2025/7/29

Creating a Sustainable Ecosystem for Innovative Regenerative Medical Products

Objective

Build a sustainable ecosystem for Regenerative Medical Products to ensure access to transformative treatments for patients with serious medical needs in Japan

Aim of white paper:

- Raise awareness of the clinical and societal value of regenerative medical products
- Demonstrate that it is necessary to build an ecosystem that integrates R&D, manufacturing and supply, medical insurance systems, and treatments in order to spread patient access to regenerative medical products.
- Identify issues and search for opportunities. Advocate for policy improvements to support a sustainable ecosystem for regenerative medical products in Japan

※This article reflects the opinion of the author and does not represent the official view of the JRI.

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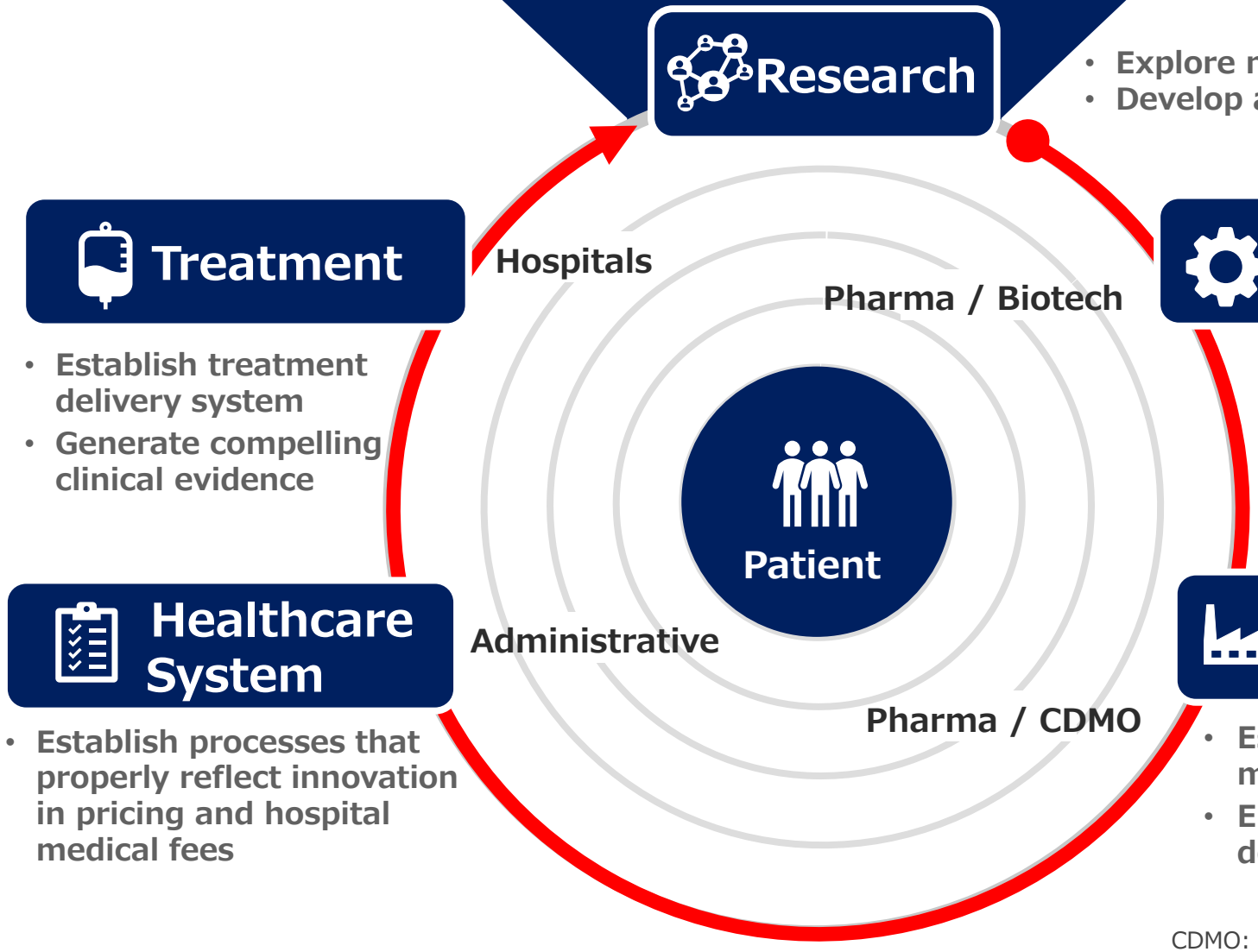
White Paper

Creating a Sustainable Ecosystem for Innovative Regenerative Medical Products

Overview of sustainable regenerative medical products ecosystem



- Explore new therapeutic targets
- Develop advanced technology

- Participate in global clinical trials preventing drug lag/loss

- Establish tailor-made manufacturing processes
- Enhance CDMO and establish dedicated distribution infrastructure

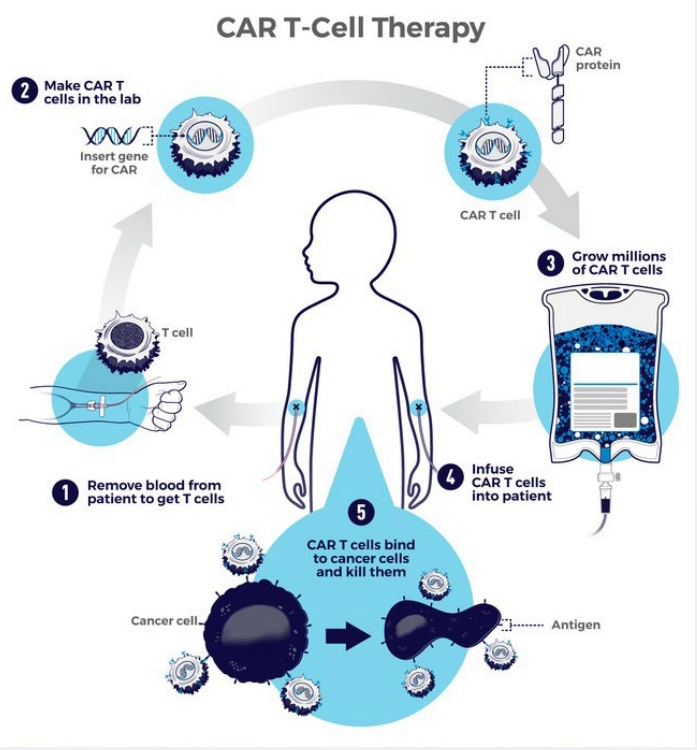
- Establish processes that properly reflect innovation in pricing and hospital medical fees

- Establish treatment delivery system
- Generate compelling clinical evidence

CDMO: Contract Development and Manufacturing Organization

Clinical and social value of CAR T an example of regenerative medical products

Personalized medicine that can transform patients' lives



CAR T-Cell Therapy: Image Details - NCI Visuals Online

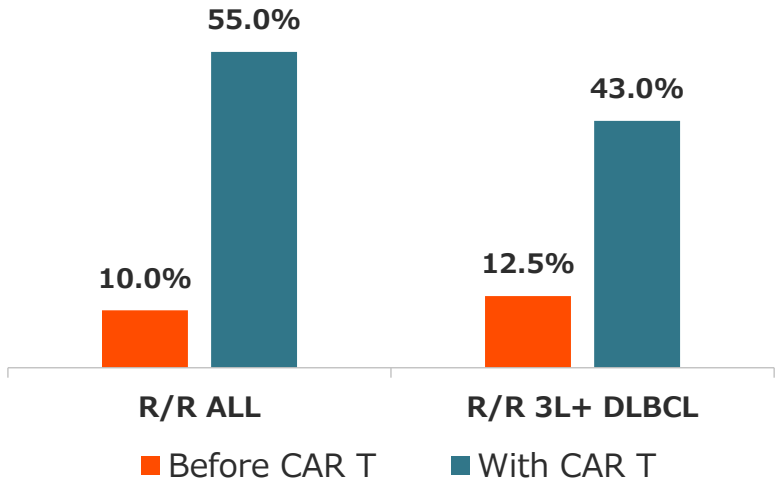
CAR T cell therapy is a type of treatment where a patient's own immune cells (T cells) are collected and modified in a lab in such a way that allows them to better recognize and attack cancer cells. The modified cells are then infused back into the patient to fight the cancer.

It offers the potential to cure cancer with a one-time treatment, resulting in significant savings in healthcare resources, including the cost of caregivers.

Revolutionizing treatment options, offering unprecedented outcomes

CAR T 5-year overall survival rates indicate their curative potential

(see footnotes 1-4)



- CAR T treatments are moving from later to **earlier lines of therapy** in haematological disorders, with trials underway for **solid tumours**[5]
- CAR T treatments are expanding into new disease areas, including **immunology and neurology**

Abbreviations: DLBCL: Diffuse Large B-cell Lymphoma; OS: Overall Survival; R/R ALL: Relapsed/Refractory Acute Lymphoblastic Leukaemia
References: 1. ACGT 2022; 2. Gilead 2021; 3. Crump et al. 2017; 4. Neelapu et al. 2023; 5. Patel et al. 2021

The importance of the clinical and societal value of CAR-T cell therapy

CAR-T cell therapy has innovative clinical and social value that differs from that of conventional treatments.

Clinical Value [1-5]

- Radical cure of severe diseases
- Radical treatment of rare diseases
- Continuation of long-term treatment-free status
- Established safety profile
- Complete with only one dose

- As a result of clinical trials, CAR-T cell therapy has the potential to cure serious disease and achieve a long-term treatment-free state.
- Clinical trials have shown that CAR-T cell therapy has a very high therapeutic efficacy after a single dose.
- Post-marketing clinical trial data also show that CAR-T cell therapy achieves a high response rate and survival rate.
- The safety profile of CAR T-cell therapy and how to manage side effects are well established.
- Advancing the development of CAR-T cell therapy will give it the potential to be an innovative treatment for other diseases.

Social Value [6]

- Patients can be rehabilitated.
- Reducing the burden on patients Improvement of QOL
- Improvement of the labor productivity of patients and families
- Reducing the burden on caregivers and medical institutions

- CAR-T cell therapy can improve the patient's quality of life (QoL) over a long period of time with short-term treatment.
- It supports the early reintegration of patients into society and their resumption of economic activity, and helps improve productivity. It also indirectly helps reduce the overall burden on those involved, such as families, caregivers, and the organizations and medical institutions where patients work.
- CAR-T cell therapy is a single-dose personalized treatment that provides significant economic value by reducing the consumption of medical resources, reducing the need for long-term hospital visits, nursing care, and hospitalization.

References: 1. BMS「TRANSCEND trial」; 2. Gilead Sciences 2021, 3. Neelapu *et al.* 2023; 4. Abramson *et al.* 2023; 5. Crombie 2023; 6. Alliance for Regenerative Medicine 2020

Expected benefits of building a regenerative medical products ecosystem in Japan

	As is	A society achieved by the spread of regenerative medical products
Patients	**Long-term hospitalization and recuperation. Limited reintegration**	**High therapeutic effect with a single dose, possibility of radical cure. Early reintegration into society leads to a life that does not change.** • Improved efficacy and expanded indications will increase treatment options for diseases that are currently difficult to treat. • As less long-term administration and care is required, the physical, mental and economic burden on patients is reduced. • The burden of nursing care in the daily life of the patient's family is also alleviated.
Society	**A heavy burden on families, caregivers, and society**	**Improving labor productivity and helping to maintain economic activity** • It supports the early rehabilitation of patients and their resumption of economic activity. • In Japan, with the labor force contracting, the economy is suffering from significant labor shortages, so the per capita economic value of workers is increasing. • Regenerative medical products contribute to economic activity by reducing the burden on society, including not only the patients themselves, but also their families, caregivers, the organizations where patients work, and medical institutions.
Industry	**Developing as an industry. The market is not yet established.**	**Creation of employment and development of highly skilled human resources will allow Japan to become a regenerative medicine hub for Asian countries** • The development and consolidation of high-level human resources will promote the development of the medical industry, which also involves local industries, and contribute to the revitalization of local economies. • R&D, and practical application of core and related technologies through industry-academia collaboration will lead to the creation of new industries and medical technologies, as well as boosting employment. • Japan is seen as an environment where some of the world's most advanced initiatives for research & development and practical application of regenerative medical products originate. It has the potential to help create activity bases, revitalizing the economy of local regions and of the country as a whole, and, as an export industry, earning foreign currency.

Improvements to the ecosystem aimed at sustainably providing patients with regenerative medical products

Category	What is going well	Areas for improvement
Research Development	Capabilities in basic clinical research for regenerative medical products are among the best in the world **Honebuto 2025** by government Promoting R&D in regenerative medicines, cell therapy, and gene therapy Establishment of manufacturing systems for pharmaceuticals, including biopharmaceuticals, and development and securing of human resources **CDMO subsidies by METI** "Regenerative Medicines Manufacturing Capital Investment Support Business"	**Increase of participation in global trials;** < 40% of RM drugs approved in JP vs. US/EU[1]; < 20% RM drugs under Phase 3 in JP vs. US/EU[1]
1 Manufacturing & supply		**Attract investment to local manufacturing in JP** to upscale supply chain and support future R&D innovation in JP. **Job creation and development of professionals** with advanced scientific knowledge.
2 Healthcare system	After regulatory approval under the Pharmaceuticals and Medical Devices Act, insurance reimbursement is made in a **short period of time under the universal health insurance system.**	**A pricing system that appropriately evaluates innovation and a medical fee system that appropriately reflects costs in the medical field**
3 Treatment	**Improved facility and capability** to administer CAR T at key hospitals in Japan	**Appropriate support for the human resources and facility resources** of treatment facilities to ensure that patients in need continue to benefit from innovative treatments.

Source: FIRM Central Social Insurance Medical Council, Drug Pricing Subcommittee Statement of Opinion (July 2023)

Deep Dive 1

Manufacturing & supply challenges

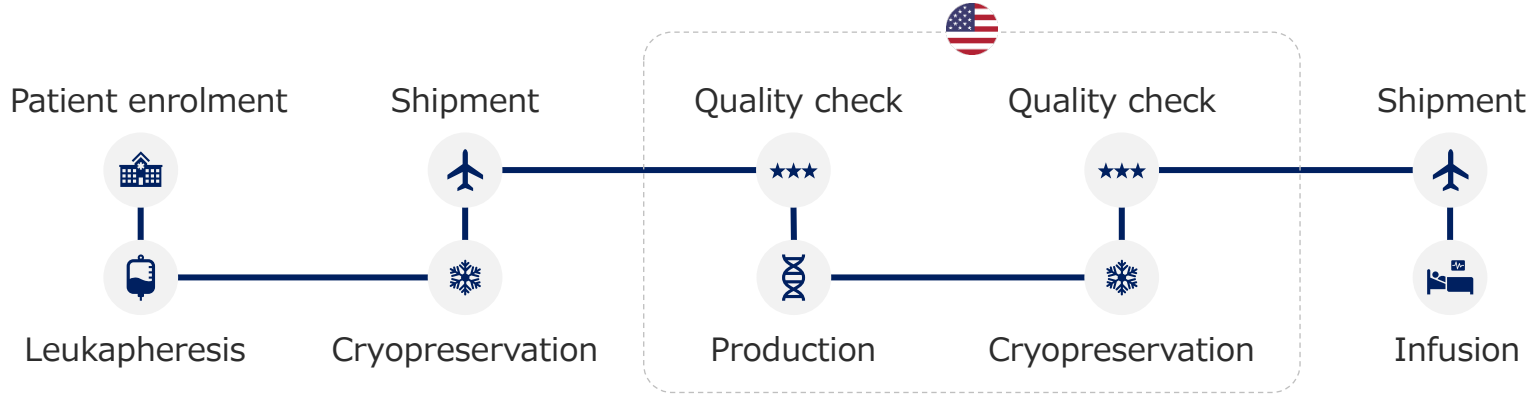
The manufacture of completely personalized CAR T treatments is complex and differs from that of conventional medicines.

At present, the U.S. leads in this field, but if Japan can address various challenges, it has the potential to become a manufacturing and supply hub in Asia.

CAR T manufacturing

- Personalized and no economies of scale
- Specialised facilities and equipment[1,2]
- Highly skilled and educated workforce[3]

CAR T production process consists of a series of **complex sequential steps**



Additionally, more than **500 points across the chain of identity** exist throughout the entire process

Complex supply chain

- **Living patient cells** that must be stored and transported in **cryogenic shipping container**[1,6]
- **Costly, GMP-grade viral vectors** face supply shortages need to be procured[1,7]

Abbreviations: GMP: Good Manufacturing Practice. **References**: 1. McKinsey & Co. 2019; 2. Wang *et al.* 2016; 3. Ho *et al.* 2022; 4. Abbasi *et al.* 2022; 5. BMS DoF 2022; 6. Moutsatsou *et al.* 2019; 7. FiercePharma 2021

Deep Dives 2 & 3

Healthcare system & treatment challenges

Need to progress and improve the health insurance processes that govern pricing / repricing & medical cost coverage in order to cover the investment in R&D, manufacturing and administration, the costs of which are higher than for conventional treatments.

Healthcare System

Pricing & repricing of regenerative medical products

- **No economies of scale**
  - ✗ Personalized and complex manufacturing
  - ✗ Mass production not feasible
- **Globally limited production and supply**
  - ✗ Infrastructure building in Asia has been slow, and supply to Japan is limited
- **Significant initial and ongoing investment in clinical trials and post-launch manufacturing needed**
- **Specialized highly trained workforce is required for R&D and manufacturing**
- **High standard of quality control capabilities and resources required**

Medical fees

Hospital resources

- Need to invest in hospital beds for the provision of CAR-T cell therapy

Establishing facilities

- Need to purchase and maintain expensive medical equipment for apheresis, administration & monitoring

Human resources & training

- Need to recruit & train medical professionals with CAR T treatment expertise, including experience of adverse event management

Source: Gagelmann *et al*. 2022; 2. Buechner *et al.* 2018; 3. EBMT 2019

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Manufacturing & supply	**CDMO subsidies by METI** "Regenerative Medicines Manufacturing Capital Investment Support Business"	**Attract investment to local manufacturing in JP** to upscale supply chain and support future R&D innovation in JP. **Job creation and development of professionals** with advanced scientific knowledge.
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Current pricing, challenges in revising this, and suggested improvements

A pricing system is required that takes into account the long-term efficacy of regenerative medical products

Current Shortcomings

Pricing doesn't reflect long-term clinical and societal value

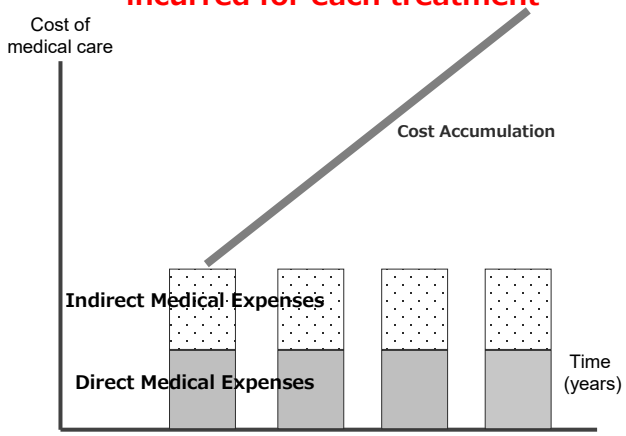
Regenerative medical products are expected to provide long-term clinical value, but it is impossible to fully prove them in the period until the application is filed, and this cannot be reflected in the price calculation.

Regenerative medical products have the potential to contribute to society, such as through patient rehabilitation and a reduction in the burden of nursing care, but these aspects of their social value are not reflected in their pricing.

Changes in medical costs depending on the course of treatment

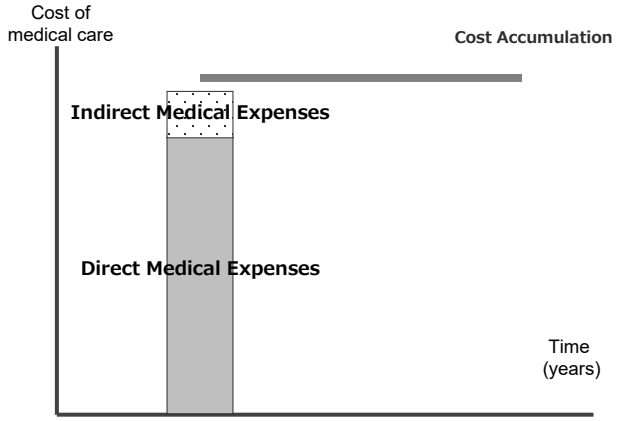
Conventional Medicines

Treatment costs and labor loss costs are incurred for each treatment



Regenerative Medical Products

No ongoing treatment and labor loss costs because it is a one-time treatment



Direct Medical Expenses :Costs directly related to treatment.
Examples: Outpatient expenses, hospitalization costs, examination costs, drug costs, etc.
Indirect Medical Expenses :Expenses incurred in connection with medical treatment that are not directly linked to medical practice.
Examples: Transportation expenses to hospitals, nursing care expenses, loss of work opportunities, etc.

Improvements

Reflect overall usefulness in pricing

In order to promote the verification of clinical and social value over a long period of time, an additional process should be considered under which the evaluation of efficacy and safety after marketing is appropriately reflected in the price.
This should be used as an incentive to develop a platform for collecting and analyzing data in actual clinical practice, and to promote reverse translational research.

Current pricing, challenges in revising this, and suggested improvements

It is impossible to reduce the cost of regenerative medical products because they are repeatedly produced in small quantities; a pricing system is required that takes into account the unique manufacturing processes

Current Shortcomings

Manufacture of individualized products doesn't yield economies of scale

The per unit cost of manufacturing conventional pharmaceuticals falls as the volume of production increases; market expansion repricing reflect these economies of scale.

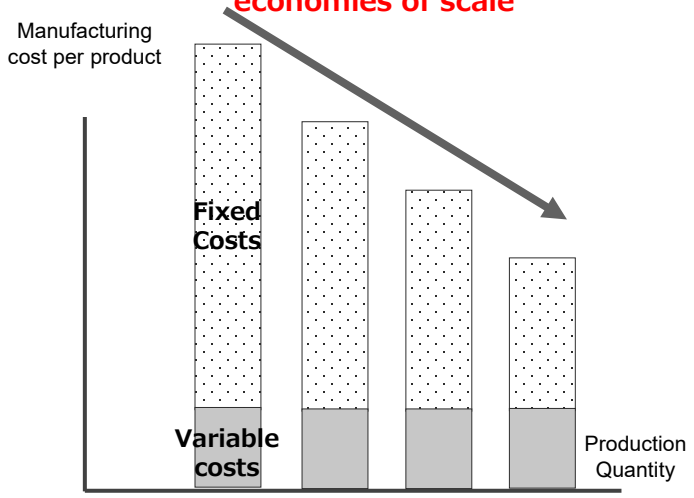
Regenerative medical products require complex and individualized manufacturing processes; even even if the number of patients supplied increases, individual manufacturing and transportation and supply lines need to be expanded. It is impossible to reduce unit costs through mass production.

While it is important to ensure a sustainable supply of products in Japan amid limited global supply, manufacturing priorities will make it difficult to ensure patient access if prices are kept down.

Changes in Manufacturing cost per product by production quantity

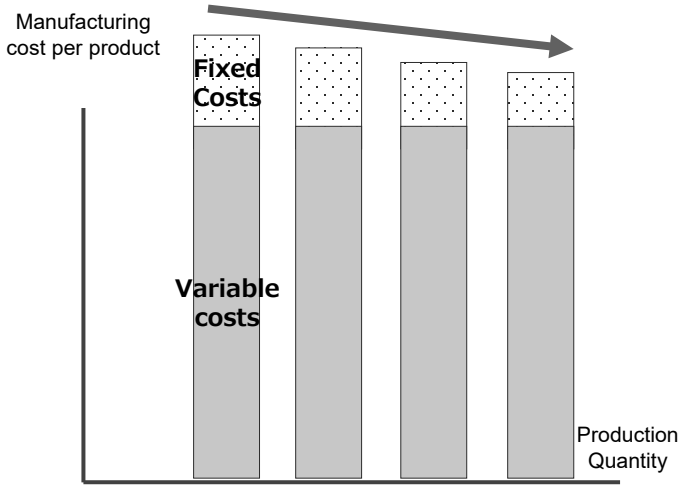
Conventional Medicines

Fixed costs decrease in line with production volume, resulting in economies of scale



Regenerative Medical Products

Small-volume production is repeated, and no major economies of scale accrue



Improvements

Revision of market expansion repricing rules

For regenerative medical products that require complex and individualized manufacturing processes that do not have economies of scale, it is necessary to review the market expansion repricing rules in order to secure a sustainable supply to patients in Japan.

Differences in the cost structure of regenerative medical products and conventional pharmaceuticals

		Regenerative Medical Products	Small Molecule and Biopharmaceuticals
R&D	Regulation	• **Japan's regulations (Cartagena, etc.) are barriers**	• International harmonization through ICH
	Patent	• Many patents are related (licensing fees increase)	• Protected by substance patents
	Human Resources	• **There are few highly skilled human resources; there is accordingly a high need for training**	• Abundant
Manufacturing	Healthcare Providers	• It is necessary to collect cells as a starting point for manufacturing.	• – (No need to collect cells at medical institutions)
	Manufacturing	• Requires expensive GMP-level vectors • **Requires the introduction of a commercial perspective** • **Dedicated capital investment in accordance with GCTP ministerial ordinances for each modality is required.** • **Mass production is not possible, and economies of scale do not accrue.**	• Equipment can be repurposed for the same modality • Related industries are limited • Mass production capable and industrial
	QC	• **Homogenization of cells and genes is difficult, and the cost of divers and multi-stage quality assurance tests (marker expression, virus testing) is high.**	• Easy to homogenize • Quality assurance testing to a certain extent
Transport	**Transport**	• **Requires dedicated transport infrastructure (e.g. -150°C)**	• **Can be transported with normal equipment**
Administration	**Healthcare Providers**	• Limited to specialized facilities and dependent on doctors' procedures (e.g., training fees) • The upper limit of SG&A expenses for medical device calculations is an issue	• Widely used
	Target Patients	• **Fewer due to it being designed to treat rare diseases** • **Autologous cells are completely personalized medicine**	• Relatively common, including lifestyle-related diseases

References: FIRM “Opinion on pricing of regenerative medical products” (July 09, 2025)

Issues of the current pricing system

Japan's medical benefit costs are expected to reach approximately 60 trillion yen by fiscal 2025, and demand for medical care is expanding due to the declining birthrate and aging population.

In response to concerns about the rapid increase in the financial burden of medical benefit costs, we have repeatedly suppressed unit prices and quantities, but there is a risk that the profits of pharmaceutical and others in the sector and will be squeezed, and there is unlikely to be sufficient return on investment to fund the development of next-generation innovations.

The following three points have been proposed and discussed as major directions to solve this problem.

Manage the total budget for medical benefits in line with economic growth rate

Introduce a guaranteed adjustment mechanism to cover nominal growth in total drug costs

- Drug costs are managed by increasing the drug cost portion of medical benefits in line with the medium- to long-term nominal GDP growth rate.
- By quantifying the upper and lower limits of the financial resources quota in advance, it is necessary to ensure the appropriate allocation of resources to innovative pharmaceuticals and to create a highly predictable environment in which sudden and mechanical drug price reductions do not occur.
- Since any growth of the GDP deflator index is reflected in nominal GDP growth rates, it is reasonable to see increases in drug spending as a component of economic growth.

Mechanism for evaluating high-value medical care

Introduce a system that evaluates diverse aspects of value and reflects these in drug prices

- The current opaque process, which is effectively a centripetal operation of only Cost and QALY, should be reviewed. A fundamental adjustment should be made to value assessment, by incorporating a wide range of factors (impact on work, health status of caregivers and family members, etc., and overall social impact).

Mechanisms to exclude low-value medical care

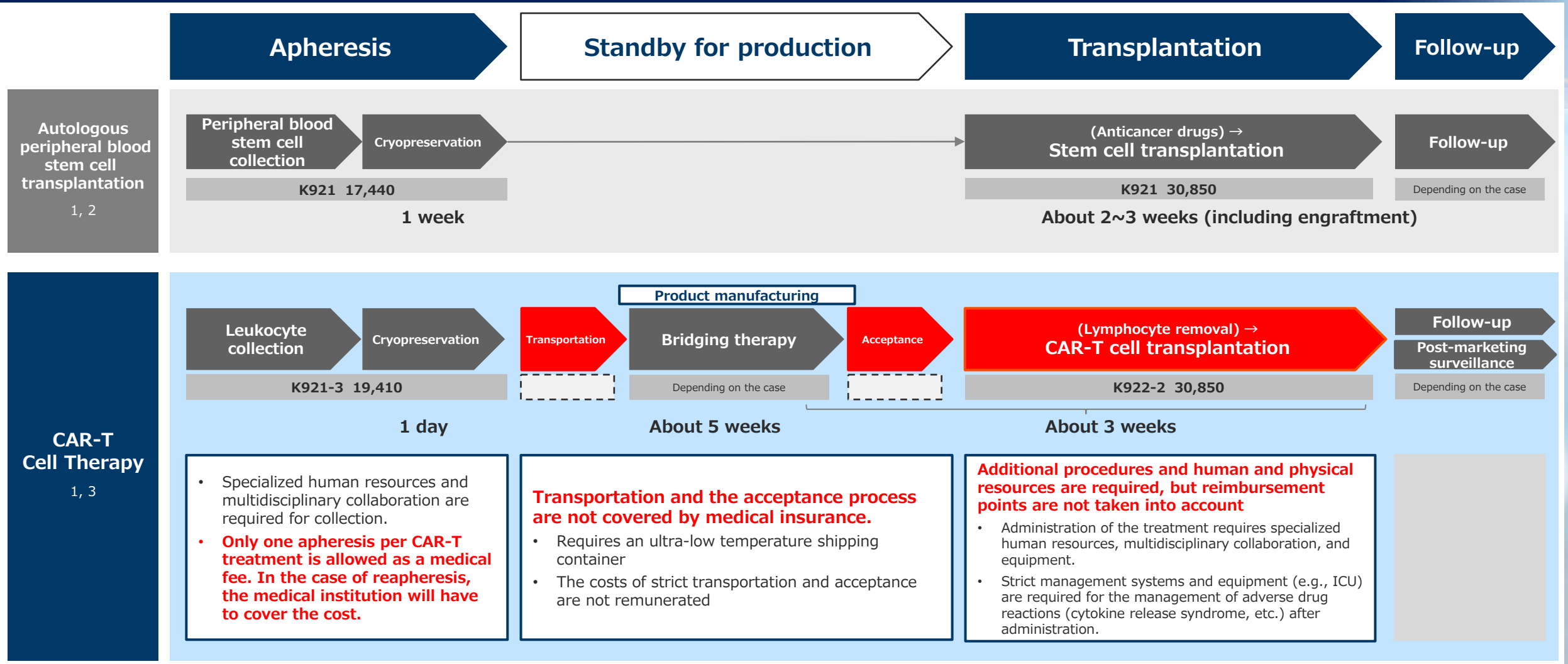
Introduce a "low-value healthcare" category

- Drugs and technologies whose clinical efficacy or social benefits fall below a certain standard should be classified as "low-value medicine," and alternative treatments should be proposed, as well as gradual reductions in scores and withdrawal from insurance coverage.

References: Institute for New Era Strategies "Recommendations of the Association for the Revival of Drug Discovery Innovation" (May 13, 2025)

Issues with the current medical fee system
Comparison with autologous peripheral blood stem cell transplantation

CAR-T cell therapy is eligible for medical fee reimbursement for autologous peripheral blood stem cell transplantation, which has a similar process, but the cost of medical care, such as the personnel and equipment required for implementation, is not covered.



References: 1. Ministry of Health, Labour and Welfare Medical Fee Score Table, 2. Japan Red Cross Society Himeji Cross Hospital "Hematopoietic Stem Cell Transplantation" 3. BMS "Q&A for Patients Receiving both CART"

Patient access challenges and countermeasures for CAR-T cell therapy

In order to provide CAR-T cell therapy to more patients at an optimal timing, it is necessary to improve the current system and strengthen the network of medical institutions.

	1 Diagnosis ~ Initial Treatment ~ Recurrence	2 Access to CAR-T cell therapy ~ Therapy ~ Follow-up
Hypothesis	Patients: Major changes to daily life, anxiety, lack of information about disease progression and prognosis, or treatment options	Patients: • Anxiety about environmental changes, side effects, multiple hospital transfers, and follow-up • Facilities offering treatment are limited to certain medical institutions in urban areas, and access is difficult for patients living in rural areas. Physicians and Medical Institutions: • Uneven distribution of medical resources across regions • Insufficient cooperation between medical institutions, lack of smooth provision of medical information, insufficient incentives for patient referrals, etc. • Increased effort in the apheresis department • Compared to U.S. clinical guidelines, the position of CAR-T cell therapy is ambiguous
Proposed Measures	Promote awareness-raising activities among patients to understand diseases and various treatment options, and to raise awareness of immunotherapy as a whole (including antibody drugs and CAR-T) e.g. Support for providing information to patients to academic conferences, patient associations, etc., booklets and websites for patients, sharing experiences of patients treated with CAR T	• Expand the medical fee system so that it appropriately reflects all medical costs, as well as providing coverage of the human and financial cost incurred by facilities that can offer CAR T therapy • Create a forum where patients, academic societies, medical institutions, and pharmaceutical companies can share and discuss the latest information on treatments and products • Facilitate cooperation among medical institutions and promote the assignment of specialized coordinators (e.g. in hematopoietic stem cell transplantation, a coordinator is assigned to coordinate with medical institutions and provide care to patients. • Clarify the position of CAR-T cell therapy in clinical guidelines to secure treatment options for patients

Note 1 : Summary of discussions regarding the use of private insurance

In Japan, there are concerns about the sustainability of the public health insurance system given that medical expenses are increasing every year. A proposal to control social insurance premiums by excluding some high-priced drugs from public insurance coverage and making use of private insurance is currently under consideration.

- While the public health insurance system aims to realize the concept of universal health coverage, which would allow everyone to be shielded from significant risk and receive the medical services they need without significant financial burden, excluding costly medicines from public insurance coverage may threaten this concept.
- In addition, as medical technology advances, with diversified treatments and increased patient choice, limiting options for economic reasons goes against the concept of improving the quality of healthcare and access to it.

Regenerative medical products and related technologies should continue to be treated as reimbursable under the public health insurance system

- The government intends to expand the scope of uninsured combination therapies so that cutting-edge medical technologies for which efficacy evaluations are not sufficiently evaluated can be used without any delay until they are covered by insurance.
- At present, knowledge of regenerative medicine as a medical treatment not covered by insurance (medical technology under the Safety Assurance Act) is not fully utilized in the ecosystem. In the future, it is necessary to reflect it in the research and development of next-generation treatments through active reverse translational research. For example, we believe that (a) research plans and treatment plans for which evidence is obtained should be recognized as uninsured combination therapies such as advanced medical care and patient-requested medical treatment, (b) the public should participate in research plans and treatment plans for which evidence is obtained, (c) the number of patients receiving treatment should be increased by reducing the burden on them, and (d) the quality of research and treatment should be improved.
- In addition, it is desirable to alleviate the personal burden of medical expenses associated with this through the development and utilization of private insurance.

Note 2 : Cost-Effectiveness Evaluation System

The “Basic Policy on Economic and Fiscal Management and Reform 2025” (“Honebuto no Hoshin 2025”) 30 states:

“Based on objective verification, further utilization of the cost-effectiveness evaluation system will be considered, including appropriate evaluation methods, the scope of application, and the implementation structure, as well as its use in the drug pricing system and clinical practice.”

This indicates a direction toward expanded application of the system in the future.

Analyzing the European HTA landscape, 'cost-effectiveness evaluation,' or 'economic HTA,' is not applied to regenerative medical products in key reference countries like Germany and France. The primary reason for this is that standard economic HTA lacks the flexibility to account for broader considerations, such as long-term economic and scientific values. Applying standard economic HTA could lead to significant drug lag and loss for regenerative medical products.

- While economic HTA is not undertaken in countries like Germany and France, clinical HTA focuses on clinical value assessment, including patient-reported outcomes (PRO). However, regenerative medical products are highly complex, with challenges in blinding, randomization, endpoint selection, and choice of comparator, which results in uncertain evidence regarding their long-term value at the time of regulatory submission. Even clinical HTA has limitations in fully capturing the long-term, potentially lifetime, benefits of regenerative medical products.
- However, for example, in Sweden, economic HTA is applied to with greater flexibility which helps regenerative medical products. They incorporate flexible thresholds for the Incremental Cost-Effectiveness Ratio (ICER), Quality-Adjusted Life Years (QALY), cost-benefit analysis, and budget impact to enable faster patient access to life-saving regenerative medical products. Sweden’s HTA system also systematically includes ‘Indirect costs and benefits’, which supports their access as regenerative medical products have a positive impact on this domain of HTA.

Note 3 : Price Stability and Manufacturing Incentives to Promote Innovation and Investment in France

In France, a framework agreement between LEEM (The French Pharmaceutical Companies Association) and CEPS (The Economic Committee for Health Products) has established a system providing price stability and manufacturing incentives (currently under renegotiation). It incorporates incentives designed to promote domestic manufacturing, support exports, by ensuring that prices for highly innovative medicines do not fall below those in other European countries.

They include the following:

- To promote domestic manufacturing of innovative medicines, for products rated ASMR 1–3 (indicating high added clinical value compared to existing therapies), if all major manufacturing steps are conducted in France, the price must not be lower than the lowest price in either the UK, Germany, Italy, or Spain.
- If current or future investments in manufacturing, R&D, or digital health related to the product are made within the EU—particularly in France—up to five years of price stability may be granted.
- To encourage exports, products for which at least one significant manufacturing step is conducted in the EU (especially in France), batch release is performed in France, and more than 60% of production volume is exported, may be granted two years of price stability (renewable once for up to two additional years).
- For many innovative medicines rated ASMR 1–3, if the price is set by referencing other European countries and the health economic assessment is valid, net and list price stability is granted for the first five years after market launch (three years in other cases).

In Japan, similar incentives may be necessary to promote the R&D and manufacturing of regenerative medicine and related products, and to support their development as an export industry. Specifically, ensuring that domestic prices do not fall below referenced European prices could be a key policy consideration.

Recommendation 1: Reform the pricing system and medical fee system to promote the spread of regenerative medical products

The current health insurance system is hindering the development and operation of the current ecosystem in Japan. Academia, industry and the government should jointly establish a forum for discussions on the design of systems that take into account the characteristics of regenerative medical products and other products.

In order to make efficient use of limited medical resources, it is necessary to evaluate high-value medical technologies and consider measures to reduce medical costs through appropriate use.

Product pricing system

Adequate reflection of the usability rating in the price

- Regenerative medical products not only bring clinical value; they are also likely to make a positive impact on society by rehabilitating patients and reducing the burden of nursing care.
- In order to facilitate the validation of long-term clinical and social value through reverse translational research, concrete research should be conducted into a system in which post-marketing efficacy and safety evaluations are sufficiently reflected in prices.

Revision of the application of the market expansion repricing

- Economies of scale do not work for regenerative medical products, and it is impossible to reduce costs through mass production. Current market expansion repricing are based on the assumption that economies of scale are applicable, and if these are applied, it will be difficult to continue ensuring patient access to the therapy.
- In order to maintain an environment in which companies can sustainably supply innovative treatments, market expansion repricing rules should be reviewed.

Medical fee system

Improvement of the medical fee system to properly reflect medical costs

- In addition to adequately covering the cost of the medical care required to provide regenerative medical products within current medical fees, it is necessary to incorporate a mechanism that allows medical institutions to recoup their investment in equipment and human resources.

Recommendation 2: Review Ecosystem Challenges and Continue with Policies that will Enhance Next-Generation Cycles

In order to develop an ecosystem of regenerative medical products, it is important to take a bird's-eye view to identify issues, make improvements, and make further improvement to the next-generation technology cycle.

Stakeholder Collaboration

Research & Development

- Translational research is important for the efficient introduction of innovative technologies to the market. The government should support technology originating from universities and take measures to promote technology transfer to companies, including startups.
- Data obtained from actual medical care will serve as a foundation for next-generation research, and patient participation will be an important factor, as will collaboration between treatment facilities, academia and development companies.

Treatment

- In order to provide regenerative medical products more smoothly, there is an urgent need to improve systems and networks to effectively connect treatment providers and patient referral facilities. To ensure that patients in need can receive treatment promptly and, when appropriate, we should promote clarification of clinical practice guidelines and strengthen incentives for patient referrals.
- In order to promote patient participation, it is essential to raise awareness and ensure access to treatment. Comprehensive and easy-to-understand guidance needs to be generated by creating a forum where patient groups, academic societies, medical institutions, and pharmaceutical companies can collaborate to share and discuss the latest information on diseases and various treatment options, including immune cell therapy.

Reduce costs

Develop infrastructure

Manufacturing & Supply

- The manufacturing, quality control and supply of regenerative medical products are still in the early stages of commercialization; these continue to be expensive to manufacture, but as technology advances, costs are expected to fall, and more patients will be able to benefit from new therapeutic opportunities featuring regenerative medical products capable of treating a variety of diseases.
- With the aim of achieving this, the government should promote the development of highly specialized human resources and the necessary facilities; build a foundation for the upgrading of supply chains, construct a domestic ecosystem, and establish a base for expansion across Asian countries.

Benefits accruing from the establishment of an ecosystem of regenerative medical products in Japan

The spread of regenerative medical products will bring great benefits to Japan's medical, industrial, and social systems, and will strengthen the country’s global competitiveness by demonstrating its leadership in this field.

Medical environment in Japan	• By manufacturing regenerative medical products for Japan-based patients in Japan, we will be able to address global manufacturing constraints and enable a sustainable supply of these therapies. • Enabling patient access from an early stage of treatment for serious diseases will make a significant difference in the lives of patients in Japan and their families. • In addition to current demand, there is the potential to meet the therapeutic needs of various other diseases such as autoimmune diseases in the future.
Active participation of human resources in Japan	• By building an ecosystem, we can create a place where highly qualified human resources can play an active role in the fields of R&D and manufacturing in Japan. • It will reduce the burden on healthcare professionals and create an environment where they can focus on treating other diseases. • Patients and their families who have been cured of serious diseases will be able to resume social and economic activity, boosting the economy and benefiting society as a whole.
Global competitiveness	• We can quickly supply regenerative medical products to Asian countries. • Technologies related to regenerative medical products have the potential to become the foundation of Japan's biotechnology industry, leading to the acceleration of research and development originating here. • These will lead to opportunities for international leadership and expand Japan’s influence in Asian countries and globally.