

*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 ciloleucecl	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 maraleucecl	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]