HGPI Expert Policy Advocacy Platform Project

Towards the Establishment of a Value-Based Health Care System

Policy Proposal

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(The content of the presentation is the personal opinion of the presenter and does not represent the organization.)

Executive Summary
Towards the Establishment of a Value-Based Health Care System

Health and Global Policy Institute (HGPI) has released a policy proposal, "Toward the Establishment of a Value-Based Healthcare System."
HGPI has launched the "HGPI Expert Policy Advocacy Platform" project, which allows fellows and other related parties affiliated with HGPI to individually present and promote policy recommendations from FY2022. The fellows' policy recommendations on pressing issues are scrutinized and approved by a review committee established within HGPI, and upon approval, are included as a part of the policy proposals issued by HGPI, thereby presenting options to address the issues with the aim of providing creative and feasible solutions for persons interested in policy.
In the first phase of the project, the theme "Towards the Establishment of a Value-Based Health Care System," a topic that has been the subject of much international debate in recent years, was proposed by Dr. Ataru Igarashi, an HGPI fellow. This proposal presents a value-based pricing (VBP) system, which is a multifaceted drug value-based pricing system for evaluating innovative drugs. Please note that the content of the presentation is the personal opinion of the presenter and does not represent the organization.

1 Sustainability of the healthcare system

- Measures to address rising medical costs due to the declining birthrate, aging population, and increasing advanced medical care are urgently needed.
- The effects of medical services can be divided into two categories: "employment-inducing effects and production spillover effects" and "effects gained by patients," with the latter affecting a wide range of costs, including productivity losses and care costs. The value of medical care needs to be redefined.
- Although the focus has been on revising the drug pricing system (lowering drug prices) in order to sustain the health insurance system, drug costs account for approximately 20% of healthcare costs, and it is difficult to reduce healthcare costs and improve overall healthcare efficiency using this approach alone
- The current price adjustment system is designed to drastically reduce prices when drugs become widely used, which could hinder international drug innovation in Japan.

2 Value-based drug pricing methodology

- VBP is proposed as a specific quantitative and qualitative evaluation method to reflect multifaceted value
- VBP "reflects multiple factors such as safety, efficacy, and economic factors in the price."
- It is possible to proposed quantify factors that are difficult to quantify, such as the size of unmet needs, severity of disease, and rarity, by using variable decision-making criteria.

3 Specific drug value assessment

- As a result of comparison between the current NHI prices and "the quantifiable value accumulation prices" based on currently available data, there were big differences depending on drugs.
- For treatments showing significant efficacy within a short period, the calculated price is significantly higher than the current price, but for treatments for serious disease and with a small life-extension effect, the calculated price is significantly lower than the current price.
- Although there is a high unmet medical need for drugs such as oncology drugs, the value of drugs

is not reflected in prices, and there is a risk that quantitative value accumulation alone will lead to access restrictions.

- VBP, which evaluates both quantitative and qualitative values, is useful as a system to reflect qualitative values, which cannot be directly quantified, in the final drug price.

Policy Proposal "Towards the Establishment of a Value-Based Health Care System"

This proposal was developed after discussions with several stakeholders based on the following three elements: sustainability of the system, evaluation of innovation, and implementation of reforms. Our views on these elements are presented below. In addition, as the first set of proposals, we are proposing a value-based drug pricing system.

Sustainability of the healthcare system

Measures to address the increasing healthcare cost due to the declining birthrate, aging population, and increasing advanced medical care are urgently needed. All countries with public healthcare systems share the common challenge of maintaining sustainable social insurance systems while ensuring access to new medicines. In addition, now that the finite nature of medical resources has been made visible and widely understood during the novel coronavirus pandemic, the solution is not to cover the increase in medical costs by increasing co-payments, taxes, and social insurance premiums in the traditional way, but to provide benefits in a more flexible manner.

In terms of healthcare efficiency, Japan has been facing problems with medical practices that need improvement, such as longer hospital stays, doctor shopping, and polypharmacy, compared to other countries. On the other hand, basic medical care that is affordable and of high quality, and advanced medical care that is highly effective are highly valuable to patients and to society.

Sato et al. (2021) [1] divided the effects of medical services into two categories: "employment-inducing effects and production spillover effects" from a macro perspective and "effects gained by patients and their families" from a micro perspective. For the former, medical services have a large employment inducement and production spillover effect compared to those of other industries, and demand for medical services exists regardless of region or environment. Regarding the latter, the report points out that the latter affects a wide range of costs, including productivity loss and nursing care costs, in addition to medical costs, and states that it is important to redefine the value of medical care broadly to include factors other than the amount of medical costs. In addition, they advocated policy formation that takes into account not only the health insurance system, but also the sustainability of innovation.

Until now, measures to sustain the health insurance system, and more specifically, measures to deal with rising healthcare costs, have focused on reforming the drug pricing system (basically, lowering drug prices). However, drug costs account for only about 20% of total healthcare costs (Chuikyo 2021[2]) making it somewhat difficult to achieve overall healthcare efficiency through this approach alone. In addition, the current price adjustment system is designed so that an increase in sales due to the widespread acceptance of an innovative drug in the clinical setting leads to a significant reduction in price, which has a negative impact on the sustainability of the innovation.

Regarding the current drug pricing system and innovation, there are several proposals for a new system that could more appropriately reflect the multifaceted value of drugs, rather than merely raising issues (INES2021[3], PHARMA JAPAN 2022[4]). However, specific new systems have not been adequately discussed.

This project is not limited to drug costs, but considers the compatibility of "improving the efficiency of the healthcare system" and "promoting innovation" from a broader perspective. The purpose of this first proposal

[1] Sato, Motohiro [Supervisor]. To hand over the universal health insurance system to the next generation: A study on the restructuring of benefits and burdens. Japan Public Affairs Association, 2021. [URL: https://www.j-paa.or.jp/policyproposal/556]

[2] Central Social Insurance Medical Council. August 4, 2021. NHI Drug Price Subcommittee (180th Meeting). [URL: https://www.mhlw.go.jp/content/12404000/000816054.pdf]

[3] INES. Proposal of new drug pricing reform consistent with fiscal sustainability. [URL: http://inesjapan.com/wp/wp-content/uploads/2021/05/document-20210528.pdf]

[4] It's Time to Look at Supply Status, NHI-Market Price Gap to Revisit Drug Pricing: MHLW Official. PHARMA JAPAN April 11, 2022

is to make more concrete recommendations regarding the "value-based drug pricing system," which is already in place and is the subject of active discussion among various stakeholders, including the concerned groups.

Evaluation of innovation - evaluation of multiple values -

In order to examine more specifically the reflection of multiple values, we conducted an examination of the feasibility of VBP using several existing drugs, and found it is necessary to evaluate both quantitative and qualitative values to establish VBP in the true sense of the word. However, the extent to which the quantifiable part can be explained has not been verified in practice. Therefore, we selected several drugs for different disease areas and conducted a trial calculation of the extent to which quantification is possible based on currently available evidence (medical costs, productivity loss, caregiver's costs, improvement in QOL, etc.).

As a result, there were many limitations to accumulation based only on quantitative value evaluation, and in some cases, significantly lower prices were found. Both qualitative and quantitative evaluations have been revealed to be required for implementation of VBP.

Implementing reforms

There is no doubt that optimization of overall healthcare is needed. This first set of proposals focused the discussion on how to reflect the drug values in their costs, which is already the subject of advanced debate in both industry and academia. In the future, we will not only propose concepts for areas other than drug costs, but also discuss the processes necessary for implementation with various stakeholders, with the aim of making second and third proposals and implementing the content of the proposals in society.

Policy Proposal "Towards the Establishment of a Value-Based Health Care System"

First proposal: Proposal for a value-based drug pricing system

In this proposal (April 2022 edition), the first of the proposals, "Towards the Establishment of a Value-Based Health Care System," we present a value-based pricing (VBP) system, which is a multifaceted drug value-based pricing system to evaluate innovative drugs. In the future, we will make a series of proposals from other perspectives as well.

Introduction

The aging of society and the declining birthrate have created an urgent need to address the increasing costs of medical care. However, measures taken to date have focused on reform of the drug pricing system. In the past reforms of the drug pricing system, the design was adopted so that the increase in sales of innovative drugs due to their wide acceptance in clinical settings led to a substantial reduction in prices, which has also been a disincentive to innovation. Drug costs account for only about 20% of total healthcare costs, and it is difficult to go beyond mere healthcare cost reductions to improve the efficiency of overall healthcare. The loss of predictability in the NHI drug pricing system will also lead to a decline in Japan's relative position in the international market, with a projected CAGR of -2% to +1% from 2020 to 2025[5], making Japan the only one of the 10 industrialized nations expected to experience negative growth. Global pharmaceutical companies are beginning to invest in new drug development in China rather than Japan[6].

Various stakeholders have pointed out that the current NHI drug pricing system can lead to a stifling of innovation. In addition, there have been several proposals for a new system that would better reflect multiple values, rather than merely raising the issues. However, the "reflection of multifaceted value" in the proposals to date has remained abstract, and there has been insufficient discussion on how to actually reflect the value, or how the value itself should be quantitatively and qualitatively evaluated.

Value-based pricing (VBP) is a drug pricing system that can reflect multifaceted value, and there have been various discussions overseas about VBP, which tends to be confused with a simple performance-based, outcome-based payment system or cost-effectiveness analysis (Tsevat, 2018[7]). In fact, VBP overlaps with these concepts, but the key point is that it incorporates broad values that are not captured by traditional evaluation methods. The market for pharmaceuticals is changing rapidly as a result of R&D investments in cutting-edge science and technology, such as the emergence of new treatments that can achieve remission in a short period of time at high rates, and treatments that can solve social problems such as infectious diseases and dementia, and the factors that should be emphasized as value will change from time to time. In addition, there are cases in which the introduction of a new drug reduces the burden on healthcare professionals and has an impact on society by enabling patients to return to society, so it is difficult to say that controlling only drug costs leads to overall optimization.

This proposal was prepared with the aim of making more concrete recommendations regarding a "value-based drug pricing system," which is desired by various stakeholders in Japan, as well as meeting the need to optimize overall healthcare. We hope that these recommendations will accelerate discussions toward the implementation of a "value-based drug pricing system."

[5] Exhibit 24: Global Invoice Spending and Growth in Selected Countries. [In: IQVIA. Global Medicine Spending and Usage Trends Outlook to 2025. IQVIA, 2021.]

[6] Exhibit 42: Number of drugs and country share of emerging biopharma pipeline Phase I to regulatory submission based on company headquarter location, 2006–2021. [In: Global Trends in R&D overview through 2021. IQVIA, February 2022. URL: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d-2022/iqvia-institute-global-trends-in-randd-to-2021.pdf]

[7] Tsevat J, Moriates C. Value-Based Health Care Meets Cost-Effectiveness Analysis. Ann Intern Med. 2018; 169(5): 329-32.

Methodology for value-based drug price calculation

The VBP concept is understood as "reflecting multiple factors such as safety, effectiveness, and even economic factors in the price." However, there are many misconceptions such as "measuring safety, effectiveness, and economic factors is sufficient as a value assessment" and "all elements of value are quantifiable (or what cannot be quantified cannot be called value)." In practice, many factors other than effectiveness, safety, and economic factors have been proposed, some of which are not quantifiable. Other than medical costs and QALYs, which are commonly used in "economic evaluation," factors that can be quantitatively measured and have been included in actual evaluations include work productivity, nursing care costs, and the burden of informal care (e.g., family members)[8]. On the other hand, factors such as the size of unmet needs and the severity and rarity of the disease cannot be quantified, but there are cases in which they are being addressed through quantification by varying the decision-making criteria depending on the disease. The premium in the current NHI drug pricing system is also an example of converting a qualitative evaluation into a quantitative value in the form of an additional price through "proposed quantification." Considering the above, it is impossible to evaluate everything quantitatively in advance, and it is necessary to consider how to clarify qualitative elements. The basic concept of value-based drug pricing is therefore to calculate drug prices based on value, including such aspects.

Jommi et al. (2020) defined four steps as "Operational step for value-based pricing": Identification of value domains, Measurement of value, Aggregation of measures, and Conversion of value into prices[9]. The report also suggested that factors such as "unmet needs" and "impact on dignity" are difficult or impossible to measure quantitatively and should be evaluated in the form of stepwise categories (such as the level of additional therapeutic benefit) or on a binary scale (such as large or small unmet need), and that proposed quantification be conducted and reflected in the final drug price.

Figure 1 The operational process of value-based pricing[9]

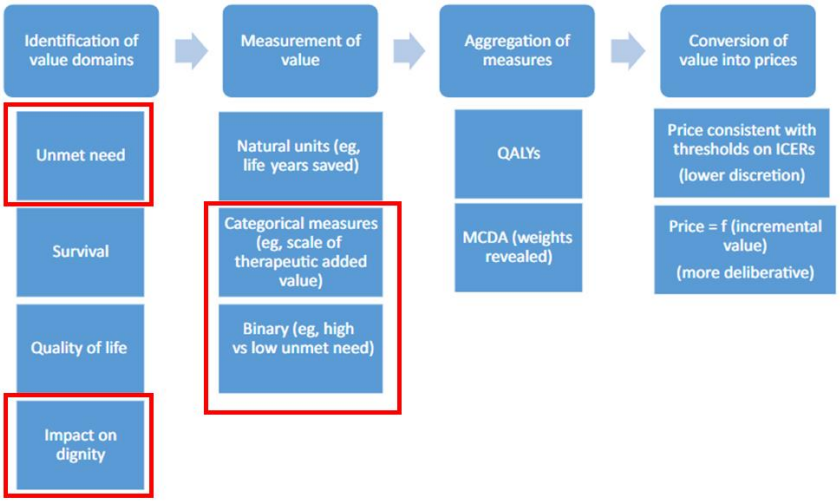


Figure 1. Operational steps for value-based pricing. ICER = incremental cost-effectiveness ratio; MCDA = multi-criteria decision analysis; QALYs = quality-adjusted life years. Elaboration on Sussex et al[5].

In this proposal, we aimed to show specifically what kind of deviation from the current drug prices would occur when calculating the estimated drug prices if only quantitative values were accumulated, using publicly available data on existing drugs.

[8] Lakdawalla, D.N., Doshi, J.A., Garrison, L.P., et al. Defining elements of value in health care—a health economics approach: an ISPOR Special Task Force report. Value Health. 2018; 21: 131-9.
[9] Jommi C, Armeni P, Costa F, et al. Implementation of Value-based Pricing for Medicines. Clin Ther. 2020 Jan;42(1):15-24.

Analysis of specific drugs

The following four areas (hepatitis C, neurodegenerative diseases, rheumatoid arthritis, and cancer) were evaluated based on data published in papers and other sources. With regard to cancer drugs, one CAR-T therapeutic agent and two molecular-targeted drugs were analyzed. The characteristics of each drug are shown in the table below.

Table 1 Characteristics of the drugs for which the analysis was performed

Drug	Feature
Hepatitis C drugs	Treatment was completed in 2-3 months, and more than 95% of patients were cured.
CAR-T	Next-generation drugs with long-term efficacy after a single dose
Rheumatoid arthritis drugs	Long-term remission improves QOL
Treatment of neurodegenerative diseases	Significant contribution of non-medical care costs and informal care costs
2 targeted agents	Molecular-targeted therapy for advanced cancer. Elderly patients were included, and PFS and OS were prolonged on a monthly basis.

For these drugs, we attempted to calculate a "value-reflected price" for the quantifiable portion of the drug. The reduction in medical costs was determined by the reduction in medical costs replaced by the introduction of the drug (i.e., the cost of the comparator) and the reduction in those for related diseases associated with the introduction of the drug.

Improvements in productivity (i.e., productivity losses) and improvements in nursing care costs and informal care were also calculated in the same way, using the "reduction in the relevant cost items when the new drug is used versus an existing drug."

The improvement in QOL was converted to monetary terms using the standard cost-effectiveness value of "5 million yen per QALY gained," after calculating the range of QALY improvement resulting from the introduction of the drug in question. This method itself is similar to the "calculation of Net Health Benefit (NHB) and monetary conversion of outcome improvement" used in cost-benefit analysis[10].

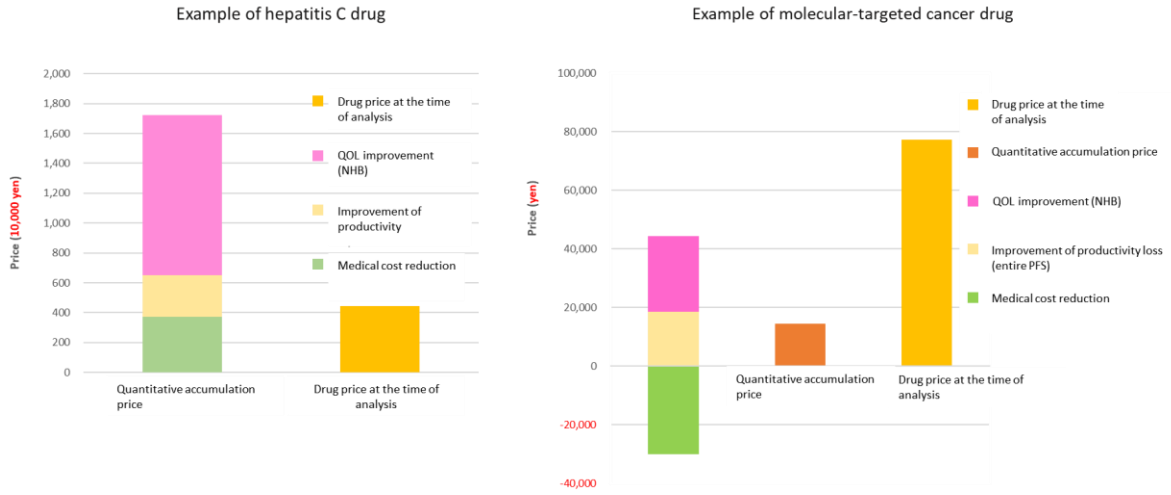
Table 2 shows the range of increase/decrease in the "quantitative value accumulation price" calculated by the above method compared to the price at the time of NHI drug price listing. The quantitative value accumulation prices of hepatitis C drugs, CAR-T, and RA drugs were higher than the NHI prices. On the other hand, the quantitative value accumulation prices of drugs for the treatment of neurodegenerative disease and 2 cancer drugs were significantly lower than the NHI prices. The actual price calculations for hepatitis C and molecular-targeted cancer drugs are shown in Figure 2.

[10] For example, if the expected QALY for a new drug is 4.0 QALY and 3.4 QALY for an existing drug, 0.6 QALY can be gained by introducing the new drug. Multiplying this 0.6 QALY by "5 million yen per QALY," NHB is 0.6 x 5 million yen = 3 million yen.

Table 2 Quantitative value calculation results

Drug	Medical cost reduction	Productivity loss improvement	Nursing care cost reduction	Informal care cost reduction	QOL improvement	Difference of VBP quantitative value vs. the drug price
Hepatitis C drugs	○	○	–	–	○	+286%
CAR-T	○	○	–	–	○	+72%
Rheumatoid arthritis drugs	○	○	–	–	○	+32%
Treatment of neurodegenerative diseases	○	–	○	○	○	-92%
Molecular-targeted cancer drug	○	○	–	–	○	-91%
Molecular-targeted cancer drug	○	○	–	–	○	-63%

Figure 2 Analysis of Hepatitis C Drugs and Molecular-Targeted Cancer Drugs



Based on this analysis, the "quantitative value accumulation price" was higher than the price at the time of listing for drugs that can be expected to achieve remission in a short treatment period, drugs that require continuous treatment but have a large total QALY gain, and drugs that are indicated for relatively young patients. On the other hand, when the target patients are relatively elderly or when the target disease is serious, the expected life expectancy is short and the life-prolonging effect of the intervention is small, resulting in the quantitative value accumulation price being significantly lower than the NHI price. In order to set "value-based pricing" in the true sense of the word, we believe that a system is needed to reflect qualitative values that cannot be quantified in the final drug price through proposed quantification or other means.

Qualitative value assessment

When conducting a qualitative evaluation, we propose which value elements are appropriate for qualitative value assessment. As shown in the table below, (1) drugs for serious diseases, (2) drugs for end-of-life care, (3) drugs for rare diseases, (4) drugs that enable a reduction in the burden on healthcare professionals, and (5) innovation are candidates for elements for qualitative value assessment. These are also elements that are actually evaluated overseas as values other than drug efficacy, safety, and cost-effectiveness, based on the characteristics of the drug. It is also necessary to consider what the value of the drug is to the patients actually receiving treatment. For example, which value is more important, OS (overall survival) or PFS (progression-free

survival), which are generally judged as clinical values for cancer patients, or other values (improvement of QoL due to reduced side effects, ability to continue working while receiving treatment) should also be discussed depending on the disease area.

Outcomes considered important by physicians and other providers of medical care, such as OS and PFS in oncology drugs, may not necessarily be important to patients. Although there are individual differences, the degree to which the patient can enjoy his or her life and the degree to which the patient can share his or her value with family members and others is important. In some cases, continuing treatment itself may become a burden if treatment continues for a long period of time. In addition, the value of the treatment may increase or decrease significantly depending on the long-term efficacy and safety data. In order to "value" in the correct sense of the term, it is essential to "update the value-based price over time, " which will be discussed later, and to have not only healthcare providers but also patients on the healthcare consumer side actively involved in the value assessment framework.

We believe that qualitative values require a method of "creating certain rules to determine the ratio of weighting to the drug price," similar to the additions in the current drug pricing system. We believe that the following values of drugs described in Table 3 are possible examples: (1) drugs for serious diseases, (2) drugs for end-of-life care, and (3) drugs for rare diseases, which are already used by NICE in the UK to weight the threshold, which determines whether the ICER value is high or low[11]. Changing the threshold value for serious diseases is similarly practiced by TLV, a Swedish HTA organization [12], and ZIN, a Dutch HTA organization [13]. As shown in the table below, we believe that it is feasible to use these as a reference for weighting the value of improvement in patient quality of life and the weighting of the final VBP calculated.

On the other hand, with regard to (4) drugs that enable a reduction in the burden on healthcare professionals, and (5) innovation, there are no clear rules for operating quantitative evaluation, even overseas, and basically, the evaluation is qualitative. Companies show the elements to be evaluated (or their improvement) by such methods as presenting data on the reduction of the burden on healthcare professionals due to the new intervention and having patients to refer to the benefits of improved convenience of treatment, and then qualitative evaluation is conducted through discussions at appraisals. In order to incorporate these value elements in NHI price calculation in Japan, it is necessary to somehow convert these qualitative values into quantitative values. As a method of reflecting these values in NHI prices, we believe that the weighting methods proposed in (1)-(3) above, or an addition to the overall NHI price, as in the current addition method of the NHI drug pricing system, is possible. In order to advocate these methods, the pharmaceutical companies have responsibility to show values.

If, as in the current drug pricing system, drug prices are basically determined by the administration, rules for quantification need to be established in advance. In other words, the drug price would consist of two portions: A: "the portion that can be quantified at present" and B: "the portion for which the qualitative value is converted into a price through proposed quantification."

If the company proposes the drug price in the style described in the latter section, the proposed price would consist of A: "the portion that can be quantified at present (based on data)" and B: "the portion converted to a price by proposed quantification," with the addition of C: "the portion for which the validity of an addition based on qualitative value should be examined" if there remain unquantifiable portions.

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[11] Neither the original threshold at NICE in the U.K. (20,000-30,000 pounds/QALY), nor the threshold for critical illness treatment and terminal care (up to 50,000 pounds/QALY), nor the threshold for drugs for ultra-rare diseases (100,000-300,000 pounds/QALY) are "quantitatively measured (e.g., by the willingness to pay method)." In this sense, the figures are determined by "proposed quantification" in the same way as the current drug price addition rule.

[12] Svensson M, Nilsson FO, Amberg K. Reimbursement Decisions for Pharmaceuticals in Sweden: The Impact of Disease Severity and Cost Effectiveness. Pharmacoeconomics. 2015 Nov;33(11):1229-36.

[13] Franken M, Koopmanschap M, Steenhoek A. Health economic evaluations in reimbursement decision making in the Netherlands: time to take it seriously? Z Evid Fortbild Qual Gesundhwes. 2014; 108(7): 383-9.

Table 3 Examples of possible qualitative valuations

Examples of value elements	Proposed example of weighting	Overseas operations
Elements for which there have been overseas examples of "qualitative → quantitative" process through a prososed quantification process		
Seriousness of disease	1. Change coefficient for monetary conversion of QoL/QALY improvement 2. Multiply the entire calculated quantified price by the adjustment factor	In the UK, the threshold has been raised up to 1.7-fold (usually from £30,000 to £50,000) for the evaluation of drugs for serious diseases or for end-of-life care. US-ICER presents "benchmark price" in steps from $50,000 to $200,000, without specifying a threshold.
End-of-life treatment		
Rare Disease		In the UK, the threshold for ultra-rare disease was increased from 3 times to a maximum of 10 times (from £100,000 to £300,000).
Elements for which there is no "qualitative → quantitative" case and that require new quantification for pricing		
Reduction of medical burden	1. Calculate value of resources "that become available for other diseases" as a result of reducing the burden of medical care (It is possible to save lives by investing the available resources → Case of the US ICER COVID drug) 2. Use normal addition method when weighing is not possible	In the UK, Canada, and the US, there have been cases wherecases in which reduction of medical burden was considered at appraisals
Innovation	1. For innovative products, multiples are added similarly to the above "serious disease/end-of-life treatment." 2. As in the previous premium system, a plus alpha premium is given to the final result.	In countries such as the UK, there have been casesare cases where in which "innovative nature" was qualitatively evaluated as a "positive factor" when determining the acceptability of benefits.

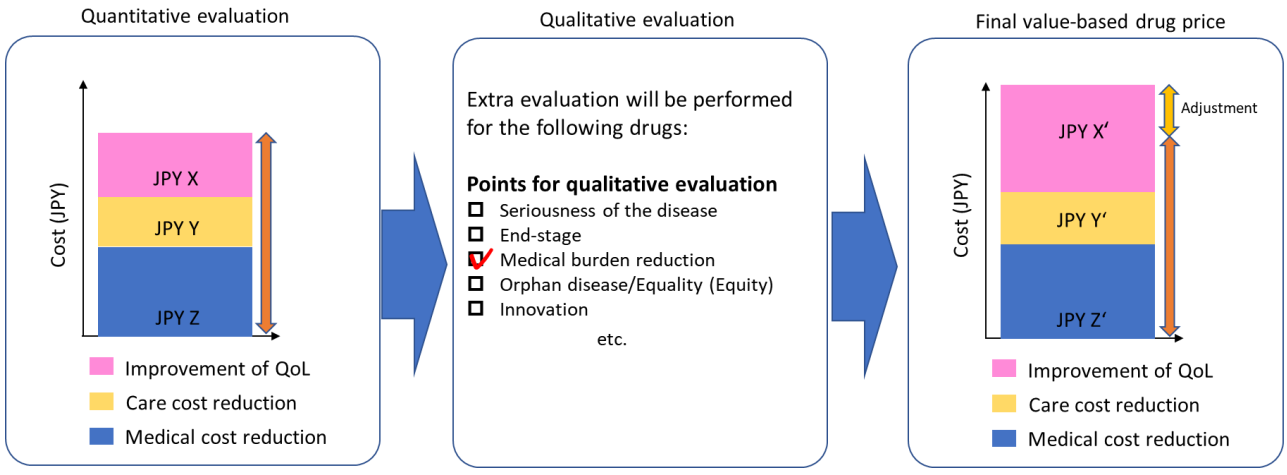
Proposal of new drug pricing system

Based on the above analysis, we propose a value-based drug pricing system that evaluates both quantitative and qualitative values.

From this analysis, the matters that should be discussed in the future in order to implement this method have become clear. Further, data-based discussions with various stakeholders will be necessary to further develop this policy proposal.

Figure 3 Proposed Value-based pricing method

To calculate the final drug price by quantitative value accumulation and qualitative value evaluation



Life cycle of drug prices based on multiple values

The value of a drug is expected to change over time. In some cases, the value may decrease because the outcome improvements shown in clinical trials are not obtained in the real world, while in other cases, the value may increase through the demonstration of true outcome improvements in the real world or through the expansion of indications into disease areas where there is a high unmet need. In addition, the element of value itself may change due to various external factors (e.g., the value of "avoiding a medical collapse" would have changed

significantly after the advent of COVID-19).
In addition, it would be reasonable to reduce the price after the expiration of the patent rights and set a generic equivalent price, since innovation is no longer applicable.
Currently, for drugs that are recognized as valuable in clinical practice and used extensively, and thus expand to a certain market size, the NHI price is reduced based on the market expansion repricing rule. The repricing is a method that allows for regular price reductions and cannot be said to be a value-based decision. In setting drug prices based on value, we believe that drug prices should not be fluctuated based solely on market expansion.
On the other hand, in order to evaluate such value fluctuations, an infrastructure for continuous scrutiny of drug value is necessary. Rapid analysis and approval of drug prices that do not impede access to the market at the time of launch, implementation of reevaluation of drug prices according to real-world evidence, and scrutiny of drug prices at the expiration of patent terms are necessary. The infrastructure necessary to conduct scrutiny is essential for implementation, and we will further discuss this area and make recommendations in the future.

Innovation investment and system sustainability

If only system sustainability is considered, the price of pharmaceuticals (medical technology) could be reduced uniformly, but such a system could severely damage the sustainability of innovation. Therefore, it is highly significant to redefine "value-based price" from a broader perspective than simply the amount of medical costs. Of course, if a higher price is given on the basis of higher value, it is assumed that the price will be reduced for those that do not adequately demonstrate value (or for those that becomes less valuable).
Even if only the quantitative part is taken, considering the existence of uncertainty in the underlying data itself and the existence of multiple patient populations (e.g., multiple indications and stratification by age), it is difficult to uniquely quantify "value," and for this reason it is also difficult to uniquely determine value-based prices. Just as there are ranges of values for efficacy, safety, and efficiency, "value-based price" will also have some range and will need to be evaluated as a distribution in some form. When assigning a value to the fact that a disease has been cured by a drug, it is also necessary to consider the extent to which the drug itself has contributed to the cure (i.e., whether other factors, such as changes in the healthcare system, have had any effect).
In the case of the system in which the administration determines the drug price, some rationale for the price as a whole is necessary. As mentioned above, the "value-based price" is the sum of A: "the portion that can be directly quantified from data at this time," and B: "the portion of qualitative value that has been converted to monetary value through proposed quantification." It is necessary to preliminarily determine how to examine the uncertainty of the method A as well as that of the method B.
If the proposed new NHI drug pricing system is based on a system in which "companies propose drug prices and are accountable for them," as is currently the case, the proposed price would be divided into two elements, A: "the portion that can be quantified at present" and B: "the portion that can be converted to a price by proposed quantification," and if A and B are not sufficient to explain the price, C: "the portion in which the qualitative value is qualitatively added." If a company's proposed price is significantly higher than the proven value (A, B), or if A, B itself is highly uncertain, the explainability (or transparency) of the price will be reduced, which is an unfavorable factor during price negotiations.

Summary

The recent active discussion of the consideration of multifaceted value in the pricing of pharmaceuticals is a desirable change. However, there is still much confusion between the discussion of value and the discussion of cost-effectiveness/medical technology evaluation, and many cases with a focus on only the quantifiable portion. Examination using specific examples revealed some cases in which the quantifiable portion alone does not

adequately reflect value. In order to build a sustainable healthcare system, it is important to define the optimal pricing method while involving various stakeholders.

Acknowledgments
We would like to thank Ms. Naomi Sakurai (President, Cancer Solutions, Inc.) and Mr. Motohiro Sato (Professor, Graduate School of Economics, Hitotsubashi University) for their advice as research collaborators in writing this proposal.

Expert Policy Advocacy Platform of the Health and Global Policy Institute (HGPI)

As a non-profit, independent health policy think tank, the Health and Global Policy Institute (HGPI) has been working to realize public- and party-driven healthcare policies by making a wide variety of policy proposals since its establishment in 2004. In many cases, HGPI's policy proposals have helped promote discussion and policy progress in areas such as oncology measures, women's health, dementia, drug-resistant bacteria, and health technology assessment.

When formulating policy proposals, HGPI places importance on the process of identifying issues through discussions among multi-stakeholder and global experts. While being closed to the public, flat discussions are held between multi-stakeholders of industrial, governmental, academic, and private sectors, to clarify policy issues, identify the points to discuss, and offer directions for solutions. In addition, we hold expert meetings and public symposiums, inviting global experts, to share policy issues internationally and disseminate them to society at large.

This process of formulating policy proposals is meaningful in Japan, where opportunities for flat discussions among multi-stakeholder groups are limited, and we believe that it has attracted interest from many stakeholders, including government officials, and led to the formulation of feasible policy proposals. On the other hand, the formulation of policy proposals through multi-stakeholder discussions requires multiple processes, including the setting up of repeated discussion forums, and takes a lot of time. In some policy areas, urgent themes and specific proposals that do not necessarily require multi-stakeholder consensus are valuable, and there is a need for a different process for formulating policy proposals than those used in the past.

Therefore, HGPI has launched the "HGPI Expert Policy Advocacy Platform" project, in which fellows and other concerned parties affiliated with HGPI can individually present and promote their policy recommendations. The content of policy recommendations that the fellows identify as pressing issues will be scrutinized and approved by a committee established within HGPI, and will be included as part of the policy proposals issued by HGPI, thereby presenting options to address the issues with the aim of providing creative and feasible solutions to persons interested in policy. Please note that the content of the presentation is the personal opinion of the presenter and does not represent the organization.

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