

*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]