Reimbursement of immunotherapy in the health insurance system in Japan

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An overview of the health insurance system in Japan

 The objects of the reimbursement: health technologies (e.g., clinical practices, drugs, medical devices) approved with solid evidence on safety and clinical efficacy based on the Pharmaceutical Affairs Law

 The fee schedule: the official price set for health care services covered by the public insurance, modified in every two years



* Calculated based on medical fee scheme, 1 points = 10 JPY

The fee shcedule:

医科診療報酬点数表

Lists and price of clinical practices



 Lists and price of drugs / medical devices

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The policy for co-payment of high-amount of medical expenses (for those aged below 70 years)

Annual household income	One to three times to pay the expensive medical expense during the past year	Four times or more to pay the expensive medical expense during the past year	
Tax-exempt household	35,400 JPY (118,000 JPY)	24,600 JPY	
Below 3.7 millions JPY (except tax-exempt household)	57,600 JPY (192,000 JPY)	44,400 JPY	
3.7 to 7.7 millions JPY	80,100 JPY + (medical expense – 267,000 JPY) × 1%	44,400 JPY	
7.7 to 11.6 millions JPY	167,400 JPY + (medical expense – 558,000 JPY) × 1%	93,000 JPY	
Above 11.6 millions JPY	252,600 JPY + (medical expense – 842,000 JPY) × 1%	140,100 JPY	

The reimbursement in the health insurance system A mixed medical care series is prohibited Manufacturers in the Health Insurance Law in general sellina purchasing Payment based on public insurance: Clinical practices performed by healthcare providers Out of pocket Payment for autonomous self-funded medical care Insured medical care uninsured medical care Autonomous self-funded medical care 70% 30% Public insurancebased medical Out of pocket Why prudent: care (dominant) Concerns in inequality and potential financial burden - Concerns in furtherance of non-evidence-based special clinical practices in terms of safety and efficacy

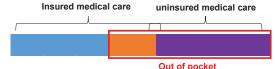
With justification

accumulating

evidence

Conditional deregulation of the mixed medical care series for advanced medicine

 The ban on the mixed medical care series has been deregulated for some advanced medical care at qualified hospitals, subject to an official review and approval.



- · Medical care services that are considered in combination with insured treatment:
 - · Advanced treatment approved by the MHLW, with hospitals assigned
 - · Those related to Research & Development trials

Special committee for cost-effectiveness

Adjust prices based on

The expert committee for drug

based on market For some items, re-pricing is

- Those approved based on the Pharmaceutical Affairs Law but in the process of listing in the public insurance
- Off label use of those approved and insured (under review)
- Patient-proposed medical care and enrollment of critical patients to clinical trials from a compassionate perspective (launched in April 2016)

Pricing mechanism for the insured products

Current status of immunotherapy in the health insurance system

• Drugs covered in the public insurance:

Types	Drugs	
PD-1 inhibitors	Nivolmab	
	Pembrolizumab	
CTLA-4 inhibitors	lpilimumab	
PD-L1 inhibitors	Durvalumab	
	Atezolizumab	
	Avelumab	
BCG (for urothelial carcinoma)		

- Others are subject to either conditional deregulation of the mixed medical care series or Payment for autonomous selffunded medical care
- Those not approved by the Pharmaceutical Affair Law and covered in the public insurance are out of the recommendation of the clinical guideline.
- Concerns on the regulatory issues

Largely reduced price of Nivolumab, as result of pharmaceutical price reform including A similar drug exists No similar drug exists introduction of health technology assessment By comparison to the similar one Cost calculation methods P_{new drug} = P_{baseline} + α, Where α refers to additional Fixed costs for R&D marginal profit and distribution based on 「オプジーボ」薬価の推移 premiums, including that for: the average of pharmaceutical Improved effectiveness (5~30% industry ※100mg10mL1瓶の場合 35~60%) Based on comparative Market size (5%, 10~20%) effectiveness, safety and 72万9849月 - Pediatric population (5~20%) innovativeness, a floating profit Innovation (70~120%) rate ranging from -50% to 100% **▲50.0%** 収載時と比べると - Initiative approval (10~20%) 76.2%安く ▲23.8% Adjustment based on prices in other developed countries ▲37.5% Reference: MHLW 2016 Reference: Chu-i-kvo 2019

Approved

2017年2月

緊急薬価改定

薬価改定

Dilemma of sustaining a generous healthcare system Revenues Expenditures \$800 billio \$800 billio 80 79 60 60 40 30 20 15 0 0 15 20 30 40 人口(万人) Medical expenditure in Japan 450 000 400 000 8.00 Raising concerns and arguments on high-cost 350 000 and advanced medicine, including 300 000 6.00 immunotherapy 年度緊急薬価改定について 5.00 250 000 200 000 4.00 3.00 150 000 100 000 2.00 50 000 1.00 health expenditure —Ratio to GDF

2018年11月

「年4回」の再算定

Resource: AnswersNews 2018

navi.com/pharmanews/14616/

https://answers.ten-

Immunotherapy in future

Challenges

- Accumulation of solid evidence on safety and efficacy
- Financial burden at individual and social level

Perspectives

- Technical advancement in reducing serious adverse effects
- Enabling domestic environment for trials, data assembly and evidence generation
- Health technology assessment
- International collaborations and knowledge sharing