(* This is a provisional translation by an external company for reference purpose only. The original text is in Japanese.)

Fiscal Year 2024

Guidebook on Insurance Coverage for Medical Devices and In Vitro Diagnostics

December 2024

Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare

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Introduction "The purpose of this guidebook"

In Japan, the universal health insurance system allows everyone to receive medical care with peace of mind. Under the public health care insurance system, a "medical fee system" has been established for medical treatment performed at insured medical facilities, and the medical services, prices, requirements, etc., permitted for insured medical treatment are defined. For medical devices and in vitro diagnostics used in such medical treatment, there is an "Insured Medical Materials System," and procedures for insurance coverage are required in order for new devices and in vitro diagnostics to be used in insured medical treatment.

However, the medical fee system and insured medical materials system are complicated, and these systems themselves are revised every two years. As a result, some companies, and especially those considering marketing new medical devices or in vitro diagnostics, have difficulty understanding the systems themselves and the procedures for insurance application.

Within this context, the first edition of this guidebook was prepared in 2017, with the hope that it will serve as a reference for many entities, including companies considering marketing medical devices, and thus help to promote medical device development in Japan, by introducing the medical fee system and the insured medical materials system and by focusing on the steps in the application procedures and instructions for filling out forms. Additionally, a revised version was prepared in FY 2020 by adding in vitro diagnostics, taking into account the reforms of the insured medical materials system made in FY 2018 and 2020. In FY 2022, another revised version was prepared by adding software as a medical device (SaMD) which has been increasing in recent years. This year, revisions have been made based on revision of the medical fees and reform of the insured medical materials system in FY 2024.

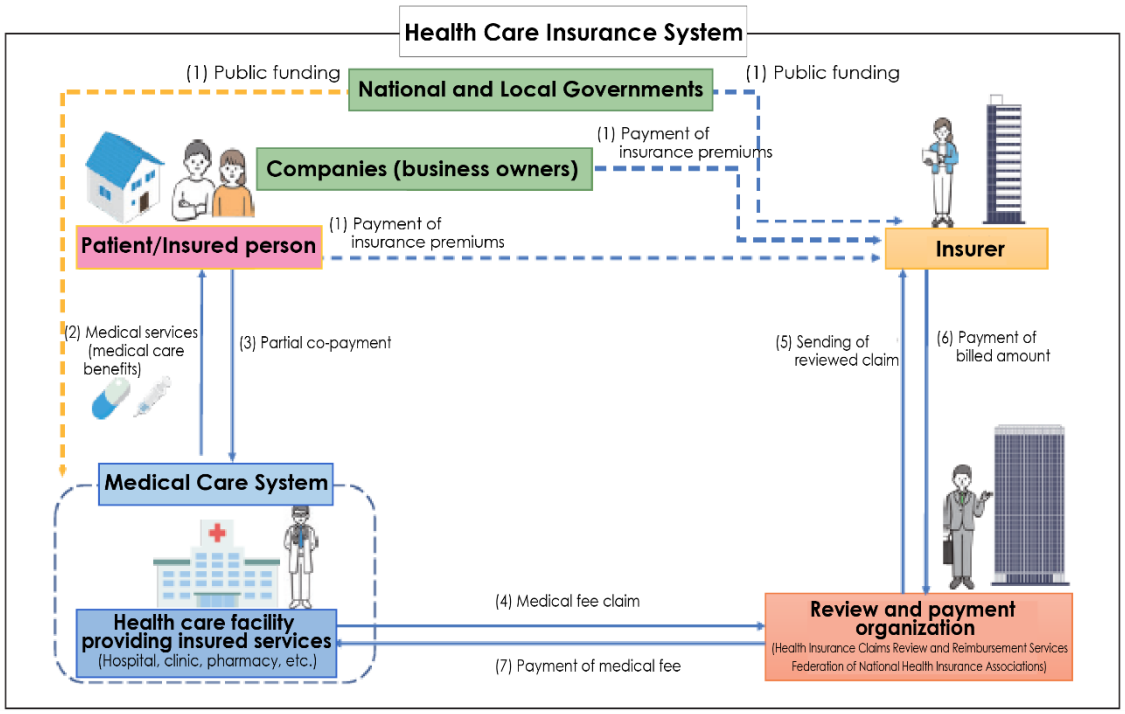
Regarding the mechanism of the system, simple terminology may be used or simplified diagrams may be included since clarity is prioritized. In addition, the system may be subject to changes due to future revision of the medical fees. Be sure to check the latest laws, regulations, etc.

1. Overview of the Public Health Care Insurance System

(1) Structure of the public health care insurance system

- Under the public health care insurance system, when a patient receives medical services from an insured medical facility, the insured medical facility is reimbursed for its "medical fees" by the insurer and the patient. The specific steps are shown in the figure below. The patients pay a portion of the medical expenses (30% for those of working age) at the counter. The insured medical facility then submits the receipt to the Review and Payment Agency, which reviews it and then bills each insurer, and the insurance benefits are paid to the insured medical facility through the Review and Payment Agency.
- This medical fee is calculated and billed based on the points table for medical fees. The points table for medical fees is a list of services (medical treatment) covered by public medical insurance, and at the same time, it is a price list that specifies the unit price and the requirements (facility standards and calculation requirements) for calculation (insurance claim) of each service (medical treatment). The points table for medical fees is displayed in “points” and not “yen,” and the current unit price per point is 10 yen.
- Generally, the amount claimed for insurance will be the "technical fee + specified insured medical materials fee + medication fee."

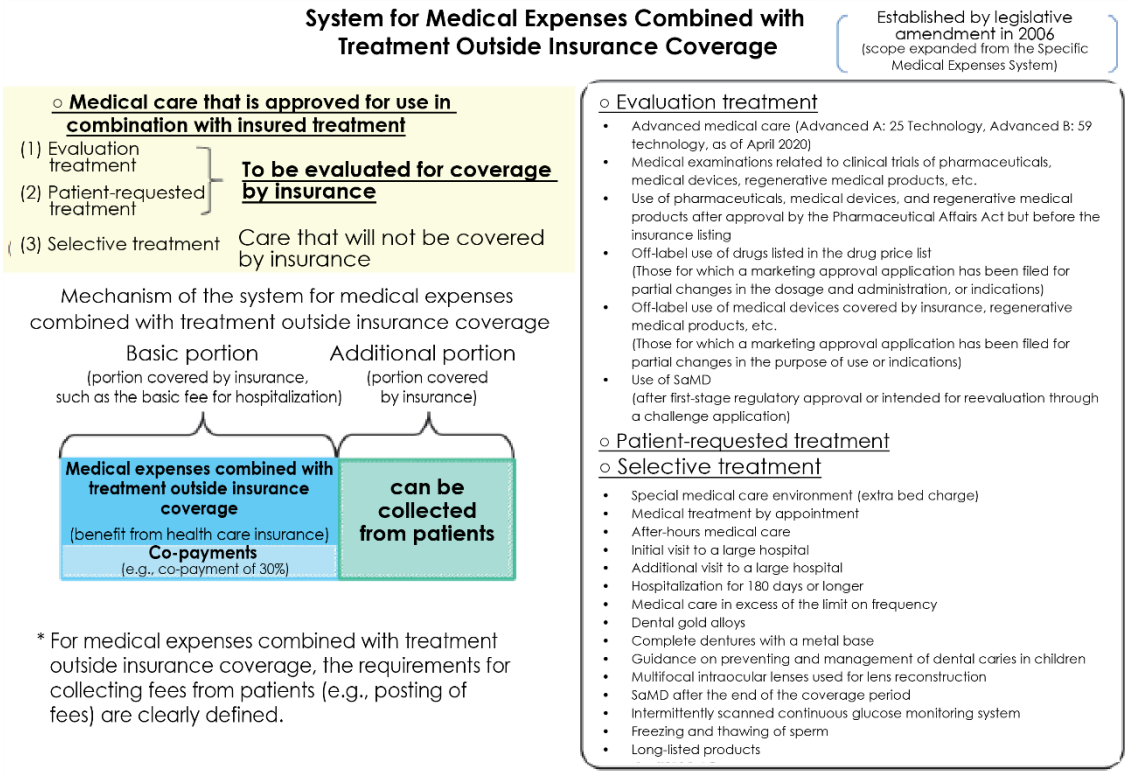
Chart 1 Structure of the Public Health Care Insurance System



(2) What is the System for Medical Expenses Combined with Treatment Outside Insurance Coverage?

- In Japan, when a patient receives an uninsured treatment that is not covered by public health care insurance, the full amount of the medical cost is borne by the patient, including treatment that would normally be covered by public medical care insurance.
- However, even when a patient receives medical treatment that is not covered by public health care insurance, if it is "evaluation treatment," "patient-requested treatment," or "selective treatment" as specified by the Minister of Health, Labor and Welfare, then it can be combined with insured medical treatment. In other words, the expenses for the portion that is the same as regular medical services (the basic portion such as examinations, testing, medication, hospitalization fees, etc.) are covered by public health care insurance as "medical expenses combined with treatment outside insurance coverage" in the same manner as typical insured medical treatment, and a portion of the expenses is borne by the patient. Expenses not covered by insurance are at the discretion of the patient, who pays the full amount to the insured medical facility.
- "evaluation treatment" and "patient-requested treatment" are systems to evaluate treatment for coverage by insurance, and include medical treatment related to clinical trials of advanced medical care and medical devices. In contrast, "selective treatment" is a system that does not assume coverage by insurance and includes medical treatment by appointment or after-hours treatment, medical procedures that exceed the number of times limited by medical fees, and multifocal intraocular lenses used for lens reconstruction.
- This system also involves insurance coverage for medical devices, so understanding the concept is important.

Chart 2 System for Medical Expenses Combined with Treatment Outside Insurance Coverage

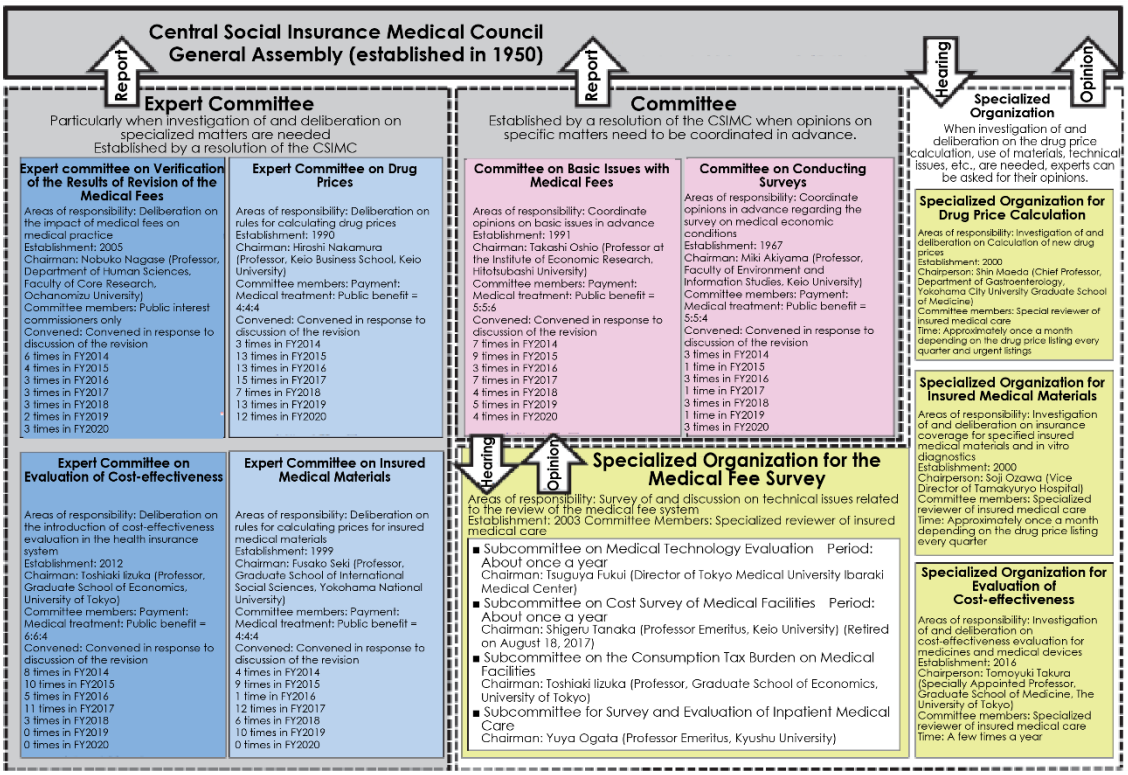


Source: MHLW website https://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000118805.pdf

(3) Overview of Revision of the Medical Fees

- The medical fee system is revised every two years, and the details of the revisions are discussed at the Central Social Insurance Medical Council (CSIMC), an advisory council under the jurisdiction of the MHLW (the secretariat is the Medical Economics Division, Health Insurance Bureau, MHLW).
- The CSIMC has expert committees and specialized organizations, as shown in Chart 3.
- Those that are mainly related to medical devices (insured medical materials) and in vitro diagnostics are the Expert Committee on Insured Medical Materials and the Specialized Organization for Insured Medical Materials. For medical devices (specified insured medical materials), the Expert Committee on Evaluation of Cost-Effectiveness and Specialized Organization for Evaluation of Cost-Effectiveness may be involved.
- The Expert Committee on Insured Medical Materials deliberates on the rules for calculating prices for insured medical materials and in vitro diagnostics. The Specialized Organization for Insured Medical Materials conducts surveys and deliberates on the insurance coverage of individual specified insured medical materials in normal times, and it reviews functional categories when revisions are made.
- Technical fees related to medical devices and in vitro diagnostics are reviewed by the Subcommittee on Health Technology Assessment of the Special Organization for Medical Fees, based on the proposals for evaluation of medical technology submitted by academic societies.

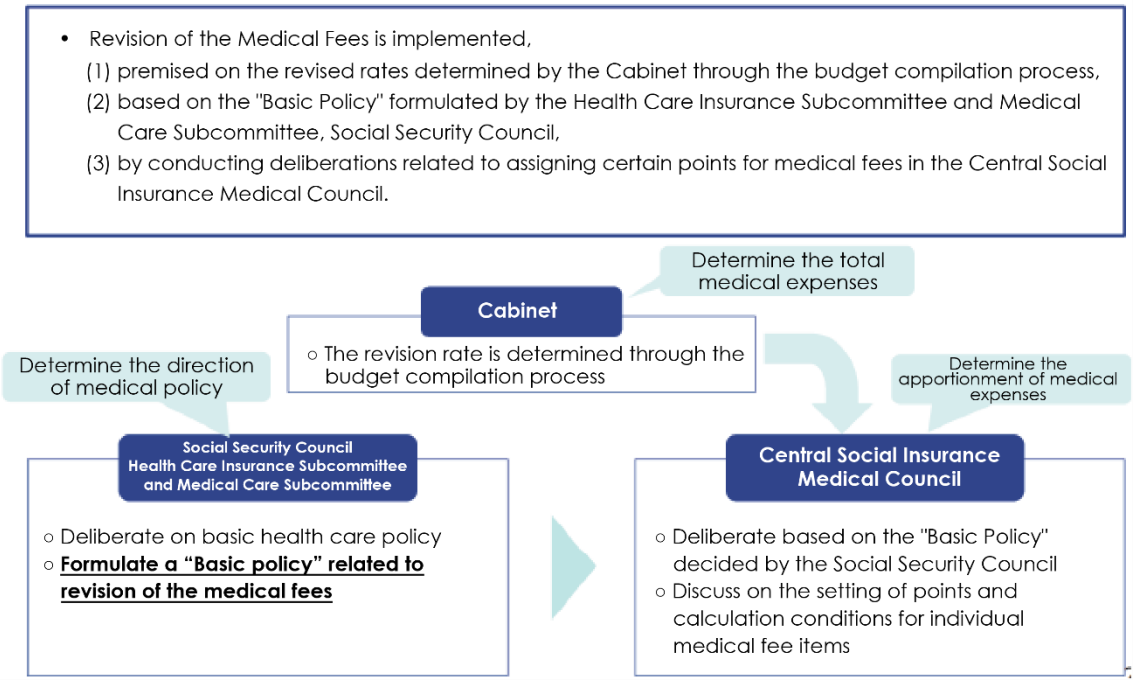
Chart 3 Organizations Affiliated with the Central Social Insurance Medical Council



Source: Documents from the Central Social Insurance Medical Council (March 23, 2022)

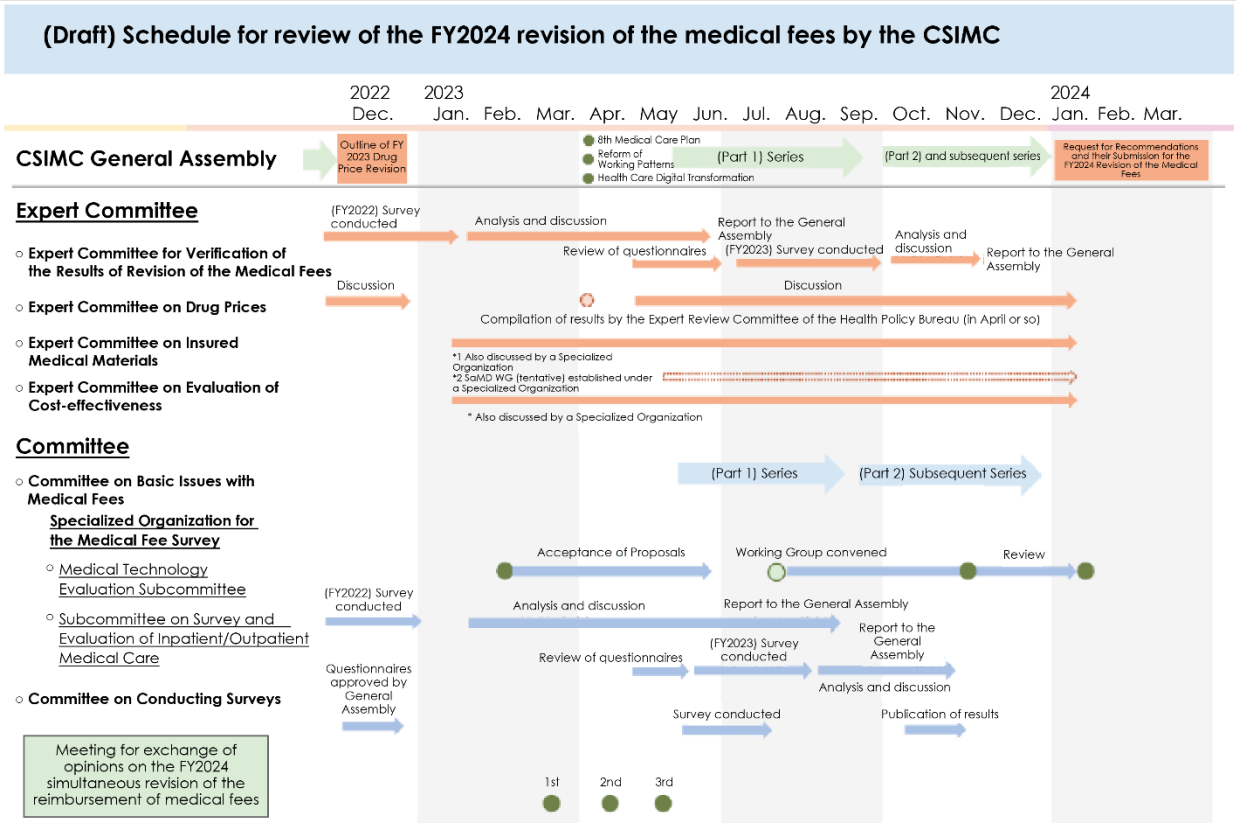
- Revision of the medical fees will be implemented in the following steps.
- In the two years prior to revision of the medical fees, the Central Social Insurance Medical Council begins discussions for the next revision and necessary surveys. Subsequently, in parallel with the survey conducted by the Central Social Insurance Medical Council, the Health Care Insurance Subcommittee and Medical Care Subcommittee of the Social Security Council deliberate on the basic policy for revision of the medical fees in the year prior to the revision, and the basic policy for the next revision is compiled around early December. Then, around late December, the Cabinet determines the revision rate through the budgeting process (the figure shown as "determination of total medical expenses," but to be precise, the "revision rate" is determined and announced). Based on the basic policy and the revision rate, the Central Social Insurance Medical Council then deliberates on the setting of points and calculation conditions for individual medical fees, and it compiles a report on the next revision usually around the beginning of February of the following year.
- These materials from the CSIMC are available on the MHLW website.

Chart 4 Steps in Revision of the Medical Fees



Source: Documents from the 166th Social Security Council Health Care Insurance Subcommittee (August 24, 2023)

Chart 5 Schedule for the Revision of Medical Fees in the FY 2024 by the Central Social Insurance Medical Council (image)



Source: Materials from the General Meeting of the Central Social Insurance Medical Council (January 18, 2023)

(4) Overview of the FY 2024 Revision of the Medical Fees

- In FY 2024, revision of the medical fees was carried out from the following four basic perspectives: (1) "Promotion of the attraction and retention of human resources and reform of working patterns, taking into account the current employment situation", (2) "furthering and promoting the community-based integrated care system and promoting the differentiation, enhancement, and coordination of medical functions, including a medical digital transformation, after 2025," (3) "Promoting safe, reliable, and quality medical care," and (4) "Improvement of the stability and sustainability of the medical insurance system through efficiency and optimization."
- For details on revision of the medical fees, refer to the MHLW website. (https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000188411_00045.html).

Chart 6 Overview of the FY 2024 Revision of the Medical Fees

Basic Perspectives on and Specific Directions for Revision

(1) Promoting the attraction and retention of human resources and the reform of working patterns, taking into account the current employment situation

[Key Issues]

[Examples of specific directions]

- ○ Efforts to attract and retain human resources and raise wages for healthcare professionals
- ○ Improving working conditions, task sharing/task shifting, and promoting team medical care so that each professional can fully demonstrate a high level of expertise
- ○ Evaluation of efforts to promote the use of ICT to improve operational efficiency and alleviation of harsh working conditions such as long working hours
- ○ From the perspective of ensuring regional medical care and facilitating functional differentiation, ensuring the establishment of a needed emergency medical care system, including a review to ensure the effectiveness of reduced working hours
- ○ Expanding evaluations based on diverse working patterns
- ○ Addressing the uneven distribution of medical personnel and resources

(3) Promotion of safe, reliable, and quality medical care

[Examples of specific directions]

- ○ Response in light of rising prices, including food and utility costs
- ○ Evaluation of the system to ensure that patients can receive safe and reliable medical care
- ○ Promotion of evaluation with a focus on outcomes
- ○ Appropriate evaluation of areas that require focused responses (pediatric care, perinatal care, emergency care, etc.)
- ○ Promotion of efforts for effective and efficient disease management and prevention of progression in response to the increase in lifestyle-related diseases
- ○ Prevention of the progression of oral diseases, improved response to diminished oral function, and promotion of dental care that considers quality of life
- ○ Appropriate evaluation of pharmacies according to their family pharmacist role in the community, promotion of the shift of pharmacy and pharmacist services from item-centered to person-centered, and evaluation of hospital pharmacist services
- ○ Promotion of the evaluation of the role of pharmacies as drug supply bases that meet the needs of local patients and residents, taking into account the business conditions of pharmacies
- ○ Appropriate evaluation of innovation and ensuring a stable supply of medical products, with a view to transforming the structure of the pharmaceutical industry

(2) Furthering and promoting community-based integrated care systems for after 2025 and promoting the differentiation, enhancement, coordination of medical functions, including a medical DX

[Examples of specific directions]

- ○ Effective utilization of medical information and promotion of telemedicine through promotion of a medical DX
- ○ Efforts to further and promote community-based integrated care systems, including the promotion of medical care that takes everyday activities into account
- ○ Coordination and promotion of rehabilitation, nutritional management, and oral care
- ○ Evaluation of inpatient medical care according to patient condition and medical functions deemed necessary
- ○ Functional differentiation and enhancement of outpatient medical care
- ○ Efforts to establish a regional medical care system that can respond to emerging infectious diseases
- ○ Evaluation of the functions of family doctors, family dentists, and family pharmacists
- ○ Ensuring quality at-home medical care and visiting nursing

(4) Improve the stability and sustainability of the health care insurance system through increased efficiency and appropriateness

[Examples of specific directions]

- ○ Promotion of the use of generic drugs and biosimilars and reviewing the insurance benefits for long-listed drugs
- ○ Utilizing the cost-effectiveness evaluation system
- ○ Appropriate evaluation based on current market prices
- ○ Effective utilization of medical information and promotion of telemedicine through promotion of a medical DX (previously listed)
- ○ Evaluation of inpatient medical care according to patient condition and medical functions deemed necessary (previously listed)
- ○ Functional differentiation and enhancement of outpatient medical care (previously listed)
- ○ Promotion of efforts for effective and efficient disease management and prevention of progression in response to the increase in lifestyle-related diseases (previously listed)
- ○ Promotion of the proper use of medicines through collaborative efforts by physicians, hospital pharmacists, and pharmacy pharmacists
- ○ Promotion of the evaluation of the role of pharmacies as drug supply bases that meet the needs of local patients and residents, taking into account the business conditions of pharmacies (previously listed)

Source: "Basic Perspectives on and the Specific Direction for the Revision" excerpted from the "Overview of the FY 2024 Revision of the Medical Fees," Medical Economics Division, Health Insurance Bureau, MHLW.

(5) Overview of the Points Table for Medical Fees

- Medical fees are based on "points" assessed for each form of medical treatment. This information is summarized in the points table for medical fees, which consists of three tables: the Points Table for Medical Fees, the Points Table for Dental Fees, and the Points Table for Pharmacy Fees. The points table for medical fees is a listing that specifies the scope of insured medical treatment and that can also be regarded as a price list.
- For medical treatments performed at insured medical facilities other than dental clinics, the amount of the insurance claim (including patient copayments) is calculated based on the points table for medical fees.
- The points table for medical fees consists of the following:

Chart 7 Composition of the Points Table for Medical Fees

Chapter 1 Basic Treatment Fees
Part 1 Initial Visit Fee and Additional Visit Fee
Section 1 Initial Visit Fee
Section 2 Additional Visit Fee
Part 2 Hospitalization Fees
Section 1 Basic Fee for Hospitalization
Section 2 Points added to the Basic Fee for Hospitalization
Section 3 Specified Hospitalization Fee
Section 4 Basic Fee for Surgery involving a Short-term Stay
Chapter 2 Special Treatment Fees
Part 1 Guidance/Management
Section 1 Guidance/Management Fee
Section 2 Deleted
Section 3 Specified Insured Medical Material Fee
Part 2 At-home Medical care
Section 1 At-home Patient Care and Guidance Fee
Section 2 At-home Care Guidance and Management Fee
Subsection 1 At-home Care Guidance and Management Fee
Subsection 2 Points added to the At-home Care Guidance and Management Material Fee
Section 3 Drug Fee
Section 4 Specified Insured Medical Material Fee
Part 3 Testing
Section 1 Specimen Testing Fee
Subsection 1 Specimen Testing Fee
Subsection 2 Specimen Testing and Interpretation Fee
Section 2 Deleted
Section 3 Biopsy Fee
Section 4 Diagnostic Puncture and Specimen Collection Fee
Section 5 Drug fee

Subsection 8 Heart/Blood Vessels
Subsection 9 Abdomen
Subsection 10 Urinary system/Adrenal glands
Subsection 11 Genitals
Subsection 12 Deleted
Subsection 13 Surgical Management Fee
Section 2 Blood Transfusion Fee
Section 3 Points added for Surgery involving Medical Devices
Section 4 Drug Fee
Section 5 Specified Insured Medical Material Fee
Part 11 Anesthesia
Section 1 Anesthesia Fee
Section 2 Nerve Block Fee
Section 3 Drug Fee
Section 4 Specified Insured Medical Material Fee
Part 12 Radiotherapy
Section 1 Radiotherapy Management and Treatment Fee
Section 2 Specified Insured Medical Material Fee
Part 13 Pathology
Section 1 Pathology Specimen Preparation Fee
Section 2 Pathology and Interpretation Fee
Chapter 3 Medical Fee for Residents of Long-term Care Health Facilities (omitted)
Chapter 4 Transitional Measures (omitted)

- Each medical fee includes items that specify conditions to calculate (billing insurance) the points for that fee. These conditions include "facility standards" and "calculation requirements."
- Facility standards are the standards that facilities are required to meet. The calculation requirements are requirements regarding the medical treatments performed and the applicable patients.

2. Overview of the Insured Medical Materials System

(1) What is the Insured Medical Materials System?

- For medical devices[1], the handling of insured medical treatment and procedures for insurance coverage differ depending on which evaluation category the device belongs to in terms of insurance. The insurance mechanism for medical devices is called the insured medical materials system, and it is reviewed every two years as part of the revision of the medical fees.
- This system is based on the ideas presented in the CSIMC Recommendations[2] in 1993.

Chart 8 Principles for Evaluation of Insured Medical Materials

(Reference) Principles for Evaluation of Insured Medical Materials (from the CSIMC Recommendations in 1993)

1. Insured Medical Materials that should be Evaluated as Additions to the Technical Fee **(A2)**
(1) Those for which the technology used is limited: Example) Ultrasonic coagulation incision device
(2) Those on loan from medical facilities: Example) Oxygen tank for in-home care
2. Insured medical materials that should be evaluated as an integral part of specific technical fees on a bundled basis **(A2)**
Materials integrated with technology: Examples) Laparoscope port, electroencephalograph
3. Insured medical materials that should be evaluated on average as an integral part of technical fees on a bundled basis **(A1)**
Inexpensive materials: Examples) Intravenous blood collection needles, tubes
4. Insured medical materials for which prices should be set (other than 1. to 3.) **(B, C1, C2)**
(1) Those with a relatively high cost compared to related technical fees: Example) Artificial heart valve
(2) Those with a large market size: Examples) PTCA catheter, pacemaker

Source: Compiled based on the "Overview of the FY 2022 Reform of the Insured Medical Materials System: Reference," Medical Economics Division, Health Insurance Bureau, MHLW

- Currently, the insurance coverage categories for medical devices include "A1 (bundled)," "A2 (specifically bundled)," "A3 (existing technology, with changes)," "B1 (existing functional category)," "B2 (existing functional category, with changes)," "B3 (limited-time premium for improvement)," "C1 (new function)," "C2 (new technology)," "R (remanufacturing)," and "F (items not fit for insurance coverage)" (see Chart 9).
- For medical devices that fall under "A1 (bundled)," "A2 (specifically bundled)," or "A3 (existing technology, with changes)," the price of the product is included in the medical fee points (technical fee).[3] Therefore, insured medical facilities cannot claim the price of the medical device separately from the medical fee points (technical fee).
- In contrast, for medical devices that fall under "B1 (existing functional category)," "B2 (existing functional category, with changes)," or "B3 (limited-time premium for

[1] This guidebook uses the terms "medical device" and "insured medical materials" in accordance with legal and system descriptions. Generally, an "insured medical material" refers to a medical device that is (or will be) covered by insurance, while "medical device" refers to a medical device in a broader sense, regardless of insurance coverage (insured medical materials are included in medical devices).

[2] The document's official title is the "Recommendations for the Evaluation of Specified Insured Medical Materials," Central Social Insurance Medical Council (September 24, 1993).

[3] More precisely, the devices are referred to as being "evaluated on a bundled basis."

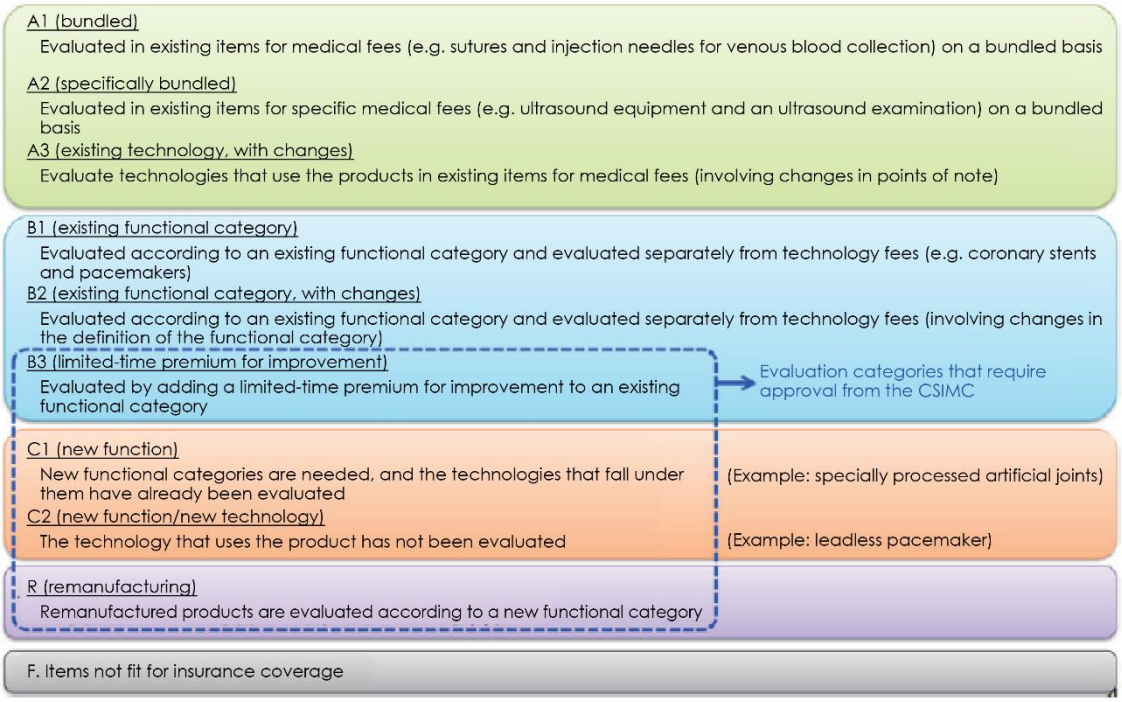
improvement, provisional functional category)," insured medical facilities can claim the price of the medical devices separately from the medical fee points (technical fee). In this case, the price in the insurance claim for the medical device is determined for each "functional category" of insured medical materials.

- "B2 (existing functional category, with changes)" involves changes to the definition of the existing functional category, and "B3 (limited-time premium for improvement)" is the price for the existing functional category with the limited-time premium for improvement added.
- The price of medical devices that fall under "C1 (new function)" and "C2 (new technology)" and in which the relevant products are listed as specified insured medical materials can be claimed by insured medical facilities separately from the medical fee points (technical fee) as in the case of B1, B2, and B3. However, unlike B1, B2, and B3, they do not fall into any of the existing functional categories, and therefore a new functional category is required. In addition, "C2 (new technology)" is for when technology that uses the medical device is not listed in the points table for medical fees.
- "R (Remanufactured)" is a remanufactured single-use medical device (remanufactured product)[4]for which the original medical device[5]belongs to an existing functional category or provisional functional category, which does not correspond to C1 or C2, and for which a new functional category as a remanufactured product is required.

[4] This refers to single-use medical devices (medical devices that can be used only once) that have been remanufactured (inspected, disassembled, cleaned, sterilized, or otherwise treated as necessary for the purpose of new manufacturing and sales) after use, that have the same quality, efficacy, and safety as the original medical device, and that have the same purpose of use or effect as the original medical device.

[5] This refers to single-use medical devices that are made available for remanufacturing and that have not yet been remanufactured.

Chart 9 Evaluation Categories for Insured Medical Materials



Source: "Discussion of the review of the insured medical materials system (Part 1)," Central Social Insurance Medical Council, Expert Committee on Insured Medical Materials (September 20, 2023)

(Note) The definitions for each evaluation category are provided on pages 1-2 of the appendix to "Handling of Insurance Coverage of Medical Devices" (Sanjo Notification No. 0214-5, Notification HIB No. 0214-4, February 14, 2024), Notification from the Director-General of the Health Policy Bureau and the Director-General of the Health Insurance Bureau, MHLW.

(2) What are Specified Insured Medical Materials?

- Among insured medical materials, medical materials for which the average cost required to provide medical materials at insured medical facilities is determined separately are referred to as "specified insured medical materials."[6]
- For Specified insured medical materials, insurance reimbursement prices (the amounts that insured medical facilities can claim) are set for each "functional category." This is called the "standard material price."[6] In the points table for medical fees, each medical practice (technical fee) is indicated in "points," while the standard material prices are indicated in "yen."
- The functional category is defined in the notification as "a category determined by the Minister of MHLW after hearing the opinions of the Central Social Insurance Medical Council, as a group of specified insured medical materials that are recognized as similar in terms of structure, purpose of use, indications, etc."[6]

Chart 10Examples of Specified Insured Medical Materials and their Prices (Material Price Standards)

Functional category	Material price
・・・	・・・
130 Cardiac Surgery Catheter	
(1) Catheter for percutaneous coronary angioplasty	
①General catheter	29,000 yen
②Infusion catheter	157,000 yen
③Perfusion catheter	146,000 yen
④Cutting catheter	110,000 yen
⑤Non-slip catheter	95,000 yen
⑥Restenosis-inhibiting catheter	173,000 yen
(2) Catheter to pass through coronary artery stenosis	36,700 yen
・・・	・・・

- Each functional category is defined respectively in "Definition of Specified Insured Medical Materials,"[7] and products that meet this definition are in the same functional category and have the same reimbursement prices.
- The standard prices for each functional category are published in Ministry of Health, Labour and Welfare Notification "Specified Insured Medical Materials and Material Prices (Material Price Standards)."In principle, the material price standards are revised every two years as part of revision of the medical fees.
- If the product does not fall under any of the existing functional categories and does not fall under A1, A2, or A3, the need for a new functional category will be examined. In short, an examination is conducted to determine whether the product falls under C1 or C2 (when listing as a specified insured medical material is desired), and if it is recognized as C1 or C2, a new "functional category" and reimbursement price will be determined.

[6] These are defined in Chapter 1 of the Appendix to "Standards for calculating insurance reimbursement prices for specified insured medical materials," Notification from the Director-General of the Health Insurance Bureau, MHLW, (Notification HIB No. 0214-3, February 14, 2024).

[7] The definitions of each functional category can be found in "The definition of Specified Insured Medical Materials" (HIB/MED Notification No. 0305-12, March 5, 2024), Notification from the Director of the Medical Economics Division, Health Insurance Bureau, MHLW, and the Director of the Dental Care Administration, Health Insurance Bureau, MHLW.

(3) Features of Specified Insured Medical Materials

- Compared to pharmaceuticals, specified insured medical materials have the following characteristics.
- For specified insured medical materials, the insurance reimbursement prices are determined for each functional category, which is called "listing by functional category." In contrast, insurance reimbursement prices for pharmaceuticals are determined for each brand, and this is called "brand-specific listing."

Chart 11 Characteristics of the System for Specified Insured Medical Materials (based on a comparison to pharmaceuticals)

	Pharmaceuticals	Specified insured medical materials
Market size	Approximately 9.6 trillion yen Number of high-cost items: over 100 billion yen: 15 items Number of products: Approximately 18,000 products	Approximately 1.1 trillion yen Number of high-cost categories: Over 5 billion yen, approximately 50 categories Number of products: Approximately 1,300 functional categories, approximately 200,000 yen products
Usage	Patients taking medication themselves or being administered medication at medical facilities	Mainly used by physicians (tools for technology)
Direction of Innovation	Focus on novel mechanisms	Mainly improvements and modifications based on experience in clinical use (lighter weight, improved operability, etc.)
Outline of the mechanism of action	• After administration, the ingredients have an effect by acting on the body. (effects on immunity, genome, etc.)	• Few of the products themselves change, and many of them are implanted in the body over a long period of time or involve the skill of physician. (→ An "improvement premium" has been created) • Development and use of products based on the same principle Examples: Pacemaker → implantable cardioverter defibrillator, pain relief stimulator, etc.
Replacement of products on the market	Older drugs are often sold and used for long periods of time	Because improvements and modifications are constantly being made, older products are rarely sold or used for a long period of time.

Source: "Discussion of the review of the insured medical materials system (Part 1)," Central Social Insurance Medical Council, Expert Committee on Insured Medical Materials (September 20, 2023)

(4) History of the System for Specified Insured Medical Materials

- In the past, insured medical materials were reimbursed at the purchase price in the medical facility (purchase price billing). Subsequently, when the CSIMC met in 1993, general rules for setting prices for medical materials were discussed and "Recommendations for the Evaluation of Specified Insurance Medical Materials" were compiled.
- Based on the Recommendations, the CSIMC established price calculation rules, taking into account opinions from related industries, and the system has been reviewed since then.
- Based on the discussion of the insured medical materials system up to FY 2002, the system has been repeatedly reviewed since 2004 from the viewpoint of correcting the difference between domestic and foreign prices and evaluating innovation in groundbreaking new medical materials.

Chart 12 History of the Setting of Major Price Calculation Rules under the System for Specified Insured Medical Materials

Time	Major responses
October 1958	• Announcement of film reimbursement prices (classified by function) • Reimbursement for "Splints" and other items at the prefectural purchase price as "specified medical treatment materials"
November 1967	• Insurance listing of dialyzers (called "cellophane for dialysis" at the time) (purchase price reimbursement).
March 1968	• Insurance listing of pacemakers (purchase price reimbursement)
February 1978	• Inclusion of dialyzers in the procedure fee for artificial kidneys
June 1981	• Separation of dialyzers from the procedure fee for artificial kidneys • Announcement of dialyzer reimbursement prices (classified by function)
April 1990	• Inclusion of some specified insured medical materials such as surgical staplers in the procedure fee
April 1992	• Announcement of reimbursement prices for pacemakers by brand • Insurance coverage of intraocular lenses (evaluated in the procedure fee from the beginning)
September 1993	• CSIMC recommendations (Prices will thereafter be set based on these recommendations) Some issues were pointed out. Medical facilities tend to lack cost-consciousness regarding medical materials that are reimbursed at the purchase price, hampering action by the principle of competition to form market prices. Reimbursement prices for the same medical supplies vary among medical facilities.
April 1994	• Announcement of reimbursement prices for 7 items (*) including artificial joints (classified by function) * Artificial joints (knee joints, hip joints), artificial heart valves (mechanical valves, biological valves), disposable heart-lung machines, balloon catheters for balloon pumping, catheters for percutaneous coronary angioplasty
April 1996	• Announcement of reimbursement prices for 16 items (*) including guide wires for angiography (classified by function) * Guide wires for angiography, sheath introducer sets and dilators for angiography, catheters for angiography, guide wires for catheters used in percutaneous coronary angioplasty, disposable catheters for placement in the bladder, optional parts for artificial hip joints and knee joints, internal splints for fixation, sets for sclerotherapy for esophageal varices, sets for endoscopic ligation of esophageal varices, cannulas for extracorporeal circulation, guiding catheters for catheters used in percutaneous coronary angioplasty • Review of the grouping of dialyzers • Inclusion of special sutures and lower back braces in the procedure fee
April 1998	• Review of the revision of standard material prices to an extent • Addition of facility standards for pacemakers, PTCA, etc.

April 2000	• Special exception for FY 2000 only with reduction to an extent (setting of the range of adjustment) • Responding to international price fluctuations in precious metals for dental use (setting of the range of adjustment)
October 2000	• Review of functional categories of pacemakers, PTCA catheters, and artificial joints • Abolition of the prefectural purchase price system (actual purchase price system) • Outline of the procedures for determining categories for new products (including provisional prices for C1) • Outline of the procedures for setting new functional categories when material prices are revised • Establishment of expert committee for insured medical materials
April 2002	• A method for calculating the reimbursement price of specified insured medical materials for new functional categories (C1 and C2) was developed for the case when the definition of existing functional categories will be reviewed and for the case when new functional categories will be established. • When establishing a new functional category, the comparative method based on similar functional categories was used as a general rule, and if there was no similar functional category, the cost calculation method was used to perform calculation. • If the calculated price differed significantly from the current market price in other countries, a price adjustment was made to an extent. • From the viewpoint of optimizing the prices of existing insured medical materials, re-calculation was implemented for fields that meet certain requirements. • Existing functional categories were reviewed when material prices were revised.
April 2004	• Review of the standards for price adjustments in calculating the prices of specified insured medical materials that require the establishment of new functional categories (C1 and C2) • Specified insured medical materials assigned as decision category C1 were covered by insurance four times a year. (Note) C2 (new technology) is covered by insurance when coverage is extended to the new medical technology. • Review of price adjustment rules for recalculation • Review of the revision of standard material prices to an extent
April 2006	• Insurance coverage four times a year for assigned as decision category C2 (new technology) • Review of the revision of standard material prices to an extent • Expansion of the scope of specified insured medical materials to be examined for pertinence to the conditions for reimbursement • Review of measures to mitigate sudden changes during recalculation
April 2008	• Review of adjustment premiums • Review of the price adjustment rules for new medical materials and in recalculation • Review of the revision of standard material prices to an extent • Expression of objection
April 2010	• Review of the price adjustment rules for new medical materials and in recalculation • Handling of product cost in cost calculation method • Review of the wording of the requirements for the improvement premium • Review of the revision of standard material prices to an extent • Clarification of rules regarding the withdrawal of insurance coverage • Clarification of procedures for materials that are extremely difficult to supply and not fully reimbursed • Review of rules for occasional revision of the prices of precious metals for dental use
April 2012	• Review of the price adjustment rules for new medical materials and in recalculation • Addition of Australia to the Foreign Price Reference System • Handling of expenses related to post-marketing surveillance (PMS) in cost

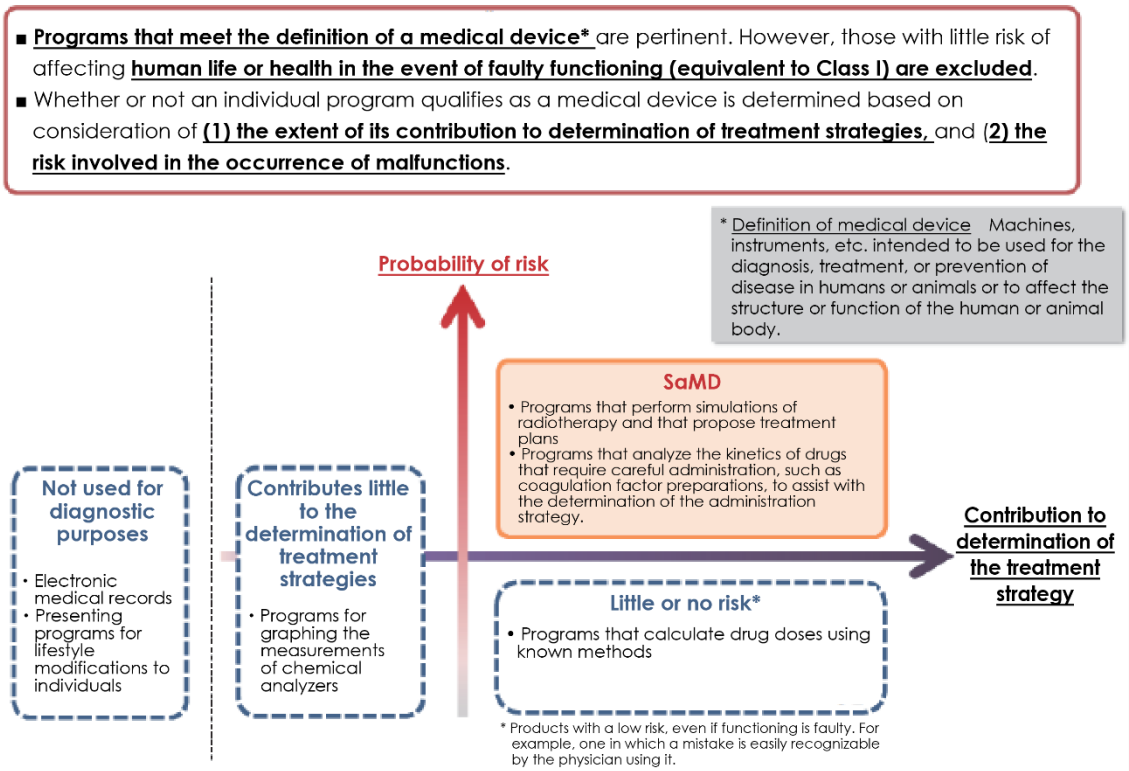
	calculation method • Review of the requirements for adjustment premiums (clarification of what is eligible for a premium) • Establishment of an evaluation for expedited insurance listing • Response to sudden fluctuations in exchange rates
April 2014	• Review of price adjustments related to new functional categories (method of calculating average foreign prices, response to products with a markedly low ratio to the average foreign price) • Review of the evaluation of innovation related to new functional categories (continued evaluation of expedited insurance listing, use of the operating margin in the cost calculation method, special exceptions for functional categories, addition of requirements for adjustment premiums) • Matters related to the recalculation of existing functional categories (review of recalculation rates, response to changes in the consumption tax rate) • Review of standard material prices • Review of functional categories • Response to ensure a stable supply
April 2016	• Review of price adjustments related to new functional categories (review of comparison standards, refinement of responses to products with a markedly low ratio to the average foreign price) • Review of the evaluation of innovation related to new functional categories (evaluation of highly needed medical devices, continuation of evaluation and review of requirements related to expedited insurance listing, continuation of special exceptions for functional categories, addition of a concept for recalculation based on comparative method based on similar functional categories, clarification of the concept of category C2, etc.) • Review of recalculation of existing functional categories (review of comparison standards, review of the method of calculating average foreign prices) • Accelerated insurance coverage
April 2018	• Review of price adjustment in new functional categories (review of the method of calculating average foreign prices) • Review of the evaluation of innovation for new functional categories (establishment of a challenge application system for products that require evaluation based on actual past use, establishment of a limited-time premium for improvement for replacement products, establishment of a system for deducting the functional category of an existing product when a new product that is simpler than an existing product is developed, response to products designated under the SAKIGAKE approval review and designation system, continuation of evaluation and review of requirements for expedited insurance listing, continuation and expansion of special exceptions for functional categories, and continuation of evaluation of highly needed medical devices) • Review of recalculation of existing functional categories (review of the method of recalculating average foreign prices) • Trial introduction of cost-effectiveness • Establishment and simplification of the procedures for the categories of insurance coverage for insured medical materials and in vitro diagnostics
April 2019	• Introduction of cost-effectiveness evaluation
April 2020	• Review of price adjustment in new functional categories (review of comparison standards for foreign price adjustments) • Review of the evaluation of innovation for new functional categories (the adjustment premium in the cost calculation method is changed from operating profit only to the entire price (the price calculated before the premium is applied), establishment of a premium rate in according to the extent of cost disclosure, a premium for products with a markedly high unit price, price calculation for remanufactured single-use medical devices, expansion of the applicable products for challenge applications, etc.) • Review of recalculation of existing functional categories (introduction of

	the recalculation of market expansion, lowering of the lower limit of recalculated prices based on the average foreign price) • Introduction of a special exception for the timing of insurance coverage • Simplification of procedures for insurance coverage for products similar to those in category B3 • Response to ensure a stable supply
April 2022	• Review of evaluation for innovation related to new functional categories -Expansion of the scope of applications related to reevaluation based on actual past use (challenge applications) (medical devices that are evaluated as an integral part of bundled technical fees and that involve highly innovative technologies also made eligible) - Establishment of evaluation of SaMD (medical management premium for SaMD) - Review of the evaluation of pioneering medical devices and specific use medical devices - Review of adjustment premiums related to new functional categories (pioneering premium, specific use premium) • Review of foreign price adjustments for newly listed products (review of the method of calculating the average foreign price) • Review related to recalculation of an existing functional category (review of comparison standards for foreign price adjustments and the method of calculating the average foreign price) • Review of procedures for insurance coverage (both A3 and B2 were covered the following month when the categories were assigned, an insurance coverage request form can be submitted for notification in relation to the system of procedures to confirm a change plan for a medical device that will be improved, procedures for insurance coverage of SaMD) • A stable supply of medical devices (standardization of reporting formats) • Creation of a specialized organization for insured medical materials
June 2024	• Evaluation of innovation related to new functional categories - Expansion of the scope of applications for reevaluation based on actual past use (challenge applications) - Evaluation of economically superior medical devices - Evaluation of in vitro diagnostics used to test for rare diseases - Evaluation of SaMD • Review related to the recalculation of existing functional categories (changes in the comparison standards for foreign price adjustments, responses to unprofitable functional classifications, and recalculation for market expansion) • Review of the procedures for insurance coverage (review of the timing of insurance coverage, clarification of B2 minor, etc.) • Stable supply of medical devices (e.g., allowing a request for cooperation from marketing authorization holders, distributors, industry associations for alternative products, etc.)

(5) What is SaMD?

- Over the past few years, a variety of new programs have been developed and are now being used thanks to the development of science and technology. Like conventional medical devices, some of those new products are intended to be used for the diagnosis or treatment of diseases, so the Pharmaceutical Affairs Law was amended in 2013, and the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 145 of 1960, hereinafter referred to as the "Pharmaceutical and Medical Device Act") was enacted. Therefore, standalone programs are also now subject to regulation under the Pharmaceuticals and Medical Devices Act.
- SaMD regulated under the Pharmaceuticals and Medical Devices Act is (1) a program (software) intended to be a medical device, (2) a program that may affect the life and health of the patient (or user) if it does not function as intended, and (3) a program with little or no risk of affecting human life or health.
- In addition, general medical devices equivalent to Class I do not fall under the category of SaMD.

Chart 13 The Concept of the Pertinence of SaMD under the Pharmaceuticals and Medical Devices Act



Source: "Outline of the FY 2022 reform of the insured medical materials system (Reference)" (December 22, 2021), Central Social Insurance Medical Council

- The basic approach to whether a program is a medical device or not is indicated in the "Guidelines on the Pertinence of Programs as Medical Devices" (Partially revised PSEHB/MDE Notification No. 0331-1 and PSEHB/CND Notification No. 0331-4, March 31, 2023).
- In addition, an "SaMD Case Study Database" is available on the MHLW website[8]. This case studies will explain what sort of programs fall under the category of SaMD.

(6) Evaluation of SaMD

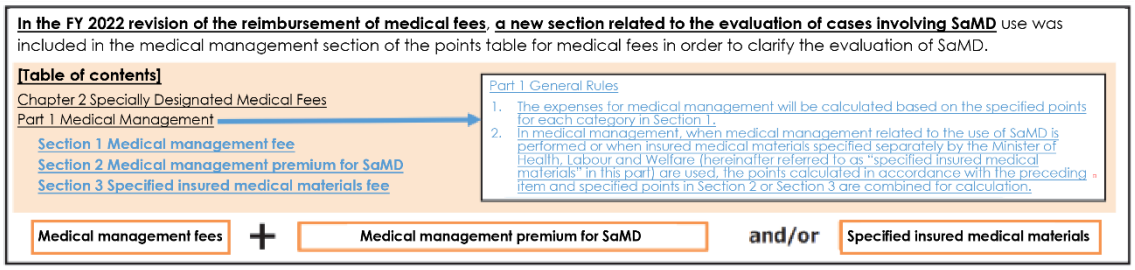
- SaMD with pertinence as a medical device includes, depending on its characteristics,
  (1) Products that are evaluated on average as a part of technical fees on a bundled basis,
  (2) Products that are evaluated in addition to specific technical fees,
  (3) Products that are evaluated in a bundled and integral manner as part of specific technical fees, and
  (4) Products that are evaluated as specified insured medical materials.

- When an insurance coverage request form is submitted, SaMD will, like other medical devices, be evaluated by the Central Social Insurance Medical Council's Specialized Organization for Insured Medical Materials based on its characteristics.
- Moreover, the FY 2022 reform of the insured medical materials system indicated that
  - "when evaluating SaMD, the evaluation will include its reflection in facility standards, based on the characteristics of each product taking into account the perspective of reform of physicians' working patterns"
  - and "Coverage by insurance is not assumed. If a product is selected by the patient and it is SaMD, the system of selective treatment (the system for medical expenses combined with treatment outside insurance coverage) may be utilized" as has been done thus far.

- Examples of the practical use of SaMD are indicated in 4 depictions of programs with different characteristics.[9].
- The details of the FY 2024 revision can be found on the MHLW's website[10], and the concept of evaluation of SaMD in terms of medical fees has been clarified, taking into account the diversity of clinical purposes of use. When SaMD is used by patients for medical management outside of medical facilities and use of the SaMD improves clinical efficacy in terms of medical management in comparison to existing methods, it will, in principle, be evaluated as a specified insured medical material. Accordingly, "SaMD Guidance and Management Fees" were created to evaluate guidance related to and management of medical care using SaMD.

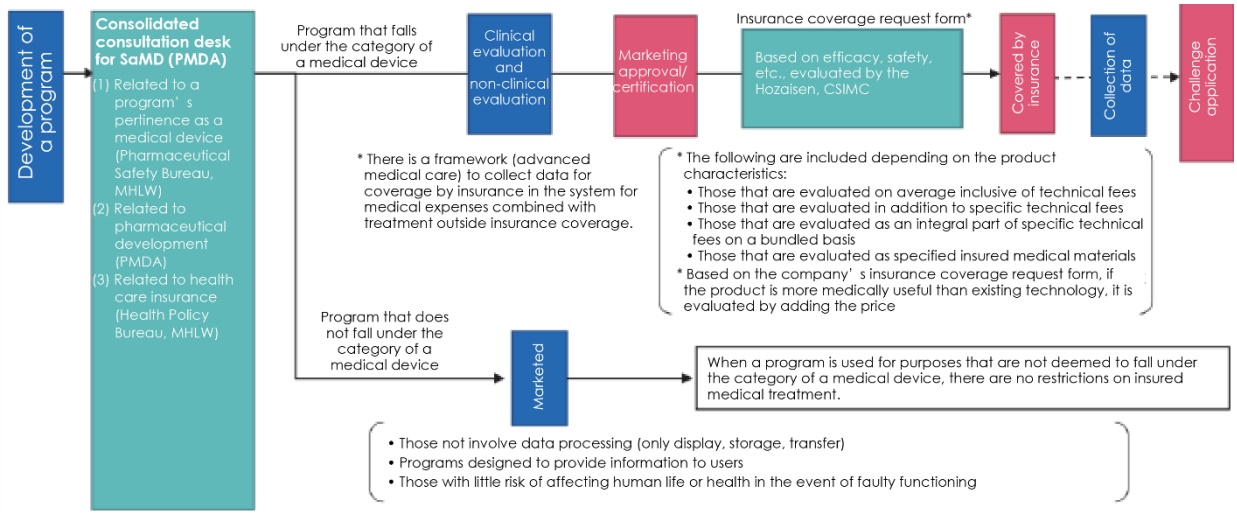
[8] https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000179749_00004.html
[9] Pages 10 to 13 in the meeting materials on the MHLW's website (https://www.mhlw.go.jp/stf/shingi2/0000212455_00038.html)
[10] https://www.mhlw.go.jp/content/12400000/001251540.pdf

Chart 14 Evaluation of Medical Fees for SaMD



Source: "Discussion of the review of the insured medical materials system (Part 3)," Central Social Insurance Medical Council, Expert Committee on Insured Medical Materials (November 17, 2023)

Chart 15 Steps in Insurance Coverage for SaMD



- To clarify and refine the determination regarding a program's pertinence as a medical device, specific cases are posted on the MHLW website as needed.
- Based on the perspective of the reform of physicians' working patterns, if, for example, assisting physicians with their practice helps to ensure the same quality of care with fewer healthcare professionals, this may be reflected in facility standards.
- For care that will not be covered by insurance and care selected by the patient, the mechanism of selective treatment (the system for medical expenses combined with treatment outside insurance coverage) may be utilized.

Source: "Discussion of the review of the insured medical materials system (Part 3)," Central Social Insurance Medical Council, Expert Committee on Insured Medical Materials (November 17, 2023)

Chart 16 Criteria for Evaluating the Usefulness of SaMD

[Criteria for evaluation of the usefulness of SaMD] (extracted from of the outline of the FY2024 reform of the insured medical materials system)

(1) SaMD that facilitates the performance of existing examinations, the formulation of treatment plans, or the treatment itself, such as surgery.

- If the use of the SaMD clearly improves the clinical effectiveness of the existing technology to be supported, it will be assessed as an addition to the related technology fee.
- In cases where the number of healthcare professionals or the deployment of physicians with specialized knowledge and experience is required as a facility standard for the existing technology to be supported, if the use of the SaMD:
  - enables implementation with a smaller number of personnel,
  - results in treatment performed by physicians other than those with specialized knowledge and experience achieving efficacy equivalent to that of treatment performed by physicians with specialized knowledge and experience,

  the facility standard may be relaxed. In cases where the deployment of healthcare professionals is not required as a facility standard for the existing technology to be supported, this alone, in principle, will not be evaluated as an addition.
- If the use of the SaMD reduces the working hours of healthcare professionals, this alone, in principle, will not be evaluated as an addition.

(2) SaMD necessary for the actual performance of the intended examinations

- The technology will be evaluated as a whole, including the parts involving the program, and will be evaluated in the same way as medical devices in the normal C2 (new technology) category.

(3) SaMD used to control medical devices for medical treatment

- An evaluation will be conducted when the use of the SaMD clearly improves the clinical effectiveness of the medical device to be supported compared to when the SaMD is not used.
- In this case, if the medical device to be controlled is evaluated as being included in the technology fees, it will be evaluated, as a general rule, as an addition to the technology fees, and if the medical device in question is a specified insured medical material, the SaMD itself or the combination of the SaMD and the medical device to be supported will be evaluated as a specified insured medical material.

(4) Medical devices used by patients themselves outside medical facilities for medical management

- In principle, the SaMD will be evaluated as a specified insured medical material if its use results in improved clinical effectiveness of medical management or similar practices compared to conventional methods.

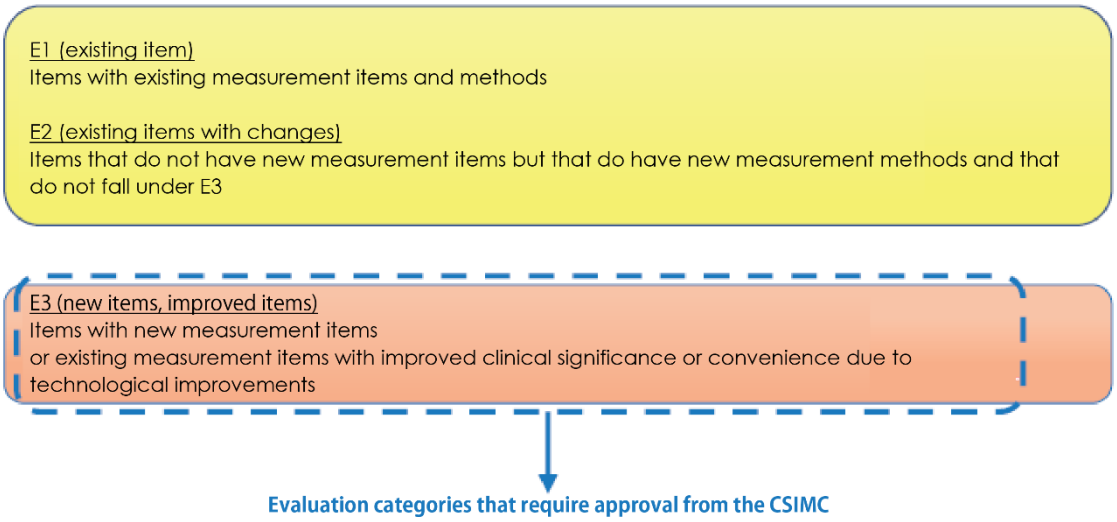
Source: "Clarification of the evaluation criteria for SaMD" excerpted from the "Overview of the FY 2024 Revision of the Medical Fees," Medical Economics Division, Health Insurance Bureau, MHLW.

3. Overview of the System for in vitro Diagnostics

(1) Overview of Insurance Coverage for in vitro Diagnostics

- The price of in vitro diagnostics is included in medical fees as a "technical fee," and prices are set for each test rather than for individual in vitro diagnostics (test reagents).
- Currently, in vitro diagnostics are classified into three categories for insurance coverage: "E1 (existing items)," "E2 (existing items with changes)," and "E3 (new items, improved items)."
- "E1 (existing items)" are items that have existing measurement items and a method of measurement. Specifically, they are existing items for which measurement items and a method of measurement are both listed in the "Points Table for Medical Fees" or "Notes on Implementation due to Partial Revision of the Method of Calculating Medical Fees" (Notification regarding Points of Note).
- "E2 (Existing items with changes)" are items with measurement items that are not new[11]but the method of measurement is new and items that do not fall under E3.
- "E3 (new items, improved items)" are items with measurement items that are new or with existing measurement items with improved clinical significance[12], convenience, etc.[13]due to technical improvements.

Chart 17 Evaluation Categories for in vitro Diagnostics



Source: Prepared based on the "Overview of the FY 2018 Reform of the Insured Medical Materials System," MHLW

[11]"Measurement items (methods) that are not new" and "Existing measurement items (methods)" mean that the measurement item (method) is already included in the "Points Table for Medical Fees" or the "Notification regarding Points of Note."
[12]"Improved clinical significance" means that superiority, such as improved sensitivity compared to existing items or enabling more accurate identification of diseases or better decisions regarding treatment strategies, has been objectively recognized in clinical trials.
[13]"Improved convenience" means being able to concretely prove that a new method or an improvement on an existing method has increased medical usefulness and economic efficiency. (For details about the footnotes on this page, refer to "Guidelines for Insurance Coverage of In Vitro Diagnostics" from the Japan Clinical Diagnostics Association)

(2) History of Insurance Coverage for in vitro Diagnostics

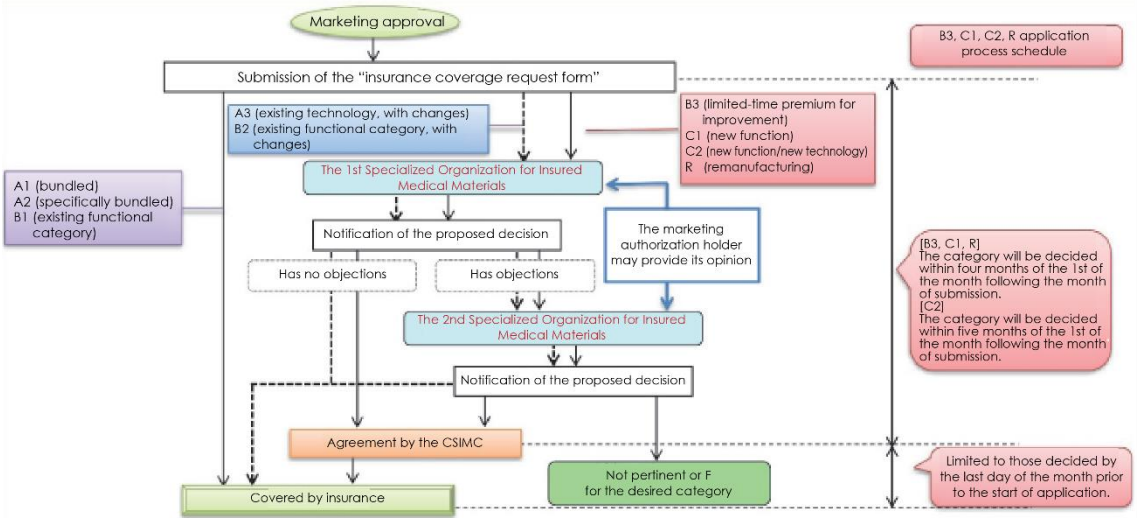
- The procedures for coverage of in vitro diagnostics by insurance were clarified in "Handling of Rules on Insurance Coverage related to Medical Instruments and In Vitro Diagnostics" (Notification PB No. 156/Notification HIB No. 9, February 19, 1987) and "Notes on Handling of the Rules on Insurance Coverage for Medical Instruments and In Vitro Diagnostics" (PB/EAD Notification No. 12, HIB/MED Notification No. 3, February 19, 1987) and came into effect on March 1, 1987.
- Since then, the system has been reviewed appropriately, and when medical fees were revised in FY 2014, improved items were added to the definition of the E3 category that previously included only new measurement items.
- Due to revision of the medical fees in FY 2016, in vitro diagnostics, like medical devices, became subject to deliberation by the Specialized Organization for Insured Medical Materials and the Expert Committee on Insured Medical Materials.
- In the FY 2018 revision of the medical fees, the format for an insurance coverage request form was announced, the requirements for evaluation categories were revised, and the procedures to apply for the E2 category were simplified.
- In the FY 2024 revision of the medical fees, a new system was established to evaluate in vitro diagnostics designated by pharmaceutical affairs for use in rare diseases and in vitro diagnostics for companion diagnostics that are anticipated to seldom be used. In addition, the revision clearly indicated that if the request only involves adding an additional testing method to existing test items, like B2 minor for medical devices, and the change is considered to be minor and approved by the Chairman of the Specialized Organization for Insured Medical Materials, the change will be classified as E2 minor.

4. Mechanism of Insurance Coverage for Medical Devices and in vitro Diagnostics

(1) Mechanism of Insurance Coverage for Medical Devices

- The procedures for insurance coverage vary depending on the insurance evaluation category of the medical device (Chart 18). For details, refer to "5. How to apply for new insurance coverage."Therefore, the evaluation category for the medical device that you seek to have covered by insurance needs to be determined before proceeding with the application procedures. Determining the evaluation category that the SaMD falls under may be particularly difficult due to its highly individualized nature. In such cases, use of the "SaMD Consolidated Consultation Desk (General Consultation on SaMD)" as described below is recommended to conduct pre-consultation.
- Medical devices to be covered by insurance must be approved or certified under the Pharmaceuticals and Medical Devices Act or a notification of those devices must be accepted.

Chart 18 Steps from Application to Insurance Coverage (Insured Medical Materials)



* For SaMD, prior to an examination by the Specialized Organization for Insured Medical Materials (Hozaisen), confirmation will be made that development, modification, etc. has been completed and sales can begin without delay after insurance coverage, and the details of the confirmation will be reported at the Hozaisen.

[Initiation of insurance coverage]

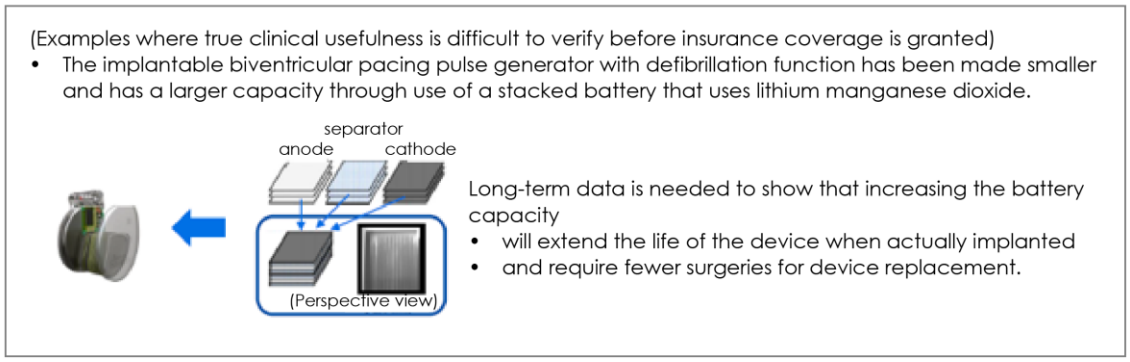
- ○ A1 (bundled): 20 days after the date of submission of the insurance coverage request form (the date of approval or certification granted for those separately specified on a bundled basis)
- ○ A2 (specifically bundled)/B1 (existing functional category): The 1st of the following month for submissions made by the 10th every month
- ○ A3 (existing technology, with changes) / B2 (existing functional category, with changes): The 1st of the month following the month in which the category is determined
- ○ C1 (new function), C2 (new technology)*, B3 (limited-time premium for improvement), R (remanufacturing): Four times a year (March, June, September, and December)
  - * For medical devices used to assist in determining the indications for pharmaceuticals, insurance coverage may be granted, as an exception, from the 1st of the month following the month in which the insurance coverage for the medical device was determined, taking into account the insurance coverage status of the pharmaceuticals.

Source: "(Draft) Outline of the FY 2024 Reform of the Insured Medical Materials System," Central Social Insurance Medical Council General Meeting (December 20, 2023).

(Challenge application)

- Some medical devices are implanted in the body for long periods of time or involve highly innovative technology, and verifying the final evaluation items before they are covered by insurance can be difficult. In response, a new system called a "challenge application" was established in the FY 2018 revision to cover medical devices that are evaluated as specified insured medical materials among products requiring evaluation based on actual past use. This system allows for re-evaluation of the pertinence of the product to new functional categories once it is covered, based on actual past use, when aspects cannot be evaluated during product introduction. The scope of items that are eligible for this system was expanded in FY 2020.

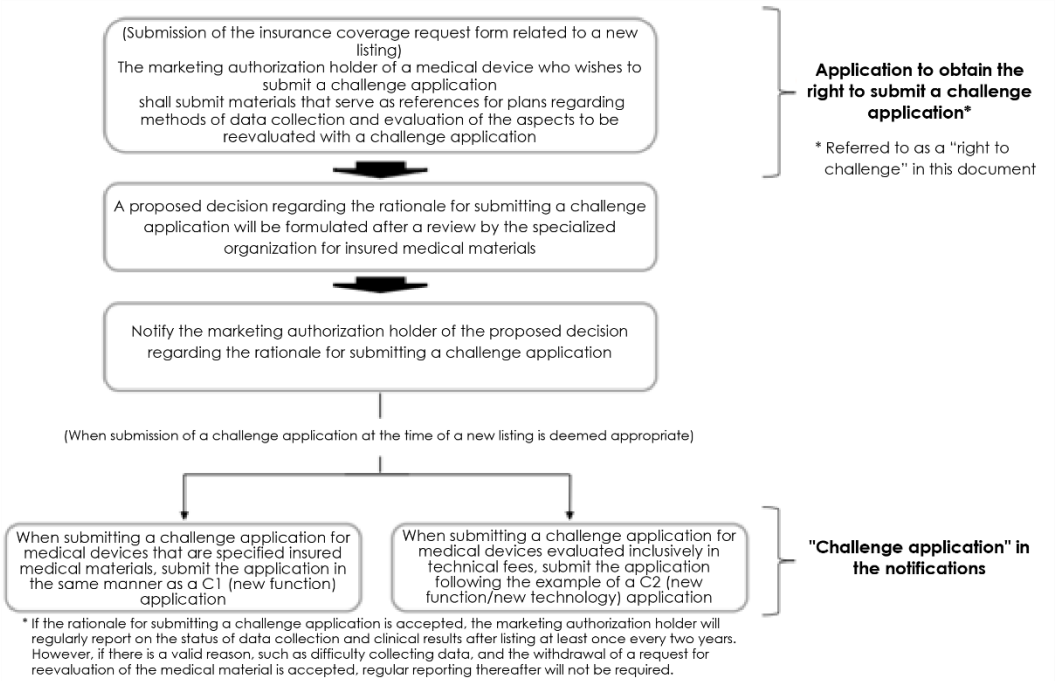
Chart 19 Examples where a Product's True Clinical Usefulness is Difficult to Verify Before It is Covered by Insurance



Source: "Overview of the FY 2022 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

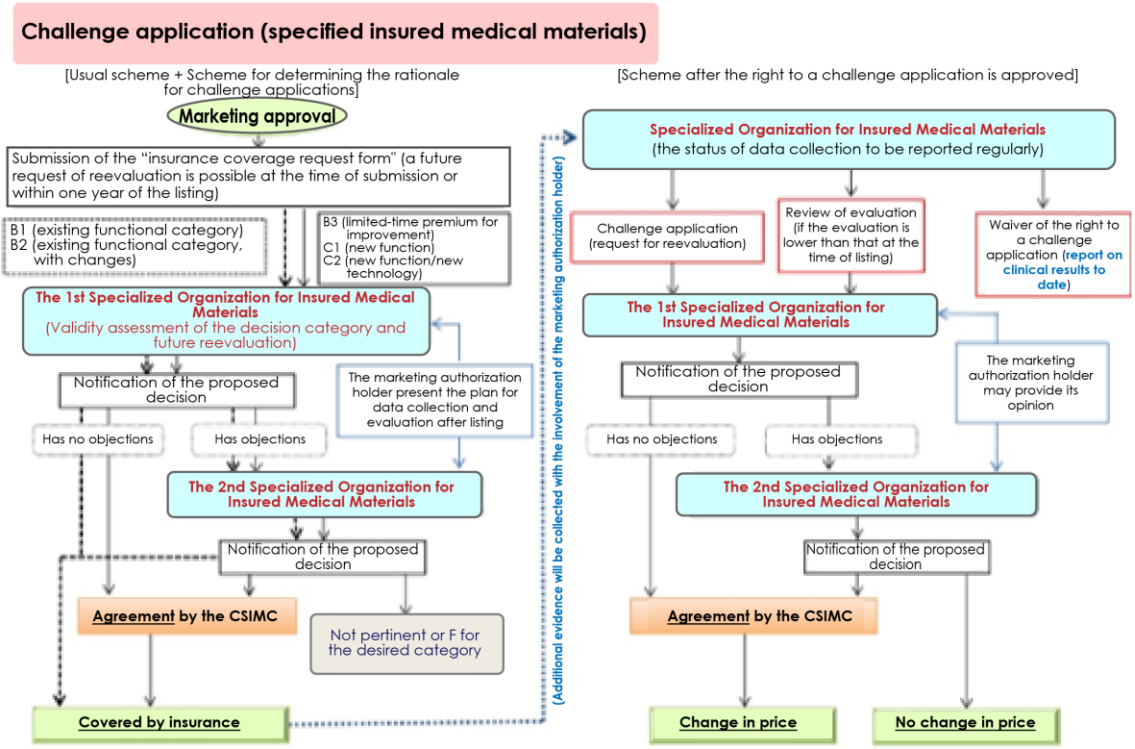
- In the FY 2022 revision, medical devices that are evaluated as an integral part of bundled technical fees and that involve highly innovative technologies were also made eligible for a challenge application. This means that A1, A2, A3, and C2 also became eligible for challenge applications.
- The FY 2024 revision clarified that applications related to the obtaining of a right to a challenge can be submitted up to one year after insurance coverage is provided and that a product is eligible for a challenge application when data are prospectively collected with the involvement of the marketing authorization holder after acquisition of the right to a challenge. In vitro diagnostics also became eligible for a challenge application.

Chart 20: Steps for an Application Related to a Challenge Application (Terminology Organized)



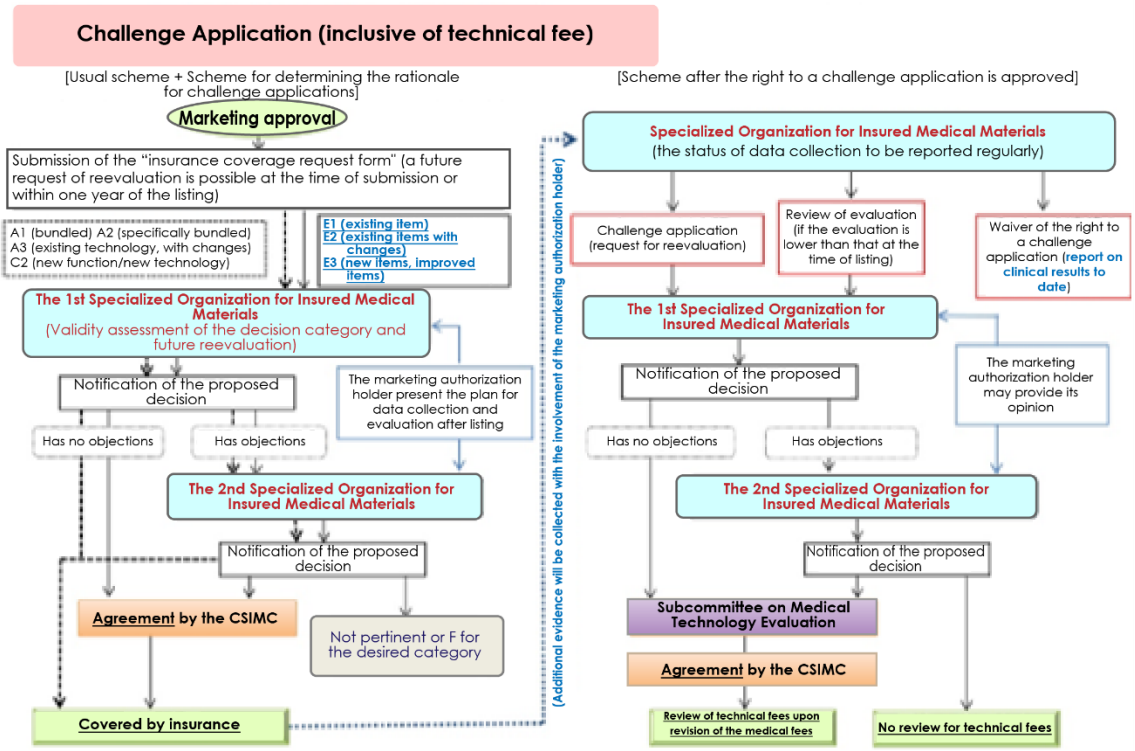
Source: "FY 2024 Review of the Insured Medical Materials System," Central Social Insurance Medical Council, Expert Committee on Insured Medical Materials (January 17, 2024)

Chart 21 Steps for a Challenge Application [Specified Insured Medical Material]



Source: "Overview of the FY 2024 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

Chart 22 Steps for a Challenge Application [Technology fee included]



Source: "Overview of the FY 2024 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

- If a challenge application is planned, materials that will serve as a reference for the plan for data collection and evaluation methods for the aspects to be reevaluated through a challenge application upon submission of an insurance coverage request form need to be submitted.
- The following items are presented as a plan for data collection and methods of evaluating data after listing.

Chart 23 Plan for Data Collection and Evaluation in a Challenge Application after a Product is Covered by Insurance

Plan for Data Collection and Evaluation after Listing
● **Applicable patients**: Patients for whom this product is applicable ● **Existing treatments (comparative control)**: Existing standard treatments for applicable patients ● **Current issues**: Current clinical issues to be resolved ● **Efficacy of the product**: Efficacy of the product as a solution to the current issues ● **Reasons efficacy cannot be evaluated at the time of insurance coverage** ● **Method of evaluation** • Test type • Test purpose • Applicable patients • Number of patients and the rationale for that number • Enrollment period and evaluation period • Evaluation items • Analysis Plan

Source: "Overview of the FY 2022 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

(Pioneering Medical Devices, Specific Use Medical devices)

- The "SAKIGAKE approval review and designation system" was established to designate pharmaceuticals that are developed ahead of the rest of the world and that are expected to have prominent efficacy in the early clinical trial stage and to facilitate early practical use with various types of support. The system became law as the system for designation of "Pioneering Medical Devices" by amendment of the Pharmaceuticals and Medical Devices Act (Article 77-2, Paragraph 2).
- For medical devices to meet largely unmet medical needs, such as those used for pediatric diseases, "Specific Use Medical devices" have been similarly legislated (Article 77-2, Paragraph 3).
- For pioneering medical devices and specific use medical devices, the evaluation was reviewed as follows in the FY 2022 revision. If the product is designated as the medical device, it will receive preferential treatment in terms of evaluation.

Chart 24 Evaluation of Pioneering Medical Devices and Specific use Medical Devices

Evaluation of Pioneering Medical Devices and Specific Use Medical Devices

Pursuant to Article 77-2, Paragraph 2 or 3 of the Pharmaceuticals and Medical Devices Act, the evaluation of items designated as pioneering medical devices or specific use medical devices will be reviewed as follows.

Name	Designation requirements	Addition due to a device's designation	Relaxation of the comparative level of foreign price adjustments	Exceptions to the functional category
Orphan medical devices	(1) Number of patients affected (2) Medical necessity (3) Development potential	○	○	○
Pioneering medical devices	(1) Breakthrough in treatment/diagnostic methods (2) Seriousness of the target disease (3) Extremely high efficacy against target diseases (4) Intention for early development and application ahead of the rest of the world	× → ○ (※1)	× → ○	○ (※3)
Specific use medical devices	(1) For use in the diagnosis, treatment, or prevention of pediatric diseases (including addition of indications) (2) Significantly under met for the needs for the intended use (3) Exceptional utility with regard to the intended use	× → ○ (※2)	× → ○	× → ○

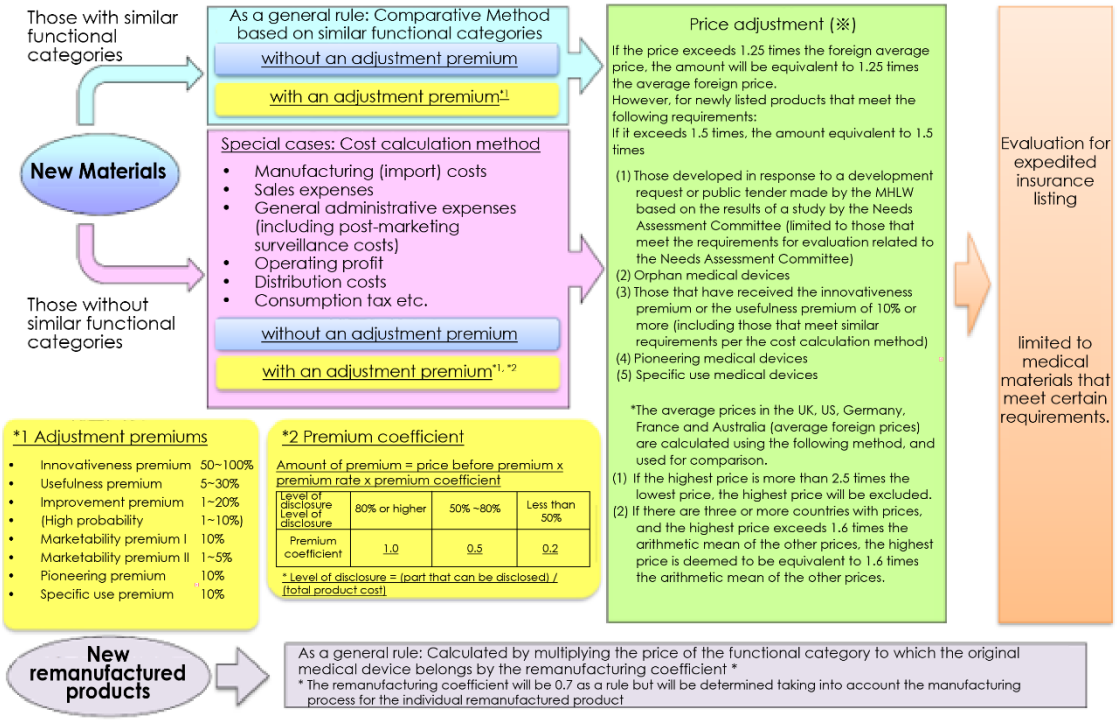
*1 If the product becomes eligible for a premium due to its being designated as a pioneering medical device, evaluation for its expedited insurance listing will not be applied.
*2 If the product becomes eligible for a premium due to its being designated as a specific use medical device, the improvement premium (2) will not be applied.
*3 Name changed from the "SAKIGAKE approval review and designation system," which is the current system.

Source: "Overview of the FY 2022 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

(2) Method of Calculating Standard Material Prices for New Functional Categories

- "New Functional Category" refers to a functional category created to include newly listed products that are recognized as clearly differing from those defined in existing functional categories (structure, intended use, efficacy or effectiveness, etc.) due to new development, invention, or improvements or innovations in structure, operation, etc.[14]
- For remanufactured products, a new functional category will be established separate from the existing functional category that includes the original medical device that is being remanufactured as a product.
- There are two methods for calculating standard material prices for a new functional category: the "comparative method based on similar functional categories" and the "cost calculation method."
- In principle, "comparative method based on similar functional categories" is used. The "cost calculation method" is a special exception only for when there is no similar functional category.

Chart 25 Method of Calculating Standard Material Prices for a New Functional Category



Source: "Overview of the FY 2022 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

* In the FY 2024 revision of the medical fees, a cost-effectiveness premium was created in addition to the adjustment premiums shown in the figure above.

[14] The definition is provided in "Standards for calculating insurance reimbursement prices for specified insured medical materials," Notification from the Director-General of the Health Insurance Bureau, MHLW, (Notification HIB No. 0214-3, February 14, 2024).

(Comparative Method Based on Similar Functional Categories and Cost calculation method)

- "Comparative method based on similar functional categories" refers to a method in which the standard material price of a similar functional category is used as the standard material price of the new functional category to which the newly listed product belongs. In cases where they can be regarded as similar functional categories by combining existing functional categories or by using differences between functional categories, the sum or difference of the standard material prices of the existing functional categories may be used as the standard material price of the new functional category to which the newly listed product belongs
- When setting the standard material price for a new functional category, if there is an existing functional category that includes a listed product with the same basic constituent materials but with a differing length, area, volume, etc., the standard material price of the similar functional category allocated by the length, area, volume, etc. of the product can be used as the standard material price of the new functional category to which the newly listed product belongs, with the existing functional category serving as a similar functional category.
- The "cost calculation method" means a method in which the cost of manufacturing or importing a newly listed product plus an amount equivalent to sales, general and administrative expenses, operating profit, distribution costs, consumption tax, and local consumption tax is used as the standard material price for the new functional category to which the newly listed product belongs.

(Adjustment Premiums)

- When calculating the standard material prices for a new functional category, an "（adjustment premium" is allowed if the requirements are met. This includes 1) An "Innovativeness premium," 2) A "Usefulness premium," 3) An "Improvement premium," 4) A "Marketability premium (I)," 5) A "Marketability premium (II)," 6) A "Pioneering premium," and 7) A "Specific use premium."

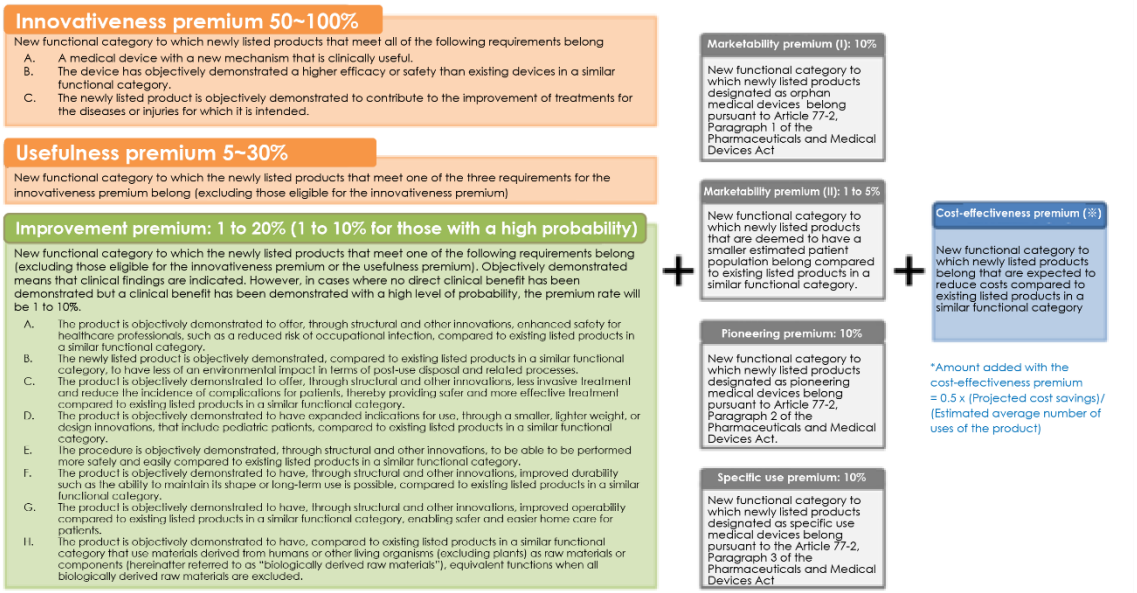
  For the method of calculating the adjustment premium, refer to Appendix Table 1-1 of the notification[14].

(Cost-Effectiveness Premium)

- Cost-effectiveness premium is an addition to a new functional category when the target disease and purpose of use are the same, in principle, as those of already listed products, the clinical efficacy is equivalent or superior, and the product can be a substitute for the already listed product, and reduction in costs related to the specified insured medical material is expected compared to the case where the already listed products are used.

  For the method of calculating the cost-effectiveness premium, refer to Appendix Table 1-1 of the notification[14].

Chart 26 Adjustment Premiums Related to New Functional Categories



Source: "Overview of the FY 2024 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

(Addition Coefficient)

- When the cost calculation method is used, the standard material prices are adjusted with a "premium coefficient" depending on the level of cost disclosure.
- The level of cost disclosure refers to the ratio of the amount that can be disclosed to the Specialized Organization for Insured Medical Materials compared to the total cost of the product in the cost calculation method.
- The premium coefficient is 1.0 for a disclosure level of 80% or more, 0.6 for a level of 50% or more but less than 80%, and 0.2 for a level less than 50%. If the level of disclosure is low, the product is evaluated lower when calculating the standard material price.

(Price Adjustment Based on the Average Foreign Price)

- In both the "comparative method based on similar functional categories" and the "cost calculation method," there is a "price adjustment based on average foreign prices." Basically, if the price exceeds 1.25 times the average foreign price, the amount will be equivalent to 1.25 times the average foreign price.
  - ☞ The "Average Foreign Price" is calculated and compared to the average foreign prices in the UK, US, Germany, France, and Australia.

    (1) If the highest price is more than 2.5 times the lowest price, the highest price will be excluded.
    (2) If there are more than three prices and the highest price exceeds 1.6 times the arithmetic mean of the other prices, the highest price will be deemed to be equivalent to 1.6 times the arithmetic mean of the other prices.
- For newly listed products that meet the following requirements, if the amount exceeds 1.5 times, the amount will be equivalent to 1.5 times that amount.
  (1) Those developed in response to a development request or public tender made by the MHLW based on the results of a study by the Needs Assessment Committee (limited to those that meet the requirements for evaluation related to the Needs Assessment Committee)
  (2) Orphan medical devices
  (3) Those that have received an innovativeness premium or a usefulness premium of 10% or more (including those that meet similar requirements in the cost calculation method)
  (4) Pioneering medical devices
  (5) Specific use medical devices

(Reference Technology)

- When selecting reference technologies, the basic approach is to estimate costs based on the "2020 Draft Proposal of the Japanese Health Insurance Federation for Surgery" from the Japanese Health Insurance Federation for Surgery (Gaihoren) and the "Proposal for Medical Fee Evaluation for Internal Medicine Techniques ver. 1" from the Social Insurance Union of Societies Related to Internal Medicine (Naihoren) and then to select a reference technology with similar aspects.
- In addition, if the usefulness of the product in the application is objectively demonstrated through clinical trial results showing superior treatment outcomes compared to existing treatments, there is also the option to request a technical fee based on those results, applying a reference different from that of existing treatments.
- In addition, even if the medical device is based on a different principle from already listed products, similar procedures may be performed. Taking into consideration the usefulness of the product in the application and the similarity of the procedures, an applicant can

request that the technical fees for existing treatments serve as a reference.

- Thus, references that are deemed appropriate are specified, taking into account the treatment outcomes of the product in the application, similarities in applicable patients and procedures, costs, etc.

(Remanufactured Product)

- For the standard material price for remanufactured products, the standard material price for the functional category to which the original medical device of the newly listed product belongs is multiplied by the remanufacturing coefficient. This amount is considered to be the standard material price for the new functional category to which the newly listed product belongs.
- The remanufacturing coefficient is generally set at 0.7, but this is to be determined taking into consideration the manufacturing process for the remanufactured product.

(Special Provisions for Newly Listed Products (Provisional Prices))

- For newly listed products that have been approved for insurance reimbursement at a provisional price, insurance reimbursement will be made at the standard material price for the functional category to which the existing specified insured medical material that is deemed to be most similar to the newly listed product belongs in accordance with a notification indicating the definition of a material until the functional category of the newly listed product is clarified.

(Cost-Effectiveness Evaluation)

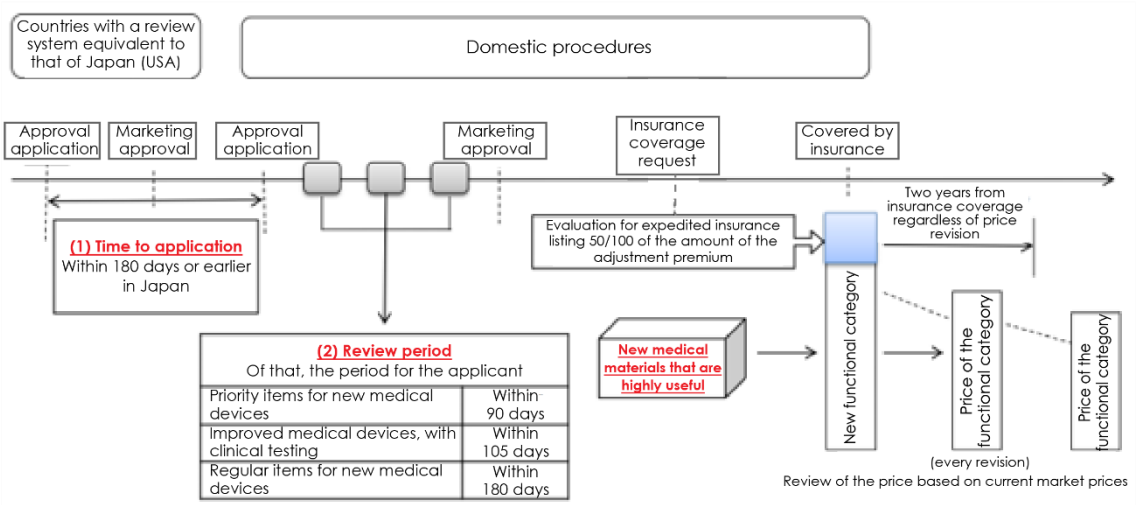
- For items that may be subject to cost-effectiveness evaluation, the pertinence of the designation criteria should be considered. Details of the cost-effectiveness evaluation system are described in the "Handling of Cost-Effectiveness Evaluations of Pharmaceuticals, Medical Devices, and Regenerative Medical Products" (Sanjo Notification No. 0214-3, Notification HIB No. 0214-5, February 14, 2024), notification from the Assistant Vice-Minister for Pharmaceutical Industry Promotion and Medical Information Bureau, and the Director-General of Health Insurance Bureau.

(Evaluation for Expedited Insurance Listing)

- In the FY 2012 revision, a trial framework for "Evaluation for Expedited Insurance Listing" was established in order to eliminate device lag.
- Eligible items are specified insurance medical materials for which the standard material prices of newly listed items are calculated via the comparative method based on similar functional categories or the cost calculation method and which meet the requirements for adjustment premiums.
- For specified insured medical materials that meet all of the following requirements, the system allows the calculation of 50/100 of the adjustment premium for such medical devices for two years only, in addition to the price of the new functional category.
  (1) The filing of an approval application in Japan under the Pharmaceuticals and Medical Devices Act is within 180 days of the date of completion of a marketing approval application or a premarket notification in the United States under the Federal Food, Drug, and Cosmetic Act (FFDCA, FDCA, FD&C), or the filing of an approval application in Japan under the Pharmaceuticals and Medical Devices Act is earlier than the date of the completion of a marketing approval application or a premarket notification in the United States under the Federal Food, Drug, and Cosmetic Act. (This includes a marketing approval application or premarket notification under the Food, Drug and Cosmetic Act to

the United States).
(2) Of the total review period, the period for the applicant is within 90 days for priority items that are new medical devices, 180 days for ordinary items that are new medical devices, and 105 days for improved medical devices with clinical trials.

Chart 27 Evaluation for Expedited Insurance Listing



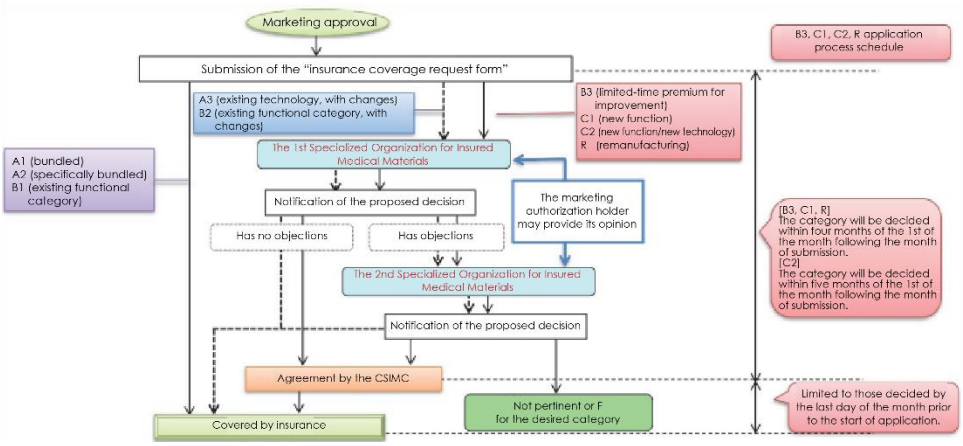
Source: "Key points of the FY 2022 Reform of the Insured Medical Materials System (Reference)" (3.12.22), Central Social Insurance Medical Council

5. Methods of Applying for New Insurance Coverage

(1) Steps in Insurance Coverage for Medical Devices

- For medical devices for which insurance coverage is desired, notification under the Pharmaceuticals and Medical Devices Act should be made or approval/certification should be received depending on the risk classification. Then, submit an insurance coverage request form according to the desired category of insurance.
- For A1 (bundled), A2 (specifically bundled), and B1 (existing functional category), the company's procedure is completed when the insurance coverage request form is submitted and accepted, while for other categories, review of an insurance coverage request form by a specialized organization is required.
- For medical devices specified separately among A1 (bundled) (medical devices separately specified on a bundled basis)[15], no written request is required, as insurance coverage begins on the date of approval or certification, or on the date the notification is accepted. In other words, the comprehensively separately specified medical device[15] is automatically covered by insurance as A1 (bundled) upon approval, certification, or acceptance of notification, so if insurance coverage is desired under other than A1 (bundled) or insurance coverage is not desired, a "Notice requesting that a device not be classified as decision category A1 (bundled)"[16] must be submitted before approval is granted.
- The main steps from application to insurance coverage are as follows:

Chart 28 Steps from Application to Insurance Coverage (Insured Medical Materials) (Reposted)



* For SaMD, prior to an examination by the Specialized Organization for Insured Medical Materials (Hozaisen), confirmation will be made that development, modification, etc. has been completed and sales can begin without delay after insurance coverage, and the details of the confirmation will be reported at the Hozaisen.

[Initiation of insurance coverage]
- ○ A1 (bundled): 20 days after the date of submission of the insurance coverage request form (the date of approval or certification granted for those separately specified on a bundled basis)
- ○ A2 (specifically bundled)/B1 (existing functional category): The 1st of the following month for submissions made by the 10th every month
- ○ A3 (existing technology, with changes) / B2 (existing functional category, with changes): The 1st of the month following the month in which the category is determined
- ○ C1 (new function), C2 (new technology)*, B3 (limited-time premium for improvement), R (remanufacturing): Four times a year (March, June, September, and December)
  - * For medical devices used to assist in determining the indications for pharmaceuticals, insurance coverage may be granted, as an exception, from the 1st of the month following the month in which the insurance coverage for the medical device was determined, taking into account the insurance coverage status of the pharmaceuticals.

Source: "Overview of the FY 2024 Reform of the Insured Medical Materials System," Medical Economics Division, Health Insurance Bureau, MHLW

[15] The definition is provided in the "Definition of Medical Devices Subject to Specific Medical Fees" (March 5, 2024, HIB/MED Notification No. 0305-11), the notification by the Director of the Medical Economics Division, Health Insurance Bureau, MHLW and the Dental Medical Management Officer, Health Insurance Bureau, MHLW.

[16] Guidance is provided in the Office of Medical Devices Policy's administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

Chart 29 Procedures and Timing of Insurance Coverage for Each Category

	Necessity for submission of a request form	Procedures for insurance coverage		Timing of coverage
		Hozaisen	CSIMC	
A1 * Separately specified on a bundled basis	Submission not required			The date of approval or certification, or the date of acceptance of the notification
A1 * Other than separately specified on a bundled basis	Accepted at any time	—	—	20 business days after receipt of the request form
A2/B1	Accepted at any time	—	—	A request form received by the 10th of each month will be processed on the 1st of the following month
A3/B2	Accepted at any time	Required	—	The 1st of the month following the month in which the category is determined by the Specialized Organization for Insured Medical Materials
B3/C1/C2/R	Accepted at any time	Required	Required	Four times a year (March, June, September, and December)

- For medical devices for which A1 (bundled), A2 (specifically bundled), or B1 (existing functional category) is desired, submit the insurance coverage request form according to the respective category. Medical devices that are deemed appropriate for coverage by insurance as desired will be covered by insurance at the timing of insurance coverage specified for each category upon this submission of the insurance coverage request form. As for the timing of insurance coverage, A1 will be granted insurance coverage as of the day 20 days (excluding holidays) after the date of receipt of an insurance coverage request form (the day on which any errors on the form have been corrected). A2 and B1 will be granted insurance coverage, as a general rule, as of the 1st of the following month if an insurance coverage request form is received (i.e., any errors on the form have been corrected) by the 10th of each month. For A2 and B1, a notification addressed to the head of the Medical Division of the Regional Health and Welfare Bureau will be issued. For A2 and B1, no notification will be issued for "3. Addition of or change in the purpose of use or effect" by the type of request for insurance coverage.
- For medical devices for which A3 (existing technology, with changes) or B2 (existing functional category, with changes) is desired, submit an insurance coverage request form according to the respective category. During the review of an insurance coverage request form, a hearing with the applying company will be conducted as needed. After that, a proposed decision will be formulated after a review by the Specialized Organization for Insured Medical Materials, and the applying company will be notified of the details. In the event of an objection to the proposed decision by the Specialized Organization for Insured Medical Materials, an objection can be registered once. If the applying company agrees to the proposed decision, insurance coverage will start as of the 1st of the month following the month in which the decision was made. For A3 and B2,

a notification addressed to the head of Medical Economics Division of the Regional Health and Welfare Bureau will be issued.

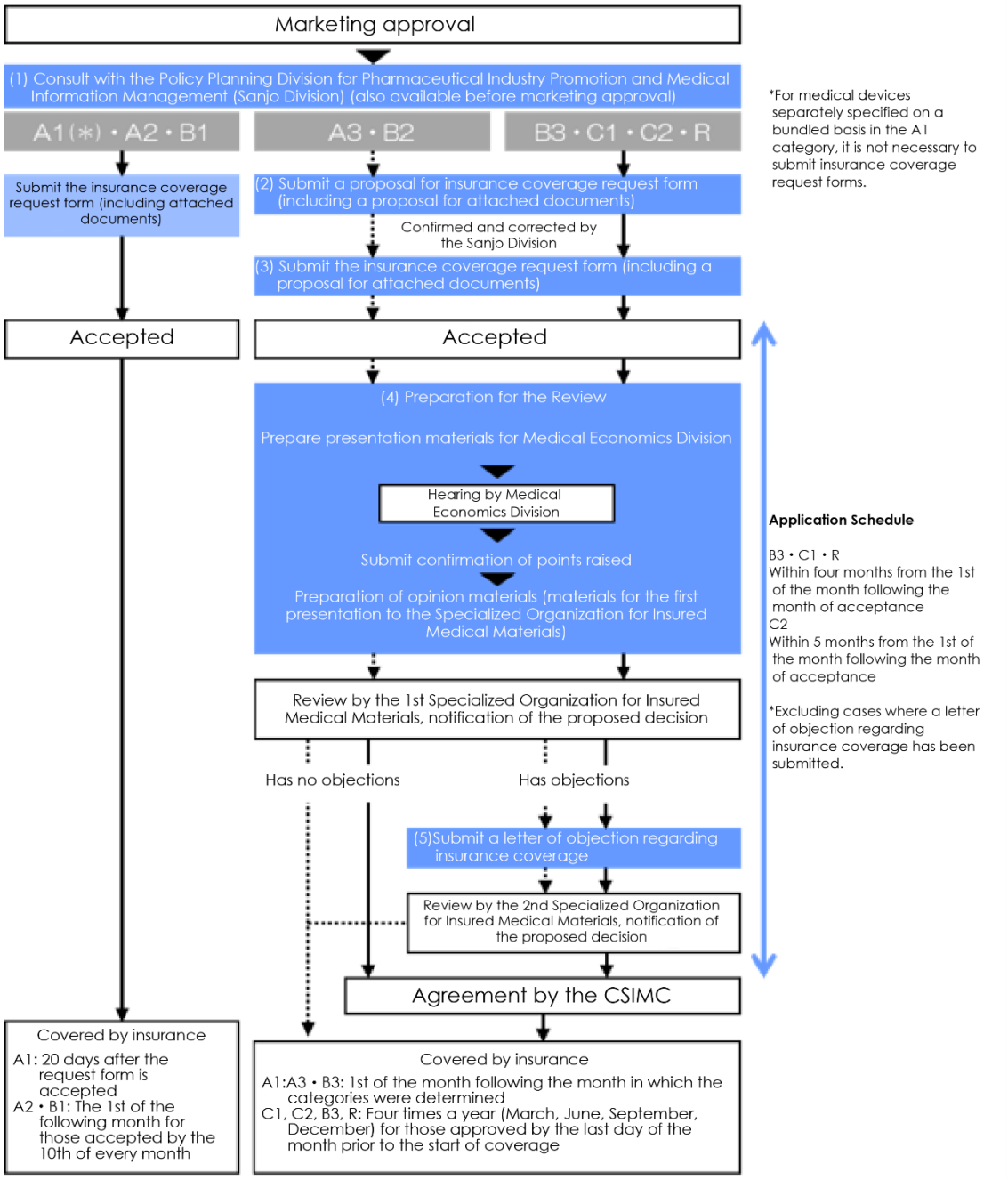
- For medical devices for which C1(new function), C2 (new technology), B3 (limited-time premium for improvement/provisional functional category), or R(remanufacturing) is desired, submit an insurance coverage request form according to the respective category. During the review of an insurance coverage request form, a hearing with the applying company will be conducted as needed. After that, a proposed decision will be formulated after a review by the Specialized Organization for Insured Medical Materials, and the applying company will be notified of the details. In the event of an objection to the proposed decision by the Specialized Organization for Insured Medical Materials, an objection can be registered once. If there is no objection to the details indicated, insurance coverage will start following deliberation and approval at the CSIMC General Assembly Meeting. Medical devices determined to be C1, C2, B3, or R are granted insurance coverage four times per year as standard. The standard months for the timing of insurance coverage are March, June, September, and December. In short, those approved at the CSIMC General Assembly Meetings from December to February will be granted insurance coverage starting in March, those approved from March to May will be granted coverage starting in June, those approved from June to August will be granted coverage starting in September, and those approved from September to November will be granted coverage starting in December (Chart 30). For C1, C2, B3, and R, a notification addressed to the head of Medical Economics Division of the Regional Health and Welfare Bureau will be issued.

Chart 30 Insurance Coverage Timing for Categories B3, C1, C2, and R

Schedule of the CSIMC General Assembly Meetings*	Timing of insurance coverage
December to February	March
March to May	June
June to August	September
September to November	December

* The CSIMC General Assembly Meeting that is held after the notification of the proposed decision by the Specialized Organization for Insured Medical Materials.

Chart 31 Steps from Application to Insurance Coverage (Insured Medical Materials)



Source: Prepared by the Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, MHLW

- For medical devices that have already been granted insurance coverage under one of the categories, an insurance coverage request form should be submitted when there is a change as specified in[17] 1(6) or (7) of the notification on methods of submission. If the notification on methods of submission is not applicable, as a general rule, an insurance coverage request form cannot be submitted.
- If an insurance coverage request form is not submitted properly, insurance coverage may not be granted. Particularly be careful of the cases like those shown in Chart 32. In order to prevent cases like those, please ensure that procedures are carried out in accordance with the relevant notifications and that multiple staff members check the procedures.

Chart 32 Examples of Cases Where Insurance Coverage may Not Be Granted

Examples	Examples of causes
Failure to submit an insurance coverage request form	• When approval was obtained again as a result of a company merger • When a person in charge resigned or was transferred, and the duties were not properly handed over • When insurance coverage became necessary due to a change in sales policy • When a product does not meet the definition but is misidentified as "separately specified on a bundled basis" • For a product with integrated functional categories, when only one functional category is submitted • When there is a change in the "purpose of use or effect" due to a partial change application
Errors in an insurance coverage request form	• For medical devices that fall under multiple categories in category A2, when some categories are not listed • When an incorrect product code was entered • When the product code for a single product distribution was not stated

[17] Refer to the notification on "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (HPB/DPMM Notification No. 0214-2, HIB/MED Notification No. 0214-2, February 14, 2024).

(2) Steps in insurance coverage for SaMD

- For SaMD, the procedures are basically the same as for other medical devices, and an insurance coverage request form is submitted according to the insurance evaluation category. For SaMD in A2 and B1, the appropriateness of the category is to be reviewed by the Specialized Organization for Insured Medical Materials, and the standard administrative processing time and timing of insurance coverage will follow A3 AND B2.
- Prior to the review by the Specialized Organization for Insured Medical Materials, confirmation will be made that development and modification is complete and that sales can begin without delay after the product is covered by insurance. The details of this confirmation are reported to the Specialized Organization for Insured Medical Materials.

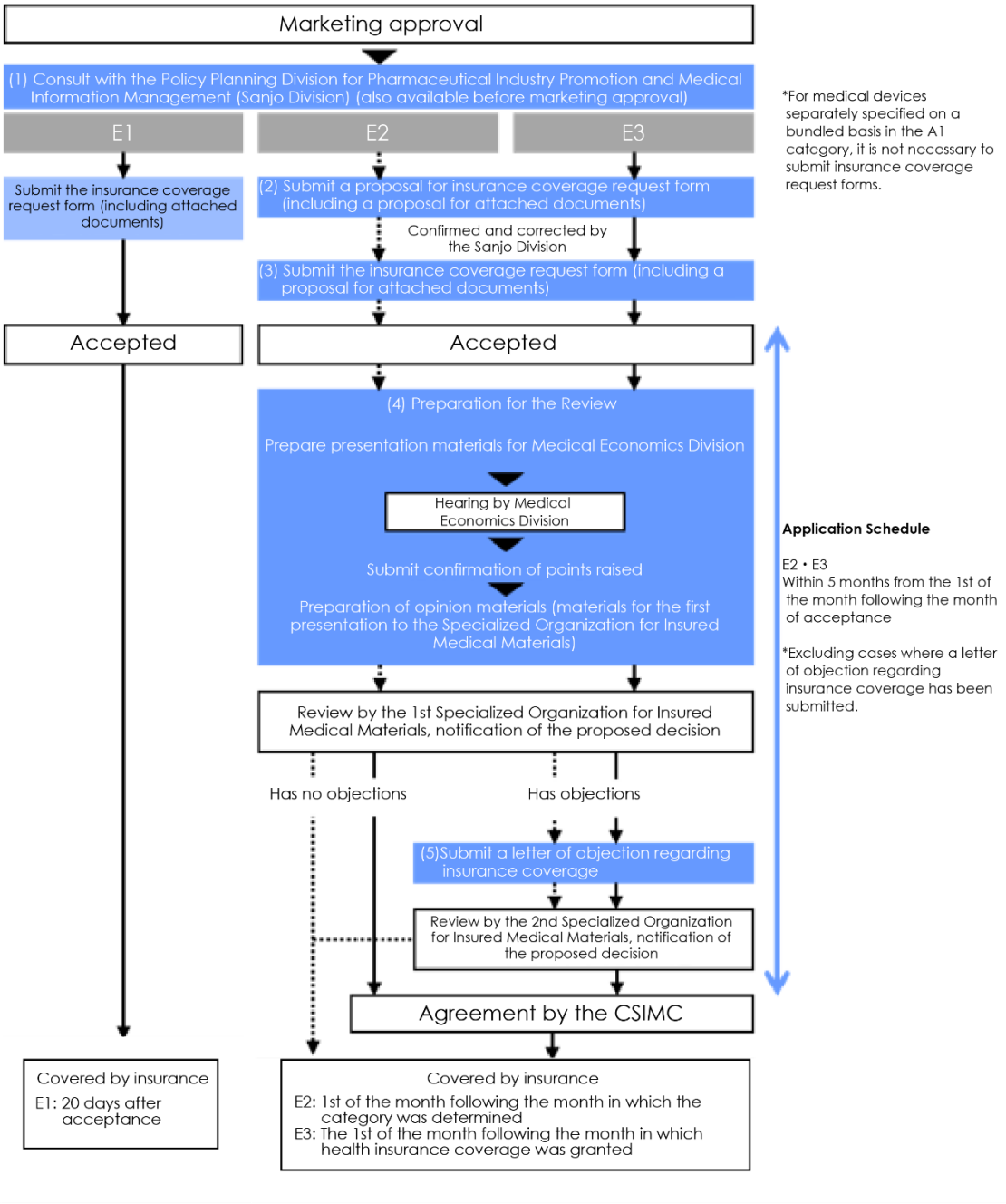
(3) Steps in insurance coverage for in vitro diagnostics

- For in vitro diagnostics for which insurance coverage is desired, notification under the Pharmaceuticals and Medical Devices Act should be made or approval/certification should be received. Then, submit an insurance coverage request form according to the desired insurance category.
- For E1, the company's procedure is completed when an insurance coverage request form is submitted and accepted. For E2 and E3, review of an insurance coverage request form by a specialized organization is essential. Specifically, notification of the proposed decisions made by the CSIMC's Specialized Organization for Insured Medical Materials regarding the review and category will be given.
- For E1, insurance coverage starts as of the day 20 days after an insurance coverage request form is submitted and received.
- For E2, insurance coverage starts as of the 1st of the following month upon notification of the proposed decision by the CSIMC's Specialized Organization for Insured Medical Materials regarding the category.
- For E3, after review and determination of the proposed category by the CSIMC's Specialized Organization for Insured Medical Materials, insurance coverage starts on the 1st of the following month after approval of the proposed decision at the CSIMC General Assembly Meeting.
- In the event of an objection to the proposed decision by the Specialized Organization for Insured Medical Materials, an objection can be registered once.
- For "items that do not require approval or certification," insurance coverage begins from the date of notification in accordance with Article 23-2-12 of the Pharmaceuticals and Medical Devices Act.

Chart 16 Procedures and Timing of Insurance Coverage in E1, E2, and E3 Categories

	Necessity for submission of a request form	Procedures for insurance coverage		Timing of coverage
		Hozaisen	CSIMC	
E1	Accepted at any time	—	—	The day after 20 days have elapsed since the receipt of the request form
E2	Accepted at any time	Required	—	The 1st of the month following the month in which the category is determined by the Specialized Organization for Insured Medical Materials
E3	Accepted at any time	Required	Required	The 1st of the month following the month in which the category was determined by the CSIMC General Assembly Meeting

Chart 34 Steps from Application to Insurance Coverage (in vitro Diagnostics)



Source: Prepared by the Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, MHLW

(4) Methods of Applying for New Insurance Coverage

(1) Consultation with the Office of Medical Devices Policy (available even before marketing approval)

If insurance coverage for new medical devices, in vitro diagnostics, etc., is considered, pre-consultation with the Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare is recommended regarding whether the applied category is appropriate. The Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Planning (formerly the Economics Division) is primarily responsible for promoting the pharmaceutical industry in terms of its drugs, quasi-drugs, and medical devices. The division will work with the staff of the Office of Medical Devices Policy to prepare for insurance coverage of medical devices, in vitro diagnostics, etc.

If pre-consultation is desired, send the "Contact Form for a Pre-consultation on Insurance Coverage" (Form 10-1), which is available on the MHLW website[18], by e-mail (refer to page 138 for how to fill out the form). Pre-consultation meetings will be held online as a general rule. Consultations are generally limited to 60 minutes. Although the application for insurance coverage is to be submitted after manufacturing and marketing approval, pre-consultation can be done regardless of the status of the manufacturing and marketing approval. After you send the e-mail, the staff of the Office of Medical Devices Policy will contact you to arrange a date and time. Provide meeting materials prepared based on the following information to the extent possible at least three business days, as a general rule, prior to the meeting. On the day of the consultation, use the meeting materials to specifically explain the product in the application and which matters you like consultation on.

Explanation on the day of consultation
(Medical devices) *Including SaMD

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current treatments for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background of the development for the product in the application based on the problems and needs (including an explanation of the product's characteristics and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether guidelines for proper use, including requests for early introduction and requirements for the physician, have been prepared, and if prepared, those details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

[18] https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000188411_00045.html
The form is specified in "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (notification), and a modifiable form (Word format) is available in the "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice) on the MHLW website.

[Details on the insurance coverage requested]

- If you wish to set a new technical fee, please explain the details of the insurance coverage you would like to receive (including an explanation of the medical fee points and points of note regarding existing treatments, as well as the details of the requested insurance coverage for the product in the application and the reasons for selecting the reference technical fee).
- If coverage as a specified insured medical material is desired, whether setting of a similar functional category is desired and the desired price (if a similar functional category is not believed to exist, the reason why the product does not fall under any of the existing functional categories and the details of the new functional category desired. In case of cost calculation, the breakdown. If a premium is desired, applicable items and an explanation of their pertinence).

[Schedule]

- Details of previous consultations with the Industrial Affairs Division and the status of any responses (if multiple consultations have been done)
- Regulatory status, future schedule ／etc.

(In vitro diagnostics)

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current methods of testing for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background to the development of the product in the application based on the issues and needs (including an explanation of the product's features and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether or not a statement has been prepared, including a request for early introduction, the applicable patients for the product in the application, and a summary of its clinical positioning; if such a statement has been prepared, its details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

[Details on the insurance coverage requested]

- If you wish to set a new technical fee, explain the details of the insurance coverage you would like to receive (including an explanation of the medical fee points and points of note regarding existing tests, as well as the details of the insurance coverage you would like for the product in the application and the reasons for selecting the reference technical fee).

[Schedule]

- Details of previous consultations with the Industrial Affairs Division and the status of any responses (if multiple consultations have been done)
- Regulatory status, future schedule ／etc.

(2) Pre-Consultation for SaMD

For software as a medical device (SaMD), a consolidated SaMD consultation service is provided in the "SaMD Consolidated Consultation Desk (General Consultation on SaMD)" at the PMDA in order to promote the early practical use of the most advanced SaMD. Consultations on SaMD have thus far been done by the MHLW and the PMDA.

Here, consolidated consultation will be provided from the early stages of the development on matters related to 1) pertinence as a medical device (Pharmaceutical and Medical Products Bureau, MHLW), 2) pharmaceutical development (PMDA), and 3) medical insurance (Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Planning, Health Policy Bureau, MHLW). Refer to the same website[19]for the form to record the details you wish to discuss and how to apply for consultation. If the developed product falls under the category of a medical device, an application for a pre-consultation can be submitted directly to the Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare.

Since the evaluation of insurance coverage for SaMD varies widely, development plans and insurance coverage strategies that take into account the end result of the evaluation of insurance coverage, including the collection of data necessary for marketing approval/certification and insurance coverage, are needed.

In addition, MHLW's "MEDical Innovation Support Office (MEDISO)" provides consultation services to ventures, including individuals, and academia that seek to commercialize pharmaceuticals, medical devices, regenerative medical products, etc. For details, visit the website[20].

(3) Preparation of the Insurance Coverage Request Form

The documents to be submitted in relation to the procedures for insurance coverage of categories A1, A2, B1, and E1 are as follows. For details on completing forms and where to submit them, refer to the attachment to the MHLW's notification on "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (HPB/DPMM Notification No. 0214-2, HIB/MED Notification No. 0214-2, February 14, 2024) and the administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024), and the administrative notice on "Sample Entries for the Insurance Coverage Request Form of an In Vitro Diagnostic" (March 6, 2024).

(For category A1)

Request Form	● Insurance Coverage Request Form (decision category A1 (bundled)) **[Appendix 1]**
Attached documents	● A copy of the marketing approval dossier and its attached application form, certification and its attached application form or notification

(For category A2)

Request Form	● Insurance Coverage Request Form (decision category A2 (specifically bundled)) **[Appendix 2]** ● Attachment 1 Product Name and Product Code List (if the request form is not complete)
Attached documents	● Format for Notification of Insurance Coverage ● Application Form for Insurance Coverage of a Medical Device **[From 1-1]** ● Desired Category and the Rationale for its Selection **[Form 2-1]** ● A copy of the marketing approval dossier and its attached application form, certification and its attached application form or notification

[19] https://www.pmda.go.jp/review-services/f2f-pre/strategies/0011.html
[20] https://mediso.mhlw.go.jp/

(For B1 category)

Request Form	● Insurance Coverage Request Form (decision category B1 (existing functional category)) **[Appendix 3]** ● Attachment 1 Product Name and Product Code List (if the request form is not complete)
Attached documents	● Format for Notification of Insurance Coverage ● Application Form for Insurance Coverage of a Medical Device **[From 1-1]** ● Desired Category and the Rationale for its Selection **[Form 2-1]** ● A copy of the marketing approval dossier and its attached application form, certification and its attached application form or notification

(For E1 category)

Request Form	● Insurance Coverage Request Form **[Appendix 1]**
Attached documents	● A copy of the marketing approval dossier and its attached application form, certification and its attached application form

The form for an insurance coverage request form and attached documents (Word file) can be downloaded from MHLW's website. For more information, refer to "7. Frequently Asked Questions."

Refer to "6. How to Fill Out the Application Form" for documents to submit and how to fill out the main forms for categories A3, B1, B2, B3, C1, C2, E2, E3, and R.

If category A3, B2, B3, C1, C2, E2, E3, or R and a challenge application is desired, prepare a draft of an insurance coverage request form and send it by e-mail to the Office of Medical Devices Policy. After the Office of Medical Devices Policy checks the entries, it will request additions or revisions as needed. If the functional category for which listing is desired includes an item that is subject to cost-effectiveness evaluation, or if the item for which revision is desired can be subject to cost effectiveness evaluation based on the "Handling of Cost-Effectiveness Evaluations of Pharmaceuticals, Medical Devices, and Regenerative Medical Products" (Sanjo Notification No. 0214-3, Notification HIB No. 0214-5, February 14, 2024), schedule a pre-consultation with the Office of Medical Devices Policy since submission of Appendix 13 may be required.

For category A1, A2, B1, or E1, there is no prior confirmation of entries, so submit an insurance coverage request form to the Office of Medical Devices Policy as soon as it is ready. When submitting under category B1, the functional category for which listing is desired includes an item that is subject to cost-effectiveness evaluation, schedule a pre-consultation with the Office of Medical Devices Policy since submission of Appendix 13 may be required.

(4) Submission of the Insurance Coverage Request Form

For category A3, B2, B3, C1, C2, E2, E3, or R, official submission will be made after the completion of document verification and document revision by the Office of Medical Devices Policy. Please submit an insurance coverage request form (including attachment documents) on electronic media to the Office of Medical Devices Policy.

Please send the following electronic files to the staff at the Office of Medical Device Policy by mail or other means after saving them on a CD or other storage media (floppy disks and USB memory sticks are not acceptable). The staff of the Office of Medical Device Policy will contact you for more details upon formal submission.

- Insurance Coverage Request Form (a copy and the form in one Word file)
- A copy of an insurance coverage request form (PDF file)
- Latest package insert (PDF file)
- A copy of the marketing approval dossier and its attached application form, certification and its attached application form or notification (PDF file)
- Attachments to the marketing approval application or attachments to the certification (PDF file)
- References (PDF file)

[Address for submission]

Processing fee: none

Address for submission: 〒100-8916

Central Government Building No. 5, 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo

Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, MHLW

Business hours: Monday to Friday 9:30 to 18:15 (excluding public holidays and New Year holidays)

Method of submission:

Submit documents to the contact desk at the Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare

(5) Preparation for the Review

After the official submission of an insurance coverage request form, a hearing will be held by the Medical Economics Division, Health Insurance Bureau, MHLW (Medical Affairs Division Hearing), generally via web conference, prior to the review by the Specialized Organization for Insured Medical Materials. The Medical Economics Division is in charge of matters related to medical fees and general affairs of the CSIMC and checks whether the desired functional category of the product in the application is appropriate and whether the application can proceed to review by the Specialized Organization for Insured Medical Materials. Therefore, after an insurance coverage request form is accepted, prepare for a presentation to the Medical Economics Division Hearing while following the advice of the staff of the Office of Medical Devices Policy. After the Medical Economics Division hearing, the applicant will be asked to submit a summary memo summarizing the details of the hearing and any questions asked at the hearing, as well as any supplemental data (Response to Points Raised). You will be informed of the details by the staff of the Office of Medical Devices Policy.

Outline of the Medical Economics Division hearing

- Generally, a presentation is made by the company to the Medical Economics Division in the form of a web conference.
- There is no limit on the number of participants from the company (attendance of a physician or other specialist is recommended)
- Presentation: 20 minutes, Q&A: 40 minutes
- Before the hearing, presentation materials are submitted to the Office of Medical Devices Policy
- Explanations are given via screen sharing. (In the case of face-to-face meetings, presentation materials (on paper) will be brought)
- After the hearing, a summary memo of the hearing and a response to the points raised will be submitted.

Once the response to the points raised is submitted and approved by the Medical Economics Division, the review by the Specialized Organization for Insured Medical Materials will proceed. On the day of the review, the applicant will be able to give an explanation in a web conference format based on the opinion document, and the applicant will receive advice from the staff of the Office of Medical Device Policy in preparation for this. Presentation time is strictly limited to six minutes, and exceeding that time is not allowed. In preparation for the review, an insurance coverage request form along with the aforementioned confirmation of points raised will be submitted by e-mail by the deadline as instructed by the Office of Medical Devices Policy. You will be informed of the details by the staff of the Office of Medical Devices Policy. A connection test is conducted immediately before the hearing.

Outline of the Review by the Specialized Organization for Insured Medical Materials

- A presentation will be made by the company to the committee members of the specialized organization in the form of a web conference.
- Maximum of 4 participants from the company (attendance of a physician or other specialist is recommended)
- Presentation: strictly 6 minutes, Q&A: 10 minutes
- Before the review, the opinion presentation materials are submitted to the Office of Medical Devices Policy

(6) Submitting a Letter of Objection regarding Insurance Coverag

After the review, the Specialized Organization for Insured Medical Materials will notify the company of its proposed decision. In the case of an objection to the proposed decision, a re-review can be done once. If re-review is desired, submit a letter of objection regarding insurance coverage to the Office of Medical Devices Policy within 7 days (excluding holidays) of receiving notification of the proposed decision. If submitting supporting documents along with the objection is deemed difficult, the deadline for submitting the documents will be extended to within 14 days (excluding holidays) of the date of submission of the objection.

6. How to Fill Out the Application Form

This section provides a summary of the key points, entry details, and precautions for preparing documents, including an insurance coverage request form and main attached documents required to apply for insurance coverage. Please use this information as a reference when preparing documents.

<Points to remember when preparing documents>

- Please use the form provided by the MHLW as a basis, and make the document easy to read by including graphs and illustrations and summaries for items with a large number of entries or attached materials.
- "How the product in the application will solve the problems faced by healthcare professionals and patients" needs to be explained in an ordered manner throughout the submitted documents. Be careful not to have logical contradictions.
- The insurance coverage request form needs to fit on a single A4 page. Other documents do not need to fit on a single A4 page.

<List of required documents (for a medical device)>

○： mandatory　　△： as needed

*In addition, other documents may need to be attached depending on entries.

Document Name	A1, A2, B1 + Challenge Rights Acquired	A3	B2	B3	C1, C2 (with similar functional categories)	C1, C2 (without similar functional categories)	R	Sample entry page
Insurance Coverage Request Form for a Medical Device [Appendix 1] Insurance Coverage Request Form for a Medical Device [Appendix 2] Insurance Coverage Request Form for a Medical Device [Appendix 3]	○							
Insurance Coverage Request Form for a Medical Device [Appendix 4]		○	○					58
Insurance Coverage Request Form for a Medical Device [Appendix 5]				○	○			62
Insurance Coverage Request Form for a Medical Device [Appendix 6]						○		68
Insurance Coverage Request Form for a Medical Device [Appendix 7-1]							○	72
Statement of reasons for C1, C2 and B3 applications for generic medical devices [Appendix 12]				△	△	△		
Review documents for Pertinence with Regard to the Criteria for Designation of Cost-effectiveness Evaluation [Appendix 13]	△	△	△	△	△	△	△	

Document Name	A1, A2, B1 + Challenge Rights Acquired	A3	B2	B3	C1, C2 (with similar functional categories)	C1, C2 (without similar functional categories)	R	Sample entry page
Application Form for Insurance Coverage of a Medical Device [From 1-1]	○	○	○	○	○	○	○	76
Supporting Documents on the Estimated Number of Applicable Patients and Projected Sales Volume [Form 1-2]	○	○	○	○	○	○	○	78
Desired Category and the Rationale for its Selection [Form 2-1]	○							
Similar Functional Category and the Rationale for its Selection [Form 2-2]		△*	○	○	○		○	80
Rationale for the Lack of a Similar Functional Category [Form 2-3]						○		82
Rationale for the Application of an Adjustment Premium (Innovativeness Premium or Usefulness Premium) [Form 3-1]				△	△	△		84
Rationale for the Application of an adjustment Premium (Improvement Premium or Limited-time Premium for Improvement) [Form 3-2]				△	△	△		86
Rationale for the Application of an Adjustment Premium (Marketability Premium [I], [II] • Pioneering Premium, Specific use Premium) [Form 3-3]				△	△	△		88
Rationale for Application of the Cost-Effectiveness Premium [Form 3-4]				△	△	△		90
Documents regarding the Justification for Submitting a Challenge Application [Form 3-5]	○	△	△	△	△	△		92
Rationale for Medical Devices that Require Special Consideration as Those Used in Testing for Rare Diseases [Form 3-6]					△	△		94
Medical Technology Related to the Medical Device [Form 4]	△	○	○	○	○	○	○	96
Documents on Cost Calculation Method [Form 5]						○	△	98
Documents on Price Adjustment [Form 6]					○	○	○	104
Documents on Evaluation for Expedited Insurance Listing [Form 7]					△	△		106

Document Name	A1, A2, B1 + Challenge Rights Acquired	A3	B2	B3	C1, C2 (with similar functional categories)	C1, C2 (without similar functional categories)	R	Sample entry page
Documents on Usefulness in Terms of Healthcare Economics [Form 8]		○	○	○	○	○	○	108
Document on Maintenance [Form 9]			○	○	○	○	○	110
Package insert	○	○	○	○	○	○	○	
A copy of the marketing approval dossier and its attached application form, certification and its attached application form	○	○	○	○	○	○	○	
Summary document of the attached dossier for a marketing approval application or Documents on equivalence to an existing approved medical device or Summary documentation of the attached dossier for an authentication application or Documents for equivalence to an existing authenticated medical device	○	○	○	○	○	○	○	
A copy of the marketing approval review report (if prepared at the time of pharmaceutical approval review)	△	△	△	△	△	△	△	
A list of the domestic and foreign literature (including clinical trial results) and references, including controlled trial results that clarify indications and usefulness in terms of healthcare economics	△	△	△	△	△	△	△	
Instruction manual and pamphlet for medical facilities	△	△	△	△	△	△	△	

*Submit only if a change in the definition of a medical device subject to specific medical fees is desired.

Document Name	A1, A2, B1 + Challenge Rights Acquired	A3	B2	B3	C1, C2 (with similar functional categories)	C1, C2 (without similar functional categories)	R	Sample entry page
Documents certifying that the "application for marketing approval in Japan is within 180 days of the date of completion of an application for marketing approval or premarket notification in the US" or the "application for marketing approval in Japan is earlier than the date of completion of an application for marketing approval or premarket notification in the US," documents certifying that "of the total review period, the period for the applicant is within 120 days for priority items that are new medical devices or improved medical devices with clinical trials and within 210 days for regular items that are new medical devices"				△	△	△		

<List of required documents (for in vitro diagnostics)>

○： mandatory ：△ as needed

*In addition, other documents may need to be attached depending on entries.

Document Name	E2	E3	Page of sample entries
Insurance Coverage Request Form for a Medical Device [Appendix 1]	○	○	112
Requested Insurance Points and the Rationale for them [Form 1]	○	○	114
Supporting Documents on the Estimated Number of Applicable Patients and the Estimated Market Size (Estimated Number of Tests) [Form 2-1]	○	○	116
Reagent Price (Price per Test) [Form 2-2]	△	○	118
Document Summarizing Testing [Form 3]	○	○	126
Documents on Clinical Effectiveness and Significance, Improvement of Convenience, etc. [Form 4]	△	○	128
Rationale for In Vitro Diagnostics that Require Special Consideration for Use in Testing for Rare Diseases [Form 5]		△	130
Documents on the Justification for Submitting a Challenge Application [Form 6]	△	△	132
Documents Demonstrating Usefulness in Terms of Healthcare Economics [Form 7]		○	136
Package insert	○	○	
A copy of the marketing approval dossier and its attached application form, certification and its attached application form	○	○	
Summary document of the attached dossier for a marketing approval application or Documents on equivalence to an existing approved medical device or Summary documentation of the attached dossier for an authentication application or Documents for equivalence to an existing authenticated medical device	○	○	
A copy of the marketing approval review report (if prepared at the time of pharmaceutical approval review)	○	○	
A list of the domestic and foreign literature (including clinical trial results) and references, including controlled trial results that clarify indications and usefulness in terms of healthcare economics	△	△	
Instruction manual and pamphlet for medical facilities	△	△	

<Contact Form for Pre-Consultation [Form 10-1] or [Form 9]>

Use Form 10-1 for medical devices and Form 9 for in vitro diagnostics, and clearly state the consultation items, taking into account the precautions described below.

(blank)

Insurance Coverage Request Form for a Medical Device [decision category A3, B2] [Appendix 4]

<Notes>

- Keep it to one A4 sheet. If your application does not fit on a single A4 page, attach additional sheets as necessary.

1 Leave the reference number section blank when submitting the form.

2 Circle either “A3 (existing technology, with changes)” or “B2 (existing functional category, with changes)” depending on the category being applied for.

3 Enter the product name and product code (if there are multiple product names, please indicate the correspondence with the product code). Enter the 13-digit JAN code as the product code. If the product code cannot be written down, submit it as Attachment 1. The method for preparing Attachment 1 is described in the Ministry of Health, Labour and Welfare's administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

4 Transcribe the information contained in the marketing approval dossier or certification.

5 Provide a brief summary of the product in the application. Include a photo of the product's appearance (a small photo is acceptable as long as the product’s aspects are evident).

6 Provide a brief summary of the changes desired.

7 In B2 (Existing functional category, with changes), circle yes or no for a challenge application after the new listing. If yes, attach documentation that will serve as a reference for the plan for data collection and methods of evaluation of the details of a desired reevaluation through a challenge application. For details, refer to Form 3-5, “Document on the Justification for Submitting a Challenge Application.”

8 If there are multiple persons in charge, underline one main person in charge.

9 If any of the following apply, indicate so in the "Remarks" column.
(1) Details of the most recent application for a partial change or minor change
(2) Details of succession, a change in company name, and a change in the Designated Marketing Authorization Holder (submit documents that allow details to be verified)
(3) Records of past coverage of the product by insurance (date of coverage by insurance (date an insurance coverage request form was submitted with regard to decision category A1) and the decision category)
(4) Record of submission of the "Notice of not wishing to be classified as decision category A1 (bundled)" for the product (date of submission)
(5) Reasons for not having either a JAN code or a GS1 code
(6) The applicable field number and name of the functional category are not listed in the “desired category for a specified insured medical material” column in an insurance

coverage request form that corresponds to item 10 in the notification of methods of submission.

(7) Date of implementation of changes according to the change plan

Reference number 1

Attachment 1

2

Insurance Coverage Request Form for a Medical Device

[Decision category A3 (existing technology, with changes), B2 (existing functional category, with changes)]

Brand name			
Product name and product code 3	Product name	Product code	
Category 4		Generic name	
Approval number, Certification number, or notification number		Date of approval, Date of certification or Date of notification (and the date of the last partial change)	
5 Product Overview	Photo of the product		
6 Summary of desired changes 7			
Request for reevaluation based on actual past use	Yes (at the time of listing, after listing), No		
Applicability as a medical material	Yes/No		
Applicability as a material for at-home care	Yes/No		
Applicability as a dental material	Yes/No		
Applicability as a dispensing material	Yes/No		
Contact Details	Contact Name: 8 *Taro Yamada, Hanako Yamada*	Telephone number: E-mail:	
Remarks 9			

Based on the above, I request that this medical device be covered by insurance.

Date (Month/Date/Year)

Address (in the case of a corporation, the location of its principal office)

Name (in the case of a corporation, its name and the name of its representative)

To the Minister of Health, Labour and Welfare

Note: Submit using the Japanese-language forms.

整理番号

別紙４

医療機器保険適用希望書

〔決定区分Ａ３（既存技術・変更あり）、Ｂ２（既存機能区分・変更あり）〕

販 売 名			
製品名・製品コード	製品名	製品コード	
類別		一般的名称	
承認番号、認証番号又は届出番号		承認年月日、認証年月日又は届出年月日（及び最終一部変更年月日）	
製品概要	製品の外観写真		
変更希望の概要			
使用成績を踏まえた再評価希望の有無	有（収載時・収載後）・ 無		
医科材料該当性の有無	有 ・ 無		
在宅材料該当性の有無	有 ・ 無		
歯科材料該当性の有無	有 ・ 無		
調剤材料該当性の有無	有 ・ 無		
担当者連絡先	担当者名： *山田太郎、山田花子*	電話番号： Ｅ－ｍａｉｌ：	
備 考			

上記により、医療機器の保険適用を希望いたします。

年 月 日

住所（法人にあっては、主たる事務所の所在地）

氏名（法人にあっては、名称及び代表者の氏名）

厚生労働大臣

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Insurance Coverage Request Form for a Medical Device [Decision Category B3, C1, C2 (in cases where a similar functional category exists)] [Attachment 5]

<Notes>

- Keep it to one A4 sheet. If your application does not fit on a single A4 page, attach additional sheets as necessary.

1 Leave the reference number section blank when submitting the form.

2 Depending on the applied category, please circle "C1 (New Function)," "C2 (New Technology)," or "B3 (Limited-time Premium for Improvement/Provisional Functional Category)."

3 Enter the product name and product code (if there are multiple product names, please indicate the correspondence with the product code). Enter the 13-digit JAN code as the product code. If the product code cannot be written down, submit it as Attachment 1. The method for preparing Attachment 1 is described in the Ministry of Health, Labour and Welfare's administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

4 Transcribe the information contained in the marketing approval dossier or certification.

5 Provide a brief summary of the product in the application. Include a photo of the product's appearance (a small photo is acceptable as long as the product's aspects are evident).

6 Indicate whether the instruction manual and pamphlet for medical facilities are available by circling "Yes" or "No."If so, please attach the relevant documents.

7 For a similar functional category, enter the category number and name of the material price standard and the price (material price standards can be found on the Ministry of Health, Labor and Welfare's website. For more information, refer to "7. Frequently Asked Questions").

8 If you wish for an adjustment premium to be applied, enter the name of the premium and the rate. Up to two of the following premiums can be applied: either the innovativeness premium, usefulness premium, or improvement premium and either marketability premium I or II. If you wish for a cost-effectiveness premium to be applied, enter the amount of the premium and the rate. If not, please write "None."

<Determining whether or not the adjustment premium is applicable>

- About the innovativeness premium, usefulness premium
  If all of the following requirements are met, you can apply for the innovativeness premium; if any of the requirements are met, you can apply for the usefulness premium.

A. A medical device with a new mechanism that is clinically useful.
B. The device has objectively demonstrated a higher efficacy or safety than existing devices in a similar functional category.
C. The newly listed product is objectively demonstrated to contribute to the improvement of treatments for the diseases or injuries for which it is intended.

■ About improvement premium:
If any of the requirements are met, you can request that the improvement premium be applied.
In addition, the requirement "objectively demonstrated" refers to clinical findings being demonstrated (even if the clinical effectiveness has not been directly demonstrated, but the clinical efficacy has been demonstrated with a high level of probability, a premium can be applied, but the rate will be 1-10%).

A. The product is objectively demonstrated to offer, through structural and other innovations, enhanced safety for healthcare professionals, such as a reduced risk of occupational infection, compared to existing listed products in a similar functional category.
B. The newly listed product is objectively demonstrated, compared to existing listed products in a similar functional category, to have less of an environmental impact in terms of post-use disposal and related processes.
C. The product is objectively demonstrated to offer, through structural and other innovations, less invasive treatment and reduce the incidence of complications for patients, thereby providing safer and more effective treatment compared to existing listed products in a similar functional category.
D. The product is objectively demonstrated to have expanded indications for use, through a smaller, lighter weight, or design innovations, that include pediatric patients, compared to existing listed products in a similar functional category.
E. The procedure is objectively demonstrated, through structural and other innovations, to be able to be performed more safely and easily compared to existing listed products in a similar functional category.
F. The product is objectively demonstrated to have, through structural and other innovations, improved durability such as the ability to maintain its shape or long-term use is possible, compared to existing listed products in a similar functional category.
G. The product is objectively demonstrated to have, through structural and other innovations, improved operability compared to existing listed products in a similar functional category, enabling safer and easier home care for patients.
H. The product excludes all biologically derived raw materials and is objectively demonstrated to have equivalent functions to existing listed products in a similar functional category that use raw materials derived from humans or other living organisms (excluding plants) (hereinafter referred to as “biologically derived raw materials”).

■ The marketability premium, pioneering premium, and specific use premium
Marketability premium (I) applies to devices designated as orphan medical devices.
Marketability premium (II) applies when the estimated number of applicable patients for the product in the application is less than that for products in a similar functional category.
The pioneering premium applies to devices designated as pioneering medical devices.
Medical materials designated under the SAKIGAKE approval review and designation system are treated in the same manner.
Specific use premium applies to devices designated as specific use medical devices.

<Setting the adjustment premium rate>

Each company should set an appropriate premium rate within the range below. For the innovativeness premium, usefulness premium, and improvement premium, refer to "Research on Quantitative Evaluation of the Standards for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials" (Takura Tomoyuki, co-researcher (medical device specialist)) (http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000078087.pdf).

Innovativeness premium: 50% to 100% Usefulness premium: 5% to 30%
Improvement premium: 1% to 20% (clinical efficacy has been demonstrated with a high degree of probability, the rate will be 1-10%)
Marketability premium (I): 10% Marketability premium (II): 1% to 5%
Pioneering premium: 10% Specific use premium: 10%

9 Enter the requested calculated price including the adjustment premium (round to the nearest thousand). Generally, applications cannot be made for a price that exceeds 1.25 times the average foreign price (up to 1.5 times the average foreign price is permitted for products developed in response to a request from the Ministry of Health, Labour and Welfare based on the results of deliberations by the Needs Review Committee, products designated as orphan medical devices, and products that have been given a new functional category with an innovativeness premium or usefulness premium of 10% or more).

<Method of calculating adjustment premiums>

Depending on the number of adjustment premiums, the amount of the premium can be calculated using the formula below. Please calculate each adjustment premium so that the premium rate (a) falls within the range below.

When there is one adjustment premium: Premium amount = X x a
When there are two adjustment premiums: Premium amount = X x (a1＋a2・・・)

$$\alpha = \frac{A}{100} \times 1.5^{\frac{\log(X/B)}{\log(0.5 \times B/B)}}$$

A: Application rate (%)
B: The arithmetic average of the standard material prices in the field to which the similar functional category belongs
X: Calculated value

(Range of a)
Innovativeness premium: 0.25% to 1.5% Usefulness premium: 0.025% to 0.45%
Improvement premium: 0.025% to 0.3% Marketability premium (I): 0.05% to 0.15%
Marketability premium (II): 0.015% to 0.045%
Pioneering premium: 0.05% to 0.15% Specific use premium: 0.05% to 0.15%

10 If the product in the application has been sold in the United States, the United Kingdom, Germany, France, or Australia, enter the average price in those countries and the ratio of the estimated suggested price to the average price (round to one decimal place). The exchange rate used will be the average rate for the year immediately prior to application (the Office of Medical Devices Policy will instruct you on the rate to be used during pre-consultation). Refer to Form 6, "Document on Price Adjustment" for more information.

11 Until the category is determined, insurance coverage will be available at the price for the functional category that includes the specified insured medical material that is most similar to the product in the application. If you wish to request insurance coverage at a provisional price, please indicate by circling.

12 Circle yes or no for challenge application after the new listing. If yes, attach documentation that will serve as a reference for the plan for data collection and methods of evaluation of the details of a desired reevaluation through a challenge application. For details, refer to Form 3-5, "Document on the Justification for Submitting a Challenge Application."

13 If there are multiple people in charge, underline one main person in charge.

14 If any of the following apply, indicate in the "Remarks" column.
(1) Details of the most recent application for a partial change or minor change
(2) Details of succession, a change in company name, and a change in the Designated Marketing Authorization Holder (submit documents that allow details to be verified)
(3) Records of past coverage of the product by insurance (date of coverage by insurance (date an insurance coverage request form was submitted with regard to decision category A1) and the decision category)
(4) Record of submission of the "Notice of not wishing to be classified as decision category A1 (bundled)" for the product (date of submission)
(5) Reasons for not having either a JAN code or a GS1 code
(6) The applicable field number and name of the functional category are not listed in the "desired category for a specified insured medical material" column in an insurance coverage request form that corresponds to item 10 in the notification of methods of submission.
(7) Date of implementation of changes according to the change plan

Reference number

Attachment 5

Insurance Coverage Request Form for a Medical Device

[Decision Category C1 (New Function)," "C2 (New Technology)," or "B3 (Limited-time Premium for Improvement/Provisional Functional Category (in cases where a similar functional category exists)]

Brand name			
Product name and product code	Product name	Product code	
Category		Generic name	
Approval number, Certification number or Notification number		Date of approval, Date of certification or Date of notification (and the date of the last partial change)	
Product Overview	Photo of the product		
Availability of an instruction manual/pamphlet for medical facilities	Instruction manual for medical facilities: Yes / No Pamphlet: Yes / No		
Need for Maintenance	Required / Not required		
Requested calculation details: Method of calculation	Comparative method based on similar functional categories		
Similar functional category	*112 Pacemaker (1) Single Chamber (i) Standard Type 391,000 yen*		
Adjustment premium	*Improvement premium (a) 5%*		
Requested calculated price	*yen*		
Average foreign price and price in comparison to the average foreign price	*Average foreign price: yen, Price in comparison to the average foreign price:*		
Request for evaluation for expedited insurance listing	Yes / No		
Request for provisional price	Yes / No		
Request for reevaluation based on actual past use	Yes (at the time of listing/after listing) / No		
Applicability as a medical material	Yes / No		
Applicability as a material for at-home care	Yes / No		
Applicability as a dental material	Yes / No		
Applicability as a dispensing material	Yes / No		
Contact Details	Contact Name *Taro Yamada,* *Hanako Yamada*	Telephone number: E-mail:	
Remarks			

Based on the above, I request that this medical device be covered by insurance.

Date (Month/Date/Year)

Address (in the case of a corporation, the location of its principal office)

Name (in the case of a corporation, its name and the name of its representative)

To the Minister of Health, Labour and Welfare

Note: Submit using the Japanese-language forms.

整理番号 1

別紙5 2

医療機器保険適用希望書

〔決定区分C1（新機能）、C2（新機能・新技術）、B3（期限付改良加算・暫定機能区分）（類似機能区分がある場合）〕

販売名 3			
製品名・製品コード	製品名	製品コード	
類　別 4		一般的名称	
承認番号、認証番号又は届出番号 5		承認年月日、認証年月日又は届出年月日（及び最終一部変更年月日）	
製品概要 6			製品の外観写真
医療機関向け取扱い説明書又はパンフレットの有無	医療機関向け取扱い説明書　有　・　無 パンフレット　有　・　無		
メンテナンスの要・不要	要　・　不要		
算定希望内容	算定方式	類似機能区分比較方式	
	類似機能区分 7	112 ﾍﾟｰｽﾒｰｶｰ (1)ｼﾝｸﾞﾙﾁｬﾝﾊﾞ ①標準型 391,000 円	
	補正加算 8	改良加算（イ） ５％	
	算定希望価格	～～～円	
	外国平均価格及び外国平均価格との比 9	外国平均価格：～～～円、外国平均価格と比：～～	
	迅速な保険導入に係る評価の希望の有無 10	有　・　無	
	暫定価格希望の有無 11	有　・　無	
	使用成績を踏まえた再評価希望の有無 12	有（収載時・収載後）・　無	
	医科材料該当性の有無	有　・　無	
	在宅材料該当性の有無	有　・　無	
	歯科材料該当性の有無	有　・　無	
	調剤材料該当性の有無	有　・　無	
担当者連絡先 13 14	担当者名　山田太郎、山田花子	電話番号： Ｅ－ｍａｉｌ：	
備　考			

上記により、医療機器の保険適用を希望いたします。

年　　月　　日

住所（法人にあっては、主たる事務所の所在地）

氏名（法人にあっては、名称及び代表者の氏名）

厚生労働大臣　　殿

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Insurance Coverage Request Form for a Medical Device [Decision Category C1, C2 (in cases where no similar functional category exists)] [Attachment 6]

<Notes>

- Keep it to one A4 sheet. If your application does not fit on a single A4 page, attach additional sheets as necessary.

1 Leave the reference number section blank when submitting the form.

2 Depending on the category you are applying for, please indicate by circling "C1 (New Function)", "C2 (New Technology)".

3 Enter the product name and product code (if there are multiple product names, please indicate the correspondence with the product code). Enter the 13-digit JAN code as the product code. If the product code cannot be written down, submit it as Attachment 1. The method for preparing Attachment 1 is described in the Ministry of Health, Labour and Welfare's administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

4 Transcribe the information contained in the marketing approval dossier or certification.

5 Provide a brief summary of the product in the application. Include a photo of the product's appearance (a small photo is acceptable as long as the product's aspects are evident).

6 Indicate whether the instruction manual and pamphlet for medical facilities are available by circling "Yes" or "No."If so, please attach the relevant documents.

7 Enter the amount specified in Form 5, "Document on Cost Calculation Method."Refer to Form 5, "Document on Cost Calculation Method" for methods of calculation.
If you only request to establish a new technical fee, enter the method of calculation as "evaluation for a technical fee is requested, and the product is not to be specified as a specified insured medical material."

8 If the product in the application has been sold in the United States, the United Kingdom, Germany, France, or Australia, enter the average price in those countries and the ratio of the estimated suggested price to the average price (round to one decimal place). The exchange rate used will be the average rate for the year immediately prior to application (the Office of Medical Devices Policy will instruct you on the rate to be used during pre-consultation). Refer to Form 6, "Document on Price Adjustment" for more information.

9 Circle yes or no for a challenge application after the new listing. If yes, attach documentation that will serve as a reference for the plan for data collection and methods of evaluation of the details of a desired reevaluation through a challenge application. For details, refer to Form 3-5, "Document on the Justification for Submitting a Challenge Application."

10 If there are multiple people in charge, underline one main person in charge.

11 If any of the following apply, indicate in the "Remarks" column.
(1) Details of the most recent application for a partial change or minor change
(2) Details of succession, a change in company name, and a change in the Designated Marketing Authorization Holder (submit documents that allow details to be verified)
(3) Records of past coverage of the product by insurance (date of coverage by insurance (date an insurance coverage request form was submitted with regard to decision category A1) and the decision category)
(4) Record of submission of the "Notice of not wishing to be classified as decision category A1 (bundled)" for the product (date of submission)
(5) Reasons for not having either a JAN code or a GS1 code
(6) The applicable field number and name of the functional category are not listed in the "desired category for a specified insured medical material" column in an insurance coverage request form that corresponds to item 10 in the notification of methods of submission.
(7) Date of implementation of changes according to the change plan

Reference number

Attachment 6

Insurance Coverage Request Form for a Medical Device

[Decision Category C1 (New Function), C2 (New Technology) (in cases where no similar functional category exists, or only new technology is involved)]

Brand name			
Product name and product code	Product name	Product code	
Category		Generic name	
Approval number, Certification number or Notification number		Date of approval, Date of certification or Date of notification (and the date of the last partial change)	
Product Overview			Photo of the product
Instruction manual for medical facilities /pamphlet for medical facilities	Instruction manual for medical facilities: Yes / No Pamphlet: Yes / No		
Need for Maintenance	Required / Not required		
Requested calculation details — Method of calculation	Cost calculation method		
Cost calculation — Raw material costs			
Selling, general and administrative expenses			
Research and development expenses			
Operating profit			
Distribution costs			
Consumption tax equivalent amount			
Requested calculated price			
Average foreign price and price in comparison to the average foreign price	*Average foreign price: yen, Price in comparison to the average foreign :*		
Request for evaluation for expedited insurance listing	Yes / No		
Request for reevaluation based on actual past use	Yes / No		
Applicability as a medical material	Yes / No		
Applicability as a material for at-home care	Yes / No		
Applicability as a dental material	Yes / No		
Applicability as a dispensing material	Yes / No		
Contact Details	Contact Name: *Taro Yamada, Hanako Yamada*	Telephone number: E-mail:	
Remarks			

Based on the above, I request that this medical device be covered by insurance.

Date (Month/Date/Year)

Address (in the case of a corporation, the location of its principal office)

Name (in the case of a corporation, its name and the name of its representative)

To the Minister of Health, Labour and Welfare

Note: Submit using the Japanese-language forms.

整理番号

別紙６

医療機器保険適用希望書

〔決定区分Ｃ１（新機能）、Ｃ２（新機能・新技術）（類似機能区分がない場合、新技術のみの場合）〕

販売名			
製品名・製品コード	製品名	製品コード	
類　別		一般的名称	
承認番号、認証番号又は届出番号		承認年月日、認証年月日又は届出年月日（及び最終一部変更年月日）	
製品概要			製品の外観写真
医療機関向け取扱い説明書又はパンフレットの有無	医療機関向け取扱い説明書　有・無 パンフレット　有・無		
メンテナンスの要・不要	要・不要		
算定希望内容　算定方式	原価計算方式		
原価計算　原材料費			
一般管理販売費			
研究開発費			
営業利益			
流通経費			
消費税相当額			
算定希望価格			
外国平均価格及び外国平均価格との比	*外国平均価格：～～～円、外国平均価格と比：～～*		
迅速な保険導入に係る評価の希望の有無	有・無		
使用成績を踏まえた再評価希望の有無	有・無		
医科材料該当性の有無	有・無		
在宅材料該当性の有無	有・無		
歯科材料該当性の有無	有・無		
調剤材料該当性の有無	有・無		
担当者連絡先	担当者名 *山田太郎、山田花子*	電話番号： Ｅ－ｍａｉｌ：	
備　考			

上記により、医療機器の保険適用を希望いたします。

年　　月　　日

住所（法人にあっては、主たる事務所の所在地）

氏名（法人にあっては、名称及び代表者の氏名）

厚生労働大臣　　殿

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Insurance Coverage Request Form for a Medical Device [Decision Category R] [Attachment 7-1]

<Notes>

- Keep it to one A4 sheet. If your application does not fit on a single A4 page, attach additional sheets as necessary.

1 Leave the reference number section blank when submitting the form.

2 Enter product name and product code (if there are multiple product names, please indicate the correspondence with the product code). Enter the 13-digit JAN code as the product code. If the product code cannot be written down, submit it as Attachment 1. The method for preparing Attachment 1 is described in the Ministry of Health, Labour and Welfare's administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

3 Transcribe the information contained in the marketing approval dossier or certification.

4 Provide a brief summary of the product in the application. Include a photo of the product's appearance (a small photo is acceptable as long as the product's aspects are evident).

5 Indicate whether an instruction manual and pamphlet for medical facilities are available by circling "Yes" or "No." If so, please attach the relevant documents.

6 For a similar functional category, enter the category number and name of the material price standard and the price (material price standards can be found on the Ministry of Health, Labor and Welfare's website. For more information, refer to "7. Frequently Asked Questions").

7 Enter the requested calculated price (round to the nearest thousand). For the calculation of the standard material price for remanufactured products, the standard material price for the new functional category to which the original medical device of the newly listed product belongs is multiplied by the remanufacturing coefficient. This amount is considered to be the standard material price for the new functional category to which the newly listed product belongs. The remanufacturing coefficient is generally set at 0.7, but this is to be determined taking into consideration the manufacturing process for the remanufactured product.

8 If the product in the application has been sold in the United States, the United Kingdom, Germany, France, or Australia, enter the average price in those countries and the ratio of the estimated suggested price to the average price (round to one decimal place). The exchange rate used will be the average rate for the year immediately prior to application (the Office of Medical Devices Policy will instruct you on the rate to be used during pre-consultation). Refer to Form 6, "Document on Price Adjustment" for more information.

9 If there are multiple people in charge, underline one main person in charge.

10 If any of the following apply, indicate in the "Remarks" column.
(1) Details of the most recent application for a partial change or minor change
(2) Details of succession, a change in company name, and a change in the Designated

Marketing Authorization Holder (submit documents that allow details to be verified)
(3) Records of past coverage of the product by insurance (date of coverage by insurance (date an insurance coverage request form was submitted with regard to decision category A1) and the decision category)
(4) Record of submission of the "Notice of not wishing to be classified as decision category A1 (bundled)" for the product (date of submission)
(5) Reasons for not having either a JAN code or a GS1 code
(6) The applicable field number and name of the functional category are not listed in the "desired category for a specified insured medical material" column in an insurance coverage request form that corresponds to item 10 in the notification of methods of submission.
(7) Date of implementation of changes according to the change plan

Reference number

Attachment 7-1

Insurance Coverage Request Form for a Medical Device

[Decision category R (Remanufacturing)]

Brand name				
Product name and product code	Product name		Product code	
Category		Generic name		
Approval number or Certification number		Date of approval or Date of certification (and the date of the last partial change)		
Product Overview	Photo of the product			
Instruction manual for medical facilities /pamphlet for medical facilities	Instruction manual for medical facilities	Yes / No		
	Pamphlet	Yes / No		
Need for maintenance	Required	Not required		
Requested calculation details: Method of calculation	Comparative method based on similar functional categories			
Similar functional category	*112 Pacemaker (1) Single Chamber (i) Standard Type 391,000 yen*			
Requested calculated price	*yen*			
Average foreign price and price in comparison to the average foreign price	*Average foreign price:*	*Yen, Price in comparison to the average foreign price:*		
For expedited insurance listing expedited insurance coverage	Yes / No			
Applicability as a medical material	Yes / No			
Applicability as a material for at-home care	Yes / No			
Applicability as a dental material	Yes / No			
Applicability as a dispensing material	Yes / No			
Applicability to other medical materials	Yes / No			
Contact Details	Contact Name: *Taro Yamada, Hanako Yamada*	Telephone number: E-mail:		
Remarks				

Based on the above, I request that this medical device be covered by insurance.

Date (Month/Date/Year)

Address (in the case of a corporation, the location of its principal office)

Name (in the case of a corporation, its name and the name of its representative)

To the Minister of Health, Labour and Welfare

Note: Submit using the Japanese-language forms.

整理番号 1

別紙７－１

医療機器保険適用希望書

〔決定区分Ｒ（再製造）〕

販売名 2			
製品名・製品コード	製品名	製品コード	
類　別 3		一般的名称	
承認番号又は認証番号		承認年月日 又は 認証年月日 （及び最終一部変更年月日）	
製品概要 4			製品の外観写真
医療機関向け取扱い説明書又はパンフレットの有無 5	医療機関向け取扱い説明書	有 ・ 無	
	パンフレット	有 ・ 無	
メンテナンスの要・不要	要 ・ 不要		
算定希望内容	算定方式	類似機能区分比較方式	
	類似機能区分 6	*112 ﾍﾟｰｽﾒｰｶｰ (1)ｼﾝｸﾞﾙﾁｬﾝﾊﾞ ①標準型 391,000 円*	
	算定希望価格 7	*～～～円*	
	外国平均価格及び外国平均価格との比 8	*外国平均価格：～～～円、外国平均価格と比：～～*	
	迅速な保険導入に係る評価の希望の有無	有 ・ 無	
	医科材料該当性の有無	有 ・ 無	
	在宅材料該当性の有無	有 ・ 無	
	歯科材料該当性の有無	有 ・ 無	
	調剤材料該当性の有無	有 ・ 無	
	その他の医療材料該当性の有無	有 ・ 無	
担当者連絡先	担当者名： 9 *山田太郎、山田花子*	電話番号： Ｅ－ｍａｉｌ：	
備　考 10			

上記により、医療機器の保険適用を希望いたします。

年　　月　　日

住所（法人にあっては、主たる事務所の所在地）

氏名（法人にあっては、名称及び代表者の氏名）

厚生労働大臣　　殿

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Application Form for Insurance Coverage of a Medical Device [From 1-1]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

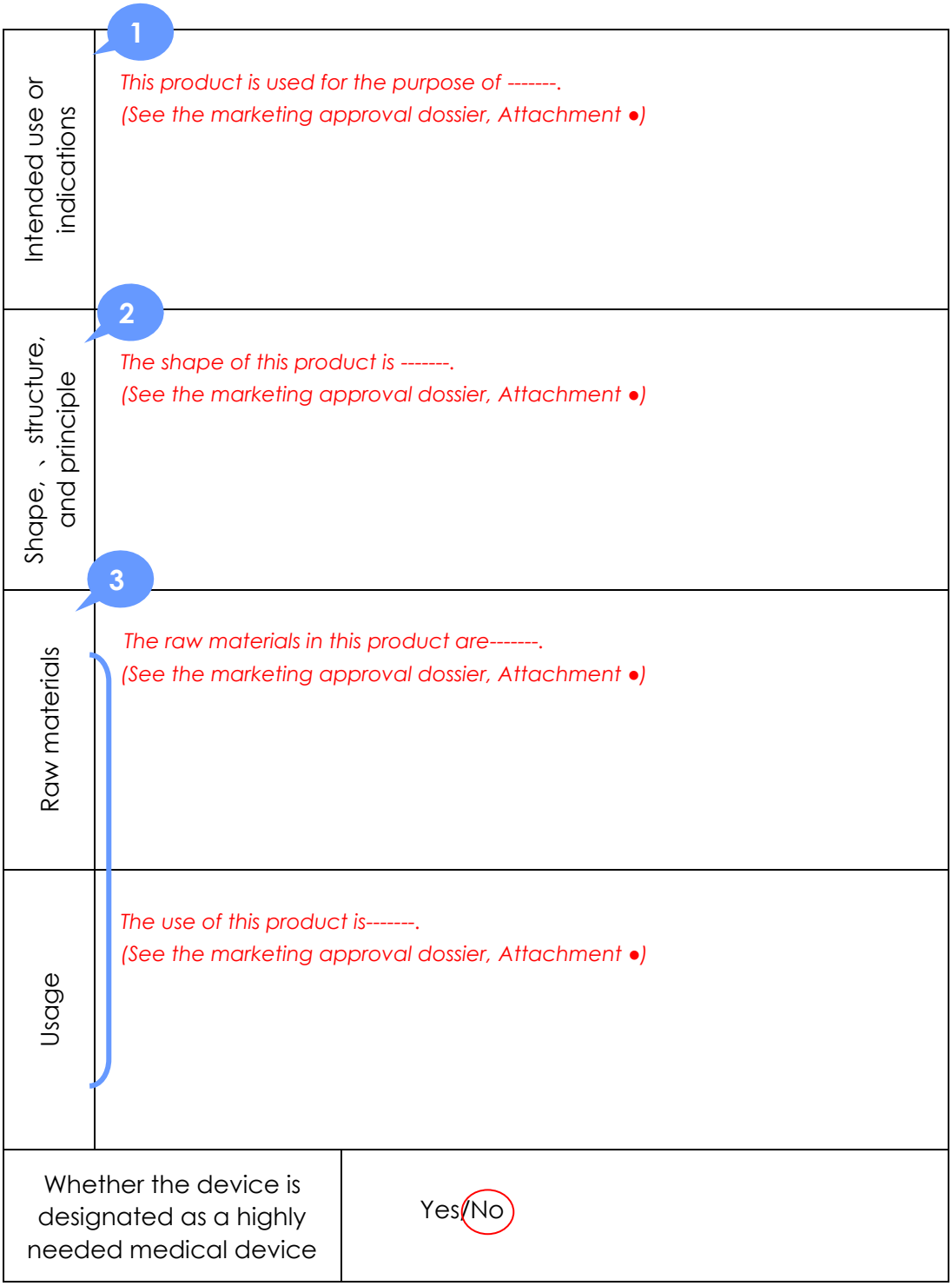
1 Transcribe the information in "Intended Use and Indications" from the marketing approval dossier or certification document, and specify the corresponding attachment number.

2 Transcribe the information in “Shape, Structure, and Principle" from the marketing approval dossier or certification document, and specify the corresponding attachment number. If there is a lot to write, you may just excerpt the important parts.

3 If there are any definition-related items to explain the rationale for selecting the requested category, please transcribe the relevant sections from the marketing approval dossier or certification document and specify the corresponding attachment number. If they are not relevant to the rationale for selecting the requested category, please indicate "No Definition-related Items" and specify the corresponding attachment number.

Form 1-1

Application Form for Insurance Coverage of a Medical Device



Note: Submit using the Japanese-language forms.

様式１－１

医療機器保険適用希望資料

使用目的又は効果	1 *本品は～～～～～～～の目的のために使用する。* *（薬事承認書　別紙●　参照）*
形状、構造及び原理	2 *本品の形状は～～～～～～～～～～。* *（薬事承認書　別紙●　参照）*
原材料	3 *本品の原材料は～～～～～～～。* *（薬事承認書　別紙●　参照）*
使用方法	*本品の使用方法は～～～～～～～～～～～～。* *（薬事承認書　別紙●　参照）*
医療ニーズの高い医療機器への指定の有無	有　・　無（○）

Supporting Documents on the Estimated Number of Applicable Patients and Projected Sales Volume [Form 1-2]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Enter the estimated number of patients for whom the product will be used in medical treatment over a one-year period. For example, if the product is used for lung cancer patients, the number of lung cancer patients would be entered. If the estimated number of applicable patients is expected to change in the future, enter the year in which that number will be greatest.

2 Enter the estimated number of patients covered by insurance from the first year of coverage to the 10th year.

3 Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based. When making calculations, refer to various data sources such as the Statistics on Medical Care in Public Health Insurance (formerly: Survey of Medical Care in Public Health Insurance), market research on medical devices, NDB data, and research conducted by the Ministry of Health, Labour and Welfare. If there are guidelines for proper use of or treatment involving the product in the application, please also refer to those documents to avoid any contradictions. The clinical positioning of the applicable patients for the product in the application should be clearly defined using a flow chart or the like.
The estimated number of applicable patients is determined by patient factors such as medical need. Please do not make estimates based on a company's sales efforts. When making the calculation, enter the formula for the estimated number of applicable patients.

4 Indicate the year in which you anticipate your sales will peak and your estimated sales revenue for that year.

5 Regarding the number of patients who will use this medical device, enter the number of patients who are expected to purchase and use the product, taking into account the company's sales efforts, out of the estimated number of applicable patients. The number of patients using this medical device per year will be less than the estimated number of applicable patients.

6 Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based. If there are any conditions regarding the use of the product in the application, such as facility standards or training for healthcare professionals, enter those specific conditions. Also, take into consideration the market share of competing products. When making the calculation, enter the formula for the number of patients using this medical device.

Form 1-2

Supporting Documents on the Estimated Number of Applicable Patients and Projected Sales Volume

Estimated number of applicable patients (patients/year) (1)	patients/year (peak: FY ●)

1st year _____ patients (2)
2nd year _____ patients
3rd year _____ patients
4th year _____ patients
5th year _____ patients
6th year _____ patients
7th year _____ patients
8th year _____ patients
9th year _____ patients
10th year _____ patients

The rationale (3)

Projected sales revenue for the medical device (yen/year) (4)	million yen/year (peak: FY year●)

(Sales amount) Number of patients using the medical device

1st year _____ million yen _____ patients (5)
2nd year _____ million yen _____ patients
3rd year _____ million yen _____ patients
4th year _____ million yen _____ patients
5th year _____ million yen _____ patients
6th year _____ million yen _____ patients
7th year _____ million yen _____ patients
8th year _____ million yen _____ patients
9th year _____ million yen _____ patients
10th year _____ million yen _____ patients

The rationale (6)

Note: Submit using the Japanese-language forms.

様式１－２

推定適用患者数及び予測売上高根拠資料

推定適用患者数（人／年間） 1	～～～～人／年間（ピーク時：●年度）

2

初年度	人
２年度	人
３年度	人
４年度	人
５年度	人
６年度	人
７年度	人
８年度	人
９年度	人
１０年度	人

3 その根拠

本医療機器の予測売上高（円／年間） 4	～～～億円／年間（ピーク時：●年度）

5

	（販売金額）	本医療機器使用患者数
初年度	億円	人
２年度	億円	人
３年度	億円	人
４年度	億円	人
５年度	億円	人
６年度	億円	人
７年度	億円	人
８年度	億円	人
９年度	億円	人
１０年度	億円	人

6 その根拠

Similar Functional Category and the Rationale for Its Selection [Form 2-2]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 For a similar functional category, enter the category number and name for the material price standard (material price standards can be found on the Ministry of Health, Labor and Welfare's website. For more information, refer to "7. Frequently Asked Questions").
If you wish to change the definition of a Medical Device Subject to Specific Medical Fees, enter the name of the category of the Medical Device Subject to Specific Medical Fees you wish to change (Medical Devices Subject to Specific Medical Fees can be found on the Ministry of Health, Labor and Welfare's website. For more information, refer to "7. Frequently Asked Questions").

2 Use a table as shown in the example (or a figure) to explain the aspects of and the page in the marketing approval dossier or certification document where the product is deemed to conform to the definition of a Similar Functional Category or a Medical Device Subject to Specific Medical Fees. Also, if the category or general name does not match the definition, explain the reason.

<Concept of the rationale for the selection of a similar functional category>
A similar functional category refers to an existing functional category that is most similar to the new functional category being applied for. The following four points are considered as the rationale for selection.

- Categories with a similar "intended use" (competing products)
- Categories with similar "applicable patients"
- Categories in which there are products with the same or nearly similar "structures"
- Categories with similar "indications"

List the functional categories that could be selected as similar functional categories, determine which functional category is most similar, and examine the rationale for why that category is the most similar. Please also consider and explain the rationale for why you did not select any other category.

Form 2-2

Similar Functional Category and the Rationale for Its Selection

Name of a similar functional category (1)	*112 Pacemaker (1) Single Chamber (i) Standard Type*

Rationale for the selection (2)

Definition of a similar functional category (or category of medical devices subject to specific medical fees)	*Approval page/contents*	*Supplement*
In terms of approval or certification under the Pharmaceutical Affairs Act, -------	*(See the marketing approval dossier, Attachment ● dated) ....*	*Meets the definition*

Note: Submit using the Japanese-language forms.

様式２－２

類似機能区分及び類似機能区分選定の根拠

類似機能区分の名称	*112 ﾍﾟｰｽﾒｰｶｰ (1)ｼﾝｸﾞﾙﾁｬﾝﾊﾞ ①標準型*

選定した根拠

類似機能区分（または特定診療報酬算定医療機器の区分）の定義	*承認書該当ページ／内容*	*補足*
薬事法承認又は認証上、・・・	*平成●年●月●日* *薬事承認書　別紙○―○* *・・・・・*	*定義に合致する*

Rationale for the Lack of a Similar Functional Category [Form 2-3]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Use a table as an example to explain why use of cost calculation method is appropriate when there is no similar functional category. Also list the procedure fee for similar functional categories. When applying under category C2, specify the procedure fee to be referenced by analogy, and provide the rationale if the applicable procedure fee is deemed inappropriate.
If you do not wish to have your device covered by insurance as a specified insured medical material in category C2 (such as large equipment), please state, "This device does not qualify as a specified insured medical material, so there is no similar functional category."

<Rationale for the lack of a similar functional category>

A functional category is defined as “a group of specified insured medical materials that are deemed to be similar in terms of structure, intended use, indications, etc.,” and a similar functional category is defined as “an existing functional category that is most similar to the new functional category.” Therefore, in order to show that there are no similar functional categories, list the functional categories that could be selected as similar functional categories, and provide reasons for ruling them out from the viewpoint of “structure,” “intended use,” "applicable patients," “indications,” etc.
For the product that is considered to be most similar within the listed functional category, fill in the product name, manufacturer, approval number or certification number, date of approval, date of insurance coverage, etc. to the extent possible, and fill in the information so that the product in the application is clearly not similar to existing products (change the items according to the product). Also include any relevant procedural fee.

Form 2-3

1

Rationale for the Lack of a Similar Functional Category

Rationale for the lack of similar functional categories in existing functional categories

[Functional category that can be selected as a similar functional category]

<Functional category: >

Definition of a functional category that can be selected as a similar functional category	*Approval page/contents*	*Supplement*
In terms of approval or certification under the Pharmaceutical Affairs Act, -------	*(See the marketing approval dossier, Attachment ● dated) ....*	*Do not meet the definition*

Related procedure costs:

[The most similar product among the above functional categories]

Product name: ○○
Marketing authorization holder:
Approval number:
Date of approval: Date (Month/Date/Year)
Insurance coverage date: Date (Month/Date/Year)

	Product in the application	*Existing product*	*Remarks*
Product name	---	---	
Functional category	*To be decided*	○○○	
Category/general name	---	---	
Intended Use	---	---	*(Explain that the product is not similar to existing products; the same applies below)*
Structure (overview)	---	---	
Indication	---	---	
Specification (function)	---	---	
Clinical Result	---	---	
Benefits for patients	---	---	

Related procedure fee:

Note: Submit using the Japanese-language forms.

様式２－３

類似機能区分がない根拠

1

既存の機能区分において類似機能区分がない根拠

〔類似機能区分として選定されうる機能区分〕

＜機能区分：～～～～～～～～～～＞

類似機能区分として選定されうる機能区分の定義	*承認書該当ページ／内容*	*補足*
薬事法承認又は認証上、・・・	*平成●年●月●日　薬事承認書　別紙○―○・・・・・*	*定義に合致しない*

関連手技料：～～～～～～～～～～～～～～～～

〔上記機能区分のうち、最も類似する製品〕

製品名：○○
製造販売業者：・・・・
承認番号：・・・・・・・・
承認年月日：○○年○月○日
保険適用年月日：○○年○月○日

	申請品	*既存品*	*備考*
製品名	*～～～～*	*～～～～*	
機能区分	*未定*	*○○○*	
類別・一般的名称	*～～～～*	*～～～～*	
使用目的	*～～～～*	*～～～～*	*（既存品との類似性がない旨の説明を記載する、以下同様）*
構造（概観）	*～～～～*	*～～～～*	
適用疾患	*～～～～*	*～～～～*	
スペック（機能）	*～～～～*	*～～～～*	
臨床成績	*～～～～*	*～～～～*	
患者のメリット	*～～～～*	*～～～～*	

関連手技料：～～～～～～～～～～～～

Rationale for the Application of an Adjustment Premium (Innovativeness Premium or Usefulness Premium) [Form 3-1]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- If you do not wish a premium to be applied or wish the product to be listed under an existing category (e.g., with a revision to the definition), submission of this form is not required.

1 Regarding the requirements (A) to (C) for the innovativeness premium or the usefulness premium that the product in the application meets, indicate its applicability (usefulness) in comparison to all products listed in a similar functional category. Please explain the usefulness of the product using data such as clinical trial results (published papers). If the usefulness has also been evaluated in a regulatory review, indicate the relevant page(s) of the review report or the STED. Delete any items that are not applicable.
"How the product in the application can solve the problems faced by healthcare professionals and patients" needs to be explained in a logical and ordered manner, relating it to the information contained in other documents.

<Common examples of inappropriate descriptions>
Please note that the following statements will not be accepted as a rationale:

- Compared to products that do not fall under a similar functional category (for example, products not approved in Japan or products in a different category than a similar functional category),
- Compared to a specific product that does not have high functionality among products in a similar functional category,
- Compared to data for which a direct comparison would be difficult, etc.

<Setting the adjustment premium rate>
For the innovativeness premium, usefulness premium, and improvement premium, refer to "Research on Quantitative Evaluation of the Standards for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials" (Takura Tomoyuki, co-researcher (medical device specialist)) (http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000078087.pdf).

Form 3-1

Rationale for the Application of an Adjustment Premium
(Innovativeness Premium or Usefulness Premium)

Clinical trial status	Yes/No
A. A new mechanism that is clinically useful.	
B. High level of efficacy or safety	
C. Improvement of treatments for the target disease or injury	

1

様式３－１

補正加算適用の根拠（画期性加算又は有用性加算）

治験の有無	有　・　無
イ　臨床上有用な新規の機序について	
ロ　高い有効性又は安全性について	
ハ　対象疾病又は負傷の治療方法の改善について	

1

Rationale for the Application of an Adjustment Premium (Improvement Premium/Limited-time Premium for Improvement) [Form 3-2]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- If you do not wish a premium to be applied or wish the product to be listed under an existing category (e.g., with a revision to the definition), submission of this form is not required.

1 Regarding the requirements (A) to (H) for the improvement premium that the product in the application must meet, compare the requirements to all products listed in a similar functional category and enter the applicability of the requirements (usefulness of the product in the application). Please explain the usefulness of the product using data such as clinical trial results (published papers). If the usefulness has also been evaluated in a regulatory review, indicate the relevant page(s) of the review report or the STED. Delete any items that are not applicable.
"How the product in the application can solve the problems faced by healthcare professionals and patients" needs to be explained in a logical and ordered manner, relating it to the information contained in other documents.

<Examples of cases where a probability evaluation is required>
If there are no data indicating clinical efficacy and a probabilistic evaluation is required, provide a logical explanation by including non-clinical data.

> Points you wish to assert: Acetabular cups that allow for the use of larger stem heads have been developed, thus reducing dislocation rates.
>
> Details on data: Although there are no data directly comparing the dislocation rate between conventional cups and this product, the data indicate that with conventional cups, the larger the stem head, the lower the dislocation rate.

<Setting the adjustment premium rate>
For the innovativeness premium, usefulness premium, and improvement premium, refer to "Research on Quantitative Evaluation of the Standards for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials" (Takura Tomoyuki, co-researcher (medical device specialist)) (http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000078087.pdf).

Form 3-2

Rationale for the Application of an Adjustment Premium
(Improvement Premium/Limited-time Premium for Improvement)

Clinical trial status	Yes/No
A. Safety for healthcare professionals	
B. Impact of waste disposal on the environment	
C. Safety and efficacy for patients	
D. Expansion of indications to children	
E. Possibility of safe and simple procedures	
F. Improved durability and the possibility of long-term use	
G. Safety and ease for patients receiving at-home care	
H. Functional equivalence when excluding biologically derived raw materials	

1

Note: Submit using the Japanese-language forms.

様式３－２

補正加算適用の根拠（改良加算・期限付改良加算）

治験の有無	有　・　無
イ　医療従事者への安全性について	
ロ　廃棄処分等が環境に及ぼす影響について	
ハ　患者にとっての安全性及び有効性について	
ニ　小児等への適応の拡大について	
ホ　安全かつ簡易な手技の可能性について	
ヘ　耐久性の向上及び長期使用の可能性について	
ト　患者にとっての在宅での療養の安全性及び容易性について	
チ　生物由来原料等を除いた場合における機能の同等性について	

Rationale for the Application of Adjustment Premiums (Marketability Premium [I], [II], Pioneering Premium, and Specific Use Premium) [Form 3-3]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- If you do not wish a premium to be applied or wish the product to be listed under an existing category (e.g., with a revision to the definition), submission of this form is not required.

1 Fill in if you wish for the marketability premium (I), pioneering premium, or specific use premium to be applied.

2 Fill in if you wish for the marketability premium (II) to be applied. In the "Estimated number of patients" section, enter the number of patients who are estimated to receive medical treatment using the product in the application in one year. Make sure that this number is the same as the estimated number of applicable patients entered in "Supporting Documents on the Estimated Number of Applicable Patients and Projected Sales Volume" [Form 1-2]

Form 3-3

Rationale for the Application of Adjustment Premiums (Marketability Premium [I], [II], Pioneering Premium, and Specific Use Premium)

1

1. Orphan medical device designation under the Pharmaceutical and Medical Device Act [Marketability premium (I)], Pioneering medical device designation, or Specific use medical device designation

Yes/No

Date of the designation: Date (Month/Date/Year)

2

2. If not applicable for an orphan medical device designation [marketability premium (II)] under the Pharmaceutical and Medical Device Act

Target disease		Estimated number of patients	

Rationale for the estimated number of patients

Note: Submit using the Japanese-language forms.

様式３－３

補正加算適用の根拠（市場性加算（Ⅰ）・（Ⅱ）、先駆加算及び特定用途加算）

1

１　医薬品医療機器等法に基づく希少疾病用医療機器（市場性加算（Ⅰ））、先駆的医療機器及び特定用途医療機器指定 有　・　無 指定年月日　　年　　月　　日

2

２　医薬品医療機器等法に基づく希少疾病用医療機器に該当しない場合（市場性加算（Ⅱ））			
対象疾病		推定患者数	
推定患者数の根拠			

Rationale for Application of the Cost-Effectiveness Premium [Form 3-4]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- If you do not wish a premium to be applied or wish the product to be listed under an existing category (e.g., with a revision to the definition), submission of this form is not required.

1 Circle yes or no for clinical trial status.

2 Enter the total amount obtained by multiplying the average number of existing listed products used at one time in a single treatment by the standard material price for the functional category to which the existing listed product belongs. Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based.

3 Enter the total amount calculated by multiplying the expected average number of newly listed products used at one time in a single treatment by the reimbursement price for the existing functional category. Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based.

Enter the reasons why the cost-effectiveness premium applies, including the following points:

(1) The target disease, intended use, etc. are the same as those of existing products

(2) The product has equivalent or greater clinical efficacy and can be used as an alternative to the existing listed product.

(3) Costs related to specified insured medical materials are expected to be reduced compared to using existing listed products.

In addition, based on the amounts calculated in (1) and (2) above, please calculate the premium amount using the following formula.

$$\text{Premium amount} = \frac{\text{(Projected cost savings)}}{\text{(Estimated average number of uses of the product)}} \times 0.5$$

Form 3-4

Rationale for Application of the Cost-Effectiveness Premium

1

Clinical trial status	Yes/No

A. Costs associated with the use of existing products

2

B. Costs associated with the use of the relevant product

3

C. Rationale for the Cost-Effectiveness Premium

(1) The target disease, intended use, etc. are the same as those of existing products.

○○○

4

(2) The product has equivalent or greater clinical efficacy and can be used as an alternative to the existing listed product.

△△△

(3) Costs related to specified insured medical materials are expected to be reduced compared to using existing listed products.

□□□

The premium amount is -

Note: Submit using the Japanese-language forms.

様式３－４

経済性加算適用の根拠

1

治験の有無	有　・　無

イ　既存製品を用いた場合の費用について

2

ロ　当該製品を用いた場合の費用について

3

ハ　経済性加算に該当する根拠について

① 対象疾患及び使用目的等が既収載品と同じであること

〇〇〇

4

② 臨床的な有効性が同等以上であり当該既収載品の代替となるものであること

△△△

３既収載品を使用した場合と比較して特定保険医療材料に係る費用の削減が期待されること

□□□

加算額は～

Documents on the Justification for Submitting a Challenge Application [Form 3-5]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- Submit this form only if you wish to submit a challenge application after listing.

1 Briefly explain the rationale justifying a challenge application.

<Examples where verifying true clinical efficacy before insurance coverage may be difficult>

Bioabsorbable coronary stents

: Unlike conventional metallic stents that remain in the body, this stent has the unique feature of biodegrading and disappearing in approximately three years. The benefits of its biodegradation and disappearance are expected even after a longer period of time.

- Reduction of long-term events
- Preserving treatment options when undergoing retreatment

2 Enter your data collection and evaluation plan. Also attach any relevant documents.

Regarding the applicable patients, if any inclusion/exclusion criteria have been set, please explain the details of those criteria and describe the measures taken to ensure that only patients suitable for evaluation of the product in the application are enrolled.

Regarding the number of patients and the rationale for that number, please describe how you calculated the number of patients necessary to perform the evaluation, taking into account the evaluation items and verification contents of the product in the application (superiority, non-inferiority verification, etc.). Also, indicate that there is a sufficient number of patients to perform the evaluation.

Regarding evaluation items, indicate that the evaluation items necessary for evaluating the usefulness of the product in the application have been set. Therefore, you need to carefully explain, using clinical guidelines, what items are being evaluated for each set item (for example, the evaluation items are those that have been agreed upon by academic societies).

Regarding the analysis plan, indicate the type of analysis that will be performed to evaluate the usefulness of the product in the application (e.g., verifying superiority over currently listed products or verifying that the product meets pre-defined standards based on the literature). Also, include which item you intend to request an additional premium for, in the event that future data demonstrating the usefulness of the product becomes available (e.g., requesting an Adjustment premium for functional category 100).

Plan for Data Collection and Evaluation after Listing
● **Applicable patients**: Patients for whom this product is applicable ● **Existing treatments (comparative control)**: Existing standard treatments for applicable patients ● **Current issues**: Current clinical issues to be resolved ● **Efficacy of the product**: Efficacy of the product as a solution to the current issues ● **Reasons efficacy cannot be evaluated at the time of insurance coverage** ● **Method of evaluation** • Test type • Test purpose • Applicable patients • Number of patients and the rationale for that number • Enrollment period and evaluation period • Evaluation items • Analysis Plan

Form 3-5

1

Documents on the Justification for Submitting a Challenge Application

Applicable patients		Existing treatment (for comparison)	
Current issues			
The usefulness of the product			
Rationale for the inability to evaluate usefulness upon applying for insurance coverage			
Method of evaluation	Test type		
	Test purpose		
	2 Applicable patients		
	Number of patients and the rationale for that number		
	Enrollment period		
	Evaluation period		
	Evaluation items		
	Analysis plan		

Note: Submit using the Japanese-language forms.

様式３－５

1

チャレンジ申請を行うことの妥当性に関する資料

対象患者		既存治療 （比較対象）	
現状の課題			
当該製品の有用性			
保険適用時に有用性を評価できない理由			
評価方法	試験の種類		
	試験目的		
	対象患者		
	症例数及びその根拠		
	登録期間		
	評価期間		
	評価項目		
	解析計画		

Rationale for Medical Devices that Require Special Consideration for Use in Testing for Rare Diseases [Form 3-6]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- Submit this form only if you believe that the medical device requires special consideration for use in testing for rare diseases.

1 Regarding the orphan medical device designation under the Pharmaceutical and Medical Device Act, circle “Yes” or “No.”If yes, enter the date of designation.

2 If the medical device is related to testing used to determine the suitability of pharmaceuticals and the test is expected to seldom be performed, enter the applicable patients and the estimated number of patients. For "Estimated number of patients," enter the peak number of patients who are estimated to receive medical treatment using the product in the application in one year. Make sure that this number is the same as the estimated number of applicable patients entered in “Supporting Documents on the Estimated Number of Applicable Patients and Projected Sales Volume” [Form 1-2]

3 Enter the rationale for the estimated number of patients. If the information is the same as that in Form 1-2, you can write "Omitted since the information is the same as that in Form 1-2."

Form 3-6

Rationale for Medical Devices that Require Special Consideration for Use in Testing for Rare Diseases

1 Orphan medical device designation under the Pharmaceutical and Medical Device Act 1 Yes/No Date of the designation: Date (Month/Date/Year)			
2. If the medical device is used for testing to determine the suitability of pharmaceuticals and the test is expected to seldom be performed			
Applicable patients 2		Estimated number of patients	
Rationale for the estimated number of patients 3			

Note: Submit using the Japanese-language forms.

様式３－６

希少疾病等の検査に用いるものとして配慮が必要な医療機器の根拠

１　医薬品医療機器等法に基づく希少疾病用医療機器指定 1 有　・　無 指定年月日　　年　　月　　日
２　検査回数が少ないことが予想される医薬品の適応判定に用いる検査に係る医療機器の場合

2 対象患者		推定患者数	

推定患者数の根拠

3

Medical Technology Related to the Medical Device [Form 4]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Please separately fill in the following items regarding the medical technology related to this medical device, taking into consideration how it is positioned in the methods of calculating medical fees (Ministry of Health, Labour and Welfare Notification No. 59 of 2008).

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current treatments for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background to the development of the product in the application based on the issues and needs (including an explanation of the product's features and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether or not guidelines for proper use, including requests for early introduction and requirements for the performing physician, have been established, and if so, their details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

[Details on the insurance coverage requested]

- If you wish to set a new technical fee, please explain the details of the insurance coverage you would like to receive (including an explanation of the medical fee points and points of note regarding existing treatments, as well as the details of the requested insurance coverage for the product in the application and the reasons for selecting the reference technical fee).
- If you wish to have your product listed as a specified insured medical material, explain a similar functional category and the requested price (If you believe that there is no similar functional category, state the reason why your product does not fall under any of the existing functional categories and the details of the new functional category you are requesting. In the case of cost calculation, the breakdown. If you wish a premium to be applied, include the applicable items and an explanation of their applicability).

<How to select reference technology>

When selecting reference technologies, the basic approach is to estimate costs based on the "2020 Draft Proposal of the Japanese Health Insurance Federation for Surgery" from the Japanese Health Insurance Federation for Surgery (Gaihoren) and the "Proposal for Medical Fee Evaluation for Internal Medicine Techniques ver. 1" from the Social Insurance Union of Societies Related to Internal Medicine (Naihoren) and then to select a reference technology with similar aspects.

In addition, if the usefulness of the product in the application is objectively

demonstrated through clinical trial results showing superior treatment outcomes compared to existing treatments, there is also the option to request a technical fee based on those results, applying a reference different from that of existing treatments.

In addition, even if the medical device is based on a different principle from already listed products, similar procedures may be performed. Taking into consideration the usefulness of the product in the application and the similarity of the procedures, an applicant can request that the technical fees for existing treatments serve as a reference.

Thus, references that are deemed appropriate are specified, taking into account the treatment outcomes of the product in the application, similarities in applicable patients and procedures, costs, etc. It is important that the appropriateness of the selected reference technology be explained logically in the form, showing in a table format or other form the items that were considered when making the selection.

Form 4

Medical Technology Related to the Medical Device

1

(Technology Overview)

Note: Submit using the Japanese-language forms.

様式4

本医療機器に関連する医療技術

1

（技術の概要）

Document on Cost Calculation Method [Form 5]

<Notes>

- Extend the form frames as needed.

1 Enter the amount per product for all items.

2 For imports, enter the import cost in the amount column, and enter the date of the contract, invoice, etc. and the exchange rate in the remarks column. The exchange rate will be the average rate for the year immediately prior to application (same as Form 6, "Price Adjustment Documents").

3 “Selling, general and administrative expenses," "operating profit," and "distribution costs" should be set based on the "Coefficients for Cost Calculation Method when Calculating the Standard Material Prices of Specified Insured Medical Materials" as indicated by the Central Social Insurance Medical Council (announced around April to May each year).

4 Please set the operating profit margin to a value that each company considers appropriate, ranging from -50% to 0%, depending on the level of innovation. To set values, refer to "Research on Quantitative Evaluation of the Standards for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials" [Takura Tomoyuki, co-researcher (medical device specialist)] (http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000078087.pdf).

5 "Distribution costs" refer to the costs (wholesaler's margin) incurred when a wholesaler delivers a product to a medical facility (costs such as those incurred when a company sells to a wholesaler are included in selling, general and administrative expenses). If special distribution costs are incurred, such as a special method of shipping, please note this in the notes.

6 For large equipment, divide the total amount by the number of patients during the depreciation period and enter the amount as "¥__ per patient."

7 In the case of imports, please state the import cost (the exchange rate should be the average rate for the year immediately prior to the application) and attach documents (contracts, invoices, etc.) to prove the import cost.
If there are countries where the product is sold at a price lower than the import cost to Japan, you may be asked for a breakdown of the import cost. Please prepare a breakdown of “raw material costs,” “selling, general and administrative expenses” “research and development expenses,” “operating profit,” etc., or if providing a breakdown is difficult, please be prepared to explain the appropriateness of these costs in relation to import costs (for example, an explanation based on delivery prices to other countries).

8 In the case of imports, enter the costs of packaging materials in Japan that are directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

9 Explain the manufacturing flow chart with diagrams.

10 The unit for “Working hours” is hour(s). For "Total working hours," enter the value obtained by

multiplying the "Number of employees" by the "Working hours." For "Labor rate," enter the hourly rate. Regarding the labor rate, you may select an appropriate rate from statistics such as the Basic Survey on the Wage Structure, but indicate the reason for your selection (please be sure to indicate the source). If there is a significant discrepancy with the actual labor rate, the labor rate can be calculated based on each company's actual circumstances by providing supporting documents. In the case of imports, enter the domestic labor costs directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

11 Please fill in the actual costs whenever possible. If calculating the costs by adding up the costs for each individual product is difficult, costs for the entire factory can be apportioned based on the contribution of the product in question.
In the case of imports, enter the domestic manufacturing costs that are directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

12 Set this based on the "Coefficients for Cost Calculation Method when Calculating the Standard Material Prices of Specified Insured Medical Materials" as indicated by the Central Social Insurance Medical Council. Also, if "maintenance costs" are incurred, attach a catalog or documents provided to the customer.

13 When allocating research and development expenses per product, calculate by dividing it by the cumulative sales forecast for a reasonable number of years after sales begin.
For “Basic research expenses,” provide a detailed breakdown (this can be written on the form or on a separate sheet). In the case of imports for which the applying company has not borne the research costs, do not include them in the calculation.
For "Clinical research expenses," provide a specific breakdown of the costs of clinical trials and marketing approval applications (this can be written on the form or on a separate sheet). In the case of imports for which the applying company has not borne the research costs, do not include them in the calculation.
For “Post-Marketing Surveillance Expenses,” enter an estimate of the costs related to post-marketing surveillance.

Form 5

Document on Cost Calculation Method

(Summary table)

Cost elements		Amount (yen)	Notes (rationale)
Raw material costs	Raw material costs (*1)		
	Packaging material costs (*2)		
	Labor costs (*3)		
	Manufacturing costs (*4)		
	Subtotal (1)		
Selling, general and administrative expenses (*5)			
Research and development expenses (*6)			
Operating profit			
Subtotal (2)			
Distribution costs			
Subtotal (3)			
Consumption tax			
Total			

Note 1: In the case of imported medical devices, documents providing the rationale for setting the import cost, such as the price in the importing country and the export price to countries other than Japan, must be attached.

Note 2: For items *1 to 6 in the table, transcribe the total amounts for each item in the following breakdown.

(breakdown)

1 Raw material costs

Name of raw materials	Required quantity	Unit price (yen)	Amount (yen)	Remarks
Total				(*1)

2. Packaging material costs

Item	Required quantity	Unit price (yen)	Amount (yen)	Remarks
Total				(*2)

3. Labor costs
1) Manufacturing flow chart
2) List of working hours by process

	Work item	Number of personnel	Working hours	Total working hours	Labor rate	Amount (yen) (Total working hours × Labor rate)	Remarks
Raw material							
Package							
Total							(*3)

4. Manufacturing costs

	Raw material (yen)	Package (yen)	Remarks
Energy Electricity cost Gas cost Water cost Subtotal			
Equipment depreciation expense Depreciation expense Insurance cost Taxes and charges Subtotal			
Consumables Consumables cost Service department cost Other Subtotal			
Total			(*4)

5 Selling, general and administrative expenses

	Amount (yen)	Remarks
Sales and general and administrative expenses	12	
Royalties		
Tracking costs		
Maintenance costs		
Total		(*5)

6 Research and development expenses

		Amount (yen)	Remarks
Basic research expenses			
Clinical research expenses			
Post-marketing surveillance expenses	Yes/No		
Other			
Total			(*6)

Note: Submit using the Japanese-language forms.

様式５

原価計算方式の資料

（総括表）

原価要素		金額（円）	備考（設定の根拠）
原材料費	原料費（※１）		
	包装材料費（※２）		
	労務費（※３）		
	製造経費（※４）		
	小計（１）		
一般管理販売費（※５）			
研究開発費（※６）			
営業利益			
小計（２）			
流通経費			
小計（３）			
消費税			
計			

注１　輸入医療機器の場合は、輸入先国の価格の状況、日本以外の国への輸出価格の状況等の輸入原価設定の根拠となる資料を添付すること。

注２　表中※１～６については、次の内訳の各項目の合計金額等を転記すること。

（内訳）

１　原料費

原料名	所要数量	単価（円）	金額（円）	備考
合計				（※１）

2　包装材料費 8

品　　名	所要数量	単価（円）	金額（円）	備　考
合　　計				（※２）

3　労務費

1）製造フローチャート 9

2）工程別作業時間一覧 10

	作　業　名	員数	作業時間	延作業時間	賃率	金額（円） （延作業時間×賃率）	備　考
原体							
包装							
合　　計							（※３）

4　製造経費 11

	原　　体（円）	包　　装（円）	備　　考
エネルギー 電　気　代 ガ　ス　代 水　道　料 小　計			
設備償却費 減価償却費 保　険　料 租税公課 小　計			
消耗品他 消耗品費 補助部門費 そ　の　他 小　計			
合　　計			（※４）

5　一般管理販売費

	金額（円）	備考
一般管理費・販売費用		
ロイヤリティー		
トラッキング費用		
メンテナンス費用		
合　計		（※５）

6　研究開発費

	金額（円）	備考
基礎研究費		
臨床研究費		
市販後調査に係る費用（有　・　無）		
その他		
合　計		（※６）

(blank)

Documents on Price Adjustment [Form 6]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Enter the requested price stated in the "Insurance Coverage Request Form for a Medical Device."

2 In the "Price" section, enter both the price before and after conversion. The exchange rate used will be the average rate for the year immediately prior to application (the Office of Medical Devices Policy will instruct you on the rate to be used during pre-consultation). For prices in other countries, you will need to attach supporting documentation such as a price list (if providing a price list is difficult, a letter from overseas is acceptable).

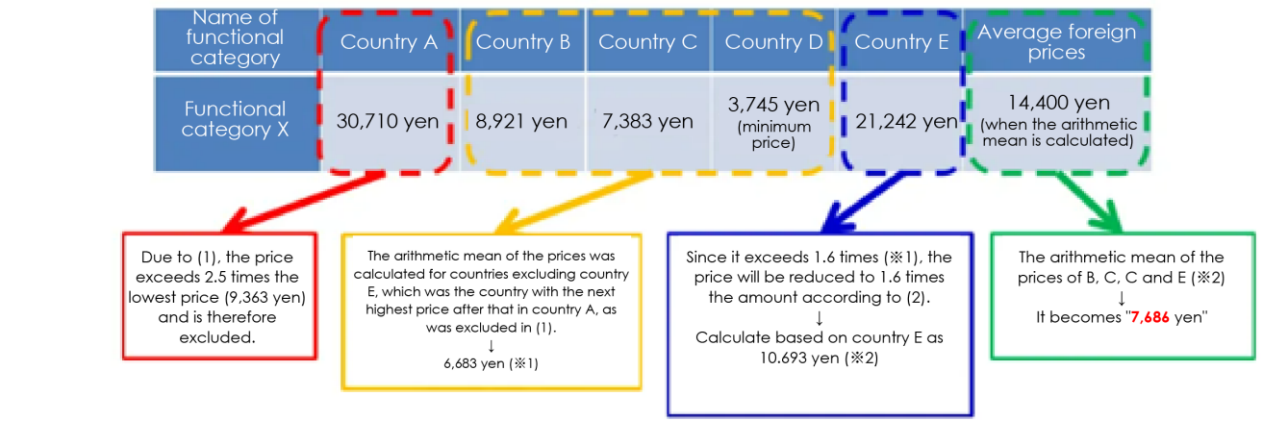
3 Please calculate the average foreign price based on the following rules.

Calculation method for average foreign prices

(1) If the highest price is more than 2.5 times the lowest price, the highest price will be excluded.
(2) If there are three or more countries with prices, and the highest price exceeds **1.6 times** the arithmetic mean of the other prices, the highest price is deemed to be equivalent to **1.6 times** the arithmetic mean of the other prices.

* Reference (rules before the revision in 2022)
(1) If the highest price is more than 2.5 times the lowest price, the highest price will be excluded.
(2) If there are three or more countries with prices, and the highest price exceeds 1.8 times the arithmetic mean of the other prices, the highest price is deemed to be equivalent to 1.8 times the arithmetic mean of the other prices.

<Specific examples>



Source: Medical Economics Division, Health Insurance Bureau, Ministry of Health and Welfare, "FY 2024 Outline of the Reform of the Insured Medical Materials System"

4 A price that exceeds 1.25 times the average foreign price cannot be set (up to 1.5 times the average foreign price is permitted for products developed in response to a request from the Ministry of Health, Labour and Welfare based on the results of deliberations by the Needs Review Committee, products designated as orphan medical devices, and products that have been assigned a new functional category with an innovativeness premium or usefulness premium of 10% or more).

Form 6

Document on Price Adjustment

Requested calculated price	*yen* (*1)
Manufacturer (country of manufacture)	*Japan*

Price and other relevant conditions in foreign countries

Country name	Price (local price/yen conversion)	Marketed	Approved	Submission of marketing approval	Remarks
US	*$/yen*	Yes/No	Yes/No	Yes/No	
UK		Yes/No	Yes/No	Yes/No	
Germany		Yes/No	Yes/No	Yes/No	
France	*€/yen*	Yes/No	Yes/No	Yes/No	
Australia		Yes/No	Yes/No	Yes/No	

○ Exchange rate [*April 1, 2022* - *March 31, 2023* Average of the exchange rate according to the Bank of Japan (for the year immediately prior to application)]
1 US dollar = yen
1 British pound = yen
1 euro = yen
1 Australian dollar = yen

○ Average foreign price = Yen (*2)
Note: If the foreign price calculation rules (2.5x/1.6x) apply, enter the calculation formula.

○ Adjustment formula
Ratio with respect to the average foreign price ((*1)/(*2)): *1.2*

Note: Submit using the Japanese-language forms.

様式6

価格調整の資料

算定希望価格	（※１） ～～～円
製造元（製造国）	日本

諸外国における価格等の状況

国　　名	価　　格 (現地価格／円換算)	販売の有無	承認の有無	承認申請の有無	備　　考
アメリカ合衆国	$--- /～～～円	有・無	有・無	有・無	
連合王国		有・無	有・無	有・無	
ドイツ		有・無	有・無	有・無	
フランス	€--- /～～～円	有・無	有・無	有・無	
オーストラリア		有・無	有・無	有・無	

○為替レート（2022/4/1～2023/3/31（申請直前の１年間）の日銀による為替レートの平均）

１　米　ド　ル＝ ～～～～円
１　英　ポ　ン　ド＝　　円
１　ユ　ー　ロ＝ ～～～～円
１オーストラリアドル＝　　円

○外　国　平　均　価　格＝　～～～～円（※２）

注）外国価格算出ルール（2.5 倍／1.6 倍）に該当する場合は計算式を記載すること。

○調整式

外国平均価格との比（（※１）／（※２））：　1.2

Document on Evaluation for Expedited Insurance Listing [Form 7]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- If you are not requesting an evaluation for expedited insurance listing, you do not need to submit this form.

1 Indicate the status of the application for marketing approval in the United States when submitting documents and enter the date of application (If you have completed premarket notification, indicate the date of completion and note this in the margin). Attach supporting documents (documents showing the date of the application for marketing approval in the US, the time clock provided by the Pharmaceuticals and Medical Devices Agency (PMDA), etc.).
Confirm that the difference between the above (*2) and (*1) is within 180 days, or the date of the application for marketing approval in Japan must be the same as the date of the application for marketing approval in the United States or earlier than the date of completion of premarket notification

2 Check the appropriate item and enter the period for the applicant out of the total review period. Also attach supporting documents.
Confirm that the date falls within the appropriate review period: within 90 days for priority items that are new medical devices, within 180 days for ordinary items that are new medical devices, and within 105 days for improved medical devices with clinical trials.

Form 7

Document on Evaluation for Expedited Insurance Listing

1

○ Status of the application for marketing approval in Japan and the United States

Status of marketing approval under the Federal Food, Drug, and Cosmetic Act in the US.

Approved　Pending approval　Not Submitted

Date of application for marketing approval under the Federal Food, Drug, and Cosmetic Act in the US (*1)

Date

Date of application for marketing approval under the Pharmaceuticals and Medical Devices Act in Japan (*2)

Date

The difference between the above ((*2) - (*1)) *100* Days

2

○ The period for the applicant out of the total review period under the Pharmaceutical and Medical Device Act

☑ Priority items that are new medical devices or improved medical devices with clinical trials　Days

□ Ordinary items that are new medical devices　Days

□ Other

Note: Submit using the Japanese-language forms.

様式７

迅速な保険導入に係る評価に関する資料

1

○日本及びアメリカ合衆国における承認申請状況

アメリカ合衆国における食品医薬品化粧品法に基づく承認申請状況　　承認　・　承認申請中　・　未申請

アメリカ合衆国における食品医薬品化粧品法に基づく承認申請日（※１）　～～～年　～月　～日

日本における医薬品医療機器法に基づく承認申請日（※２）　～～～年　～月　～日

上記の差（（※２）－（※１））　*100* 日間

2

○医薬品医療機器法に基づく総審査期間のうち、申請者側の期間

☑ □　新医療機器の優先品目又は改良医療機器の臨床あり　～～日間

□　新医療機器の通常品目　日間

□　その他

Documents on Usefulness of Medical Economics [Form 8]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Please indicate the amount of the increase, the amount of the decrease, and the net change due to the impact on annual healthcare expenditures nationwide in Japan (not on a per-patient basis).

<Scope of medical expenses covered>

Medical expenses should be calculated based on medical fees and fees charged to patients. The amount of the increase refers to the costs incurred by using the product in the application and any associated costs. The amount of the decrease refers to the cost of the device that will no longer be used due to use of the product in the application. Please note that the following expenses are not covered:

• Reduction in labor costs as a result of physicians taking less time to perform procedures
• Reductions as a result of improved labor productivity (including patients and caregivers such as their family members),
• Improved QOL, etc.

2 Clearly indicate the respective rationale for the amount of the increase, the amount of the decrease, and the net change due to the impact on healthcare expenditures. When applying for category C2 in particular, compare the technology to existing technologies. For medical fees used as a reference to calculate medical expenses, provide the names of the fees and the reasons for referring to them.

If there are similar functional categories, fill in the form taking into consideration the information on the "Rationale for the Application of an Adjustment Premium" in Forms 3-1, 3-2, and 3-3.If there is no similar functional category, fill in the information taking into consideration the clinical efficacy (requirements for the innovativeness premium and the usefulness premium).

"How the product in the application will solve the problems faced by healthcare professionals and patients" needs to be explained in an ordered manner throughout the application documents.Be careful not to have logical contradictions.

Form 8

Documents on Usefulness in Terms of Healthcare Economics

1

Increase in medical expenses due to use of the material (*1)	Yen
Decrease in medical expenses due to use of the material (*2)	Yen
Ultimate impact on total medical expenses [(*1)-(*2)]	Yen

<Rationale> 2

[Amount of the increase]

[Amount of the decrease]

[Amount of the impact]

Note: Submit using the Japanese-language forms.

様式8

医療経済上の有用性に関する資料

1

本材料の使用による医療費の増額分　（※１）	円
本材料の使用による医療費の減額分　（※２）	円
最終的に医療費全体に与える影響額分 （（※１）－（※２））	円

＜根拠＞ 2

【増額分について】

【減額分について】

【影響額分について】

Document on Maintenance [Form 9]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Circle the necessity for maintenance.

2 If maintenance is required, describe it.
If maintenance is not required, enter the reason why (e.g., this product is for single use only, so no maintenance is required).

Form 9

1

Document on Maintenance

Need for maintenance	Yes / No
Maintenance details 2 *This product is for single use only and requires no maintenance.*	

様式９

メンテナンスに関する資料

1

メンテナンスの要・不要	要　・　不要

メンテナンスの内容

2

本品は単回使用のためメンテナンスは不要

Insurance Coverage Request Form of an In Vitro Diagnostic [Decision Category E2/E3] [Attachment 1]

<Notes>

- Keep it to one A4 sheet. If your application does not fit on a single A4 page, attach additional sheets as necessary.
- Prepare one request form for insurance coverage for each approvalIf, however, one approval dossier contains multiple products (items in a series), prepare an insurance coverage request form for each product that has the same measurement items, purpose of measurement, and method of measurement.

1 Leave the reference number section blank when submitting the form.

2 For the measurement items, enter the "Category Number" and "Category Name" shown in the estimate notification. If you are applying under category E3, enter the name you consider appropriate.
Transcribe the sales name (product name), measurement items, and method of measurement from the approval dossier.

3 Fill in "E2 (Existing Items with Changes)" or "E3 (New Items or Improved Items)" depending on the category of your application.

4 If there are multiple people in charge, underline one main person in charge.

5 If a new item needs to be specified, please fill in the applicable testing technology.
Also, please fill in the following if applicable:

(1) Details of the most recent application for a partial change or minor change

(2) Details of succession, a change in company name, and a change in the Designated Marketing Authorization Holder (submit documents that allow details to be verified)

(3) Past insurance coverage history for the product (date of submission of an insurance coverage request form, application category, decision category (withdrawal), date of coverage by insurance).

(4) In cases where approval has been granted for multiple products (series items) under one approval dossier, the handling of items that do not fall under the required category (names of component items, required category, or a statement that insurance coverage is not required).

Attachment 1

Reference number

Insurance Coverage Request Form of an In Vitro Diagnostic

Measurement item	*D000 --- test ## XXX*
Brand name	*--- test kit*
Purpose of measurement	*Measurement of ---*
Method of measurement	□Qualitative ☑Semi-quantitative □Quantitative *--- method*
Marketing approval (Certification) number and Approval (certification) date	*Approval number: 00000□□□00000000* *Date of approval: Date* (Month/Date/Year)
Insurance Category	*For E2: E2 (Existing Items with Changes)* *For E3: E3 (New or Improved Items)*
Request for reevaluation based on actual past use	□Yes (at the time of listing/after listing)/☑No
Contact Details	Contact Name: *Taro Yamada* telephone number: **-****-**** E-mail: ******@****
Remarks	*Technology referenced for adaptation:* *D○○○ΔΔΔtest ## ××× **,*** points*

Based on the above, I request that this in vitro diagnostic be covered by insurance.

Date (Month/Date/Year)
Address (in the case of a corporation, the location of its principal office)
Name (in the case of a corporation, its name and the name of its representative)

To the Minister of Health, Labour and Welfare

Note: Submit using the Japanese-language forms.

別紙１

整理番号

体外診断用医薬品保険適用希望書

測　定　項　目	*D000　～～～検査　##　×××*
販　売　名	*～～～検査キット*
測　定　目　的	*～～～の測定*
測　定　方　法	□定性　☑半定量　□定量 *～～～法*
薬事承認（認証）番号及び承認（認証）年月	*承認番号：00000□□□00000000* *承認年月日：令和～年～月～日*
保　険　区　分	*E2 の場合：E2（既存項目・変更あり）* *E3 の場合：E3（新規項目又は改良項目）*
使用成績を踏まえた再評価希望の有無	□有（収載時・収載後）　・　☑無
担当者連絡先	担当者名：*山田 太郎*　　電話番号：**-****-**** Ｅ－ｍａｉｌ：******@****
備　考	*準用希望技術：* *D○○○　△△△検査　##　×××　**, ***点*

上記により、体外診断用医薬品の保険適用を希望いたします。

年　　月　　日

住所（法人にあっては、主たる事務所の所在地）

氏名（法人にあっては、名称及び代表者の氏名）

厚生労働大臣　　殿

Requested Insurance Points and the Rationale for them [Form 1]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Indicate the points for the existing item you are requesting or the same points as the technology referenced for adaptation. If there are multiple technologies referenced for adaptation, please provide the total combined points.

2 For each technology referenced for adaptation, specify the "Category Code," "Category Name," and "Points" as indicated in the notice on reimbursement. If you are combining multiple technologies referenced for adaptation, please list the corresponding "Category Code," "Category Name," and "Points" for all of them. If there are no technologies referenced for adaptation, you may leave this section blank.

3 Provide the rationale justifying the appropriateness of the requested points and the technology referenced for adaptation.
For E2: Indicate the equivalence between this test and existing tests. Also, indicate any modifications to the existing item you are requesting.
For E3 (New Item): Explain the similarity between this test and the technology referenced for adaptation.
For E3 (Improvement Items): Indicate differences, such as clinical efficacy, between this test and existing tests and similarities to the technology referenced for adaptation.
Indicate the similarities in terms of the measurement principle, applicable patients, target area, etc.

Form 1

Requested Insurance Points and Their Rationale

Insurance coverage category	☑E2 (Existing Items with Changes) □E3 (New Items) □E3 (Improved Items)
Measurement item	For E2: *D000 --- test ## XXX* *For E3: --- antibody*
Method of measurement	*--- method* (□Qualitative ☑Semi-quantitative □Quantitative)
Requested points	*--- points*
Requested technology referenced for adaptation	*D000 △△△test***points and D999 □□□ test ### points were added together ***points*

The rationale

[For E2]

This technology is exists as a △△△ test and...

[For E3 (New Items)]

The measurement principle of this test is the --- method, and the existing test, the D999 □□□ test, is similar to --- in that... The applicable patients are....

[E3 (Improvement Items)]

*Existing △△△ tests are performed on patients suspected of having XX disease... The existing △△△ test is performed on patients suspected of having XX disease. However, this test is considered clinically useful in that it is ～～～ for patients suspected of having □□□ disease and a ○○ level of ** or higher.*

Note: Submit using the Japanese-language forms.

様式１

希望点数及びその根拠

保険適用区分	☐E2(既存項目・変更有り)　☐E3(新項目)　☐E3(改良項目)
測定項目	*E2 の場合：D000 ～～～検査 ## ×××* *E3 の場合：～～～～抗体*
測定方法	*～～～～法* (☐定性　☐半定量　☐定量)
希望点数	*～～～～点*
希望する準用検査技術	*D000 △△△検査 ***点と D999 □□□検査 ###点を合算した＊＊＊点*

その根拠

［Ｅ２の場合］
本技術は既存の△△△検査と・・・。
［Ｅ３（新項目）の場合］
本検査の測定原理は～～～～法であり、既存の検査である D999 □□□検査は～～と点で類似・・・。対象患者は・・・。
［Ｅ３（改良項目）］
既存の△△△検査は××病疑いの患者に対して行っており・・・。一方で、本検査は××病疑いのうち、○○の値が＊＊以上かつ□□□の疑いがある患者に対して～～～という点で臨床上の有用性があると考える。

Supporting Documents on the Estimated Number of Applicable Patients and the Estimated Market Size (Estimated Number of Tests) [Form 2-1]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Enter the number of patients per year to whom this test may be applicable. The number of patients should be calculated based on the estimated number of patients for the entire test item, not just the product in the application. If the estimated number of applicable patients is expected to change in the future, enter the year in which that number will be greatest.

2 Enter the estimated number of patients covered by insurance from the first year of coverage to the 10th year.

3 Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based. When making calculations, refer to If there are instructions for proper use or guidelines, please also refer to these documents to avoid any contradictions. The clinical positioning of the applicable patients for the product in the application should be clearly defined using a flow chart or the like. (When using a flow chart, please excerpt the flow of treatment after the change described in Form 4).
The estimated number of applicable patients is determined by patient factors such as medical need. Please do not make estimates based on a company's sales efforts. When making the calculation, enter the formula for the estimated number of applicable patients.

4 Indicate the year in which you anticipate your sales will peak and your estimated sales revenue for that year. The sales amount to be entered here should be calculated by multiplying "Requested points X Number of tests per year".

5 Regarding the number of patients who will use this in vitro diagnostic, enter the number of patients who are expected to purchase and use the product in the application, taking into account the company's sales efforts, out of the estimated number of applicable patients. The number of patients using this in vitro diagnostics per year will be less than the estimated number of applicable patients.

6 Enter a detailed explanation of the rationale for your estimates, including citations to the sources on which they are based. If there are any conditions regarding the use of the product in the application, such as facility standards, enter the specific conditions. Also, take into consideration the market share of competing products.

Form 2-1

Supporting Documents on the Estimated Number of Applicable Patients and the Estimated Market Size (Estimated Number of Tests)

Estimated number of applicable patients (patients/year)	patients/year (peak: FY ●)

1

	Estimated number of patients to whom the measurement item applies	Number of tests per year
1st year	patients	cases
2nd year	patients	cases
3rd year	patients	cases
4th year	patients	cases
5th year	patients	cases
6th year	patients	cases
7th year	patients	cases
8th year	patients	cases
9th year	patients	cases
10th year	patients	cases

2

3

The rationale

△△△ disease is diagnosed as shown in Figure ○. On this test, a result of ■■ or higher is considered to be a definite diagnosis, and treatment such as XX will be administered. Then, during follow-up, the test will be conducted twice as --.

Projected sales revenue for the in vitro diagnostic (yen/year)	yen/year

4

	Sales amount	Number of patients using the in vitro diagnostic	Number of tests per year
1st year	million yen	patients	tests
2nd year	million yen	patients	tests
3rd year	million yen	patients	tests
4th year	million yen	patients	tests
5th year	million yen	patients	tests
6th year	million yen	patients	tests
7th year	million yen	patients	tests
8th year	million yen	patients	tests
9th year	million yen	patients	tests
10th year	million yen	patients	tests

5

6

The rationale

For △△△ disease, the test items may be divided depending on XX and □□□, and according to data from the XX Society approximately 90% of patients may undergo this test as... Approximately 90% of patients who undergo this test will experience remission with drug treatment such as ▲▲▲, but to confirm this, patients with a score of ○○ points or higher on the □□□ test will be monitored using this test. Therefore, approximately ○○% of eligible patients will presumably undergo this test.

Note: Submit using the Japanese-language forms.

様式２－１

推定適用患者数及び市場規模予測根拠資料（検査数の予測）

推定適用患者数（人／年間）	～～～～～人／年間（ピーク時：●年度）

	当該測定項目の推定適用患者数	年間検査数
初年度	人	件
２年度	人	件
３年度	人	件
４年度	人	件
５年度	人	件
６年度	人	件
７年度	人	件
８年度	人	件
９年度	人	件
１０年度	人	件

その根拠

△△△症は図〇のように診断される。本検査で■■以上を確診例として、××等の治療を実施し、その後経過観察時に～なので２回実施する。

本体外診断用医薬品の予測売上高（円／年間）	～～～～～円／年間

	販売金額	本体外診断薬使用患者数	年間テスト数
初年度	億円	人	テスト
２年度	億円	人	テスト
３年度	億円	人	テスト
４年度	億円	人	テスト
５年度	億円	人	テスト
６年度	億円	人	テスト
７年度	億円	人	テスト
８年度	億円	人	テスト
９年度	億円	人	テスト
１０年度	億円	人	テスト

その根拠

△△△症は××及び□□□等により検査項目が分かれることがあり、××学会のデータによると・・・であることから、おおむね９割程度の患者が本検査を受ける可能性がある。本検査を受けた患者は▲▲▲等の薬物治療で９割程度の患者が寛解に向かうが、その確認として□□□テストで〇〇点以上のスコアの患者に対して本検査で経過観察するとされていることから、適用患者数の内、約〇割の患者が本検査を実施すると考える。

Reagent Price (Price per Test) [Form 2-2]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- In the case of E2 (existing items with changes) and replacing an existing product, submission of this form is not required. However, please enter the rationale for replacement in Form 2-1.

1 Enter the amount calculated in steps (1) to (5) under Rationale (Details).

2 Enter the reagent cost per test. The cost of reagents per test should be calculated from "a) the number of tests per reagent" and "b) the cost of reagents per reagent."

3 Indicate how many tests can be performed per kit, including whether they are for calibration curves, control measurements, tests, single or double measurements, etc. If "a) number of tests per reagent" varies depending on the number of specimens tested at one time, describe several patterns and explain the most appropriate pattern and the rationale for it.

4 For imports, enter the import cost in the amount section, and enter the date of the contract, invoice, etc. and the exchange rate in the remarks section. The exchange rate will be the average rate for the year immediately preceding your application.

5 "Selling, general and administrative expenses," "operating profit," and "distribution costs" should be set based on the "Coefficients for Cost Calculation Method when Calculating the Standard Material Prices of Specified Insured Medical Materials" as indicated by the Central Social Insurance Medical Council (announced around April to May each year).

6 "Distribution costs" refer to the costs (wholesaler's margin) incurred when a wholesaler delivers a product to a medical facility (costs such as those incurred when a company sells to a wholesaler are included in selling, general and administrative costs). If special distribution costs are incurred, such as a special method of shipping, please note this in the notes.

7 If you have information on export prices to other countries, please attach it and submit it.

8 In the case of imports, enter the import cost (the exchange rate should be the average rate for the year immediately prior to the application) and attach documents (contracts, invoices, etc.) to prove the import cost.
If there are countries where the product is sold at a price lower than the import cost to Japan, you may be asked for a breakdown of the import cost. Prepare a breakdown of "raw material costs," "sales and general and administrative expenses", "research and development expenses," "operating profit," etc., or if it is difficult to provide a breakdown, please be prepared to explain the appropriateness of these costs in relation to import costs (for example, an explanation based on delivery prices to other countries).

9 In the case of imports, enter the costs of packaging materials in Japan that are directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

10 Explain the manufacturing flow chart with diagrams.

11 The unit for “Working hours” is “minutes.” For "Total working hours," enter the value obtained by multiplying the "Number of employees" by the "Working hours." For "Labor rate," enter the hourly rate. Regarding the labor rate, you may select an appropriate rate from statistics such as the Basic Survey on the Wage Structure, but indicate the reason for your selection (please be sure to indicate the source). If there is a significant discrepancy with the actual labor rate, the labor rate can be calculated based on each company's actual circumstances by providing supporting documents. In the case of imports, enter the domestic labor costs directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

12 Fill in the actual costs whenever possible. If calculating the costs by adding up the costs for each individual product is difficult, costs for the entire factory can be apportioned based on the contribution of the product in question.
In the case of imports, enter the domestic manufacturing costs that are directly borne by the applying company, such as domestic repackaging and including package inserts for Japan.

13 Set this based on the "Coefficients for Cost Calculation Method when Calculating the Standard Material Prices of Specified Insured Medical Materials" as indicated by the Central Social Insurance Medical Council. Also, if "maintenance costs" are incurred, attach a catalog or documents provided to the customer.

14 When allocating R&D costs per reagent, calculate by dividing it by the predicted cumulative sales for a reasonable number of years after the product goes on sale. In addition, "Coefficients for Cost Calculation Method when Calculating the Standard Material Prices of Specified Insured Medical Materials" are not applied to research and development expenses.
For “Basic research expenses,” provide a detailed breakdown (this can be written on the form or on a separate sheet). In the case of imports for which the applying company has not borne the research costs, do not include them in the calculation.
For "Clinical Research Expenses," please provide a specific breakdown of the costs of clinical trials, clinical performance tests and marketing approval applications (this can be written on the form or on a separate sheet). In the case of imports for which the applying company has not borne the research costs, do not include them in the calculation.
For “Post-Marketing Surveillance Expenses,” enter an estimate of the costs related to post-marketing surveillance.

15 When calculating labor costs per test, calculate a reasonable amount of time based on specimen reception, preparation, measurement, reporting of results, equipment maintenance, etc. In that case, enter the working hours for each process in the remarks section.
For the technician’s hourly rate, data such as the summary of salaries for national civil servants published by the National Personnel Authority can be used (indicate the source in the notes section). Refer to the following example of the method of calculation.
In the labor cost breakdown section, enter the total time commitment, hourly rate, and number of specimens processed.

16 In the remarks section, enter the rationale for setting prices, such as the time for each process,

the rationale for setting the hourly rate, the number of specimens processed, the cost of purchasing materials, and the depreciation period for the device.

17 Calculate this by "Total time commitment x Technician's hourly rate / Number of specimens processed."

18 Calculate this by "(Annual depreciation cost of analytical equipment + Annual maintenance costs + Other costs) / Number of specimens that can be processed per year."

19 If there are any special expenses required for the test, indicate the rationale.

Form 2-2

1

Reagent Price (Price per Test)

Rationale for testing cost per test (summary table)

Testing fee			yen
	Breakdown	Amount (yen)	Remarks
	(1) Reagent costs	*yen*	*Cost per reagent is calculated by dividing it by the number of tests*
	(2) Labor costs	*yen*	
	(3) Material costs	*yen*	
	(4) Cost of analytical devices	*yen*	
	(5) Expenses	*yen*	

Note: Submit using the Japanese-language forms.

様式２－２

1

試薬の価格（テスト当たりの価格）

1テスト当たりの検査費用の根拠（総括表）

検査実施料			～～～～～円
	内訳	金額(円)	備考
	①試薬費	～～～～～円	*1 試薬あたりの費用をテスト数で按分して算出*
	②人件費	～～～～～円	
	③材料費	～～～～～円	
	④分析機器のコスト等	～～～～～円	
	⑤経費	～～～～～円	

Rationale (details)

① Reagent costs

2

Reagent cost per test (The cost of each reagent is apportioned based on the number of tests)	*yen*

a) Number of tests per reagent (number of specimens)

Calculate the number of tests (number of specimens) that can be measured per reagent, excluding the number of times each reagent is used, such as for creating a calibration curve, control measurements, duplicate measurements, and confirmation tests.

3

The rationale

Number of tests per reagent: 8 tests

This reagent allows for 24 measurements per reagent. When measuring 8 or 2 specimens at a time, the number of specimens that can be measured with one reagent is as follows:
(For each measurement, use four specimens for the calibration curve and four specimens for the control measurement).

- When measuring 8 specimens at once
For the calibration curve 4 measurements
For Control measurements 4 measurements
For tests 16 measurements (8 specimens (duplicate measurements))

- When measuring 2 specimens at once
For the calibration curve 8 measurements
For Control measurements 8 measurements
For tests 8 measurements (4 specimens (duplicate measurements))

For the following reasons, this test is expected to perform eight measurements at a time.
×××××.

Thus, limiting the number of tests per reagent to 8 tests is considered appropriate.

b) Reagent cost per reagent

(breakdown)

Cost Calculation

Cost elements		Amount (yen)	Remarks (rationale)
Raw material costs	Raw material costs (1*)	yen	
	Packaging material costs (2*)	yen	
	Labor costs (*3)	yen	
	Manufacturing costs (*4)	yen	
	Subtotal (1)	yen	
Selling, general and administrative expenses (5*)		yen	*.**% of Subtotal (2)
Research and development expenses (*6)		yen	
Operating profit		yen	*.**% of Subtotal (2)
Subtotal (2)		yen	
Distribution costs		yen	*.**% of Subtotal (3)
Subtotal (3)		yen	
Consumption tax		yen	**%
Total		yen	

Note 1: In the case of imported in vitro diagnostics, documents providing the rationale for setting the import cost, such as information on prices in the importing country and information on export prices to countries other than Japan, must be attached.

Note 2: For items *1 to 6 in the table, transcribe the total amounts for each item in the following breakdown.

(breakdown)

*1 Raw material cost (per reagent)

Name of raw materials	Required quantity	Unit price (yen)	Amount (yen)	Remarks
Total				(*1)

*2 Packaging material cost (per reagent)

Name of raw materials	Required quantity	Unit price (yen)	Amount (yen)	Remarks
Total				(*2)

*3 Labor cost (per reagent)
1) Manufacturing flow chart
2) List of working hours by process (per reagent)

	Work item	Number of personnel	Working hours	Total working hours	Labor rate	Amount (yen) (Total working hours × labor rate)	Remarks
Raw material							
Package							
Total							(*3)

*4 Manufacturing cost (per reagent)

Name of raw materials	Raw material (yen)	Package (yen)	Remarks
Energy			
Power			
Gas			
Water			
Subtotal			
Equipment depreciation expense			
Depreciation expense			
Insurance premium			
Taxes and charges			
Subtotal			
Consumables			
Consumables cost			
Service department cost			
Other			
Subtotal			
Total			(*4)

*5 Selling, and general and administrative expenses

	Amount (yen)	Remarks
Sales and general and administrative expenses		
Royalties		
Tracking costs		
Maintenance costs		
Total		(*5)

*6 Research and development expenses

		Amount (yen)	Remarks
Basic research expenses			
Clinical research expenses			
Post-marketing surveillance expenses	Yes/No		
Other			
Total			(*6)

② Labor cost (per test)

Labor costs	Breakdown	Remarks (rationale)
Total time commitment	hrs.	
Technician's hourly wage	yen	
Number of specimens processed	specimens	
Total		yen

③ Material costs (consumables required per test, accuracy control materials, co tion materials, etc.)

Material cost details	Amount broken down (yen)	Remarks (rationale)
	yen	
	yen	
	yen	
	yen	
	yen	
	yen	
Total		yen

④ Analytical device cost (per test)

Details of analytical device costs	Amount broken down (yen)	Remarks (rationale)
Depreciation expenses per analytical device per year	yen	
Cost of annual maintenance	yen	
Other costs	yen	
Number of specimens that can be processed per year	tests	
Total		yen

⑤ Expense (per test)

Expense details	Amount (yen)	Remarks (rationale)
	yen	
	yen	
	yen	
Total		yen

Document Summarizing Testing [Form 3]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Create it based on the marketing approval dossier/marketing certification, etc.

2 Enter the test method, test procedures, measurement time, etc. In addition, if a special device is used to conduct testing and it is an important factor in determining the product's economic viability, explain the necessity of using that device.

3 If other methods are available, create a table comparing the performance of those test methods (concordance rate/sensitivity/specificity, etc.).

Form 3

Document on the Test Summary

1

a. Principle
○○○○○○

2

b. Method of measurement
XXXXX

3

c. Performance (comparison to other methods)
□□□□□□

Note: Submit using the Japanese-language forms.

様式３

検査の概要に関する資料

ａ．原理

〇〇〇〇〇〇

ｂ．測定法

×××××

ｃ．性能（他法との比較等）

□□□□□□

Documents on Clinical Effectiveness, Significance, Improved Convenience, etc. [Form 4]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Fill in the following information about the utility of this test based on clinical guidelines, objective data, literature, etc. in the order below. Also, insert diagrams as appropriate to make the description easy to understand.

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current methods of testing for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background to the development of the product in the application based on the issues and needs (including an explanation of the product's features and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether or not a statement has been prepared, including a request for early introduction, the applicable patients for the product in the application, and a summary of its clinical positioning; if such a statement has been prepared, its details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

Form 4

Documents on Clinical Effectiveness, Significance, Improved Convenience, etc.

<Rationale>

Note: Submit using the Japanese-language forms.

様式４

臨床上の有用性や意義、利便性の向上等に関する資料

1

＜根拠＞

◢◢◢◢◢◢

Rationale for In Vitro Diagnostics that Require Special Consideration for Use in Testing for Rare Diseases [Form 5]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- Submit this form only if you believe that the in vitro diagnostics requires special consideration for use in testing for rare diseases.

1 Regarding the Orphan In Vitro Diagnostic Designation under the Pharmaceutical and Medical Device Act, circle “yes” or “no.”If yes, enter the date of designation.

2 If the in vitro diagnostic is related to testing used to determine the suitability of pharmaceuticals and the test is expected to seldom be performed, enter the target disease and the estimated number of tests performed annually.

3 Enter the rationale for the estimated number of patients. If the information is the same as that in Form 2-1, you can write "Omitted since the information is the same as that in Form 2-1."

Form 5

Rationale for In Vitro Diagnostics that Require Special Consideration for Use in Testing for Rare Diseases

1 Orphan In Vitro Diagnostic Designation under the Pharmaceutical and Medical Device Act

Yes/No 1

Date of the designation: Date (Month/Date/Year)

2. If an in vitro diagnostic related to testing is used to determine the suitability of pharmaceuticals and the test is expected to seldom be performed

2

Target disease		Annual number of reimbursable cases	

Rationale for the estimated number of patients

3

Note: Submit using the Japanese-language forms.

様式5

希少疾病等の検査に用いるものとして配慮が必要な体外診断用医薬品の根拠

1　医薬品医療機器等法に基づく希少疾病用体外診断用医薬品指定 有　・　無　1 指定年月日　　年　　月　　日

2　検査回数が少ないことが予想される医薬品の適応判定に用いる検査に係る体外診断用医薬品の場合　2

対象疾病		年間算定回数	

推定患者数の根拠

3

Documents on the Justification for Submitting a Challenge Application [Form 6]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.
- Submit this form only if you wish to submit a challenge application after listing.

1 Briefly explain the rationale justifying a challenge application.

<Examples where evidence has been amassed and a correlation with patient outcomes has been established after coverage by insurance>

High-sensitivity troponin

: At the time of initial listing, the test was considered useful for diagnosing acute myocardial infarction within six hours of onset. However, with improvements in sensitivity, accumulating evidence has demonstrated new clinical significance, leading to changes in patient care pathways and establishing a clear association with patient outcomes.

- Guidelines for the treatment of ST-segment elevation acute myocardial infarction: The troponin level has been shown to be useful in diagnosing the hyperacute phase (within 2 hours of onset)
- Calculation requirements for percutaneous coronary intervention and coronary stent placement: An elevated cardiac troponin level was added as a requirement
- Acute Coronary Syndrome Guidelines: A higher troponin level upon admission has been shown to involve a higher risk of death

2 Enter your data collection and evaluation plan. Also attach any relevant documents.

Regarding the applicable patients, if any inclusion/exclusion criteria have been set, please explain the details of those criteria and describe the measures taken to ensure that only patients suitable for evaluation of the product in the application are enrolled.

Regarding the number of patients and the rationale for that number, please describe how you calculated the number of patients necessary to perform the evaluation, taking into account the evaluation items and verification contents of the product in the application (superiority, non-inferiority verification, etc.). Also, indicate that there is a sufficient number of patients to perform the evaluation.

Regarding evaluation items, indicate that the evaluation items necessary for evaluating the usefulness of the product in the application have been set. Therefore, you need to carefully explain, using clinical guidelines, what items are being evaluated for each set item (for example, the evaluation items are those that have been agreed upon by academic societies).

Regarding the analysis plan, indicate the type of analysis that will be performed to evaluate the usefulness of the product in the application (e.g., verifying superiority over currently listed products or verifying that the product meets pre-defined standards based on the literature).

Also, enter your future requests in the event that evidence demonstrating the usefulness of the product in the application becomes available. For example, indicate whether you would request the establishment of a new technical fee or changes in the conditions for reimbursement.

Plan for Data Collection and Evaluation after Listing
● **Applicable patients**: Patients for whom this product is applicable ● **Existing treatments (comparative control)**: Existing standard treatments for applicable patients ● **Current issues**: Current clinical issues to be resolved ● **Efficacy of the product**: Efficacy of the product as a solution to the current issues ● **Reasons efficacy cannot be evaluated at the time of insurance coverage** ● **Method of evaluation** • Test type • Test purpose • Applicable patients • Number of patients and the rationale for that number • Enrollment period and evaluation period • Evaluation items • Analysis Plan

Form 6

1

Documents on the Justification for Submitting a Challenge Application

Measurement item		Existing test (for comparison)	
Current issues			
The usefulness of the product			
Rationale for the inability to evaluate usefulness upon applying for insurance coverage			
Method of evaluation	Test type	2	
	Test purpose		
	Applicable patients		
	Number of patients and the rationale for that number		
	Enrollment period		
	Evaluation period		
	Evaluation items		
	Analysis plan		

Note: Submit using the Japanese-language forms.

様式6

1 チャレンジ申請を行うことの妥当性に関する資料

測定項目		既存検査 （比較対象）	
現状の課題			
当該製品の有用性			
保険適用時に有用性を評価できない理由			
評価方法	試験の種類	2	
	試験目的		
	対象患者		
	症例数及びその根拠		
	登録期間		
	評価期間		
	評価項目		
	解析計画		

(blank)

Documents Demonstrating Usefulness in Terms of Healthcare Economics [Form 7]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed.

1 Indicate the increase in medical costs over the peak year due to the introduction of this test. Basically, enter the estimated sales revenue shown on Form 2-1.

2 Indicate the reduction in medical costs over the peak year as a result of introducing this test. For example, enter the estimated annual testing costs of the existing test that will be replaced by this test and the savings in drug costs and surgical/hospitalization costs due to the introduction of this test.

3 Clearly explain the rationale for any increases or reductions, and ensure that they are consistent with the estimated number of applicable patients listed in Form 2-1.

Form 7

Documents Demonstrating Usefulness in Terms of Healthcare Economics

Amount of the increase in medical expenses due to use of this test (*1) 1	yen
Amount of the decrease in medical expenses due to use of this test (*2) 2	yen
Ultimate impact on total medical expenses [(*1)-(*2)]	yen
The rationale 3 ◇◇◇◇◇◇	

Note: Submit using the Japanese-language forms.

様式７

医療経済上の有用性を示す資料

本検査の使用による医療費の増額分　（※１）	～～～～～円
本検査の使用による医療費の減額分　（※２）	～～～～～円
最終的に医療費全体に与える影響額分 （（※１）－（※２））	～～～～～円

その根拠

◇◇◇◇◇◇

Contact Form for Pre-Consultation [Form 10-1] or [Form 9]

<Notes>

- It does not have to fit on a single A4 page. Extend the form frames as needed. You may also attach a separate sheet.
- Send it as an attachment to an e-mail.

1 Enter a time limit of 60 minutes. Please provide as many dates and times as possible.

2 Attendees at online consultations should be only those parties who are expected to speak. In the case of face-to-face consultations, the number of people should be limited to three in principle.

3 All consultation matters do not need to fit on a single page. Complete the form with a clear summary of what you would like to consult us on, attaching any necessary documents. Also, in principle, share documents prepared using the following information to the extent possible at least three business days in advance. On the day of your consultation, please explain the product in the application in detail.

<Items to be explained on the day>

(Medical Devices)

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current treatments for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background to the development of the product in the application based on the issues and needs (including an explanation of the product's features and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether or not guidelines for proper use, including requests for early introduction and requirements for the performing physician, have been established, and if so, their details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

[Details on the insurance coverage requested]

- If you wish to set a new technical fee, please explain the details of the insurance coverage you would like to receive (including an explanation of the medical fee points and points of note regarding existing treatments, as well as the details of the requested insurance coverage for the product in the application and the reasons for selecting the reference technical fee).
- If you wish to have your product listed as a specified insured medical material, explain a similar functional category and the requested price (If you believe that there is no similar functional category, state the reason why your product does not fall under any of the existing functional categories and the details of the new functional category you are requesting. In the case of cost calculation, the breakdown. If you wish a premium to be applied, include the applicable items and an explanation of their applicability).

[Schedule]

- Details of previous consultations with the Industrial Affairs Division and the status of any responses (if multiple consultations have been done)
- Regulatory status, future schedule　／etc.

(In vitro diagnostics)

[Explanation regarding target diseases]

- Overview of the target disease and applicable patients for the product in the application
- Current methods of testing for the target disease (including recommendations in domestic and international clinical guidelines), their problems, and the needs of the medical field

[Description of the product in the application]

- The background to the development of the product in the application based on the issues and needs (including an explanation of the product's features and improvements compared to existing products)
- How will the product in the application address or solve that problem or need?
- The clinical positioning of the product in the application (whether it is a replacement, combination, or completely different treatment compared to standard treatments, existing treatments, and existing listed products) and changes in the flow of treatment (comparison between the current flow and the flow after introduction of the product in the application)
- The status of collaboration with relevant academic societies (whether or not a statement has been prepared, including a request for early introduction, the applicable patients for the product in the application, and a summary of its clinical positioning; if such a statement has been prepared, its details)
- Evidence that supports the effectiveness of the product in the application compared to existing listed products

[Details on the insurance coverage requested]

- If you wish to set a new technical fee, explain the details of the insurance coverage you would like to receive (including an explanation of the medical fee points and points of note regarding existing tests, as well as the details of the insurance coverage you would like for the product in the application and the reasons for selecting the reference technical fee).

[Schedule]

- Details of previous consultations with the Industrial Affairs Division and the status of any responses (if multiple consultations have been done)
- Regulatory status, future schedule　／etc.

Date (Month/Date/Year)

Form 10-1

Contact Form for Pre-Consultation

Addressee:
Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare
TEL: 03-3595-3409
E-mail: kikihoken@mhlw.go.jp

⊙ would like to receive pre-consultation on the following matters:
○ Preferred date and time
First choice Date month day, year (day), HH:mm-HH:mm
Second choice Date month day, year (day), HH:mm-HH:mm
Third choice Date month day, year (day), HH:mm-HH:mm
Fourth choice Date month day, year (day), HH:mm-HH:mm

1

○ Form of consultation □ Online consultation □ Face-to-face consultation
○ Time required
○ Number of people

2

○ Matters for consultation (if there are multiple matters for consultation, please list each briefly and specifically, referring to the points below.)
* Fill in as much as possible. If the information does not fit on one page, you can use a format of your choosing.

3

Contact details	Company name: Full name of contact:	Telephone number: E-mail:

Note: Submit using the Japanese-language forms.

様式 10-1

保険適用に係る事前相談連絡票

＜送信先＞
厚生労働省医政局産情課
ＴＥＬ：03-3595-3409
Ｅｍａｉｌ：kikihoken@mhlw.go.jp

◎以下の内容にて事前相談を希望します。
○希望日時　第一希望　　年　月　日（　）　：　ー　：
　　第二希望　　年　月　日（　）　：　ー　：
　　第三希望　　年　月　日（　）　：　ー　：
　　第四希望　　年　月　日（　）　：　ー　：
○相談方法　□オンライン相談　□対面相談
○所要時間
○人数
○相談事項（相談事項が複数ある場合は、項目毎に箇条書きにして、以下の点を参考に相談内容を簡潔かつ具体的に記載してください。）
※記載できる範囲で記載ください。１枚に収まらない場合は書式自由。

連絡先	企業名： 担当者氏名：	電話番号： E-mail：

7. Frequently Asked Questions

Q. Where can I find application forms and notifications/administrative notices regarding medical devices?

A. You can check for them on the Ministry of Health, Labour and Welfare's website. Please go to the relevant page as follows:

本文へ ▸ お問合わせ窓口 ▸ よくある御質問 ▸ サイトマップ ▸ 国民参加の場

厚生労働省 Ministry of Health, Labour and Welfare

Google カスタム検索 検索

テーマ別に探す | 報道・広報 | 政策について | 厚生労働省について | 統計情報・白書 | 所管の法令等 | 申請・募集・情報公開

ホーム > 政策について > 分野別の政策一覧 > 健康・医療 > 医療保険

健康・医療

医療保険

トピックス | 重要なお知らせ | 施策情報 | 関連審議会・検討会等 | 政策分野関連情報 | 政策分野に関連のサイト

医療保険制度の長期安定を目指して

国民皆保険制度のもと、誰もが安心して医療を受けられる医療制度を実現し、世界最高レベルの平均寿命と保健医療水準を達成してきた日本。少子高齢化、経済情勢の変化に対応し、これから[illegible]保険制度を目指します。

Click on **"Information on Medical Fees"**

- 医療保険制度ガイド
- 診療報酬関連情報
- データヘルス
- オンライン資格確認（医療機関・薬局、システムベンダ向け）
- 国民健康保険制度
- 後期高齢者の自己負担割合の変更について（令和3年改正）
- 医療費の見える化
- マイナンバーカードの健康保険証利用
- 令和6年度からの後期高齢者医療の保険料について

政策について
- 分野別の政策一覧
- 健康・医療
  - 健康
  - 食品
  - 医療
  - 医療保険
  - 医薬品・医療機器
  - 生活衛生
  - 水道
  - 福祉・介護
  - 雇用・労働

本文へ ▸ お問合わせ窓口 ▸ よくある御質問 ▸ サイトマップ ▸ 国民参加の場

厚生労働省 Ministry of Health, Labour and Welfare ホーム

Google カスタム検索 検索

テーマ別に探す | 報道・広報 | 政策について | 厚生労働省について | 統計情報・白書 | 所管の法令等 | 申請・募集・情報公開

ホーム > 政策について > 分野別の政策一覧 > 健康・医療 > 医療保険 > 診療報酬関連情報

健康・医療

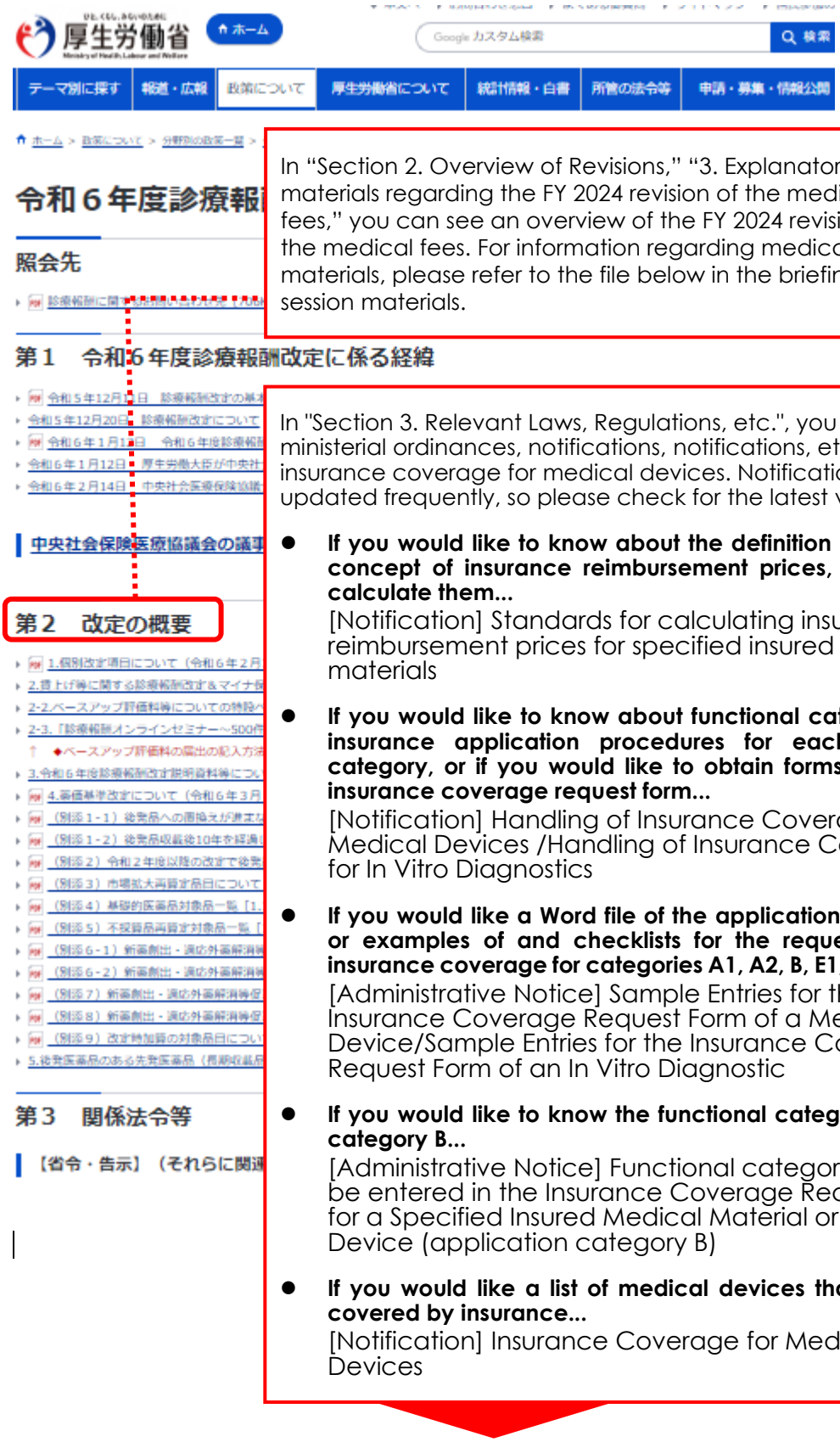
診療報酬関連情報

診療報酬改定・薬価改定 | その他

診療報酬改定・薬価改定

- 令和６年度診療報酬改定
- 令和５年４月１日からの診療報酬上の措置
- 令和５年度薬価改定
- 令和４年度診療報酬改定（10月改定分）
- 令和４年度診療報酬改定

政策について
- 分野別の政策一覧
- 健康・医療
  - 健康
  - 食品
  - 医療
  - 医療保険
  - 医薬品・医療機器



In "Section 2. Overview of Revisions," "3. Explanatory materials regarding the FY 2024 revision of the medical fees," you can see an overview of the FY 2024 revision of the medical fees. For information regarding medical materials, please refer to the file below in the briefing session materials.

In "Section 3. Relevant Laws, Regulations, etc.", you can check ministerial ordinances, notifications, notifications, etc. related to insurance coverage for medical devices. Notifications are updated frequently, so please check for the latest version.

- **If you would like to know about the definition of terms, the concept of insurance reimbursement prices, and how to calculate them...**
  [Notification] Standards for calculating insurance reimbursement prices for specified insured medical materials
- **If you would like to know about functional categories and insurance application procedures for each functional category, or if you would like to obtain forms such as an insurance coverage request form...**
  [Notification] Handling of Insurance Coverage for Medical Devices /Handling of Insurance Coverage for In Vitro Diagnostics
- **If you would like a Word file of the application documents, or examples of and checklists for the request forms for insurance coverage for categories A1, A2, B, E1, E2, and E3...**
  [Administrative Notice] Sample Entries for the Insurance Coverage Request Form of a Medical Device/Sample Entries for the Insurance Coverage Request Form of an In Vitro Diagnostic
- **If you would like to know the functional category code for category B...**
  [Administrative Notice] Functional category code to be entered in the Insurance Coverage Request Form for a Specified Insured Medical Material or a Medical Device (application category B)
- **If you would like a list of medical devices that are newly covered by insurance...**
  [Notification] Insurance Coverage for Medical Devices

【事務連絡】

		名称	番号・日付	ダウンロード
(1)	1	医療機器に係る保険適用希望書の記載例等について	令和６年３月６日 事務連絡	本文 PDF [1.8MB] 別紙１ Word [40KB] 別紙２ Word [44KB] 別紙３ Word [45KB] 別紙４～15 Word [95KB] 様式１-１～12 Word [65KB] 申出書 Word [29KB] 保険適用通知 フォーマット Excel [207KB]
	2	体外診断用医薬品に係る保険適用希望書の記載例等について	令和６年３月６日 事務連絡	本文 PDF [1.3MB] 別紙１～６ Word [36KB] 様式１～11 Word [61KB]

In addition, links to the main notifications cited in this document are provided below. Notifications may be revised due to changes in medical fees, so please be sure to check for the latest notifications.

[Medical Devices]
(Public Notification)

- Partial Revision of Specified Insured Medical Materials and Their Material Prices (Price Standards) (Public Notification No. 61 of 2024)
  https://www.mhlw.go.jp/content/12404000/001218725.pdf

(Notification)

- "Handling of Cost-Effectiveness Evaluation for Pharmaceuticals, Medical Devices, and Regenerative Medical Product" (Sanjo Notification No. 0214-3, Notification HIB No. 0214-5, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218711.pdf
- "Definition of Specified Insured Medical Materials" (HIB/MED Notification No. 0305-12, March 5, 2024)
  https://www.mhlw.go.jp/content/12404000/001219121.pdf
- "Definition of Medical Devices Subject to Specific Medical Fees" (HIB/MED Notification No.

0305-11, March 5, 2024)
https://www.mhlw.go.jp/content/12404000/001219119.pdf

- "Standards for Determining the Insurance Reimbursement Price for Specified Insured Medical Materials" (Notification HIB No. 0214-3, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218708.pdf
- "Handling of Insurance Coverage for Medical Devices" (Sanjo Notification No. 0214-5, Notification HIB No. 0214-4, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218709.pdf
- "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (HPB/DPMM Notification No. 0214-2, HIB/MED Notification No. 0214-2, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218710.pdf

(Administrative Notice)

- "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024)
  https://www.mhlw.go.jp/content/12404000/001220116.pdf

(Other)

- "Partial Amendments to the Guidelines on the Applicability of Programs as Medical Devices" (PSEHB/MDE Notification No. 0331-1 and PSEHB/CND Notification No. 0331-4, March 31, 2023)
  https://www.mhlw.go.jp/content/11120000/001082227.pdf
- "Research on Quantitative Evaluation of the Standards for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials" [Takura Tomoyuki, co-researcher (medical device specialist)]
  http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000078087.pdf

[In vitro diagnostics]

(Notification)

- Handling of Insurance Coverage for In Vitro Diagnostics (Sanjo Notification No. 0214-6, Notification HIB No. 0214-6, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218712.pdf
- Points of Note regarding the Handling of Insurance Coverage for In Vitro Diagnostics (HPB/DPMM Notification No. 0214-3, HIB/MED Notification No. 0214-3, February 14, 2024)
  https://www.mhlw.go.jp/content/12404000/001218713.pdf

(Administrative Notice)

- Sample Entries for the Insurance Coverage Request Form for an In Vitro Diagnostic (March 6, 2024)
  https://www.mhlw.go.jp/content/12404000/001220128.pdf

Q. What notifications and administrative notices do I need to check when applying?

A. The notifications that should be checked when applying for category A3, B2, B3, C1, C2, or R are "Standards for Determining the Insurance Reimbursement Price for Specified Insured Medical Materials" (Notification HIB No. 0214-3, February 14, 2024), "Handling of Insurance Coverage for Medical Devices" (Sanjo Notification No. 0214-5 and Notification HIB No. 0214-4, February 14, 2024), and "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (HPB/DPMM Notification No. 0214-2 and HIB/MED Notification No. 0214-2, February 14, 2024). In addition, the notifications that should be checked when applying under category E2 or E3 are "Handling of Insurance Coverage for In Vitro Diagnostics" (Sanjo Notification No. 0214-6 and Notification HIB No. 0214-6, February 14, 2024), "Points of Note

regarding the Handling of Insurance Coverage for In Vitro Diagnostics" (HPB/DPMM Notification No. 0214-3 and HIB/MED Notification No. 0214-3, February 14, 2024), and the administrative notice on "Sample Entries for the Insurance Coverage Request Form of an In Vitro Diagnostic" (March 6, 2024). The information in these notifications is basically presented in this guidebook.

Q. What should I do when applying for category A1, A2, or B1?

A. Please refer to "Handling of Insurance Coverage for Medical Devices" (Sanjo Notification No. 0214-5, Notification HIB No. 0214-4, February 14, 2024) and "Methods of Submitting a Insurance Coverage Request Form for a Medical Device" (HPB/DPMM Notification No. 0214-2, HIB/MED Notification No. 0214-2, February 14, 2024). Sample entries for the request form are posted in the administrative notice on "Sample Entries for the Insurance Coverage Request Form for a Medical Device" (Administrative Notice, March 6, 2024).

Q. I am not sure which category to apply for.

A. Please submit a pre-consultation form to the office of Medical Device Policy and then consult with them about the category to apply for.

Q. Can we consult with the Office of Medical Device Policy even before obtaining marketing approval?

A. We accept consultations regardless of the status of marketing approval. If you have not yet obtained marketing approval or imported the product, this is not a problem, so please fill out the contact form for pre-consultation with the details of your inquiry and send it by e-mail.

Q. We are a company in Kyushu. Do we need to go to Tokyo for consultation?

A. Pre-consultation meetings will be held online as a general rule. In the case of product explanations, we can arrange a face-to-face meeting if necessary, so please let us know the meeting format (and the reason why you prefer a face-to-face meeting) when you send us the contact form for pre-consultation.

Q. Finding Japanese data in support of documents is difficult.

A. You can also explain the underlying data by using data from overseas. Additionally, expert opinions and survey results may be used as supplementary information. However, you need to fully explain the applicability of data from overseas to healthcare conditions, patients, etc. in Japan (extrapolability), taking into account similarities and using clinical guidelines.

Q. Do I need to stamp the application form?

A. No stamp is required. Please check notifications such as "Elimination of the Requirement for Use of Seals in Administrative Procedures" (Health Policy Bureau Notification No. 0201-5, Notification HIB No. 0201-5, February 1, 2021) and "Elimination of the Requirement for Use of Seals in Administrative Procedures" (HPB/EAD Notification No. 0201-2, HIB/MED Notification No. 0201-5, February 1, 2021).

Q. Is there anything I need to prepare before applying?

A. When applying for insurance coverage, providing evidence based on data is crucial. Collecting data takes a certain amount of time, so collecting the data necessary to apply for insurance coverage starting with the application for marketing approval will enable the process to proceed smoothly. To find out what kind of data you need to collect, please contact the Office of Medical Devices Policy by submitting a pre-consultation form. You can do so before obtaining marketing approval or importing the product.

Fiscal Year 2024

Guidebook on Insurance Coverage for Medical Devices and In Vitro Diagnostics

Create/Edit: Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare