

FY2021 Representative Meeting

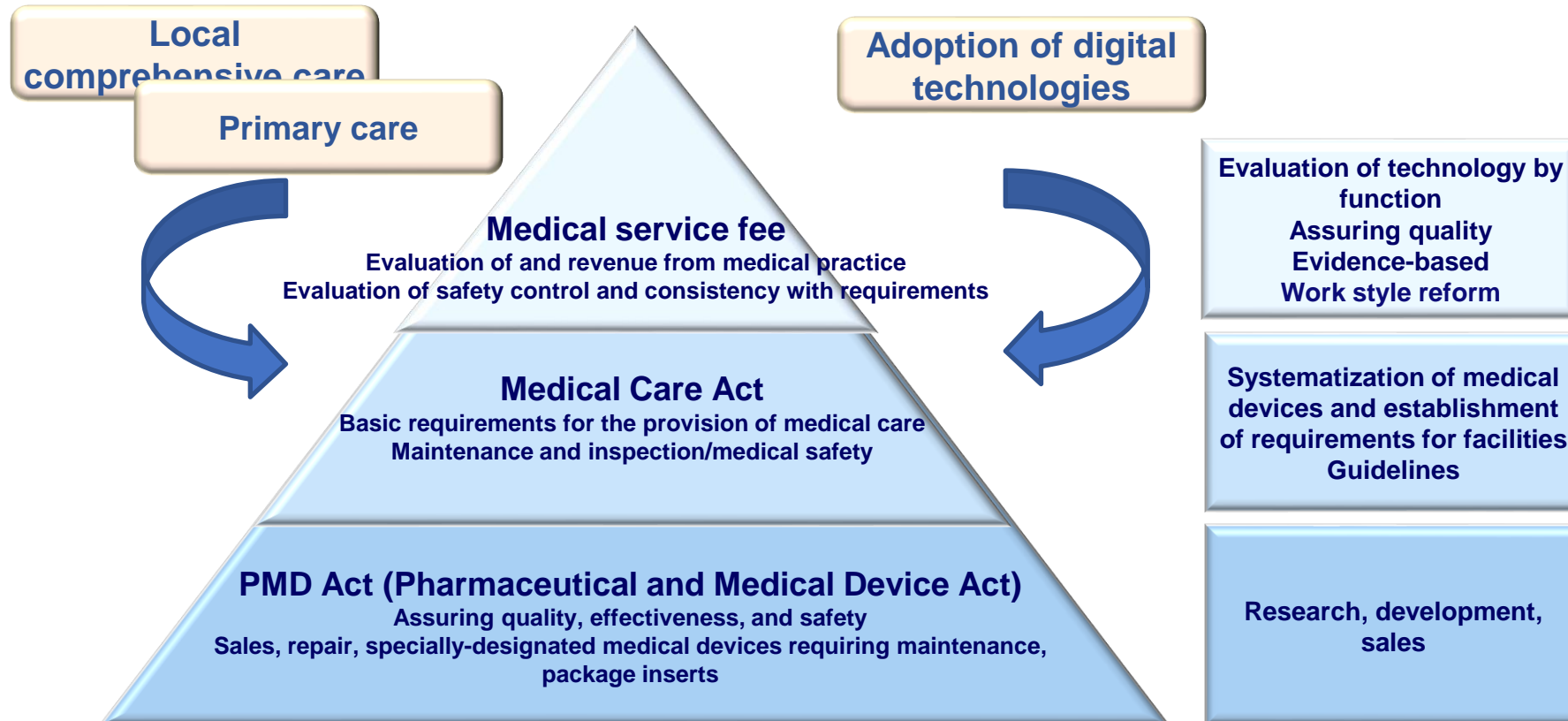
Reimbursement Subcommittee

1. Diagnostic and therapeutic devices
2. Special treatment materials

Dec. 2021

**European Business Council (EBC) Medical Devices and IVD Committee
Reimbursement Subcommittee**

- With the reform of the primary care and health sectors and the adoption of digital technologies toward 2040, it is inevitable that there will be changes in the medical service fee system.
- Let's review our approach with an emphasis on the NHI price listing as a practical benefit.



- **Reimbursement Subcommittee Activity Report for FY2021**

[1] Regular meeting/Statement of opinions Overall flow

FY2020 (41st) Regular meeting 2/18 (**Mori, Idei, Tanaka**)

Medical Technology Evaluation Proposal Hearing EBC 6/10

FY2021 (42nd) Regular meeting 7/30 **Face-to-face (Idei, Tanaka)**

Opinions of expert committee on revision of treatment materials 8/4

Central Social Insurance Medical Council (CSIMC) expert committee/Statement of opinions 8/25

Survey on foreign prices LEK (participants: 3 companies from EBC) 9/17

CSIMC expert committee Review (1st) 9/22

CSIMC expert committee Review (2nd) 10/15

CSIMC expert committee Statement of opinions by industry 11/12 (**Idei**)

Exchange of opinions with the Economic Affairs Division 10/26,* 11/10,* 12/7,* & 11/16**

CSIMC expert committee Statement of opinions 11/26 (**Idei, Tanaka**)

Expert committee Outline (draft) 12/22

[2] Cost-effectiveness assessment** Overall flow

7/13 Exchange of opinions with the Medical Affairs Division

8/4 Expert committee/Statement of opinions

9/15 Expert committee meeting (1st)

10/5 Exchange of opinions with the Medical Affairs Division

10/15 Expert committee meeting (2nd)

10/27 Exchange of opinions with the Economic Affairs Division

11/2 Deadline for statement of opinions

11/12 Expert committee meeting (3rd)/Statement of opinions

12/1 Expert committee meeting (4th)/Outline (draft)

*Diagnosis and treatment, **Special treatment materials, Dates without asterisk indicate both.

Reimbursement Subcommittee Activity Policy and Results for FY2021

- **Basic Principles of the EBC Reimbursement Subcommittee**

1. Continuation of Japan/EU/US joint proposals (Cooperation with academic societies and the government)
2. Promotion of stable supply, fair evaluation for innovation, and safety (expansion and subdivision of functional categories, reevaluation of C1 and C2, safety management, etc.)
3. Response to new trends (annual revision, consumption tax, cost effectiveness, SUD, etc.)



< Creation of a New System Design for Sustainable Universal Insurance System - Toward 2022 >

[1] Fair evaluation of innovative technologies

1) Linking of medical information with PHR	2) Time-limited premium for improvement
3) Promotion and review of C2 reevaluation	4) Online/remote robots
5) Recognition of the value of artificial intelligence	6) New insurance system

[2] Measures for adjustment based on **foreign prices**

[3] Continuous promotion of responses to subdivision and streamlining of functional categories

[4] **HTA**: Continuous monitoring of the cost-effectiveness assessment system

[5] Development of medical infrastructure utilizing **ICT** - Cooperation with academic societies, etc. In line with [1]

[6] Responses in line with trends such as regional medical care planning policies (establishment of requirements for maintenance management and radiation exposure control)



1. Diagnostic and Therapeutic Devices

- **Software as a Medical Device (SaMD) artificial intelligence management**
Requires appropriate management and support for operation in clinical practice
- **Radiation exposure reduction network**
Recognition of the value of utilization of protocol management and exposure management through proper management of a large-scale imaging information database network
- **Management of orphan disease image interpretation**
The interests of patients are protected by consulting a specialist for diagnostic interpretation of pediatric diseases.
- **Radionuclide therapy**
Since beta rays and gamma rays are generated each time treatment is performed, it requires radiation protection and radiation control for healthcare professionals and hospitalized patients and other members of the public.

Dissemination of Opinions of EBC as Statement of Opinions

1. Recognition of the value of medical technologies and innovations: C2 challenge application

Usefulness of the C2 challenge

2. Evaluation of Software as a Medical Device (SaMD) for reimbursement

Evaluation and verification of outcomes

Aim for a certain opinion/clarification

Suggestion of a possible direction toward treatment by patient choice (special or specified medical care coverage)

Discussions of special treatment materials in the framework of special treatment materials and medical devices in the framework of technical fees

- Emphasis on evidence (additional points)
- Work style reform (facility standard, etc.)
- Considerations for special or specified medical care coverage (other than approved products)



2. Special Treatment Materials

2021/7 Medical Affairs Division Regular meeting

1. Actions to assure a stable supply

- (1) Actions for medical devices with demand for a stable supply and unprofitable high-risk products
- (2) Review of the system of adjustment/repricing based on foreign prices**
- (3) Review of calculation rules for establishing a new functional category
- (4) Streamlining

2. Review of evaluation of innovations

- (1) Fair evaluation of innovative medical devices and medical devices for orphan diseases and pediatrics**
- (2) Simplification of B2 and A3 procedures**
- (3) Utilization of the B3 category
- (4) Challenge application
- (5) Recognition of values such as improving the efficiency of medical care, reducing the burden on healthcare professionals, etc.
- (6) Expansion of special exceptions for functional categories and the continuation of premiums for outpatient rapid sample testing

3. Fixed range

4. Other

- (1) Correction of coefficients for the cost accounting system
- (2) Clarification of operational rules of repricing for market expansion
- (3) Holding of organizations specializing in treatment materials, etc. in the year of revision
- (4) Fair evaluation of innovations at time of revision
- (5) Realization of value-based healthcare (AMDD)



2021/11 Central Social Insurance Medical Council (CSIMC) Statement of opinions

- 1. Stable supply of medical devices**
- 2. Evaluation of innovations**
Response to pioneering medical devices and specific use medical devices
- 3. Acceleration of listing in the NHI price list**
- 4. Correction of domestic and foreign prices**
Requests regarding adjustment and repricing based on foreign prices

- **Reimbursement Subcommittee Activity Policy for FY2022**

[1] Fair evaluation of innovative technologies

- 1) Recognition of the value of **artificial intelligence**
- 2) Online/remote robots
- 3) Linking of medical information with PHR (development of ICT infrastructure)
- 4) Fair evaluation of **radiation therapy, radionuclide** diagnosis and therapy
- 5) Recognition of values such as improving the efficiency of medical care, **reducing the burden** on healthcare professionals, etc.*

Proposal of new evaluation criteria* + Proposal of a new insurance system

(*Time-limited premium for improvement)

[2] Measures for adjustment based on foreign prices

[3] Continuous promotion of responses to subdivision and streamlining of functional categories

[4] Relaxation of rules on the withdrawal of unprofitable products of eliminated categories (confirmation required)

[5] HTA: Continuous monitoring of the cost-effectiveness assessment system (follow-up on draft outline)

[6] Responses in line with trends such as regional medical care planning policies (establishment of requirements for maintenance management and radiation exposure control)

[Working Group Activities] At the EBC, both special treatment materials and diagnostic and therapeutic devices are discussed in the Reimbursement Subcommittee. This allows sharing of studies and information. The vice chairman and the chairman of the committee are responsible for special treatment materials as well as diagnostic and therapeutic devices.

- Meanwhile, in order to accelerate individual discussions, working groups were established in FY2021 and have been operating on a trial basis since. We will continue to hold WG meetings to discuss individual topics under the monthly meetings of the Reimbursement Subcommittee.

[Subcommittee/EBC - Workshops with the Government]

- On trends such as CE marking, studies in cooperation with DTF, cost effectiveness, etc.
(Workshop on the revision of medical service fees)

[Presentation of Issues and Recommendations]

- Developing an organization capable of presenting and consolidating issues and making recommendations at WGs, monthly meetings, etc.
- Specifically, promotion of the fair evaluation of medical technologies such as AI -
Cooperation with DTF and JFMDA
- Continue activities for practical benefit!!