Health Care Reform in Japan
~for Unprecedented Aging Society~

New York Pharma Forum
March 4th, 2004
Councilor for Health Insurance and Health Policy
Minister’s Secretariat, Ministry of Health, Labour and Welfare

Masaharu NAKAJIMA, M.D., Ph.D.
## Comparison of Medical Care Service System (1998)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of beds per 1000 persons</th>
<th>Number of doctors per 100 beds</th>
<th>Number of nursing staffs per 100 beds</th>
<th>Average length of hospital stay</th>
<th>Consultation rate of outpatient (1996)</th>
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<tr>
<td>Japan</td>
<td>13.1</td>
<td>12.5</td>
<td>43.5</td>
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<td>35.2</td>
<td>69.7 (1997)</td>
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<td>40.7</td>
<td>120</td>
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<td>U.S.A</td>
<td>3.7</td>
<td>71.6</td>
<td>221</td>
<td>7.5 (1996)</td>
<td>5.8</td>
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</table>
Japanese Health Insurance Scheme

1. **Universal Coverage**: all national
2. **Free access**: all medical facilities
3. **Universal Benefit**: Inpatient, Outpatient, Pharmaceuticals, Devices
4. **Fund**:
   - Premium (Employer 50% : Employee 50%)
   - Tax
   - Co-payment (30% with upper limit)
### Medical Expenditure

<table>
<thead>
<tr>
<th>Nation</th>
<th>Per Capita ME (¥)</th>
<th>Total ME per GDP (%)</th>
<th>Aging Population (%)</th>
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<tbody>
<tr>
<td>Japan</td>
<td>289,813 9</td>
<td>7.1 19</td>
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<tr>
<td>UK</td>
<td>216,509 17</td>
<td>6.8 23</td>
<td>15.8</td>
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<tr>
<td>USA</td>
<td>546,900 1</td>
<td>12.9 1</td>
<td>12.3</td>
</tr>
</tbody>
</table>

(Notes) - Order is among OECD countries
- "Aging Population": the ratio of the population aged 65 years and over
- OECD "HEALTH DATA 2002"
Evaluation of Japan’s Health Care System

- Japan is ranked as No. 1 in “The World Health Report 2000” by WHO, which made a comprehensive assessment of the quality and equality of health care system of 191 countries.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Healthy Life Expectancy (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Japan</td>
<td>74.5</td>
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<tr>
<td>2</td>
<td>Australia</td>
<td>73.2</td>
</tr>
<tr>
<td>3</td>
<td>France</td>
<td>73.1</td>
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<tr>
<td>4</td>
<td>Sweden</td>
<td>73.0</td>
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<tr>
<td>5</td>
<td>Spain</td>
<td>72.8</td>
</tr>
</tbody>
</table>

(The World Health Report 2000)
1. Current situation of Medical Care in Japan

① Evaluation by WHO
   - Access（Convenience of consultation）
   - Quantity
   - Cost
   - Quality

② Advance in medical technology
   - Advanced medical technology
   - Reduction of length of hospital stays

③ Low co-payment

④ Less number of malpractice suits
2. Current issues

① Medical expenditure
② Quality of medical care
③ Health delivery system
④ Provision of medical information
⑤ Technology development
Changes in the National Medical Expenditure

Ratio of national medical expenses to national income (%)

Notes: 1) With the implementation of Long-Term Care Insurance System from April 2000, of the expenses subject to the previous national medical expenditure and medical expenditure for the elderly, the costs for long-term care insurance have been transferred.
Breakdown of General expenditure (Budget plan for 2004 FY)

(Unit: 100 million JPY, (%)%)

Social security 197,970 (41.6)
- Pension 58,246 (17.1)
- Long-term care 17,921 (3.8)
- Welfare etc. 40,358 (8.5)

Energy-related measures 5,065 (1.1)

Measures for small and medium-sized enterprises 1,738 (0.4)

Compulsory education 25,128 (5.3)
Science promotion 12,841 (2.7)
Cultural and educational facilities 1,443 (0.3)
Education promotion 20,572 (4.3)
Educational projects 1,346 (0.3)

General expenditures 47,632 billion (100.0)
- Public works 78,159 (16.4)
- Defense 49,030 (10.3)
- Public Servants’ Pensions 11,321 (2.4)
- Social security 197,970 (41.6)
- Miscellaneous expenses 52,784 (11.1)
- Transfer to the special account for Industrial investment 988 (0.2)
- Reserve fund 3,500 (0.7)
- Medical care 81,445
- Stable supply of food 6,749 (1.4)
- Measures for small and medium-sized enterprises 1,738 (0.4)
- Economic Cooperation 7,686 (1.6)
International comparison of national contribution ratio


[Potential National Contribution Ratio = National Contribution Ratio + the Ratio of Financial Deficit to National Income]

The ratio of financial deficit to national income
Social security burden ratio
Tax burden ratio

Potential National Contribution Ratio
National Contribution Ratio

Notes
1. Figures for Japan are based on FY 2003 budget. Figures for other countries is actual performance of calendar year.

2. The ratio of financial deficit to national income for Japan and U.S.A are based on general government account excluding social security funds. Ratios for other countries are based on general government account.

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Changes in population composition

Sources:
Medical Care Expenditure and co-payment per capita by the age bracket (average annual amount)

(Estimated figure based on figures of undertakings for FY2000)
Future estimation of population

- FY2007: 121 million (78.9% 75 years, 101 million 65 years)
- FY2025: 128 million (9.7% 75 years, 15 million 65 years)

Future estimation of medical expenditure (related with health insurance, in JPY)

- FY2007: 12.2 trillion (35.2% 75 years, 15.9 trillion 65 years)
- FY2025: 20.3 trillion (31.0% 75 years, 34.7 trillion 65 years)
3. Health Care Reform: What do we achieve?

① Health Promotion, Disease Prevention

② Health delivery system

1. Improvement of the quality and efficiency of medical services
2. Promotion of information provision
3. Securing patient comfort and public confidence in medicine
4. Infrastructure development of medical services
Lifestyle-related diseases with age and medical expenditure (Concept)

- **Medical care expenditure per person**
- **Risk factor of disease (subject to intervention)**
- **Increase in medical expenditure for the elderly**
- **Accumulation of risk factors**
- **Aggravation**
- **Disease**
- **11 teeth (11 teeth remain)**
- **17 teeth (17 teeth remain)**
- **Threshold level**
- **Number of Lost Teeth**
- **Employees Insurance**
- **Medical Care Services for Retired Employees**
- **Medical Services for the Elderly**
- **National Health Insurance**

- **Concept**
**Concept**

People should promote health by themselves. National government, local governments, providers of health services, medical institutions and concerned parties should cooperate with each other to support such efforts.

**Promotion measures:**

- Setting nationwide target
- Establishment of the plan for local health promotion (Mandated to the Prefectural governments)

**Infrastructure development**

- Promotion of scientific research
- National health and nutrition survey
- Nutritional management in feeding service
- Anti-smoking strategies
- Establishment of common guidelines about implementation methods

**Integrated promotion of health services throughout life**

- Birth
- Education
- Workplace
- Retirement
- Live long in healthy condition

**Promotion of information provision**

- Enlightenment about lifestyle
- Measures of nutrition, labeling of foods etc.

**Health promotion to the public**

- Maternal and child health
- School health service
- Industrial health service
- Health service system
- For the elderly
- Health insurer
The New Physician Training System 2004 -

1. Mandatory Training : 2 years
3. Fundamentals of Primary Care
4. Training Hospitals / Facilities (standard)
5. Trainee salary / Funding
6. Recruitment : Matching System
New Medical Resident Training System (2004)

Current

- Trainee doctor
  - priority on expertise
  - training not mandatory
  - training at the graduating university
  - compensating for low wage by extra job

- Training hospital
  - 70% of trainee doctors are trained at university hospital.
  - no or limited rotation of areas
  - insufficient training, assessment
  - lower wage to trainee doctor
  - adoption of the trainee from affiliated university

New system

- Trainee doctor
  - mandatory training
  - broad fundamental training
  - select the training hospital on the basis of the training program
  - concentrate on training

- Training hospital
  - 7 areas rotating system
  - establish training and assessment system
  - appropriate remuneration for trainee doctor
  - disclosure of training program and open recruitment of trainee doctor (matching system)
  - financial support

The expected effect

- Improve competence of new doctors
  - the ability to practice broad basic medical care
  - medical practice with patient’s view in mind
  - efficient, effective medical management

- Improve function of training hospitals
  - improvement of the basic medical care
  - adoption of the newest medical knowledge
  - improvement of senior doctors and staff for teaching trainee doctors
Grand Design for Medical Safety

Commission on the measures for medical safety (May 2001 -)
- Clarification of the problem of medical safety
- Direction for the solutions, clarification of the problem upon implementation

"The comprehensive measures for promoting medical safety" April 2002

In order to promote the measures of medical safety, government, medical institutions, as well as related industries should cooperate with each other.

**Government**
- Incident reporting system
- Education training
- Guidance for medical institutions
- Guidance for the industries
- Research, etc

**Medical institutions**
- Reporting system in hospitals
- Safe management system
- Guidance for the security measures
- Training of staff

**Industries**
- Improvement of pharmaceuticals and medical devices

**Participation by the people**

- Medical safety
  - Improvement of the quality of the medical care
Promotion of IT in Health Care

“Grand Design of Informatization in Health Care Sector”
(December 2001) 〈Targets〉

Electronic medical chart

- By FY 2004 At least 1 facility in all Secondary Medical Care Areas (363 in Japan)
- By FY 2006 60% or more of the hospitals with 400 or more beds.
  60% or more of clinics

Computerized processing system for receipts (claims for reimbursement)

- By FY 2004 50% or more of the hospitals
- By FY 2006 70% or more of the hospitals

Establishment of an “Action Plan”

An action plan has been prepared for the achievement of these targets. The role of the Government and private sectors are shown.
Reinforcement of global competitiveness of the pharmaceutical and medical device industry

○ “Vision of the Pharmaceutical Industry” (August 2002)

“3-Year Plan for National Revitalization of Clinical Trials”

establishment of a large-scale clinical trial network of hospitals and increase in the number of clinical trial coordinators ・・・・

○ “Vision of the Medical Device Industry” (March 2003)

promotion of research and development ・・・・
4. Health insurance reform

Basic Guidelines for the reform of the medical insurance system (Medical Insurance System Bill, 2002)

① The framework of medical insurance system: the merger and reorganization of insurers

② Establishment of a new medical insurance system for the elderly

③ Revising the medical reimbursement fee schedule
Concept of The Reform “Basic Guideline”

- The framework of medical insurance system
  1. Establishment of stable and sustainable medical insurance system
  2. Equality of benefits and fairness of burden
  3. Securing high quality and efficient medical care

- The medical reimbursement fee schedule
  1. Appropriate evaluation of medical technology
  2. Appropriate evaluation reflecting the operating costs and function of medical institutions
  3. Focus on patient’s view
Outline of the current health insurance schemes

- National Health Insurance (NHI)
- Employee’s Insurance (EI)
  - Government-managed Health Insurance (GMHI)
  - Society-managed Health Insurance (SMHI)

Medical system for the elderly

75 years
The merger and reorganization of insurers

- Proceed with merger and reorganization in the basic unit of prefecture.
  - Strengthen the financial foundation and activities of insurers
- Encouragement of the concerned bodies in the region to provide more qualified and efficient medical services

**NHI**

*Many small insurers*

Prefectures and Municipalities work together to proceed with merger and reorganization in the unit of prefecture. (premium is collected by the Municipalities).

**GMHI**

*One insurer (36 million insured persons)*

Introduce a new system of prefecture-unit-based financial management

**SMHI**

*Many small associations*

- Enhance merger and reorganization of the small and poor associations by deregulation
- Establish the prefecture-unit-based regional health insurance societies

**Insurers are financially managed in the unit of prefecture**
Health insurance system for the elderly

NME on the elderly (FY2003) 11.6 trillion (in Yen)

Co-payment
1.2 trillion

Contributions from insurers
of medical insurance
7.0 trillion

Public funds (Tax)
Central Gov. 2/3
Prefecture 1/6
Municipality 1/6
3.4 trillion

Contributions are calculated on the assumption that every insurer has the same portion of people over 75 years.
The framework of the health insurance scheme for the elderly

- New health insurance scheme based on the self-support of the elderly
- Two schemes, ages 75 and over and ages 65-74
- Balanced share of premium among different generations and insures

New health insurance scheme

New adjustment scheme

- New scheme is financed with premiums paid by those 75 and over, support from the NHI and EHI, and tax.

- People ages 65-74 are covered by NHI/EHI and the unbalanced burden of medical costs caused by the difference of the population composition is adjusted.
Revision of the Medical Reimbursement Fee Schedule

☆ Appropriate evaluation of medical technology
  (difficulty, time and technical skill)
  <Doctor fee element>

☆ Patient's point of view
  • Provide information
  • Patient's choice

Evaluation appropriately reflecting the operating costs and function of medical institutions
  <Hospital fee element>

Primary care function

Specialist outpatient services, referrals

Clinics and small hospitals

Large hospitals

[Outpatient care] → [Inpatient care]

Evaluation of functions

Flat Payment Schedule

Special hospitals

Evaluation: disease characteristics, severity

Evaluation: clinical condition, ADL, nursing care needs etc.

Convalescent rehabilitations etc.

Fee-for-service Surgery etc.

Acute stage

Chronic stage
5. Japan as No.1: Super-aging society

1) Aging continues for half a century

2050: Aged 65 or older (19→) 36%, Aged 75 or older (8→) 22%

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Percentage of population of the elderly aged 65 or older in developed nations: 1950-2050

- Japan (Estimation in January 2002)
- Germany
- U.K.
- Sweden
- U.S.A.
- France
- Italy
- Spain

Sources:
- Developed nations except Japan: UN, World Population Prospects: 2000
- Japan: “National Census” by the Management and Coordination Agency and “Population Projects for Japan” by the National Institute
5. Japan as No.1: Super-aging society

2) “the younger support the elderly” → “the elderly support each other also”
   ① Employment of the elderly
   ② Change the image and physical attitude of the elderly
   ③ Elderly as a growing market
   ④ Ageless tolerant society

3) Health Care Reform of Japan:
   As the Leader of World Super-aging Society

   ① Positive prevention of Lifestyle-related diseases
   ② Appropriate utilization of medical resources (Patients)
   ③ Appropriate medical service (Medical care provider)
   ④ Appropriate benefits and burden (Mutual, cooperative help)
This opinion belongs to myself, and it does not necessarily represent the official position of the Ministry of Health, Labor and Welfare.
FY 2004 Revision of Medical Fee Schedule

March 4, 2004
Toshihiko Takeda

Director,
Office of Planning & Research,
Medical Economics Division, Health Insurance Bureau,
Ministry of Health, Labour and Welfare, JAPAN
Outline of the Medical Fee Revision 2004

- Overall Revision Rate: -1.0%
  - Physician Fee: 0%
  - Dental Fee: 0%
  - Pharmacy Fee: 0%

- Drug and Medical Device Reimbursement Price Revision Rate: -1.0%
  - Drugs: -0.9%
  - Medical devices: -0.1%
## Trend of the Medical Fee Revision Rate

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<td><strong>Physician Fee</strong></td>
<td>2.8</td>
<td>3.3</td>
<td>2.3</td>
<td>4.4</td>
<td>0.11</td>
<td>3.7</td>
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<tr>
<td><strong>Drugs</strong></td>
<td>-5.1</td>
<td>-1.9</td>
<td>-1.5</td>
<td>-2.9</td>
<td>0.65</td>
<td>-2.7</td>
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<tr>
<td><strong>Total</strong></td>
<td>-2.3</td>
<td>1.4</td>
<td>0.8</td>
<td>1.5</td>
<td>0.76</td>
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<td>-2.12</td>
<td>-2.6</td>
<td>-1.32</td>
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<td>-1.7</td>
<td>-1.4</td>
<td>-1.0</td>
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<td>0.8</td>
<td>0.38</td>
<td>-1.3</td>
<td>0.2</td>
<td>-2.7</td>
<td>-1.0</td>
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Social and Economic Situation

Wage and CPI trends since last revision in 2002

- Government Employee Wage Adjustment
  (Recommendation by National Personnel Authority)
  - 4.9% in FY 2002 and 2003
    (-2.3% in 2002, -2.6% in 2003)

- Consumer Price Index
  - 0.8% in FY 2002 and 2003
    (-0.6% in 2002, -0.2% in 2003)
Medical Economics Actual Condition Survey
(By Chuikyo, June, 2003)

Operating Profit for Private Hospitals  2.2% *

*Lowest in recent 15 years.
4.6% in 2001

Operating Profit for Children’s Hospitals*  0.5%
Operating Profit for Acute Care Hospitals*  0.8%

*Not including National or Local Government Hospitals
“As for the next medical fee schedule revision, while keeping the basic principle of “free access”, and securing the sustainability of National Health Insurance Scheme, we should aim at rational and prioritized revision on the basis that we should secure the patient-centered, quality-oriented and efficient system.

While reflecting the current severe economic and social situation, next revision should put emphases on medical quality and safety, especially those items as payment with DPC, medical services for children, psychiatric care, and so on, and the revision must be understood and accepted by national people.

Both members from insurers and physicians have agreed to have revision in order to proceed the reform stated above.”
Review of Medical Service Fee System

1. Appropriate evaluation of medical skill (emphasizing difficulty, time, technical ability)
   <Doctor fee-type elements>

2. Appropriate reflection of costs and functions of medical institutions
   <Hospital fee-type elements>

3. Emphasis of patient viewpoint
   - Promotion of information provision
   - Emphasis on choice by patient

Clinic, Small/midsize hospital
Large hospital

Acute phase
Chronic phase

- Flat-sum payment
- Evaluation reflecting disease properties and severity
- Evaluation according to condition, ADL, need for nursing, etc.

Fee for service payment
Fee for service payment

Emphasis on function of primary care physician, dentist, pharmacist, primary care function, etc.
Emphasis on specialist outpatient treatment, referral and referral back, etc.

Flat-sum payment
Surgery, etc.
1. Proper evaluation of medical/surgical procedure and services
   Tentative revision of the surgical fee system based on performed surgical case numbers
   Fee-cut system to additional fee reward system
   Require information disclosure

   Evaluation of preventive medicine
   PTE (Pulmonary thromboembolism) prevention medical fee (new) 305 points

   Introducing new technology
   Ultrasound-guided breast biopsy (mammotome) 3,040 points
   Procedure for implantable heart-assist system 30,000 points

   etc
Revision of fee qualification for institutions on surgery

Current

Certain numbers of surgery performed
And
Doctors with more than ten years experience

From fee-cut system to reward system

Revised

Fee for each specified surgery

Lack of surgery numbers
OR
Lack of doctors with 10 yrs experience

Surgery numbers and doctor experience

5% addition

Doctors with more than ten years experience
(current)

+
Numbers of surgery should be displayed
Proper explanation to patients as to surgery related information
(New)

Fee for each specified surgery

Lack of surgery numbers
AND
Lack of doctors with 10 yrs experience
Major items of the 2004 revision (2)

1. Proper evaluation of medical/surgical procedures and services (continued)

   Re-evaluation of existing procedures
   Bone marrow and cord blood stem cell transplantation evaluation
   Rehabilitation evaluation (increase covered services for those patients with acute cerebrovascular diseases)
   Evaluation of testing of sleep respiratory disturbance
   Evaluation of tumor marker (use of prostatic specific antigen: PSA)

   Evaluation of long-term dosage prescription
   Additional payment for specific disease prescription
   prescription for 28 days and longer, 45 points (once a month)
2 Appropriate reflection of medical institution’s operating costs

Revision of DPC (Diagnosis-Procedure-Combination)

Evaluation of high care units (new)
Patients with sub-ICU stage, patient-nurse ratio = 4:1 (always)
3,700 points

Hospital care for patients with chronic condition
Children are exempted from coverage limit on stays over 180 days

Evaluation of sub-acute hospital care (new)
Limited 90 days, patient-nurse ratio = 2.5:1, 60% of patients to be discharged to homes, and so on.
2,050 points
2 Appropriate reflection of medical institution’s costs (continued)

Evaluation of medical care for children
- Modify qualification for child high-staff hospital care
- Raise fee for new born infant intensive care
- Raise fee for off-hour care of children

Evaluation of psychiatric medicine
- Proper treatment by psychiatric specialists with restraint
  minimize committee within hospital
- Additional fee for patient with specific drugs to flat-sum payment

etc.
2 Appropriate reflection of medical institution’s costs
(continued)

Evaluation of in-home medical care

Evaluation of multi-visits by visiting nurses for end stage cancer patients and ALS (Amyotrophic Lateral Sclerosis) Patients

Evaluation of doctor’s order of drug infusion 3 times / a week to visiting nurses

etc.
Major items of the 2004 revision (6)

3 Proper evaluation based on institution’s function

Evaluation of physician training hospitals

Fee for university hospitals and approved doctor training hospitals with some requirements to secure high-quality care on the first day at hospital 30 points
4 Rationalization, adjustment and revise to proper fee

- Fee revision of laboratory testing
  (based on actual cost survey)

- Fee revision of CT / MRI diagnostic radiology / imaging
5 Others

Dental: Evaluation of primary dental care, etc.

Pharmacy: Review of basic pharmacy’s fee, etc.
   To review the current category of basic pharmacy’s fee; from four categories to three
   To establish a new basic pharmacy’s fee in the case of divided preparation
   To deal with long-term dosage (e.g. provision of safety information)

Proper evaluation of other hospital care
   Bedsore patient care management additional evaluation (new) 20 points, once in a hospital stay
Comprehensive Coverage of Inpatient Treatment (DPC) at Special Function Hospitals

**Hospitals Subject:** University hospitals, National Cancer Centers, National Cardiovascular Centers (82 hospitals)

**Patients Subject:** Inpatients of general wards whose injury/disease, etc. falls under a diagnostic group classification (1860 classifications), excluding the following.
(Patients who died within 24 hours of hospitalization, patients who are trial subjects, organ transplant patients, etc.

**Calculation method of comprehensive evaluation**

A payment arrangement will be used based on a daily comprehensive evaluation according to diagnostic group classification. However, for surgery, anesthesia, radiation therapy and guidance/supervision, fee for service payment will apply.

To ensure that the level of comprehensive evaluation is actual medical expenses of the previous year at each medical institution, a medical institution coefficient shall be set for each medical institution.

\[
\text{Daily points of each diagnostic group classification} \times \text{medical institution coefficient} \times \text{hospital stay (days)}
\]

*Daily points set in three stages depending on hospital stay of each diagnostic group classification. In cases where the hospital stay is extremely long, calculation by fee for service.*

**Implementation Date:** April 1, 2003

However, a grace period of three months will be set for hospitals where implementation in April is difficult.
Evaluation based on length of hospital stay (Image)

Average daily cost on each DPC code

A = B

15%

DAYS I (25% tile)    DAYS II (Average LOS)    Specified Days

Fee for services
Evaluation based on length of hospital stay (2) (Short term hospital stay for chemotherapy (Image))

Average daily cost on each DPC code

C = D

Fee For Services

DAYS I (5%tile)  DAYS II (Average LOS)  Specified Days

15%
Average LOS at each DPC Hospitals

Average 19.3 days
(Previous year 22.4 days)
Specified medical coverage for drugs has been expanded in order to cover the usage of already listed drugs for un-approved treatment (off label use) with the condition that the usage is recognized as clinical trial exemption drug by appropriate authority.

- Recognized as clinical trial exemption drug by appropriate authority
- NDA
- Approve
- SMC
- Accelerated Approval process
- Insurance coverage of newly approved efficacy
## Country Comparison of Medical Service Supply System (1998)

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<td>12.0</td>
<td>6.5</td>
</tr>
<tr>
<td>France</td>
<td>8.5</td>
<td>35.2</td>
<td>69.7 (1997)</td>
<td>10.8 (1997)</td>
<td>6.5</td>
</tr>
<tr>
<td>UK</td>
<td>4.2</td>
<td>40.7</td>
<td>120</td>
<td>9.8 (1996)</td>
<td>6.1</td>
</tr>
<tr>
<td>US</td>
<td>3.7</td>
<td>71.6</td>
<td>221</td>
<td>7.5 (1996)</td>
<td>5.8</td>
</tr>
</tbody>
</table>
As a result of the shortening of the average hospital stay in the acute phase, rehabilitation will be implemented intensively for cerebrovascular disease patients and fracture patients within 3 months of crisis. In future, the needs will expand.
*In the above, beds besides general beds and convalescent beds (psychiatric beds, infection beds, TB beds) are omitted for simplification.
Drug Pricing System Reform 2004

Pricing rule for newly listed drugs
- Revision of similar drug comparison method (II)
  (i.e. for the drugs which lack novelty)
- Introduction of a new premium system
  (e.g. Co-ordination on different strength inclusions)
- Revision of pricing rule for newly listed generics

Price revision of already listed drugs
- Special rule for price revision of already listed drugs
  The rule has been applied to the Japanese Pharmacopoeia drugs
    (which has been exceptional under 2002 overall rule)
    The reduction ratio has been applied on 1/2
- Modification of market expansion re-pricing rule
  To relieve their ration of re-pricing on the drugs which have objectively revealed their true efficacy based on the data gathered after the marketing
### The reduction ratio of the special rule

<table>
<thead>
<tr>
<th>Drug category</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The drugs approved between 1\text{st} October 1967 and 30\text{th} September 1980</td>
<td>4%</td>
</tr>
<tr>
<td>2 The drugs approved after 1\text{st} October 1980, and on which the previous special rule was applied in 1997 or 1998</td>
<td>5%</td>
</tr>
<tr>
<td>3 The drugs approved after 1\text{st} October except for the above</td>
<td>6%</td>
</tr>
</tbody>
</table>

- A half of the reduction ratio has been applied to the Japanese Pharmacopoeia drugs listed with brand name.
<table>
<thead>
<tr>
<th>Classification of pharmaceutical products in the drug price list (2001)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Original Products</strong></td>
</tr>
<tr>
<td>-----------------------</td>
</tr>
<tr>
<td>During re-examination period</td>
</tr>
<tr>
<td>Re-examination period terminated, but no generic products exist</td>
</tr>
<tr>
<td>Re-examination period terminated, and generic products exist</td>
</tr>
<tr>
<td><strong>Generic products</strong></td>
</tr>
<tr>
<td><strong>Other Products (products listed in the Japanese Pharmacopoeia, herbal medicine, etc.)</strong></td>
</tr>
</tbody>
</table>

1: No. of products and market share are based on the data of drug price survey in September 2001.
2: “Re-examination” is a system during which the pharmaceutical company collects the results of post-market experience with the drug and re-examine the safety and other characteristics of the drug. A period of four to ten years is specified according to the contents of the approval.
3: “Generic products” mean products other than those that were approved as original products (except for “Other products”).
4: “Other products” mean those that are listed in JP, Chinese herbal extracts, natural medicine, and those approved before 1967.
<table>
<thead>
<tr>
<th>Use</th>
<th>No. of products</th>
<th>No. of products</th>
<th>Products listed in FY 2000</th>
<th>Products listed in FY 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Arithmetic average</td>
<td>Weighted average</td>
</tr>
<tr>
<td>Oral Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 10 ing/strs</td>
<td>3, 51 products</td>
<td>2, 27 products</td>
<td>-48.2%</td>
<td>-44.9%</td>
</tr>
<tr>
<td>10 or less ing/strs</td>
<td>8, 44 products</td>
<td>21, 37 products</td>
<td>-40.6%</td>
<td>-34.6%</td>
</tr>
<tr>
<td>Injection Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 10 ing/strs</td>
<td>NA</td>
<td>2, 31 products</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>10 or less ing/strs</td>
<td>11, 20 products</td>
<td>10, 19 products</td>
<td>-21.4%</td>
<td>-31.0%</td>
</tr>
<tr>
<td>External Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 10 ing/strs</td>
<td>NA</td>
<td>1, 13 products</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>10 or less ing/strs</td>
<td>6, 6 products</td>
<td>6, 9 products</td>
<td>-18.9%</td>
<td>-21.8%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 10 ing/strs</td>
<td>3, 51 products</td>
<td>5, 71 products</td>
<td>-48.2%</td>
<td>-44.9%</td>
</tr>
<tr>
<td>10 or less ing/strs</td>
<td>25, 70 products</td>
<td>37, 65 products</td>
<td>-33.9%</td>
<td>-33.7%</td>
</tr>
</tbody>
</table>

Ing/strs: ingredients/strengths
Overview of the revision of the drug price list in FY 2004

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of products listed</td>
<td></td>
</tr>
<tr>
<td>Oral use</td>
<td>6,646</td>
</tr>
<tr>
<td>Injections</td>
<td>3,316</td>
</tr>
<tr>
<td>External use</td>
<td>1,996</td>
</tr>
<tr>
<td>Dental use</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>11,993</td>
</tr>
<tr>
<td>Classification of the revision</td>
<td></td>
</tr>
<tr>
<td>Lowered</td>
<td>9,645</td>
</tr>
<tr>
<td>Raised</td>
<td>39</td>
</tr>
<tr>
<td>Not changed</td>
<td>2,309</td>
</tr>
<tr>
<td>Total</td>
<td>11,993</td>
</tr>
</tbody>
</table>
### Revision rates for products in main therapeutic categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Product Description</th>
<th>Revision Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Oral use)</td>
<td>antipyretic analgesics</td>
<td>-4.6%</td>
</tr>
<tr>
<td>114</td>
<td>antispasmodics</td>
<td>-4.1%</td>
</tr>
<tr>
<td>124</td>
<td>antiarrhythmics</td>
<td>-6.1%</td>
</tr>
<tr>
<td>212</td>
<td>antihypertensives</td>
<td>-5.6%</td>
</tr>
<tr>
<td>214</td>
<td>vasodepressors</td>
<td>-4.9%</td>
</tr>
<tr>
<td>217</td>
<td>antihyperlipidemias</td>
<td>-8.6%</td>
</tr>
<tr>
<td>218</td>
<td>other cardiovascular drugs</td>
<td>-3.5%</td>
</tr>
<tr>
<td>219</td>
<td>antiulcer drugs</td>
<td>-5.7%</td>
</tr>
<tr>
<td>232</td>
<td>vitamin A and D</td>
<td>-8.7%</td>
</tr>
<tr>
<td>311</td>
<td>vitamin B (except for vitamin B1)</td>
<td>-2.8%</td>
</tr>
<tr>
<td>313</td>
<td>antimetabolites</td>
<td>-3.8%</td>
</tr>
<tr>
<td>422</td>
<td>other antiallergics</td>
<td>-7.1%</td>
</tr>
<tr>
<td>520</td>
<td>Chinese herbal medicine</td>
<td>-3.8%</td>
</tr>
<tr>
<td>613</td>
<td>drugs that affect gram-positive/gram-negative bacteria</td>
<td>-4.9%</td>
</tr>
<tr>
<td>624</td>
<td>antibacterials</td>
<td>-8.0%</td>
</tr>
<tr>
<td>(Injections)</td>
<td>metabolic drugs that are not classified into other categories</td>
<td>-7.3%</td>
</tr>
<tr>
<td>399</td>
<td>drugs that affect gram-positive/gram-negative bacteria</td>
<td>-5.3%</td>
</tr>
<tr>
<td>613</td>
<td>X-ray contrast agents</td>
<td>-5.5%</td>
</tr>
<tr>
<td>(External use)</td>
<td>ophthalmological drugs</td>
<td>-2.7%</td>
</tr>
<tr>
<td>131</td>
<td>analgesics and antinflammatory drugs</td>
<td>-4.4%</td>
</tr>
</tbody>
</table>