Sept. 15, 2021
Japan Tissue Engineering Co., Ltd.

Announcing approval of Autologous Cultured Oral Mucosal Epithelium "Ocural" for NHI listing

Listing effective December 1 creates new option for treatment of bilateral limbal stem cell deficiency

Japan Tissue Engineering Co., Ltd. (J-TEC, headquarters in Gamagori, Aichi Prefecture; President & CEO Ken-ichiro Hata) announces the approval of Autologous Cultured Oral Mucosal Epithelium "Ocural" for inclusion in the National Health Insurance price list effective December 1, 2021, at the general meeting of Central Social Insurance Medical Council (Chuikyo) held today.

Ocural" is expected to be of benefit as a new treatment method for patients who have had marked declines in visual acuity owing to extensive corneal damage from limbal stem cell deficiency. [*1]

With the corporate vision of "creating a future for regenerative medicine", J-TEC is building a regenerative medicine industry while contributing to the improvement of patients' quality of life (QOL) by continually developing and launching new regenerative medical products in addition to promoting the spread of its existing products.

Autologous Cultured Oral Mucosal Epithelium "Ocural"

[Insurance reimbursement price (dated December 1, 2021)]

① Tissue transport kit [*2]	4,280,000 yen
②Cultured oral mucosal epithelium package [*3]	5,470,000 yen

[Product Features]

1. This is the world's first regenerative medical product that uses oral mucosal epithelial cells to treat limbal stem cell deficiency.
2. It is a domestic product that represents the commercial application of technology introduced by Osaka University.
3. "Ocural" expands treatment options for corneal epithelial disorders, for which no radical treatment method has existed heretofore. It will make it possible to treat patients for whom our previously approved product Autologous Cultured Corneal Epithelium "Nepic[*4]" is not indicated.

[Background/history of development]

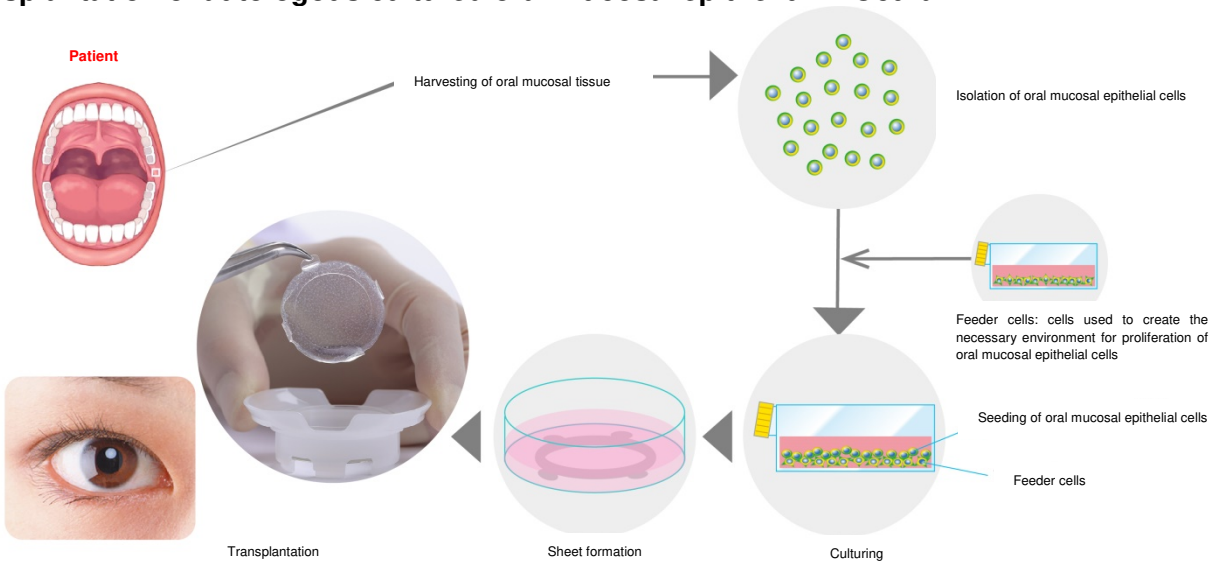
In the development of this product, an investigator-initiated clinical trial was conducted by a research team led by Professor Kohji Nishida and Lecturer Yoshinori Oie of the Department of Neural and Sensory Organ Surgery (Ophthalmology) , Graduate School of Medicine, Osaka University, with the support of AMED.[*5] Together with introducing the autologous cultured oral mucosal epithelial cell sheet transplantation technology that Professor Kohji Nishida was the first in the world to develop, J-TEC took over the investigator-initiated clinical trial in the new form of a corporate clinical trial of "Ocural" in September 2016. In September 2020, J-TEC submitted a marketing approval application to the Ministry of Health, Labour and Welfare for "Ocural" as its second regenerative medical product in the ophthalmology area, and in June 2021 marketing approval was obtained. "Ocural" was designated a regenerative medical product for orphan diseases, [*6] specifically, the treatment of limbal stem cell deficiency, in 2020.

"Ocural" will be marketed by ophthalmological medical device maker Nidek Co., Ltd. (Gamagori, Aichi; President and CEO Motoki Ozawa)

[Summary of NHI listing]

Brand name	Ocural
Date of NHI listing	December 1, 2021
Insurance reimbursement price	① Tissue transport kit[*2] 4,280,000 yen ② Cultured oral mucosal epithelium package[*3] 5,470,000 yen
Classification category	C2 (new function/new technology)
Main purposes of use	This product is “Autologous Cultured Oral Mucosal Epithelium” in which the patient’s own oral mucosal tissue is harvested and the isolated oral mucosal epithelial cells are cultured and formed into a sheet for use by the patient himself. This product is indicated for limbal stem cell deficiency, and it is applied to the ocular surface that includes the corneal limbal region to repair the corneal epithelium.
Points to note (Draft)	150 Human autologous tissue (6) Autologous cultured oral mucosal epithelium I. Fee can be calculated for one-time use in one eye only, in cases of limbal stem cell deficiency with severity of severe Stage IIA disease (limited to cases where reconstruction of corneal epithelium is not achieved even with removal of conjunctival scar tissue (when necessary, amniotic membrane graft)), Stage IIB, or Stage III. II. The fee for the autologous cultured oral mucosal epithelium preparation and transplantation kit can be calculated only in cases of use by a physician to whom one of the following applies. a Full-time physician with no less than 5 years of experience in ophthalmology and no less than 5 years of experience performing corneal transplants. b Has completed the necessary training, which consists of the following. i Items related to the indications of autologous cultured oral mucosal epithelium ii Items related to determination of the severity of limbal stem cell deficiency iii Items related to method of harvesting oral mucosal tissue iv Items related to method of transplantation III. The fee for the autologous cultured oral mucosal epithelium harvesting and culturing kit can be calculated only in cases of use by a physician who has completed the training on the method of harvesting oral mucosal tissue. IV. A detailed description of symptoms, including the severity of limbal stem cell deficiency, must be attached to the invoice when billing for medical service fees for patients using human autologous tissue (autologous cultured oral mucosal epithelium).

Transplantation of autologous cultured oral mucosal epithelium "Ocural"



[Earnings Estimate]

J-TEC announced its business plan for this product in the Mid-Term Management Plan (Items related to Business Plans and Growth Potential) dated May 11, 2021, and because the project is proceeding according to plan, it will have no effect on the earnings forecast for the full year ending in March 2022. We will promptly notify you of any new facts that will have a major impact on J-TEC's business results.

*1 A disease in which corneal epithelial stem cells, which exist in the corneal limbus at the border between the cornea and the conjunctiva, are lost owing to congenital or exogenous factors. LSCD presents with clinical symptoms such as clouding of the cornea, decline in visual acuity, and eye pain.
*2 Kit consisting of the materials used from the time the oral mucosal epithelial tissue is harvested from the patient to the time that cell culturing ends.
*3 Kit consisting of the materials used after cell culturing ends, through the preparation of the oral mucosal epithelial sheet and up until the end of the transplantation procedure.
*4 NEPIC is made by culturing corneal epithelial stem cells harvested from the patient's own corneal limbic tissue into the form of sheets that are transplanted back into the patient's eyes to reconstruct the corneal epithelium. NEPIC was included in the National Health Insurance price list in June of 2020, and it is marketed by Nidec Co., Ltd.
*5 Japan Agency for Medical Research and Development
*6 Regenerative medical products for the treatment of orphan diseases that are designated by the Minister of Health, Labour and Welfare in accordance with the Pharmaceuticals and Medical Devices Law. Products with this designation receive preferential treatment, such as grants for research, priority clinical trial consultation and review, and extension of the reexamination period. In order for a product to be designated a regenerative medical product for orphan diseases, it must have a target disease that affects fewer than 50,000 patients in Japan and lacks a suitable alternative treatment method, and the product must have exceptional medical utility value, such as efficacy and safety that can be expected to greatly surpass those of existing treatment methods.

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products whose corporate vision is "creating a future for regenerative medicine". As Japan's top runner in regenerative medicine, J-TEC obtained marketing approval for autologous cultured epidermis "JACE", Japan's first regenerative medical product, in October of 2007, and began marketing the product in January of 2009. J-TEC then went on to obtain marketing approval for Autologous Cultured Cartilage "JACC" in July of 2021, for Autologous Cultured Corneal Epithelium "Nepic" in March of 2020, and for Autologous Cultured Oral Mucosal Epithelium "Ocural" in June 2021. "JACC" was Japan's first regenerative medical product for use in orthopedic surgery, and "Nepic" was the first for use in ophthalmology. Of the 13 regenerative medical products that have been approved in Japan, four are J-TEC products.

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