

Reimbursement of immunotherapy in the health insurance system in Japan

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June 23, 2021 @ HTAi 2021

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

The fee schedule:

- Lists and price of clinical practices

医科診療報酬点数表



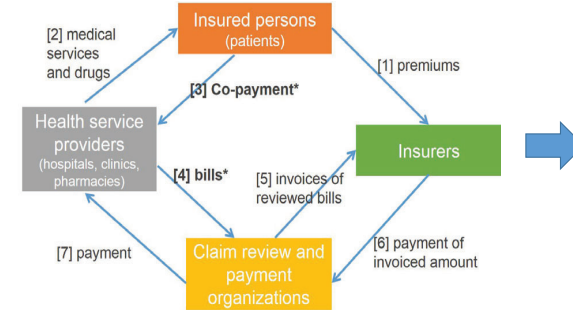
診療項目	点数
1. 内科	100
2. 外科	150
3. 小児科	80
4. 産科	120
5. 歯科	60
6. 眼科	40
7. 耳鼻科	30
8. 皮膚科	20
9. 泌尿科	15
10. 整形外科	10
11. 放射線科	5
12. 検査科	1
13. その他	0.5

- Lists and price of drugs / medical devices

第1部 内用薬



品名	単位	標準価格
アスピリン	錠	100
イブuprofen	錠	150
ロキソニン	錠	200
オピオイド	錠	300
抗がん剤	錠	500
抗生物質	錠	100
抗真菌薬	錠	150
抗ウイルス薬	錠	200
抗アレルギー薬	錠	100
抗うつ薬	錠	150
抗不安薬	錠	100
抗認知症薬	錠	150
抗糖尿病薬	錠	100
抗高血圧薬	錠	100
抗脂質薬	錠	100
抗血小板薬	錠	100
抗凝固薬	錠	100
抗血栓薬	錠	100
抗がん剤	錠	500
抗生物質	錠	100
抗真菌薬	錠	150
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抗血栓薬	錠	100

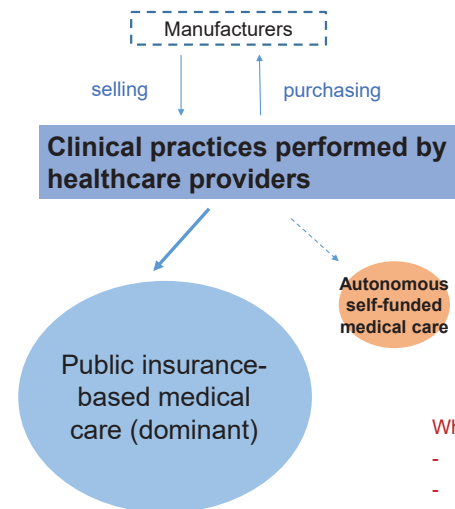


* Calculated based on medical fee scheme, 1 points = 10 JPY

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

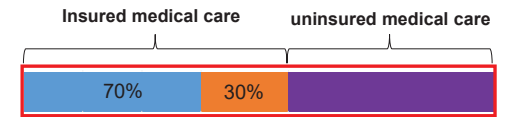
The reimbursement in the health insurance system



A mixed medical care series is prohibited in the Health Insurance Law in general

- Payment based on public insurance: 70% (Public insurance) and 30% (Out of pocket)

- Payment for autonomous self-funded medical care

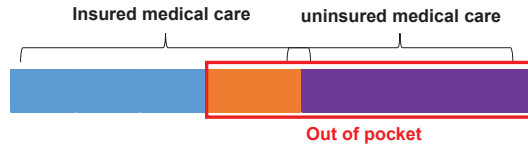


Why prudent:

- Concerns in inequality and potential financial burden
- Concerns in furtherance of non-evidence-based special clinical practices in terms of safety and efficacy

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
 - 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)

With justification of accumulating evidence

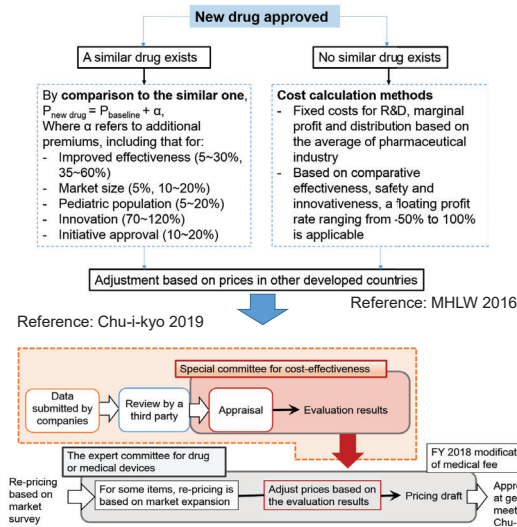
Current status of immunotherapy in the health insurance system

- Drugs covered in the public insurance:

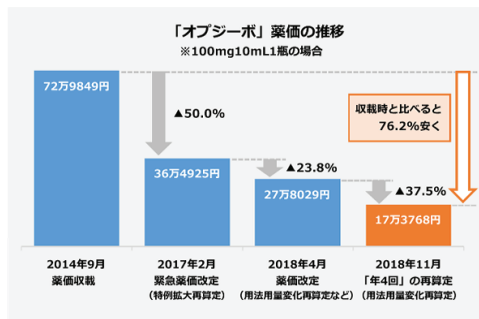
Types	Drugs
PD-1 inhibitors	Nivolumab
	Pembrolizumab
CTLA-4 inhibitors	Ipilimumab
PD-L1 inhibitors	Durvalumab
	Atezolizumab
	Avelumab
BCG (for urothelial carcinoma)	

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

Pricing mechanism for the insured products

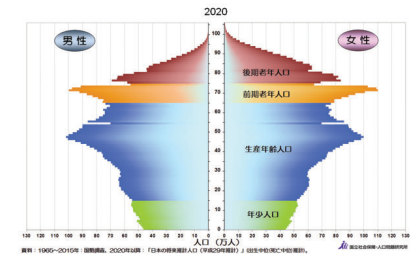
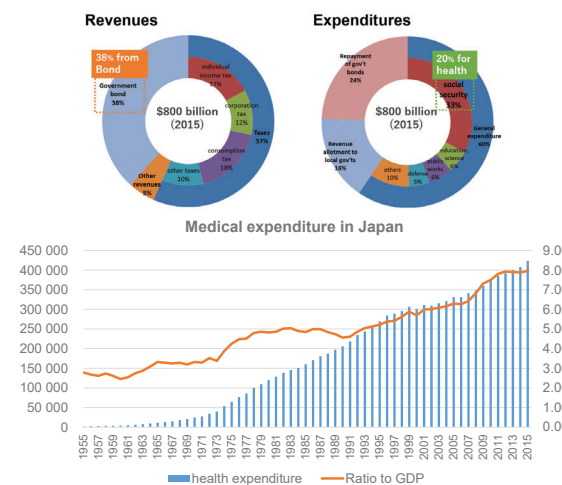


Largely reduced price of Nivolumab, as result of pharmaceutical price reform including introduction of health technology assessment



Resource: AnswersNews 2018 <https://answers.ten-navi.com/pharmanews/14616/>

Dilemma of sustaining a generous healthcare system



Raising concerns and arguments on high-cost and advanced medicine, including immunotherapy



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