List of Approved Regenerative Medical Products

April 2015 to September 2024

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html

Products Approved in FY 2024: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Jul. 31, 2024	Akuugo Suspension for Intracranial Implantation (SanBio Company Limited)	Conditional/Time-limited Approval	Human somatic stem cell-processed products	Vandefitemcel	This product is a cell suspension manufactured by introducing plasmid vectors encoding the human Notch-1 intracellular domain into bone marrow-derived mesenchymal stem cells that were collected from healthy adult donors and then cultured and separated/proliferated. The product is intended to be used for improvement of chronic motor paresis associated with traumatic brain injury by transplanting into the brain by stereotactic brain surgery. (Orphan regenerative medical product) (SAKIGAKE designation, Regenerative medical product)
Regenerative Medical Products	Aug. 16, 2024	Breyanzi Suspension for Intravenous Infusion (Bristol-Myers Squibb K.K.)	Change	Human somatic cell-processed products	Lisocabtagene maraleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that targets CD19 antigen by using a recombinant lentiviral vector for the CD4-positive and CD8-positive T cells derived from the patient's peripheral blood. This product was approved for the indications for the third- and further-line treatment in patients with relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma (Grade 3B) in March 2021. Also, the product was approved for the additional indications for the second-line treatment in patients with relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma (Grade 3B) in December 2022. The third- and further-line treatment in patients with relapsed or refractory follicular lymphoma (Grade 1, 2, 3A) and the second-line treatment in patients with relapsed or refractory high-risk follicular lymphoma (Grade 1, 2, 3A) were added to the indication of the product by this application. (Orphan regenerative medical product)

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Products Approved in FY 2023: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Gene Therapy Products	Jun. 26, 2023	Luxturna Injection (Novartis Pharma K.K.)	Approval	Viral vector products	Voretigene neparvovec	The product is a non-replicating, recombinant adeno-associated virus (rAAV) containing adeno-associated virus serotype 2 (AAV2) capsid proteins and carrying the human RPE65 gene. The product is subretinally administered and used for the treatment of inherited retinal dystrophy caused by biallelic RPE65 gene mutations. [Orphan regenerative medical product]
Regenerative Medical Products	Dec. 06, 2023	Abecma Intravenous Infusion (Bristol-Myers Squibb K.K.)	Change	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. The product was approved for the indications for relapsed or refractory multiple myeloma in patients who have received at least 3 prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-cluster of differentiation (CD)38 monoclonal antibody in January 2022. Relapsed or refractory multiple myeloma in patients who have received with 2 prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-cluster of differentiation (CD)38 monoclonal antibody was added to the indication of the product by this application. (Orphan regenerative medical product)

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Products Approved in FY 2022: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Aug. 26, 2022	Kymriah Suspension for Intravenous Infusion (Novartis Pharma K.K.)	Change	Human somatic cell-processed products	Tisagenlecleucel	The product is a human somatic cell-processed product composed of genetically modified T cells that are cultured and proliferated after introducing chimeric antigen receptor (CAR) that specifically recognizes CD19 antigen by using a lentiviral vector into the T cells derived from the patient's peripheral blood. The product was approved for the indications for relapsed or refractory B-cell acute lymphoblastic leukemia and relapsed or refractory diffuse large B-cell lymphoma in March 2019. Relapsed or refractory follicular lymphoma was added to the indication of the product by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Sep. 26, 2022	Carvykti Suspension for Intravenous Infusion (Janssen Pharmaceutical K.K.)	Approval	Human somatic cell-processed products	Ciltacabtagene autoleucel	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]
Regenerative Medical Products	Dec. 20, 2022	Breyanzi Suspension for Intravenous Infusion (Bristol-Myers Squibb K.K.)	Change	Human somatic cell-processed products	Lisocabtagene maraleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that targets CD19 antigen by using a recombinant lentiviral vector for the CD4-positive and CD8-positive T cells derived from the patient's peripheral blood. The product was approved for the indications for relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma with at least 2 lines of prior chemotherapy in March 2021. Relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma with 1 line of prior chemotherapy were added to the indication of the product by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Dec. 20, 2022	YESCARTA Intravenous Drip Infusion (Daiichi Sankyo Company, Limited)	Change	Human somatic cell-processed products	Axicabtagene ciloleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that specifically recognizes CD19 antigen by using a recombinant retrovirus vector for the T cells derived from the patient's peripheral blood. The product was approved for the indications for relapsed or refractory large B-cell lymphoma in patients who are eligible for autologous hematopoietic stem cell transplantation (HSCT) and have received 2 or more lines of prior therapy or in patients who are not ineligible for autologous HSCT and have received 1 or more lines of prior therapy in January 2021. Relapsed or refractory large B-cell lymphoma in patients who are eligible for HSCT and have received 1line of prior therapy was added by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Mar. 17, 2023	JACEMIN (Japan Tissue Engineering Co., Ltd.)	Approval	Human somatic cell-processed products	Melanocyte-containing Human (Autologous) Epidermis-derived Cell Sheet	The product is an epidermis-derived cell sheet, which is produced by culturing the epidermal cells separated from patient-derived normal skin tissues and melanocytes into a sheet shape. The product is intended to be used for transplantation for vitiligo that is ineffective or not indicated for nonsurgical treatment after abrading the epidermis for the purpose of repigmentation by supplying epidermal cells containing melanocytes.

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Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Mar. 17, 2023	Vyznova (Aurion Biotech Japan, LLC.)	Approval	Human somatic cell-processed products	Neltependocel	The product is a cell suspension composed of fully differentiated cultured human corneal endothelial cells prepared by culturing human (allogeneic) cornea-derived corneal endothelial cells separated from corneal tissue obtained from a human donor. The product is intended to be used for reconstructing damaged corneal endothelium monolayer tissue by transplanting into the anterior chamber in patients with bullous keratopathy. [Orphan regenerative medical product]

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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 *α47* gene and *γ 34.5* gene have been deleted, and the *infected cell protein 6 (ICP6)* gene has been inactivated by insertion of the *lac* Z gene from *Escherichia coli* . 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 (allogeneic) 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)

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Products Approved in FY 2020: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Jan. 22, 2021	YESCARTA Intravenous Drip Infusion (Daiichi Sankyo Company, Limited)	Approval	Human somatic cell-processed products	Axicabtagene ciloleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that specifically recognizes CD19 antigen by using a recombinant retrovirus 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 large B-cell lymphoma. [Orphan regenerative medical product]
Regenerative Medical Products	Mar. 22, 2021	Breyanzi Suspension for Intravenous Infusion (Celgene Corporation)	Approval	Human somatic cell-processed products	Lisocabtagene maraleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that targets CD19 antigen by using a recombinant lentiviral vector for the CD4-positive and CD8-positive T cells derived from the patient's peripheral blood. It is administered into a vein and used for the treatment of relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma. [Orphan regenerative medical product]

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Products Approved in FY 2019: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Gene Therapy Products	Mar. 19, 2020	ZOLGENSMA Intravenous Infusion (Novartis Pharma K.K.)	Approval	Viral vector products	Onasemnogene abeparvovec	The product is a non-replicating, recombinant adeno-associated virus (rAAV) containing adeno-associated virus serotype 9 (AAV9) capsid proteins and carrying the human survival motor neuron gene. The product is administered via intravenous infusion for the treatment of spinal muscular atrophy (including without any clinical manifestations but with predictable onset of spinal muscular atrophy as a result of genetic test) (only for use in patients who are negative for anti-AAV9 antibody). [Orphan regenerative medical product] [SAKIGAKE designation, Regenerative medical product]
Regenerative Medical Products	Mar. 19, 2020	Nepic (Japan Tissue Engineering Co., Ltd.)	Approval	Human somatic stem cell-processed products	Human (autologous) corneal limbus-derived corneal epithelial cell sheet	The product is a corneal epithelial cell sheet made from corneal epithelial cells taken from patient-derived limbal tissue, which is produced by culturing the corneal epithelial cells into a sheet shape. The product is intended for use in corneal epithelium reconstruction by transplanting the cell sheet onto the eye surface of patients with limbal stem cell deficiency（LSCD）. [Orphan regenerative medical product]

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Products Approved in FY 2018: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Dec. 28, 2018	JACE (Japan Tissue Engineering Co., Ltd.)	Change	Human somatic cell-processed product	Human (autologous) epidermis-derived cell sheet	A product consisting of a human (autologous) epidermis-derived cell sheet (main component), which is produced using Green's technique, and a container (filled with tissue transport fluid) for transporting the patient's skin tissue to the manufacturing site (sub-component). To prepare the cell sheet, epidermal cells derived from a postage-stamp-sized piece of skin taken from the patient's own skin tissue are co-cultured with mouse embryo-derived 3T3-J2 feeder cells and formed into a sheet. The product has already been approved for the indications for cases of serious and extensive burns, and giant congenital melanocytic nevus. The application was submitted for the additional indications for the treatment of "dystrophic epidermolysis bullosa" and "junctional epidermolysis bullosa." (A "partial change" application) [Orphan regenerative medical products]
Regenerative Medical Products	Dec. 28, 2018	STEMIRAC Inj. (Nipro Corporation)	Conditional/ Time-limited Approval	Human somatic stem cell-processed products	Human (autologous) bone marrow-derived mesenchymal stem cell	A product consisting of human (autologous) bone marrow-derived mesenchymal stem cells (main component), and blood collection and bone marrow harvesting kits (sub-components). To prepare the main component, mesenchymal stem cells in bone marrow fluid taken from the patient are cultured and proliferated in vitro, and then cryopreserved. The sub-components are used for collecting the patient's peripheral blood and bone marrow fluid at medical institutions and for transporting these to the manufacturing site. The cultured bone marrow-derived mesenchymal stem cells are administered via intravenous infusion and used for treatment to improve neurological symptoms and functional disorders associated with spinal cord injury (only for use in patients with traumatic spinal cord injury and ASIA Impairment Scale A, B, or C). [SAKIGAKE designation, Regenerative medical products]
Regenerative Medical Products	Mar. 26, 2019	Kymriah Suspension for Intravenous Infusion (Novartis Pharma K.K.)	Approval	Human somatic cell-processed products	Tisagenlecleucel	The product is a human somatic cell-processed product composed of genetically modified autologous T cells which are cultured and proliferated after introducing chimeric antigen receptor (CAR) which specifically recognizes CD19 antigen using a lentiviral vector into the T cells derived from the patient's peripheral blood. It is given as a single infusion (drip) into a vein and used for the treatment of CD19-positive relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) and CD19-positive relapsed or refractory diffuse large B-cell lymphoma (DLBCL). [Orphan regenerative medical products]
Gene Therapy Products	Mar. 26, 2019	Collategene Intramuscular Injection 4 mg (AnGes, Inc.)	Conditional/ Time-limited Approval	Plasmid vector products	Beperminogene perplasmid	The product is an injection of plasmid vector composed of 5,181 base pair including cDNA which encodes human hepatocyte growth factor. It is administered intramuscularly to an ischemic site of the lower limb and used for the treatment of ulcers in patients with chronic arterial occlusion (arteriosclerosis obliterans and Burger's disease) who have not responded sufficiently to the standard drug therapy and are unable to undergo revascularization.

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Products Approved in FY 2016: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company, Corporate No.)	New Approval/Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Sep. 29, 2016	JACE (Japan Tissue Engineering Co., Ltd.)	Change	Human somatic cell-processed product	Human (autologous) epidermis-derived cell sheet	A product consisting of human (autologous) epidermis-derived cell sheet, which is produced using Green's technique, packaged in a primary container (main component), and a container (filled with tissue transport fluid) for transporting the patient's skin tissue to the manufacturing site (sub-component). To prepare the cell sheet, epidermal cells derived from a postage-stamp-sized piece of skin taken from the patient's own healthy skin tissue are co-cultured with mouse embryo-derived 3T3-J2 feeder cells and formed into a sheet. The cell sheet is released in the state of being immersed in preservative liquid. The product has already been approved for an indication for cases of serious and extensive burns where sufficient donor skin sites for autologous skin grafts are not available, and at the same time, where the total area of deep dermal and full-thickness burns accounts for 30% or more of the total body surface area (Approval No. 21900BZZ00039000). The application was submitted for an additional indication for the treatment of "giant congenital melanocytic nevus" (A "partial change" application). The results from domestic clinical studies in which the product was grafted to cover the site of excised melanocytic nevus were submitted to evaluate the efficacy and safety of the product.

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Products Approved in FY 2015: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Sep. 18, 2015	TEMCELL HS Inj. (JCR Pharmaceuticals Co., Ltd.)	Approval	Human somatic stem cell-processed products	Human (allogeneic) bone marrow-derived mesenchymal stem cell	A human (allogeneic) bone marrow-derived mesenchymal stem cell that can be obtained by expanding and culturing the nucleated cell isolated from the bone marrow aspirate of healthy adult donor. The product is administered via intravenous infusion to treat acute graft-versus-host disease (acute GVHD) after allogeneic hematopoietic stem cell transplantation. [Orphan regenerative medical products]
Regenerative Medical Products	Sep. 18, 2015	HeartSheet (Terumo Corporation)	Conditional/Time-limited Approval	Human somatic stem cell-processed products	Human (autologous) skeletal myoblast-derived cell sheet	A human (autologous) skeletal myoblast-derived cell product consisting of the patient's skeletal myoblast that has been cultured, proliferated, and cryopreserved as a main component, and the instruments, etc. for shaping the cell sheets in medical institutions as sub-components. The product is used for treating serious heart failure caused by ischemic heart disease by applying the sheet-shaped cells to the surface of the heart during the open chest surgery when standard therapies are not sufficiently effective.