October 1, 2024
Japan Tissue Engineering Co., Ltd.

Announcement of NHI Listing of Autologous Cultured Epidermis Maintaining Melanocytes "JACEMIN" for the Treatment of Vitiligo

Effective October 1, 2024

Japan Tissue Engineering Co., Ltd. (J-TEC, headquarters in Gamagori, Aichi Prefecture; President & CEO Ken-ichiro Hata) has announced that, as confirmed in the notification of Ministry of Health, Labour and Wlefare today, its regenerative medical product, Autologous Cultured Epidermis Maintaining Melanocytes "JACEMIN" for the treatment of vitiligo*, will be included in the National Health Insurance (NHI) price list effective October 1, 2024.

JACEMIN is the fifth regenerative medical product launched by our company in Japan, and is expected to be of benefit as a new treatment method for patients with vitiligo. With the corporate vision of "Creating a Future for Regenerative Medicine", J-TEC will continue to develop and launch new regenerative medical products and contribute to the improvement of quality of life (QOL) for a greater number of patients.

1. Insurance reimbursement price (effective October 1, 2024)

1. Tissue transport set : 2. Cultured epidermis package :	4,460,000 yen 154,000 yen per sheet

2. Product overview

ü **Autologous cultured epidermis maintaining melanocytes**

JACEMIN is autologous cultured epidermis in which the patient's own skin tissue is harvested, and isolated cells cultured to maintain melanocytes are produced in sheet form for use in the patient.

Melanocyte-maintaining human (autologous) epidermis-derived cell sheet
JACEMIN

ü **Curing vitiligo with pigment regeneration**

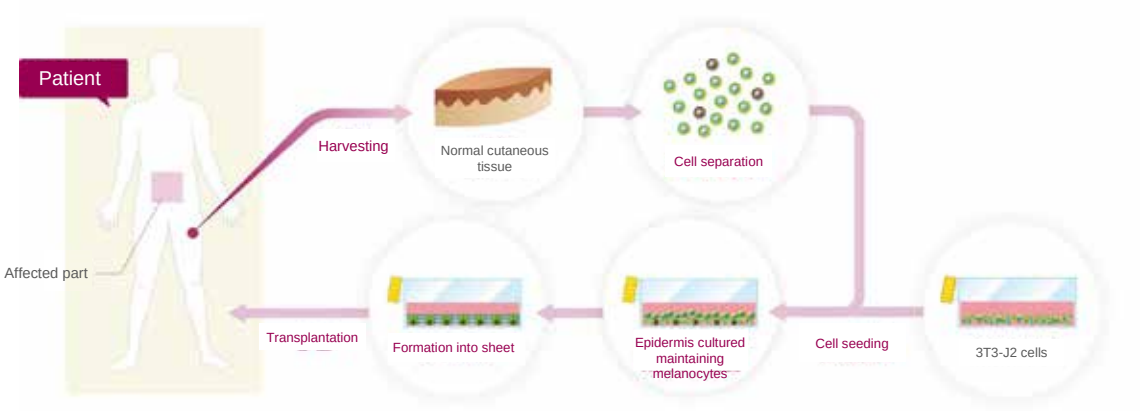
JACEMIN is transplanted into areas affected by vitiligo where nonsurgical therapy is ineffective or not indicated, after the epidermal layer has been shaved thinly. Melanocytes are supplied through transplantation of this product, and its purpose is to regenerate pigment.

ü **Low invasiveness and improvement of quality of life (QOL)**

Because JACEMIN grafts are manufactured using a smaller area of skin tissue than in existing surgical therapies, the procedure is low in invasiveness for the patient, making it possible to treat a large area at a time. Moreover, regenerating pigment with this treatment method can be expected to reduce the patient's psychological burden regarding aesthetics and improve the patient's quality of life (QOL).

* Vitiligo is a disease in which the skin loses color and turns white because of the loss or decrease of pigment cells called melanocytes that are normally present in the skin. This product is for the treatment of vitiligo for which nonsurgical therapies including topical preparations, oral medications, or phototherapy are ineffective or not indicated, such as acquired vitiligo vulgaris in which there has been destruction of melanocytes and symptoms have been stable for about 12 months, or piebaldism caused by a congenital genetic abnormality. The number of patients with vitiligo vulgaris is estimated at about 150,000 in Japan. Moreover, the incidence of piebaldism is thought to be one in 20,000 to 100,000 people.

(Transplantation of Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN)



3. Summary of NHI listing

Brand name	JACEMIN
Generic name	Melanocyte-maintaining human (autologous) epidermis-derived cell sheet
Date of NHI listing	October 1, 2024
Classification category	B2 (existing function / changes)
Insurance reimbursement price	1. Tissue transport set : 4,460,000 yen 2. Cultured epidermis package : 154,000 yen per sheet
Main purposes of use	(Effects or functions) Vitiligo for which nonsurgical therapy is ineffective or not indicated (Principle/mechanism) By transplanting the epidermal cell sheet, melanocytes are supplied along with the epidermal cells to regenerate pigment.
Points to note	150 Human autologous tissue (8) Autologous cultured epidermis (when used for vitiligo for which nonsurgical therapy is ineffective or not indicated) i. The fee can be calculated only when the product is used for a patient of vitiligo aged 12 or older for whom nonsurgical therapy is ineffective or not indicated. ii. The fee for the preparation and transplantation kit is calculated for up to 40 sheets per series of treatment plans in principle when the product is used to close the wound resulting from removal of vitiligo for which nonsurgical therapy is ineffective or not indicated. When the use of the product is necessary for a medical reason, the fee for up to 50 sheets can be calculated by stating the reason in the space for notes of the statement of medical expenses. iii. The fee can be calculated only when the product is used in accordance with the relevant academic organization's guidelines on proper use. iv. The fee is calculated only when both of the following apply to the physician who performs the procedure. a. A person with no less than 5 years of experience in dermatology or plastic surgery b. A full-time physician who has performed no less than 3 cases of the K014 skin transplantation procedure (living

	or cultured) or a full-time physician who performs the procedure under the direction of a physician who has performed no less than 3 cases of the K014 skin transplantation procedure (living or cultured) v. The patient must be informed about the medical need for the use of autologous cultured epidermis (when used for vitiligo for which nonsurgical therapy is ineffective or not indicated) and other relevant information including possible complications. The information provided to the patient must be included in the medical record, and the fact that the patient is informed about these matters must be stated in the space for notes of the statement of medical expenses. vi. The fee for the harvesting and culturing kit can be calculated only once in the first month of treatment during the series of treatment plans. vii. The medical reasons for judging that nonsurgical therapy is ineffective or not indicated and that autologous cultured epidermis is indicated (when used for vitiligo for which nonsurgical therapy is ineffective or not indicated) must be described in detail in the space for notes of the statement of medical expenses. When the planned treatment is divided into several steps, the following information about the series of treatment plans must be added to the space for notes. a. Start date and planned end date of the treatment b. Treatment period (number of days) and number of times the treatment is given c. Number of epidermal cell sheets planned to be used in the series of treatments

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products. Our vision is “Creating a Future for Regenerative Medicine”, and we have been a member of the Teijin Group since March 2021. As the top runner in Japan’s regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ü Approved Oct. 2007: Autologous Cultured Epidermis JACE® – Japan’s first regenerative medical product
- ü Approved July 2012: Autologous Cultured Cartilage JACC® – Japan’s first regenerative medical product in the plastic surgery field
- ü Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC® – Japan’s first regenerative medical product in the ophthalmology field
- ü Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
- ü Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN

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