29 December 2025
Japan Tissue Engineering Co., Ltd.

Announcement of Insurance Coverage for the Expanded Indication of Autologous Cultured Cartilage "JACC" for Knee Osteoarthritis

Japan Tissue Engineering Co., Ltd. (J-TEC, headquarters in Gamagori City, Aichi Prefecture; Representative Director, President and Executive Officer: Kazuto Yamada) hereby announces that, following today's confirmation from the Ministry of Health, Labour and Welfare, autologous cultured cartilage "JACC" will be covered by national health insurance, effective **January 1, 2026**, as a regenerative medicine product for the treatment of traumatic cartilage defects or osteochondritis dissecans, as well as knee osteoarthritis.

"JACC" is Japan's first regenerative medicine product that uses a patient's own cells to repair knee cartilage with tissue similar to normal cartilage. It was approved in 2012 for indications including traumatic cartilage defects and osteochondritis dissecans and was listed for national health insurance coverage in 2013.

On May 13, 2025, JACC obtained partial approval for an expanded indication to include knee osteoarthritis, which has now led to its inclusion under national health insurance. With this insurance coverage, JACC will provide more patients with access to a new treatment option aimed at cartilage repair.

We remain committed to improving patients' quality of life (QOL) by advancing the clinical value of regenerative medicine while steadily expanding our business in the orthopedic field.

Reference: Overview of Knee Osteoarthritis?

Knee osteoarthritis is a condition in which the cartilage of the knee joint gradually wears down or becomes damaged due to factors such as aging or injury, leading to progressive joint deformity and pain, and its prevalence is increasing with population aging.

Treatment options are selected based on patient characteristics and disease severity and include conservative therapies such as pharmacological treatments (e.g., purified sodium hyaluronate injections) and exercise therapy including muscle-strengthening programs. When these approaches are not effective, surgical treatments such as total knee arthroplasty or osteotomy may be performed.

Details

1. Insurance Listing Overview

Product Name	JACC
Approval Date	13 May 2025
Date of Listing on the National Health Insurance (NHI) System	1 January, 2026
Insurance Reimbursement Price	① Tissue Transport Set (Harvesting and Culture Kit): 1,000,000 yen ② Cultured Cartilage Package (Preparation and Implantation Kit): 1,890,000 yen
Pricing Classification	B2（Existing Functional Category with Modification）
Intended Use / Indications or Performance	The following section (underlined in the original document) was added under the partial change approval dated May 13, 2025 This product is an autologous cultured cartilage therapy in which chondrocytes isolated from healthy cartilage tissue harvested from the patient are embedded in an atelocollagen gel, cultured, and subsequently re-implanted into the same patient. Transplantation of the chondrocyte-containing atelocollagen gel into the defect site alleviates clinical symptoms associated with traumatic cartilage defects or osteochondritis dissecans and improves clinical symptoms of osteoarthritis of the knee. ＜Indications, Efficacy, or Performance of the Product＞ 1. **Traumatic Cartilage Defects or Osteochondritis Dissecans** Alleviation of clinical symptoms associated with traumatic cartilage defects or osteochondritis dissecans of the knee joint. This product is indicated only for cases in which no alternative treatment options are available and where the cartilage defect area is 4 cm² or greater. 2. **Osteoarthritis of the Knee** Improvement of clinical symptoms associated with osteoarthritis of the knee. This product is indicated only for cases in which clinical symptoms do not improve with conservative treatments such as exercise therapy, and where the cartilage defect area is 2 cm² or greater.
Precautions	The following section (underlined in the original document) contains the added and revised portions 150 Human Autologous Transplant Tissue (1) ～ (3) Omitted (4) Autologous Cultured Cartilage A) Reimbursement is permitted only when the procedure is performed in patients who meet any of the following criteria.

	a) Patients with traumatic cartilage defects or osteochondritis dissecans of the knee joint (excluding osteoarthritis of the knee), for whom no alternative treatment options are available and who have a cartilage defect area of 4 cm² or greater. b) Patients with osteoarthritis of the knee whose clinical symptoms have not improved with conservative treatments such as exercise therapy and who have a cartilage defect area of 2 cm² or greater. B) The specified price shall be claimed regardless of the number or size of units used. C) Reimbursement is permitted only when the product is used by a physician who meets all of the following criteria. a) A full-time physician with a minimum of five years of experience in orthopedic surgery, who has served as the primary surgeon in at least **100** knee joint surgeries, including **10** or more cases involving articular cartilage repair. b) The physician must have completed the designated training program, which shall include the following elements. i. Indications for autologous cultured cartilage therapy ii. Criteria for differentiating traumatic cartilage defects or osteochondritis dissecans from osteoarthritis of the knee iii. Cartilage harvesting techniques iv. Perioperative management v. Management of complications vi. Rehabilitation protocols vii. All-case post-marketing surveillance methods viii. Surgical techniques, including procedures using artificial materials similar to autologous cultured cartilage D) For patients treated with human autologous transplant tissue (autologous cultured cartilage), reimbursement claims must include a detailed clinical description in the medical fee statement, clearly documenting the medical necessity for use, the cartilage defect area, and other relevant clinical information. E) When human autologous transplant tissue (autologous cultured cartilage) is used in patients with osteoarthritis of the knee, physicians must comply with the “Guidelines for the Appropriate Use of Human (Autologous) Cartilage-Derived Tissue in the Treatment of Osteoarthritis of the Knee” issued by the Japanese Orthopaedic Association. (5) ～ (8) Omitted

2. Outlook

Product supply for this indication is expected to commence in January 2026. The impact of this development, including this indication, on the Company's financial results for the fiscal year ending March 2026 is currently under evaluation. The Company will promptly disclose any material information should it arise.

（**Reference: About Japan Tissue Engineering Co., Ltd.**）

J-TEC is a regenerative medicine manufacturer guided by the vision of "Creating a Future for Regenerative Medicine" and has been a member of the Teijin Group since March 2021. As a leading player in Japan's regenerative medicine field, the Company consistently manufactures and markets regenerative medical products. Of the regenerative medical products currently approved in Japan, five are products developed by the Company.

✓ Approved October 2007	Autologous Cultured Epidermis "JACE" - Japan's first regenerative medical product
✓ Approved July 2012	Autologous Cultured Cartilage "JACC" - Japan's first regenerative medical product in the orthopedic field
✓ Approved March 2020	Autologous Cultured Corneal Epithelium "NEPIC" - Japan's first regenerative medical product in the ophthalmology field
✓ Approved June 2021	Autologous Cultured Oral Mucosal Epithelium "OCULAR" -The world's first commercially available regenerative medical product using oral mucosal epithelial cells
✓ Approved March 2023	Melanocyte-Containing Autologous Cultured Epidermis "JACEMIN" - The second regenerative medical product approved in Japan in the dermatology field

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