

## Newly Listed drugs (on August 12, 2021)

No.	Brand name	Unit specification	Applicant	Active ingredient	Approval category	NHI price (yen)	Pricing method	Adjustment premiums etc.	Indication
1	EVRYSDI Dry Syrup	60 mg/ bottle	Chugai Pharmaceutical Co., Ltd.	risdiplam	New active ingredient	974,463.70	Price comparator method (I)	Utility premium (II) A = 5 % New drug development premium	Spinal muscular atrophy
2	VERQUVO tablets	2.5 mg/tablet 5 mg/tablet 10 mg/tablet	Bayer Yakuhin, Ltd.	vericiguat	New active ingredient	131.50 230.40 403.80	Price comparator method (I)	Cost-effectiveness assessments (H5)	Chronic cardiac insufficiency
3	TWYMEEG tablets	500 mg/tablet	Sumitomo Dainippon Pharma Co., Ltd.	imeglimin hydrochloride	New active ingredient	34.40	Price comparator method (I)	-	Type 2 diabetes
4	TAZVERIK tablets	200 mg/tablet	Eisai Co., Ltd.	tazemetostat hydrobromide	New active ingredient	3,004.60	Price comparator method (I)	Utility premium (II) A=5% New drug development premium	Relapsed or refractory <i>EZH2</i> gene mutation-positive follicular lymphoma (only when standard treatment is not applicable)
5	HIYASTA tablets	10 mg/tablet	Huya Japan	tucidinostat	New active ingredient	20,030.50	Price comparator method (I)	New drug development premium	Relapsed or refractory adult T-cell leukemia-lymphoma (ATLL).
6	AJOVY Syringes for S.C. Injection 225mg	225 mg/1.5 mL/syringe	Otsuka Pharmaceutical Co., Ltd.	fremanezumab (genetical recombination)	New active ingredient	41,356	Price comparator method (I)	Cost-effectiveness assessments (H5)	Suppression of onset of migraine attacks
7	AIMOVIG Subcutaneous Injection Pens	70 mg/1 mL/kit	Amgen Co., Ltd.	erenumab(Genetical Recombination)	New active ingredient	41,356	Price comparator method (I)	Cost-effectiveness assessments (H5)	Suppression of onset of migraine attacks
8	REVESTIVE 3.8mg for S.C.Injection	3.8 mg/vial	Takeda Pharmaceutical Company Limited	teduglutide (genetical recombination )	New active ingredient	79,302	Cost calculation method	Utility premium (II) A=5% Marketability premium (I) A=10% New drug development premium Cost-effectiveness assessments (H2)	Short bowel syndrome
9	LYSAKARE Injection	1 L/bag	Fujifilm Toyama Chemical Co., Ltd.	l-lysine hydrochloride and l-arginine hydrochloride	New medical combination	1,180	Price comparator method (I)	-	Reduction of renal radiation exposure by lutetium (177Lu) oxodotreotide
10	GIVLAARI Subcutaneous Injection	189 mg/1 mL/vial	Alnylam Japan Co., Ltd.	givosiran	New active ingredient	5,006,201	Cost calculation method	Utility premium (II) A=40 % Marketability premium (I) A=10% New drug development premium	Acute hepatic porphyria

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11	UPASITA IV Injection Syringe for Dialysis	25 µg/1 mL/syringe 50 µg/1 mL/ syringe 100 µg/1 mL/syringe 150 µg/1 mL/syringe 200 µg/1 mL/syringe 250 µg/1 mL/syringe 300 µg/1 mL/syringe	Sanwa Kagaku Kenkyusho Co., Ltd.	upacalcet sodium hydrate	New active ingredient	976 1,392 2,007 2,494 2,914 3,291 3,635	Price comparator method (I)	-	Secondary hyperparathyroidism in patients on hemodialysis
12	LUTATHERA injection	7.4 GBq/25 mL/vial	Fujifilm Toyama Chemical Co., Ltd.	lutetium (177Lu) oxodotreotide	New active ingredient	2,648,153	Cost calculation method	Utility premium (II)A=10% New drug development premium	Somatostatin receptor-positive neuroendocrine tumors
13	UNITUXIN I.V. injection 17.5mg/5mL	17.5 mg/5 mL/vial	Ohara Pharmaceutical Co., Ltd.	dinutiximab (genetical recombination)	New active ingredient	1,365,888	Cost calculation method	Utility premium (II)A=5% Marketability premium (I)A=10% New drug development premium	Neuroblastoma after high-dose chemotherapy
14	RECARBRIO Combination for Intravenous Drip Infusion	1.25 g/vial	MSD Co., Ltd.	relebactam hydrate imipenem hydrate cilastatin sodium	Drugs containing new active ingredients New prescription combination drugs	22,447	Cost calculation method	Utility premium (II)A=5 % Utility premium (II)A=10% New drug development premium	Infections due to aerobic gram-negative organisms in adults with limited treatment options
15	VEKLURY for Intravenous Injection	100 mg/vial	Gilead Sciences Inc	remdesivir	Specially Approved Pharmaceuticals. (New active ingredient)	63,342	Cost calculation method	New drug development premium Cost-effectiveness assessments (H1)	SARS-CoV-2 infection