 27 medicines come from western drugmakers, with Johnson & Johnson seeing four additions to the list: Darzalex (daratumumab), Erleada (apalutamide), and two indications for Stelara (ustekinumab).

China scored a handful of medicines for rare diseases as well; with each update to the NRDL, the government has sought to include a greater variety of medicines to provide to patients not only as part of the medical insurance “basic guarantee” but also to achieve goals outlined in the “Healthy China 2030” plan.

Orphan drugs added to this year’s NRDL include Takeda’s Replagal (Agalsidase alfa) for Fabry disease and Firazyr (icatibant) for HAE attacks, as well as Biogen’s Spinraza (nusinersen) for spinal muscular atrophy (SMA) and Accord’s Ampyra/Fampyra (fampridine tablets) for multiple sclerosis (MS).

Price cuts are always necessary for inclusion on the NRDL. For example, through NRDL negotiations, the cost of Spinraza 5 ml injection was reduced from 550,000 yuan to 460,000 yuan, with medical insurance covering 400,000 yuan and patients responsible for the remainder.

(See the list of new drugs on the next pages.)

NRDL Renewals – Domestic PD-1/L1 Inhibitors Back Again

There were also 67 renewals granted through further price reductions. Among western drugmakers, Johnson & Johnson and Novartis won big, with seven and six renewals, respectively.

Other renewals include BeiGene’s Brukinsa (zanubrutinib) and China’s domestic PD-1 inhibitors, Baize’an and Tuoyi, which were already offered up at significant price cuts in exchange for inclusion over foreign PD-1/PD-L1 inhibitors.

2020 NRDL

119 new products added to NRDL with 51% average price cut

2020 – 28 newly added Western drugs

- Novartis’s Gilenya (fingolimod)
- Novartis’s Mayzent (siponimod)
- Novartis’s Azarga (brinzolamide and timolol maleate)
- Novartis’s Simbrinza (brinzolamide and brimonidine)
- Novartis’s Tafinlar (dabrafenib)
- Novartis’s Mekinist (trametinib)
- Novartis’s Zykadia (ceritinib)
- Novartis’s Zykadia (ceritinib)*
- Novartis’s Tasigna (nilotinib)
- Novartis’s Sandostatin (octreotide microspheres)
- Novartis’s Votrient (pazopanib)
- Pfizer’s Enbrel (etanercept)
- Pfizer’s Inlyta (axitinib)
- Pfizer’s Xalkori (crizotinib)
- Pfizer’s Sutent (sunitinib)
- GSK’s Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol)
- GSK’s Belinlysta (belimumab)
- Gilead’s Letairis (ambrisentan)
- Takeda’s Takecab (vonoprazan fumarate)
- Takeda’s Entyvio (vedolizumab)
- Janssen’s Imbruvica (ibrutinib)
- Janssen’s Invega Sustenna (paliperidone palmitate)
- Eli Lilly’s Trulicity (dulaglutide)
- Eli Lilly’s Olumiant (baricitinib)
- Sanofi & Regeneron’s Dupixent (dupilumab)
- Bayer’s Stivarga (regorafenib)
- Novo Nordisk’s Ryzodeg (insulin degludec/insulin aspart)
- Boehringer Ingelheim’s Ofev (nintedanib)

*New indication

Newly Added NRDL Drugs

Company	Product	Specification	Median Price Before Negotiation (CNY)	Price in 2021 (CNY)	Price Reduction
Roche	Xofluza (baloxavir marboxil tablets)	20 mg	249	-	-
Aidea	ACC007	75 mg	19.67	8.58	56.38%
ViiV	Dovato (lamivudine and dolutegravir)	Lamivudine 300 mg + dolutegravir 50 mg	62.67	-	-
Gilead	Biktarvy (Bictegravir and emtricitabine and tenofovir alafenamide) tablets	Bictegravir 50 mg + emtricitabine 200 mg + tenofovir alafenamide 25 mg	122.67	-	-
Gilead	Volsevi (Sofosbuvir and velpatasvir and voxilaprevir) tablets	sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg	1178.5	-	-
Ascleitis	Danoprevir sodium tablets	100 mg	238.07	8.3	96.51%
Ascleitis	Ravidasvir tablets	.2 g	108	51.12	52.67%
HEC Pharma	Yimitasvir phosphate capsules	.1 g	-	-	-
Yingu	Bencycloquidum bromide nasal spray	5 ml : 5 mg	199.67	-	-
MicuRx	Contezolid tablets	400 mg	325	-	-
Zhejiang	Nemonoxacin malate sodium chloride injection	250 ml: nemonoxacin malate 0.5 g + sodium chloride 2.25 g	520	84.8	83.69%
CSPC Ouyi	Amphotericin B cholesteryl sulfate complex for injection	50 mg	1980	396	80.00%
Yangtze River	Levoornidazole phosphate disodium for injection	0.125 g	58	25.18	56.59%
Lizhuo	Perfluoropropane-human albumin microspheres for injection	0.5 g	1160	-	-
GE Healthcare	Perfluorobutane microspheres for injection	16 ul microspheres	998	-	-
Haisco	Ciprofol injection	5 ml: 50 mg	285.95	-	-
Hengrui	Remimazolam tosylate injection	36 mg	266	-	-
Humanwell Healthcare	Remimazolam besylate injection	25 mg	31.98	-	-
Tefeng	Choral hydrate syrup	0.671 g: 0.5 g	-	25.11	-
Tefeng	Chloral hydrate syrup	1.342 g: 1g	-	42.68	-
Novo Nordisk	Semaglutide injection	1.34 mg / ml, 1.5 ml (semaglutide prefilled pens)	1120	-	-
Huadong	Empagliflozin and metformin combination tablets (I)	5 mg empagliflozin + 500 mg metformin	-	-	-
Hansoh	HS-10234 tablets	25 mg	26.6	-	-
Yangtze River	Entecavir oral solution	210 ml: 10.5 mg	268	43.3	83.84%
Guizhou Taibang Health	Human coagulation factor IX	500 IU/ 10 ml/ vial	2980	-	-
Shire	Icatibant acetate injection	3 ml: 30 mg	-	-	-

Newly Added NRDL Drugs (continued)

Company	Product	Specification	Median Price Before Negotiation (CNY)	Price in 2021 (CNY)	Price Reduction
Hengrui	Hetrombopag ethanolamine tablets	2.5 mg	409.71	-	-
Zelgen Biopharma	Donafinil Tosylate tablets	0.1 g	206.65	-	-
Betta	Ensatinib Hydrochloride capsules	25 mg	203.7	-	-
Allist	Furmonertinib mesylate tablets	40 mg	571.43	-	-
Pfizer	Vizimpro (Dacomitinib) tablets	15 mg	188.67	-	-
InnoCare	Orelabrutinib tablets	50 mg	239.87	-	-
Roche	Gazyva (Obinutuzumab) injection	1000 mg (40 ml)	-	-	-
Hengrui	Azilsartan tablets	20 mg	7	-	-
Aosa	Amlodipine-folic acid tablets (II)	Amlodipine 5 mg + folic acid 0.4 mg	-	1.58	-
Hengrui	Fluzoparib capsules	50 mg	94.11	-	-
Beigene	Pamiparib capsules	20 mg	116.67	-	-
Eli Lilly	Verzenio (Abemaciclib) tablets	50 mg	179.05	-	-
Eisai	Halaven (Eribulin mesylate) injection	2 ml: 1mg	3980	-	-
Canbridge Life Science	Neratinib maleate tablets	40 mg	92.5	-	-
Hutchison China Mediatech	Surufatinib capsules	50 mg	101.19	-	-
Janssen	Darzalex (Daratumumab) injection	100 mg/ 5 ml	2358	-	-
Chia Tai Tianqing	Pomalidomide capsules	1 mg	276.95	-	-
Janssen	Erleada (Apalutamide) tablets	600 mg	332.5	-	-
Bayer	Nubeqa (Darolutamide) tablets	300 mg	196.67	-	-
RemeGen	Disitamab vedotin for injection	60 mg	13500	-	-
Humanwell Healthcare	Midazolam oral solution	0.2% (10 ml: 20 mg)	-	-	-
Biogen	Spinraza (nusinersen) injection	5 ml: 12 mg	550000	-	-
Biogen	Fampyra (Prolonged-release fampridine) tablets	10 mg	-	-	-
Shire	Agalsidase alfa for injection	3.5 mg	12180	-	-
Green Valley	Oligomannate capsules	150 mg	21.31	7.05	66.92%
Luye	Risperidone microspheres for injection (II)	25 mg	1499	-	-
Hicin	Landiolol hydrochloride for injection	50 mg	619	168	72.86%
Hisun	Hyzetimibe tablets	10 mg	8.47	6.7	20.90%

Newly Added NRDL Drugs (continued)

Company	Product	Specification	Median Price Before Negotiation (CNY)	Price in 2021 (CNY)	Price Reduction
Hisun	Hyzetimibe tablets	20 mg	14.4	11.39	20.90%
Amgen	Evolocumab injection	1 mL: 140 mg	1298	-	-
Sanofi	Alirocumab injection	1.0 mL: 75 mg	1888	-	-
AstraZeneca	Lokelma (Sodium zirconium cyclosilicate) powder	5 g	162	-	-
Pfizer	Vyndamax (Tafamidis) soft capsules	61 mg	2136.67	-	-
OT	Clotrimazole vaginal suppository	0.15 g	15.88	7.98	49.75%
Sinqi Ophthalmic Medications	Cyclosporine eye drops (II)	0.4 ml: 0.2 mg	26.63	5.5	79.35%
RemeGen	Telitacicept for injection	80 mg	2586	-	-
Janssen	Stelara (Ustekinumab) injection	45 mg/ 0.5 ml	29350	-	-
Janssen	Stelara (Ustekinumab) injection (intravenous infusion)	130 mg / 26 ml / vial	14250	-	-
Pfizer	Eurcrisa (Crisaborole) ointment	2%	450	-	-

For last year's NRDL update, PD-1 inhibitors were the hot issue between multinational corporations (MNCs) and China. Following three-day negotiations that started on December 17, 2020, in Beijing, MSD's Keytruda (pembrolizumab), Bristol Myers Squibb's Opdivo (nivolumab), AstraZeneca's Imfinzi (durvalumab) and Roche's Tecentriq (atezolizumab) all failed to make their way into the finalized 2020 list.

Instead, home-grown PD-1 efforts from Junshi Biosciences, BeiGene, and Jiangsu Hengrui took the coveted spots, with the three China-based companies offering up to a hefty 80% off the drugs' prices to win their places on the list, significantly more than the already staggering 64% that Eli Lilly offered to slash Tyvyt (sintilimab) by in the previous year's NRDL.

Dual-Channel Availability of NRDL Drugs

The updated NRDL takes effect in January, and NHSA outlined a list of mandates for provincial governments to follow and execute, including payment and insurance fund management. Essentially, provincial governments must

implement the new listings, putting these negotiated drugs online for procurement before the year's end and ensuring uptake of new products by June 30, 2022.

To ensure access to NRDL-listed drugs, Chinese authorities last year permitted dual-channel management of these products, meaning they can be supplied not only hospitals but also retail pharmacies.

Provincial medical insurance administration departments can decide which drugs should be supplied this way, considering the province's level of economic development, basic medical insurance (BMI) fund affordability, and patient need.

However, national government officials underscored the importance of making available drugs with high clinical value, urgent patient need, and low substitution.

The Jiangsu Province was a forerunner in dual-channel management of NRDL-listed products, establishing dual-channel supply of drugs that had not been available at hospitals but in pharmacies, where they were not reimbursed. To start, 100 drugs were made available through the dual channels, announced the Jiangsu Provincial Medical Insurance Bureau.

Negotiated PD-1 / L1 Inhibitors for 2020 NRDL

Company	Product	Price	Indication	Validity Period
BeiGene	Baize'an (tislelizumab)	<ul style="list-style-type: none"> 2,180 yuan/100 mg 74,100 yuan annual treatment cost (80% discount) 	<ul style="list-style-type: none"> Classical Hodgkin's lymphoma treated with at least two prior therapies Some locally advanced or metastatic urothelial carcinoma patients with PD-L1 high expression* 	March 1, 2021, to December 31, 2022
Junshi	Tuoyi (toripalimab)	<ul style="list-style-type: none"> 906.80 yuan/ bottle (80 mg/2 mL) 1,074.87 yuan/bottle (100 mg/2.5 mL) 2,100.97 yuan/bottle (240 mg/6 mL) 54,900 yuan annual treatment cost (70+% discount) 	<ul style="list-style-type: none"> Unresectable or converted patients with previously failed systemic treatment of metastatic melanoma 	March 1, 2021, to December 31, 2022
Hengrui	camrelizumab	<ul style="list-style-type: none"> 2,928 yuan/200 mg 49,800 yuan annual treatment cost (85% discount) 	<ul style="list-style-type: none"> Third-line treatment of recurrent or refractory classical Hodgkin's lymphoma First-line treatment of non-squamous NSCLC Hepatocellular carcinoma before Sorafenib treatment Post-treatment disease progression in locally advanced or metastatic esophageal squamous cell carcinoma 	March 1, 2021, to December 31, 2022
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*Whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

In addition, Chinese officials have continued urging provinces to implement these drugs as soon as possible, even with 2021 NRDL additions; the NHSA accelerated the availability of 15 drugs on the 2020 NRDL, including

domestic PD-L1/1 inhibitors, Novartis' duo Tafinlar (dabrafenib) and Mekinist (trametinib), and GSK's Zejula (niraparib), in 20 provinces last year, these products becoming available in 3,324 designated medical institutions.

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