

Products Approved in FY 2021: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Jun. 11, 2021	Ocural (Japan Tissue Engineering Co., Ltd.)	Approval	Human somatic stem cell-processed products	Human (autologous) oral mucosa-derived epithelial cell sheet	The product is an oral mucosal epithelial cell sheet, which is produced by culturing the oral mucosal epithelial cells separated from patient-derived oral mucosal tissues into a sheet shape. The product is intended to be used for repair of corneal epithelium defects by transplanting the cell sheet onto the ocular surface of patients with limbal stem cell deficiency (LSCD). [Orphan regenerative medical product]
Gene Therapy Products	Jun. 11, 2021	Delytact Injection (Daiichi Sankyo Company, Limited)	Conditional/ Time-limited Approval	Gene expression therapy products (excluding those listed in the preceding item 2)	Teserpaturev	The product is a genetically engineered herpes simplex virus type 1 in which $\alpha 47$ gene and $\gamma 34.5$ gene have been deleted, and the <i>infected cell protein 6 (ICP6)</i> gene has been inactivated by insertion of the <i>lacZ</i> gene from <i>Escherichia coli</i> . Delytact is administered intratumorally in patients with malignant glioma for the treatment of malignant glioma. [Orphan regenerative medical product] [SAKIGAKE designation, Regenerative medical product]
Regenerative Medical Products	Sep. 27, 2021	Alofisel Injection (Takeda Pharmaceutical Company Limited)	Approval	Human somatic stem cell-processed products	Darvadstrocel	The product is a cell suspension of expanded allogenic adipose-derived stem cells (eASC) that can be obtained by isolating and culturing human (allogenic) mesenchymal stem cells derived from the subcutaneous adipose tissue of healthy adults. It is locally administered into a fistula of complex perianal fistula associated with Crohn's disease and used for the treatment of complex perianal fistula in patients with non-active or mildly active Crohn's disease who have shown an inadequate response to at least one existing medicinal treatment. [Orphan regenerative medical product]
Regenerative Medical Products	Jan. 20, 2022	Sakracy (Hirosaki Lifescience Innovation, Inc.)	Approval	Human somatic stem cell-processed products	Human (autologous) oral mucosa-derived epithelial cell sheet using a human amniotic membrane substrate	The product is an autologous oral mucosal epithelial cell sheet, which is produced by seeding and culturing the oral mucosal epithelial cells isolated from patient's own oral mucosal tissues on the amniotic membrane substrate prepared from human allogeneic amniotic membranes. The product is intended to be used for alleviation of adhesions on the ocular surface by transplanting the cell sheet onto the ocular surface with adhesion of patients with limbal stem cell deficiency. (Orphan regenerative medical product)
Regenerative Medical Products	Jan. 20, 2022	Abecma Intravenous Infusion (Bristol-Myers Squibb K.K.)	Approval	Human somatic cell-processed products	Idecabtagene vicleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that specifically recognizes B-cell maturation antigen (BCMA) by using a recombinant lentivirus vector for the T cells derived from the patient's peripheral blood. It is administered as an intravenous drip into a vein and used for the treatment of relapsed or refractory multiple myeloma. (Orphan regenerative medical product)