

Japan Tissue Engineering Wins Approval for Insurance Coverage of JACC, Its First-in-Japan Therapy for Autologous Cartilage Repair in Knee Osteoarthritis

Aichi, Japan, January 22, 2026 —Japan Tissue Engineering Co., Ltd. (J-TEC) announced today that JACC, its autologous cultured cartilage product, has been granted approval by Japan's National Health Insurance system to receive reimbursement for a new indication—knee osteoarthritis—effective January 1, 2026. JACC is the first therapy in Japan to receive manufacturing and marketing approval and national insurance coverage for repairing damaged or worn knee cartilage.

“As Japan's population ages, treating knee osteoarthritis has become a major societal challenge,” said Kazuto Yamada, President of J-TEC. “Delivering JACC to osteoarthritis patients has been our longstanding aspiration. With reimbursement approval now in place, together with stable supply and support for appropriate use provided by J-TEC, access to JACC will expand. This first-in-Japan therapy will contribute to a better quality of life for more patients.”

Knee osteoarthritis is a progressive condition that can lead to pain, joint deformity and decline in motor function as the knee cartilage wears down or becomes damaged due to aging, injury or other factors. Knee cartilage supports smooth movement during walking and standing, and acts as a cushion to absorb impact. In severe cases, the disease limits daily activities, burdening patients and their families. In Japan, approximately 10 million people have knee osteoarthritis.

Current treatments include conservative care, such as hyaluronic acid injections to relieve pain and improve function and muscle-strengthening exercise therapy, as well as surgical procedures like joint replacement or osteotomy. However, until now, there has been no effective therapy that directly treats the cartilage itself.

To address this challenge, J-TEC began developing JACC, an autologous cultured cartilage product, in 2000 as a regenerative medicine treatment. In July 2012, JACC was granted approval for treatment of traumatic cartilage defects and osteochondritis dissecans of the knee. In May 2025, JACC received approval for an additional indication, knee osteoarthritis.

JACC is a gel-like artificial cartilage invented in 1996 by Mitsuo Ochi, who currently serves as President of Hiroshima University. It is manufactured by culturing chondrocytes from the patient's normal knee cartilage. Under Professor Ochi's supervision, J-TEC has led the product's development for manufacturing and marketing since 2000. Since its April 2013 launch, JACC has been used in more than 2,000 cases of traumatic cartilage defects or osteochondritis dissecans of the knee (excluding osteoarthritis).

The newly approved insurance reimbursement applies to patients diagnosed with knee osteoarthritis who have not improved with conservative therapy (e.g., exercise therapy) and who present a cartilage defect area of $\geq 2\text{cm}^2$. In the procedure, JACC is transplanted into the cartilage defect and covered with a fixation membrane (an artificial collagen membrane or periosteum) secured by sutures to the surrounding tissue. Accordingly, the target population is patients with moderate knee osteoarthritis in which sufficient cartilage remains around the defect to allow suturing.

In J-TEC's clinical study conducted since 2019 to support adding the knee osteoarthritis indication, 27 patients received JACC. In efficacy assessments, improvements in WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) from pre- to post-treatment were superior to those observed with the comparator, sodium hyaluronate (hyaluronic acid) injections. In safety

assessments, no adverse events of concern were observed. As a secondary efficacy endpoint, at 52 weeks post-treatment, the site implanted with JACC was confirmed to be repaired with tissue similar to normal cartilage.

By restoring the native functions of cartilage, JACC is expected to reduce pain and improve motor function, contributing to long-term enhancements in patients' quality of life (QOL) and reducing burdens on families. Because JACC uses the patient's own cells, the risk of immune rejection is extremely low, making it a new option for patients who have been unable to pursue other treatments.

Going forward, J-TEC will strengthen information dissemination about JACC and ensure stable supply. The company aims to deliver treatment to approximately 1,000 patients annually within a few years. As Japan's pioneer in regenerative medicine, J-TEC will continue to provide products that help resolve unmet medical needs and advance its vision of "Creating a Future for Regenerative Medicine."



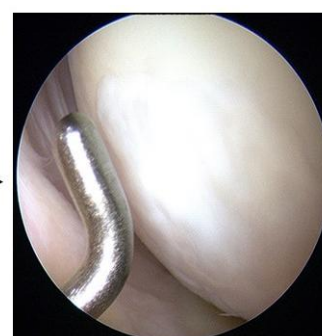
PHOTOGRAPH OF CULTURED CARTILAGE



Pre-transplantation



Six months post-transplantation



One year post-transplantation

PHOTOGRAPH OF CARTILAGE REPAIR AFTER JACC TRANSPLANTATION
(A CASE DEMONSTRATING REPAIR WITH HYALINE CARTILAGE-LIKE TISSUE)

OUTLINE OF APPROVAL

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| Product Name | JACC |
| Approval Date (Additional Approval Date) | July 27, 2012 (May 13, 2025) |
| Generic Name | Human Autologous Tissue for Transplantation |
| Additional efficacy or effects | Improvement of clinical symptoms for osteoarthritis of the knee. However, it is only applicable to cases where clinical symptoms do not improve with conservative treatments such as exercise therapy, and the area of cartilage defect is 2 cm ² or more. |

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