Fiscal 2022
Medical Devices and IVD Committee of European Business Association
Meeting of Representatives

Medical Fee Subcommittee

December 8th 2022

Chairperson of the Medical Fee Committee
Ryōichi Tanaka

Agenda

- Summary for the current year

- Administrative events and activities

- Public and Private Sector Dialogue (Minister of Health, Labour and Welfare)

- Periodic meetings and liaison meeting of SaMD-related organizations (METI)

- For the next fiscal year

Results in FY 2022 ;
Decision to institutionalization of ' C2 Challenge '
" Establishment of insurance application system based on usage records "

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Institutionalization of “C2 challenge”

1. Medical Technology and Innovation Assessment :

Application for C2 Challenge

(Industry opinion statement by Chuikyo* Expert Panel on Medical Materials, November 19, 2019)

" C2 challenge is OK " (No. 1 side: payment side)

2. Medical Technology and Innovation Assessment :

Application for C2 Challenge (Industry opinion statement by Chuikyo Expert Panel on Medical Materials, November 29, 2021)

Agree (No. 1 and 2 side: payment side and treatment side)

***Chuikyo: Government reimbursement advisory council**

Activities in 2022 are being toward to FY2024.

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● Ongoing

(1) Optimization and evaluation of innovation technologies

1) Evaluation of **artificial intelligence** technology

2) On-line and remote robots

3) Integration of medical information to PHR (ICT infrastructure development)

4) Proper evaluation of **radiation therapy, nuclear medicine and other treatment**

5 Evaluation of the efficiency improvement of medical care and **reduction of burden** of medical professionals *

Proposal of a new evaluation criteria * + Proposal of a new insurance system
(* Addition for improvement with time limit)

(2) Measures against foreign price adjustments

(3) Continuous response to subdivision and rationalization of functional category

(4) Elimination of category - Relaxation of rules for withdrawal of unprofitable products (confirmation required)

(5) HTA : Continuous monitoring of the cost-effectiveness evaluation system (following up on the outline plan)

(6) Response in line with the community medical program policy (maintenance management and formulation of requirements for exposure control)

Agenda

- Summary for the current year
- Administrative events and activities
- Public and Private Sector Dialogue (Minister of Health, Labour and Welfare)
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Participation in Medical Fee Subcommittee and related events

January 19 : Participation in Chuikyo (Review of special materials and HTA system) notification revision meeting

3 Exchange of opinions with **Ayano KUNIMITSU LDP (member of parliament)** on the selective treatment expense system

April 1st medical fee revision 2022

April 21 : Study meeting for medical fee revision (Economic Affairs Division)

May Study with Councilor Katsume LDP (member of parliament) –programmed medical devices
May 31 : Cabinet decision on the second phase of the Basic Plan for Medical Devices
(Act on Research, Development and Promotion of Medical Devices to Improve the Quality of Medical Care Received by Citizens)

June 7 : Basic Policy (Economic and Fiscal Management and Reform 2022) Cabinet Decision

August 25 Summer Lecture : Professor Toshiki Mano, Katsunobu KATO Minister of MHLW

November 28 : Public and Private Sector Dialogue with the Minister of MHLW (MHLW / MEXT / METI / PMDA/AMED)

8/29, 10/06,10/25,27, 11/01,08,18,28 3-poles Conference on Diagnosis and Treatment (JFMDA, AMDD, EBC)

9/27, 10/24, 11/15,28,30, 12/02 Special Materials 3-organizations Meeting (MTJapan, AMDD, EBC)

8/29, 9/27. 10/6, 12/12 , Pharmaceutical Industry Promotion and Medical Information Planning Div. 3-poles Meeting (Diagnosis and Treatment)

12/5, , Pharmaceutical Industry Promotion and Medical Information Planning Div. 3-poles Meeting (Special Materials)

10/05, 10/24, 10/30, 12/9 METI / MHLW / Council AI related on Pharmaceutical

Agenda

- Summary for the current year
- Administrative events and activity history
- Public and Private Sector Dialogue (Minister of MHLW) - See related materials separately
- Periodic meetings and liaison meeting of SaMD-related organizations (METI)
- For the next fiscal year

Agenda

- Summary for the current year
- Administrative events and activity history
- Public and Private Sector Dialogue (Minister of Health, Labour and Welfare)
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Special Designated Treatment Materials

Main Topics of Material WG periodic Meeting

Periodic Meeting (MHLW) 2023/1/24

1. Measures to secure stable supply

(1) Measures to rising prices of raw materials and components — New Request

(2) Dealing with medical devices that require stable security and products with unprofitable risks

(3) Review of the Foreign Price Adjustment and Repricing System — Continuation / addition

(4) Review of calculation rules when establishing new function categories — Continuation / addition

(5) Rationalization of function category — Continuous request

2. Review of Innovation Evaluation

(1) Challenge Application

(2) Expansion of exceptions to function categories and continuation of rapid additions

(3) Appropriate evaluation of medical devices for orphan diseases and children

3. Other

(1) Certain width

(2) Optimization of coefficients in the cost calculation method

(3) Holding of an expert organization for insurance-covered medical materials in the revised year

(4) Appropriate evaluation of innovation at the time of revision

(5) Simplification of procedures for B2 and A3 (with changes)

(6) Evaluation of improvement in the efficiency of medical care

(7) Calculation method of standard material prices for new functional category (draft) (AMDD)

(8) Toward realization of value-based health care (AMDD)

(9) Cost-effectiveness program (AMDD)

January 24, 2023 : Proposal for materials for the regular meeting

1. Measures to secure stable supply

New Request

(1) Responses to rising prices of raw materials and components

- The medical device industry has been greatly affected by the rise in raw material and component prices and transportation costs.
- Marketing authorization holders are making efforts to reduce costs in order to achieve stable supply. However, self-help efforts have reached the limit and they have no choice but to pass on the cost to the price.
- Because special materials have official prices, it is difficult to pass on prices.
- On the other hand, even if a stable supply is secured through price increases, etc., under the principle of standard material price revision *, **prices may not exceed the price before revision**, and as a result, the pass-on to prices will not be sufficiently reflected.

* : " Standards for Calculation of Reimbursement Prices for Special Designated Treatment Materials (PFSB 0209 No. 3, February 9, 2022) "

- If the calculation result of the revised price confirmed by the market price survey exceeds the price before revision, it should be accepted and revised to the price according to the actual price.
- Therefore, delete the phrase "However, it cannot exceed the standard material price before the standard material price revision for the relevant functional category" in the principle of the standard material price revision.

1. Measures to secure stable supply

Proposed Revision

(3) Review of the foreign price adjustment and repricing system (1/2)

- In 2002, a repricing system using foreign average prices was introduced. Since then, the gap between domestic and overseas prices has steadily narrowed due to repricing and adjustments based on foreign prices at the time of listing.
- Reimbursement prices of new insurance products in the past few years often less than 1.0 times the foreign average price
- When the product is newly included in the NHI price list, it is compared with the product concerned. When it is at the time of repricing, it is compared with the function category. Therefore, it may not be an appropriate comparison.

- In this situation, foreign price adjustment is deemed unnecessary. The foreign price adjustment system should be abolished.
- Since it is unreasonable to adjust foreign prices under the functional category system rather than by brand, if the system is to be continued, **revisions should be made at the time of listing** as a general rule.
- Only when there is no foreign price that can be referred to at the time of listing, and therefore it is calculated by the cost calculation method, foreign price repricing will be applied only once as an exception.

1. Measures to secure stable supply

Request Continuation

(4) Revision of calculation rules for standard material prices for newly listed products (2/2)

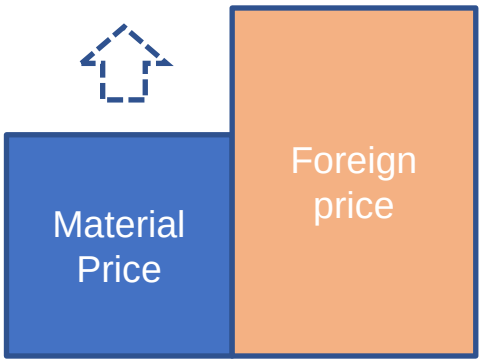
- Standard material prices for newly listed products will be reduced if they exceed 1.25 times the foreign price due to foreign price adjustments. On the other hand, even if the price falls below the foreign average price, there will be no adjustment for the increase.

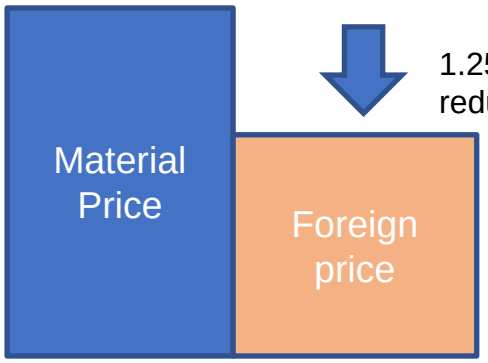
  (For pharmaceuticals, both downward and upward adjustments are being made.)

➢ The current downward price adjustment will be maintained , but the case of the price falls below 0.75 times the foreign average price, the price will be raised and adjusted in the same way as pharmaceuticals to support stable supply.

Drug pricing system : In drug pricing, when the standard drug price is less than 0.75 times the foreign average price, upward adjustment for price is performed.

0.75 times or more than foreign price
If low, request for increase!





1.25 times or more is reduced

1. Measures to secure stable supply

Request Continuation

(5) Rationalization of function category (2/2)

- Rationalization not only distorts assessments based on prevailing market prices and impedes the substitution of new technologies, but may also impede stable supply.
- As a result of the 2020 revision (Reiwa 2) , the number of rationalized categories was a few, but it is difficult to say that the transparency and predictability of processes are still ensured.

- This It does not deny the review of the functional category based on rational grounds. By sharing with the industory the specific reasons that led to the consideration of rationalization, transparency and predictability of functional category review can be ensured.
- In addition, it is requested that sufficient time by presenting the schedule at an early stage is available so that sufficient discussions can be held with related companies in the category and clinical experts.
- Functional categories newly established in C classification should not be reviewed for reasons other than requests from the industry until a certain period of time has passed.

EBC Proposal for 2022 Periodic Meeting

Procedures for Discontinued Products

- In many cases of when the company reports a supply outage, it is often difficult to procure substitute products. The current situation is that negotiations for adjustment of substitute products are left to the company.
- In reality, it is difficult for a company to make a decision to suspend supply before it becomes unprofitable, and to respond to requests for continued supply from academics.

  In particular, if there is strong opposition from academic societies and negotiations are prolonged, there is a possibility that the supply will be cut off before understanding is obtained.
- Although process charts * 1 and forms * 2 were prepared in FY 2022, the situation has not improved.

* 1 : March 4, 2022 " Examples of Entries in Application for Insurance Coverage for Medical Devices "
* 2 : February 9, 2022 " Procedures for Submission of Application for Insurance Coverage for Medical Devices "

- Regarding the procurement adjustment of substitute products, it is necessary for competitors to disclose their hidden supply capacity, which may lead to competitive disadvantages.

  Therefore, we would like the government to take the initiative in coordinating, with companies only providing information on substitute products.
- We would like to request the cooperation of the Ministry of Health, Labor and Welfare to understand the circumstances of the company that must stop the supply and to obtain the understanding of the academic society before the supply is cut off.

In cooperation with JFMDA :⇒consultation with the Economic Affairs Division

Not submitted

Material WG Discussed agenda (2)

It became a matter for continuous consultation.

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EBC Proposal for 2022 Periodic Meeting

Handling of cost calculation method

- From the Chuikyo proposal * 1 in 1993 until the notification of the current standards for calculating insurance reimbursement prices * 2
  When there is a similar functional category, the similar function category comparison method shall be used in principle.
  Although it is recognized that the costing method is an exceptional, the government's response to requests for the similar functional category comparison method is changing.
  * 1 : " [September 24, 1993] Proposal for Evaluation of Special Designated Treatment Materials "
  * 2 : " Standards for Calculation of Reimbursement Price of Special Designated Treatment Materials "

(Example) Cost calculation was strongly recommended,

Cost was requested to be presented after the insurance application request was submitted.

- Since considerable preparation time is required for the estimation of costs, if it is difficult to respond to sudden requests or there is a shortage of responses, the degree of disclosure may be affected.

- Is comparison of similar functional category no longer a principle?
- When the similar functional category comparison method is desired
  If it is necessary to prepare cost calculation, isn't it necessary to prepare a notice?

	category of similar functions Items for which comparison method is desired	category of similar functions Determination of comparison method	Determination of Cost Accounting Method	Determined amount / desired amount Average rate of change
Fiscal 2020	12	12 (100%)	0 (0%)	-5.9%
Fiscal 2021	5	5 (100%)	0 (0%)	+0.6%
Fiscal 2022	12	6 (50%)	6 (50%)	-21.0%

Diagnosis and treatment

Response based on the evaluation by the Medical Technology Assessment Subcommittee FY2022

令和４年度診療報酬改定　Ⅲ－１　患者にとって安心・安全に医療を受けられるための体制の評価や医薬品の安定供給の確保等－⑤

医療技術評価分科会の評価を踏まえた対応

➢　学会から提案のあった医療技術について、医療技術評価分科会における検討結果等を踏まえ、医療技術の評価及び再評価を行い、優先的に保険導入すべきとされた新規技術（先進医療として実施されている技術を含む。）について新たな評価を行うとともに、既存技術の評価の見直し等を行う。

学会からの提案技術

先進医療技術

先進医療会議における評価結果の報告

医療技術評価分科会における評価対象となる技術（733件）

① うち、学会等から提案のあった医療技術 **714件**※１ ※３

② うち、先進医療として実施されている医療技術 **19件**※２※３

※１　先進医療として実施中の技術、及び学会等から提案のあった技術に関連して医療技術評価分科会において検討を行った技術を含む。
※２　先進医療会議における評価結果について先進医療会議より報告された医療技術に限る。
※３　うち、７件は①及び②に該当する。

医療技術評価分科会における評価の対象としない提案、又は中央社会保険医療協議会総会において一部若しくは全部が議論された提案 188件

医療技術評価分科会における医療技術の評価

診療報酬改定において対応する優先度が高い技術 175件※４（新規77件、既存98件）

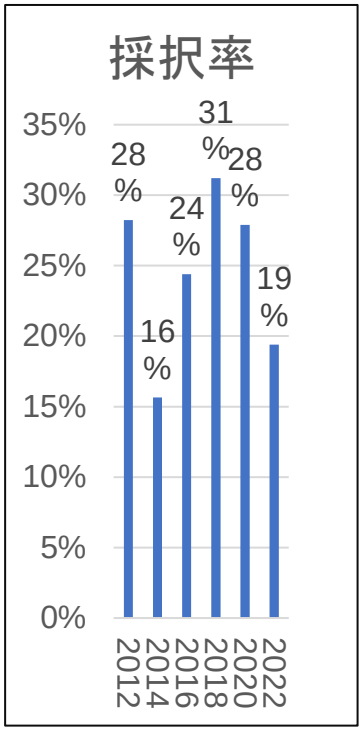
医療技術評価分科会としては、今回改定では対応を行わない技術 558件（新規206件、既存352件）

※４　うち、提案書の「ガイドライン等での位置づけ」の欄において、「ガイドライン等での記載あり」とされたものは113件（新規36件、既存77件）であった。

今後、適切に医療技術の評価・再評価を行う観点から、**医療技術評価分科会における検討結果を分析**するとともに、診療ガイドラインの改訂やレジストリ等のリアルワールドデータの解析結果を、当該分科会において把握できるよう、**医療技術評価提案書の提出に係るプロセスを見直す**。

中医協総会における検討

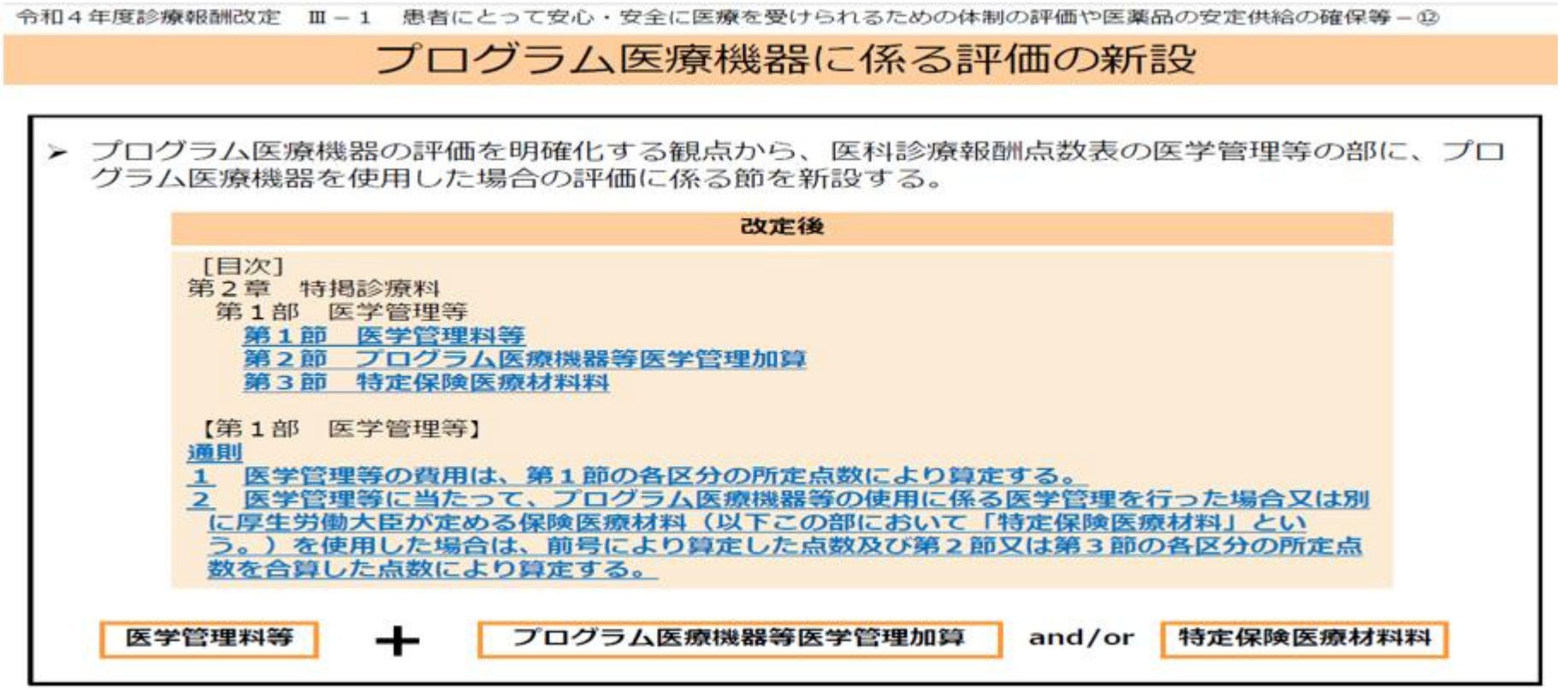
3



Source : Summary of 2022 medical fee revision (briefing session held on March 4, 2020)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000196352_00008.html

Regarding medical technologies proposed by academic societies, based on the results of examinations by the Medical Technology Evaluation Subcommittee, we will conduct new evaluations of new technologies that should be preferentially introduced into insurance, as well as re-evaluate existing technologies. .

New Section on Programmed Medical Devices



From the viewpoint of clarifying the evaluation of programmed medical devices, a new section on evaluation when programmed medical devices are used will be added to the medical management section of the medical fee point table.

Fiscal 2022

Medical Fee Subcommittee

Materials for Periodic Meetings

08 / 2022

European Business Council (EBC) Medical Devices and IVD Committee
Medical Fee Committee

- **Proper evaluation of medical technology**
  - Risk Sharing - Programmed medical devices, etc. ; Establishment of the Japanese version of DiGA and utilization of the selective treatment expense program in case of rejection
  - Flexible systems and utilization of selective treatment expenses - Flexibility of systems including 7T MRI and AI programs and medical devices (OP ; ⇒ after Evidence ⇒ C2 challenge?)
  - Correction of the comprehensive technical fee for PET examination (Is it possible to separate technical fee like CT and MR?)

- **Medical DX**
  - Framework for insurance premiums for the utilization of real-world data ; cloud premiums in collaboration with academia

- **Other**
  - Follow-up of C2 Challenge Implementation System ⇒ Opinions on Insurance Guidebook
  - Regarding development packages such as MR and CT of innovative technologies * that benefit work style reform, is there a framework for responding to **epochal function premium like special materials**?

3. Evaluation of medical device (medical technology) innovation
SaMD,SiMD: provisional approval and provisional insurance sysytem

Proposal for Public-Private Sector Dialogue 2022

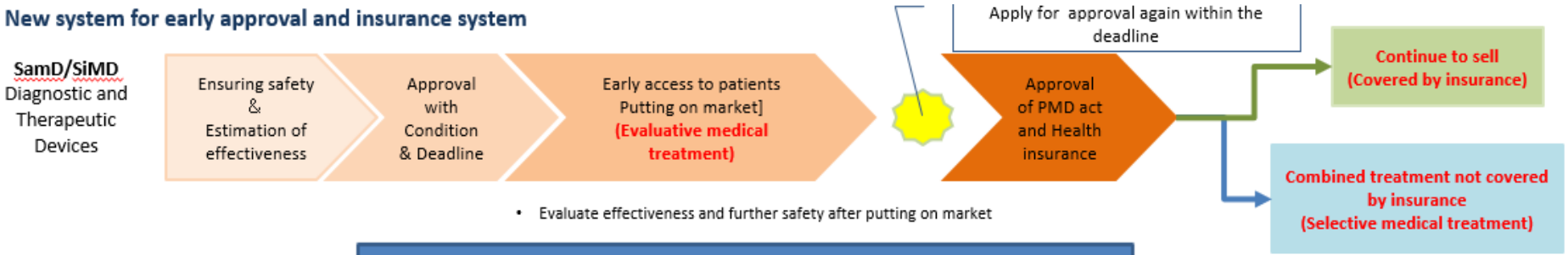
EBC Proposal for Periodic Meeting 2022

[Current status]

- In the case of Programmed Medical Devices SaMD or SiMD (Software) in Medical Device etc., the development rotation is fast and it takes time to obtain Evidence for insurance coverage, and there are cases where the value of the product is lost. Alternatively, there are cases where the development or putting on the market is abandoned due to lack of predictability by caused many major changes. In order to revitalize development, it is necessary to recover development costs as soon as possible.
- In the revision of the act in Heisei 25, a chapter on regenerative medicine products was established and approval system with conditions and deadline for regenerative medicine products was introduced.
  In Heisei 27, regenerative products were approved under this conditional and time-limited approval system, and real example pf approval system was implemented to confirm efficacy and further safety after putting on market.
- In the Heisei 29, a notice of rebalancing was issued, and early approval has begun to take place.
- In addition, in recent years, a system of having a provisional license system with insurance for programmed medical device has started oversea, and a certain degree of predictability is secured in the development and sales of start-up companies. (Germany ; DiGA System)

Issue ;

In order to ensure early access to patients, the public and private sectors will consider a system in which products whose safety is ensured by QMS standard, etc. are first put on market, and then re-evaluated and covered by health insurance.



Issue：Medical equipment that does not assume introduction of insurance

EBC Proposal for 2022 Periodic Meeting

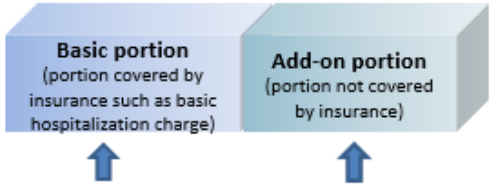
- > Suggestion of the possibility of selective treatment (non-insurance combined treatment) (industry opinion statement in 2021)
→ Supplementary opinions on programmed medical devices in the 2022 revision

https://www.mhlw.go.jp/content/12404000/000853875.pdf https://www.mhlw.go.jp/stf/shingi2/0000212500_00139.html

Medical treatment that can be used in combination with health

1 Evaluative medical treatment ⇒ Assess for insurance introduction
2 Medical treatment by patient ‘s request ⇒ Assess for insurance introduction
3 Selective medical treatment ⇒ Not premised on the insurance introduction

Structure of Medical Expenses Combined with Treatment Outside Insurance Coverage
[Cases of Evaluative Treatment]



Benefit covered by health insurance as combined medical expenses not covered by insurance

Fees can be collected from patients (Free fee)

* For medical expenses combined with treatment outside insurance coverage, the requirements for collecting fees from patients (such as posting of fees) are clearly specified.

- **Evaluative medical treatment**

Advanced medical
Medical treatment related to clinical trials of pharmaceuticals, medical devices, regenerative medicine products, etc.
Use of pharmaceuticals, medical devices, and regenerative medicine products that have not yet been covered by health insurance after being approved by the Pharmaceutical Affairs Law
Off-label use of drugs listed in the National Health Insurance drug price list
Non-applicable use of insurance-covered medical devices and regenerative medicine products

- **Patient request medical treatment**
- **Selective medical treatment**

Special recuperation environment (different price bed)
After-hours medical care
Appointment treatment
First visit/return visit at a large hospital
Hospitalization for 180 days or more
, etc

Supplementary opinion
18. With regard to the evaluation of pharmaceuticals, medical devices and medical technology, continue to consider the appropriate evaluation while understanding the status of discussions on the scope of insurance benefits, etc.

Selective treatment : Candidates for medical expenses combined with treatment outside insurance coverage ;

Programs using AI technology Medical devices Items Outside of the DiGA system

MR/CT
Short working hours
High image quality
Radiation exposure reduction AI software

Proper evaluation of medical technology
- Proper evaluation of PET examination

Reference : 2022 revised medical technology evaluation proposal

JRS/JSNM/JRPA Collaborative Issues

EBC Proposal for 2022 Periodic Meeting

Current situation

PET examination is regarded as a comprehensive technical fee including synthesizing device, drug administration, imaging, image processing, management of controlled areas, etc. This is Japan only.

PET Diagnostic reagents for PET have been approved, but supply is delayed due to comprehensive technical fee revisions every two years. In addition, there are several PET examination technologies for which technical fees are not charged.

A new reagent for PET diagnosis for brain tumors was approved in 2021, but there is an event that the technical fee has not been approved.

Issue

The price adjustment between the technical fee and the cost of diagnostic reagents has not been successful, and the setting of the technical fee has stalled, so the benefits to the patient are not being enjoyed.

Proposal

As with existing SPECT diagnostic reagents and MR/CT contrast media (pharmaceuticals), PET diagnostic reagents should be treated as technical fees that do not include synthesizers, etc.

As a result, even if new PET diagnostic reagents are developed, they can be used for PET examinations without waiting for revisions, just like CT and MR.

Since JSNM withdrew once, it is withdrawn in line.

January 24, 2022 : Proposal for materials for the periodic meeting

The 43rd periodic meeting between the Ministry of Health, Labour and Welfare and the medical device industry

" Diagnosis / Therapeutic devices / Home medical care "

Dr aft

Proposals for medical devices (medical technology)

0 / 0 / 2023

医機連 日本医療機器産業連合会 JFMDA The Japan Federation of Medical Devices Associations

AMDD 一般社団法人 米国医療機器・IVD工業会 American Medical Devices and Diagnostics Manufacturers' Association 日本を、もっと健やかに。

EBC EUROPEAN BUSINESS COUNCIL IN JAPAN

Content of today's proposal

1. Evaluation of the innovation for medical device (medical technology) P. -P.

   (1) Improvement of predictability of C2 applications (new functions and technologies)

   (2) Evaluation of the Needs Study Group for technical fee comprehensive medical devices

   (3) Regarding medical devices related to medical technology evaluation proposal

2. To promote safety assurance P. -P.

   (1) Review of long-term clinical use of specified maintenance management medical devices

   (2) Promotion of radiation exposure management in cooperation with medical institutions

   (3) Evaluation of quality control of medical monitors

1. Evaluation of the innovation for medical device (medical technology)
(3) Regarding medical devices related to medical technology evaluation proposal

[Background and current status]

① With regard to medical technology revisions, new technologies are being evaluated and existing technologies are being reevaluated based on “Medical Technology Evaluation Proposals” submitted by academic societies.

② Regarding the " Medical devices used for the proposed medical technology " described in the “Medical Technology Evaluation Proposals”, the information is shared between academic societies and related companies and describe them jointly.

③ On the other hand, when the technical fee is newly established or revised, various conditions related to medical device may be attached in the notice of " Points to Consider in Calculation " etc. There have been cases where there is a discrepancy between the contents of medical device proposed by academic society and the final medical devices that meet the conditions described in notice. Therefore, it is sometimes seen that it causes confusion in clinical practice.

④ In addition, although the " Guidelines for Preparation of Proposals for Medical Technology Evaluation " regarding drugs and medical devices have been revised, there are still some proposals that are not subject to evaluation by the Subcommittee on Medical Technology Evaluation because " approval of drugs and medical devices to be used cannot be confirmed ".

[Proposal]

① If there is possibility of a discrepancy between the medical device described and proposed by the academic society in the “Medical Technology Evaluation Proposals” and the medical device that meets the conditions (e.g. approval of the PMD act, device specifications, etc.) indicated finally in the “Points to Consider in Calculation” notice, etc. and also confusion is expected in clinical practice, in such case, the introduction of a procedure that enables confirmation of the details of the PMD act approval, etc. through related companies and organizations.

② Regarding "Medical Technology Evaluation Proposals" submitted by the industry together with academic societies, a system will be established that allows inquiries about the reasons for medical technology evaluation results via the Medical Device Policy Office.

③ Clarify the medical devices related to the technology in the "definition, etc. of medical devices for which specific medical fees are calculated"

2. To promote safety assurance

(1) Review of long-term clinical use of specified maintenance management medical devices

Current Status and Background

① There are many devices that have been used in medical practice **for 10 years or more**. (* More than 12 years according to JIRA survey)

② The company sets a maintenance management period after the discontinuation of manufacturing of Specified Maintenance Management Medical Devices. However, in actual medical practice, **there is no choice but to use it beyond the period** in which medical safety can be ensured, which hinders maintenance and management work at medical institutions.

③ Therefore, even under the situation where the parts supply including the parts stock is severe, it is not easy to replace the parts. Some companies have been forced to procure parts at a new expense **hindrance to stable supply**. * There are many people who wish to introduce a system like " **automobile inspection system** " in the term of car.

④ Cyber attacks on medical institutions are rapidly increasing and the threat of virus infection via medical devices is increasing. Therefore, providing medical devices capable of cyber security measures and handling medical devices after service termination in IMDRF guidance * are major issues. * To be applied from fiscal 2023

Proposal

① Support the establishment of a system to review the continuation of clinical use only for medical devices whose safety is difficult to ensure due to the end of supply of parts or expiration of maintenance period due to long-term use.

② Regarding medical devices that have been in clinical use for a long time and cannot be protected against cyber security, we will show measures to encourage updating to devices that can support new technology.

January 24, 2023 : Proposal for materials for the periodic meeting

The 43rd periodic meeting between the Ministry of Health, Labour and Welfare and the medical device industry

" Diagnosis / Therapeutic devices / Home medical care

Dr
aft

Proposals for Programmed Medical Devices

January 0, 2023

医機連 日本医療機器産業連合会 JFMDA The Japan Federation of Medical Devices Associations

AMDD 一般社団法人 米国医療機器・IVD工業会 American Medical Devices and Diagnostics Manufacturers' Association 日本を、もっと健やかに。

EBC EUROPEAN BUSINESS COUNCIL IN JAPAN

Main Points of EBC

EBC EUROPEAN BUSINESS COUNCIL IN JAPAN

2022 Periodic Meeting
EBC Appeal Plan

- Clarification of evaluation methods for medical treatment fees of programmed medical devices

→ Regarding programmed medical devices, evaluation method for technology that does not have facility standards, etc. is not clear at present.

→ Further improvement of predictability in medical fee evaluation is essential

- Evaluation based on the characteristics of programmed medical devices

→ Programmed Medical Devices, It was also shown that they can be evaluated as Special Designated Treatment Materials

→ For programmed medical devices with relatively high update frequency, opportunities for medical fee evaluation are the same as for conventional medical devices.

- Evaluation of programmed medical device for Physician Work Style Reform

→ It is clear that the majority of radiologists are in a state of overwork.

→ This time, in the revision of " Programmed medical devices shall be evaluated by taking into consideration the characteristics of each product and reflecting them in facility standards, etc., while bearing in mind the perspective of work style reform for physicians in the evaluation of medical devices". However, there is no clear indication of the evaluation in terms of additional points or additions to the technical fee.

- Promotion of Programmed medical devices in early introduction

→ There is concern about the so-called SaMD / SiMD lag compared to Europe and the United States for programmed medical devices using AI and machine learning

→ For regenerative medicine products, there is a " conditional and time-limited early approval system " that enables early approval and early insurance listing. However, there is no such system for programmed medical devices. Despite being a programmed medical devices with relatively high update frequency, it is the same as a normal medical device.

1. Clarification of evaluation methods for medical treatment fees of programmed medical devices

[Proposal]

January 24, 2023 : Proposal for materials for the regular meeting

(1) " If the ability to detect lesions is clearly better than existing technology, it can be evaluated as an addition. "

Exemplify specific calculation conditions to be " evaluated as an addition "

⇒ evaluation criteria, evaluation coefficient , end points of test, technology to be compared, evidence level, etc.

(2) Evaluation of " cases where interpretation is equivalent to that of a specialist " and " cases where it leads to work-style reform of physicians "

In light of the fact that there are technologies (e.g. endoscopic method, etc.) for which facility standards do not exist,

Please provide specific examples including technical fee or/and evaluation methods using DPC function evaluation factor II, etc.

(iii) Based on the evaluation methods for programmed medical devices presented by industry associations in the previous revision,

Set up study sessions and opportunitiesto exchange opinions to clarify differences in thinking between the government and the industry.

【参考試案】医療機器のアウトカム評価の事例

参考資料

事例①

胸部X線画像の読影補助

（画像出典）

【概要】

- 胸部X線画像から肺結節候補域を検出する読影補助プログラム

【主なアウトカム】

- 読影検出能の向上
  単独読影でのAUC: 0.7088 → CADあり読影でのAUC: 0.7688
- 医師の技術の均てん化の可能性に期待
  ・放射線専門医: 単独読影AUC 0.7173 → CADあり読影AUC 0.7683
  ・非専門医: 単独読影AUC 0.7002 → CADあり読影AUC 0.7693

● 読影検出能の向上 有効性

	Before		After
単独読影（医師の技術） vs CADあり読影 =	0.7088	vs	0.7688

⇨ 差分の0.06の部分は、プログラム医療機器独自の貢献

参照する技術料：（胸部X線検査の画像診断料 85点）

● 医師の技術の均てん化 社会的必要性(均てん化)

	Before		After
放射線専門医 vs 非専門医 =	(0.7173−0.7002)	vs	(0.7683-0.7693)
=	0.0171	vs	-0.001

⇨ 差分の0.0181の部分は、プログラム医療機器独自の貢献

参照する技術料：（胸部X線検査の画像診断料 85点）

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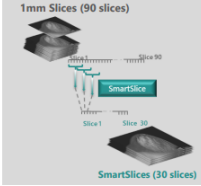
【参考試案】医療機器のアウトカム評価の事例

参考資料

事例②

マンモグラフィ(トモシンセシス)再構成処理



【概要】

・乳房2次元画像に比べ読影に2倍程度の時間を要するトモ画像を効率的に再構成し、読影枚数を削減する。1mm厚のトモ画像セットに対し、情報を欠損することなく、3mm厚の重ね合わせ処理を行う。

【主なアウトカム】

・診断時間の短縮
石灰化病変のみの症例の読影感度は1mm 画像セットによる場合に劣らず、読影時間を平均で約13% 短縮することにより医療者（読影医）の負担軽減につながる*。

*391例、15名の読影医による読影比較試験

画像出典：製品紹介資料 3DQuorum™ Imaging Technology -Improving radiologist performance through Artificial Intelligence and SmartSlices (ホロジックジャパン㈱)

● 診断時間の短縮 効率化

	Before		After
本技術なし vs 本技術あり =	100	vs	87（13%読影時間短縮）

⇨ 現行の診療報酬の13%は機器加算等の評価の根拠として妥当ではないか？

参照する技術料：（トモシンセシス/マンモグラフィーの画像診断料 306点）

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● Evaluation based on the characteristics of programmed medical devices

January 24, 2023 : Proposal for materials for the regular meeting

[Proposals and requests]

① Regarding special designated treatment materials that adopt the functional category method, the functional category is defined as “similar in terms of structure, purpose of use, medical efficacy and effect, etc.'' In the case of intangible programmable medical devices, the expression "structure" is difficult to interpret, so how about reviewing the expression?

② In the cost calculation method for special designated treatment materials, Chuikyo indicates coefficients that should be applied to general administrative sales expenses, operating income, distribution expenses, etc. against manufacturing costs. on the other hand, programmed medical devices, which are intangibles, do not have cost items corresponding to manufacturing costs, or the ratio of manufacturing costs is remarkably low compared to medical devices, which are tangibles, and cannot be calculated appropriately. Therefore, for the time being, specific examples will be accumulated in order to establish a method of setting coefficients suitable for evaluation of programmed medical devices, taking into consideration the development and manufacturing processes of individual products that are submitted for application without using coefficients. (Same treatment as individual consideration for regenerated products)

③ In light of the fact that performance will continue to be updated even after putting on market, it will be clarified that multiple challenge applications can be submitted for programmed medical devices.

In the case of an intangible programmed medical device :
The expression " structure " is difficult to interpret

How about " similar in terms of structure **(in the case of programmed medical devices, mechanism of action, content of programs, algorithms, development techniques, etc.)**, intended use, medical efficacy, etc. "?

Programmed medical equipment, which is an intangible item, does not have an element corresponding to the "raw material cost" in the case of a tangible item. Alternatively, since the cost composition ratio for tangible items is significantly different, it is not suitable for cumulative calculation based on conventional coefficients.

● For the time being, accumulate cost calculations for individual cases and **establish appropriate coefficient setting methods**

3. Evaluation of Program Medical Devices Contributing to Working Style Reform of Physicians

January 24, 2023 : Proposal for materials for the regular meeting

[Proposals and requests]

① Based on the reality that doctors' overwork is a risk factor for patient safety, it is possible to evaluate the selection of applicable techniques and the application of supplementary additions. In addition, we will clarify the evaluation criteria and evaluation coefficients to be eligible for premiums, etc., and institutionalize the spread and expansion of programmed medical devices that contribute to the work style reform of doctors.

② In the case of evaluation based on technology fees, if the introduction of applied technology in question results in more efficient medical resources compared to the overall cost of medical care using conventional similar technology, a certain part of cost reduction is newly applied to the evaluation as a "partial addition"

③ If it is evaluated as a special material, the cost reduction due to the applicable technology is reflected as a correction addition to the material price.

Reference:
A case of a university hospital where the diagnostic imaging environment of the radiology department affected the delay in recognition of abnormal findings。
" Excessive work of a radiologist "

・ In a series of CT image diagnoses at a university hospital, two urological outpatient physicians, nine primary readers of the radiology department, and two secondary readers, in total 13 persons involved, the overlooking of lung cancer occurred, and the patient died.

• There are important organizational factors behind the delay in recognition of abnormal findings, and the average rate per physician at national university hospitals is lower than that at national universities.
There was a situation in which 1.5 times of reading was performed. The environment was not suitable for accurate diagnostic imaging.

Nagoya University, " following after Surgery for Renal Cancer, Materials for Press and Publication of Cases in which Delay in Detection of Progression of Primary Lung Cancer ", 2015, https://www.med.nagoya-u.ac.jp/hospital/departments/file/author63aa4/2021/pdf/2755fd2e4b3e6171ef98fd927a6a161c072adea6.pdf

January 24, 2023 : Proposal for materials for the regular meeting

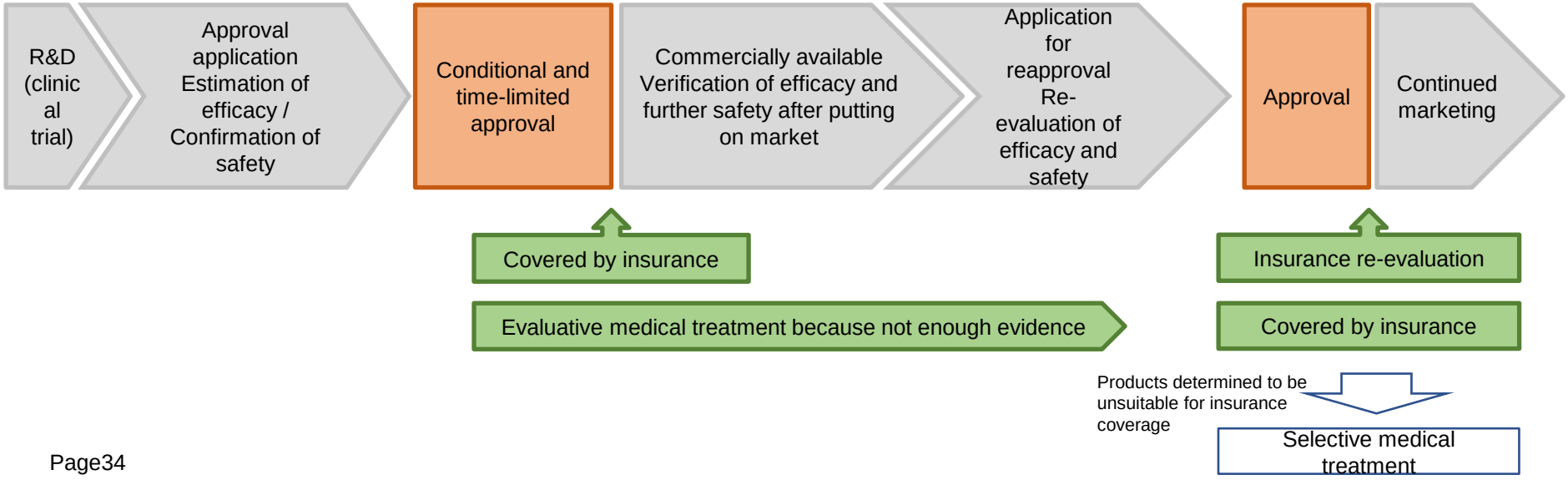
[Proposals and requests]

① Applying the “conditional and time-limited early approval system” like regenerative medicine products to programmed medical devices, and enabling early approval and insurance coverage, it will be re-evaluated (utilizing the challenge application framework) by using of additional data collected within a certain period after putting on market (e.g. RWD, etc.)

② If there is no evidence enough to be covered by health insurance, and if the company wishes, an evaluative medical treatment (advanced medical care A for which the company is the main body of application) is applied to ensure patient access. After introduction to clinical practice, RWD etc. will be used to evaluate insurance coverage.

③ For products that have obtained conditional and time-limited approval using ① and ②, even if approval is not obtained in the main review after a certain period of time, safety, etc. is confirmed at the time of the provisional review. so that it can be used continuously.

Framework for early introduction utilizing conditional and time-limited approval of regenerative medicine products (provisional)



Agenda

- Summary for the current year
- Administrative events and activity history
- Public and Private Sector Dialogue (Minister of Health, Labour and Welfare)
- Regular Meetings (Medical Division) Special materials, diagnosis and treatment equipment (program medical equipment)
  - Liaison committee of SaMD related organizations (METI)
- For the next fiscal year

Activity Policy of the Medical Fee Committee in 2023

(1) Optimization and evaluation of innovation technologies

1) Evaluation of **artificial intelligence** technology

2) On-line and remote robots

3) Integration of medical information to PHR (ICT infrastructure development)

4) Proper evaluation of **radiation therapy, nuclear medicine and other treatment**

5 Evaluation of the efficiency improvement of medical care and **reduction of burden** of medical professionals *

Proposal of a new evaluation criteria * + Proposal of a new insurance system (Challenge / Temporary approval / Mixed medical treatment)

(2) Measures against foreign price adjustments

(3) Continuous response to subdivision and rationalization of functional category

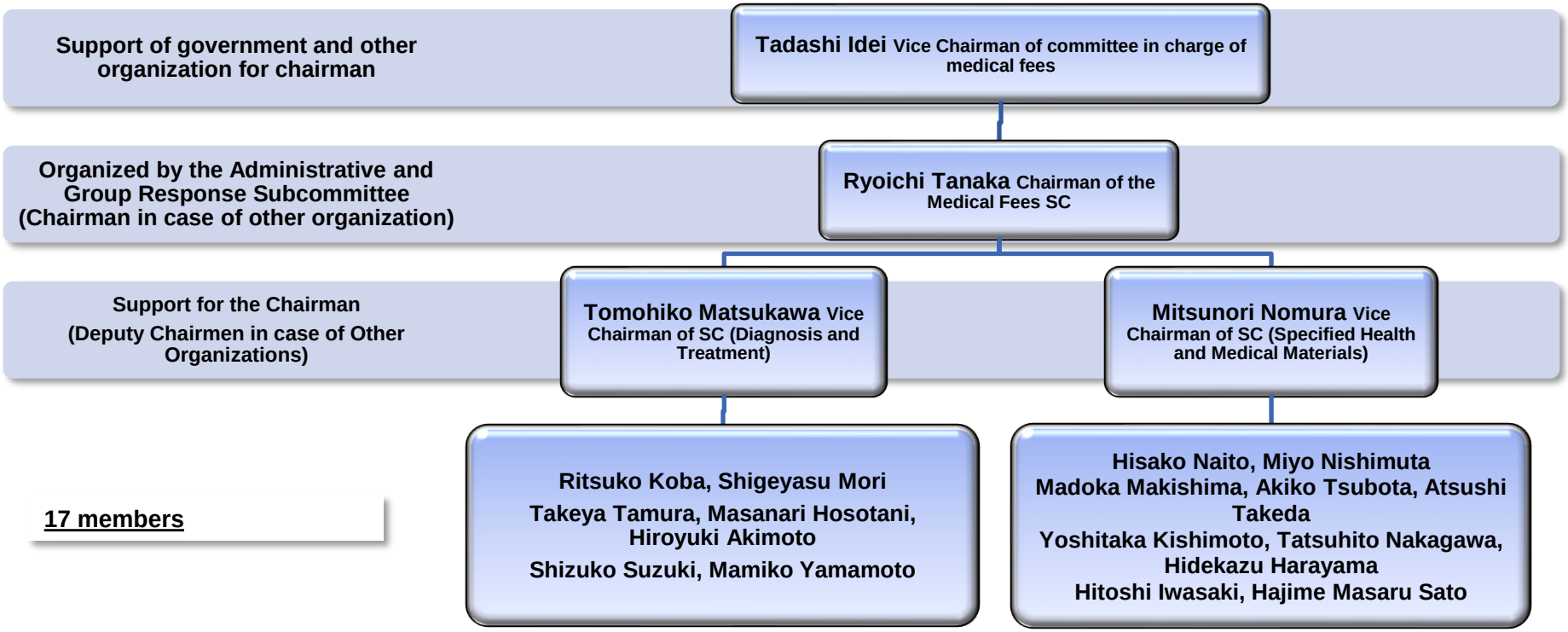
(4) Elimination of category - Relaxation of rules for withdrawal of unprofitable products (confirmation required)

(5) HTA : **Challenges and Responses to Stable Supply**

(6) Response in line with the community medical program policy (maintenance management and formulation of requirements for exposure control)

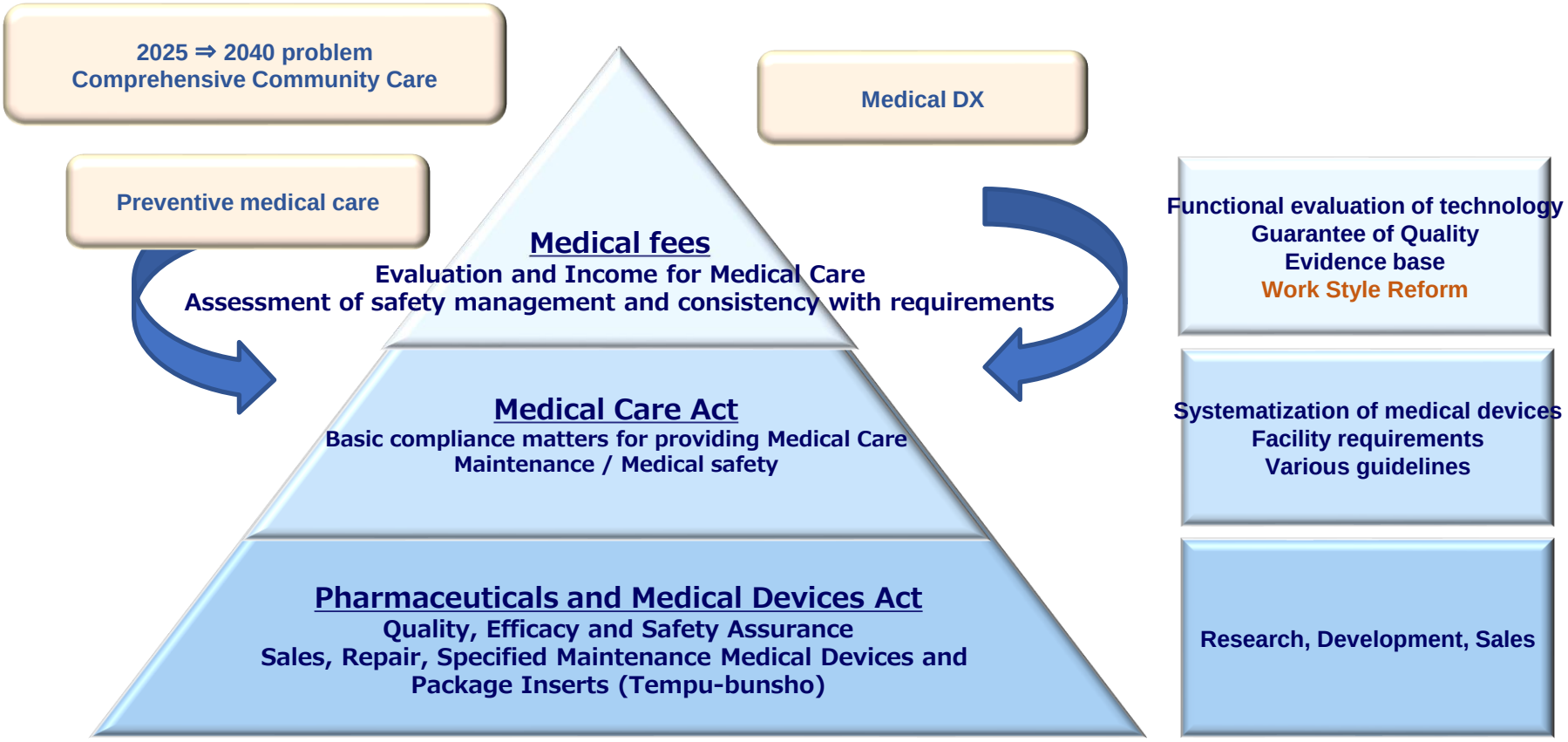
Lineup of the Medical Fee Subcommittee in anticipation of the next revision

- **Respond to rapidly changing products and applicable systems, and broadly recruit participation**
- **Encourage young members to participate in 3-poles conferences (EBC, JFMDA, AMDD), etc.**



Medical fees (covered by insurance) are the lifeline of companies.

- Towards the 2040 problem, the medical fee system will inevitably change due to the redesign of primary care and medical categories and the promotion of medical DX.
- Firmly secure our exit strategy (outcome) with practical benefits such as realization of earnings and insurance coverage



https://www.mhlw.go.jp/content/12401000/000517328.pdf

Participation in the Medical Fee Subcommittee

We ask for the cooperation of member companies.

Thank you for listening.