

*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)