

*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]