

CBER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint  
 As of June 30, 2025  
 Total Approvals 36

NDA and BLA Accelerated Approvals

Application Nummer	Proprietary Name	Established Name	Applicant	CBER Received Date	Accelerated Approval Date	Total Time to Accelerated Approval (Months)	Accelerated Approval Indication	Conversion-Withdrawal Status	Full Approval Conversion-Withdrawal Date
BLA 103661/1010	Carticel SM Service	Autologous Cultured Chondrocytes	Vericel Corporation	10/28/1999	4/28/2000	6.0	Articular Cartilage Defects in the knee	Converted	6/21/2007
BLA 125127/0	Fluarix	Influenza Virus Vaccine	GlaxoSmithKline Biologicals	5/25/2005	8/31/2005	3.2	for the prevention of influenza in adults 18 years and older	Converted	10/2/2009
BLA 125254/0	Afluria	Influenza Vaccine	Seqirus Pty Ltd	3/30/2007	9/28/2007	6.0	For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine	Converted	12/2/2011
BLA 125317/0	RiaSTAP	Fibrinogen Concentrate (Human)	CSL Behring GmbH	7/18/2008	1/16/2009	6.0	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia	Converted	6/4/2021
BLA 125317/125	RiaSTAP	Fibrinogen Concentrate (Human)	CSL Behring GmbH	10/4/2013	9/9/2016	35.2	indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency (afibrinogenemia and hypofibrinogenemia)	Converted	6/4/2021
BLA 125347/0	Hiberix	Haemophilus B Conjugate Vaccine (Tetanus Toxoid Conjugate)	GlaxoSmithKline Biologicals	3/17/2009	8/19/2009	5.1	active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b	Converted	4/30/2018
BLA 125297/0	Agriflu	Influenza Virus Vaccine	Seqirus Inc.	7/11/2008	11/27/2009	16.6	active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine	Converted	10/29/2010
BLA 125385/0	Corifact	Human Factor XIII Concentrate (Human)	CSL Behring GmbH	8/18/2010	2/17/2011	6.0	Routine prophylactic treatment of congenital factor XIII deficiency.	Converted	1/24/2013
BLA 125163/176	FluLaval; FluLaval Quadrivalent	Influenza Vaccine	ID Biomedical Corporation of Quebec	8/10/2010	6/9/2011	10.0	indicated for prevention of influenza in persons 3 to 8 years	Converted	8/15/2013
BLA 125324/262	Pprevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Wyeth Pharmaceuticals LLC	12/2/2010	12/30/2011	12.9	to include the prevention of pneumonia and invasive disease caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in persons 50 years of age or older	Converted	5/22/2015
BLA 103914/5541	Fluzone High Dose	Influenza Virus Vaccine	Sanofi Pasteur Inc.	12/1/2011	6/27/2012	6.9	indicated for prevention of influenze in adults 65 years of age and older	Converted	10/31/2014
BLA 125285/78	FluBlok	Influenza vaccine	Protein Sciences Corporation	10/23/2013	10/29/2014	12.2	is indicated for active immunization against disease caused by influenza virus subtypes A and type B contained in the vaccine. Influenza vaccine is approved for use in persons 50 years of age and older	Converted	10/7/2016
BLA 125549/0	Trumenba	Meningococcal Group B Vaccine	Wyeth Pharmaceuticals LLC	6/16/2014	10/29/2014	4.4	Active immunization to prevent invasive meningococcal disease caused by N. meningitidis serogroup B in individuals 10 through 25 years of age.	Converted	3/13/2017
BLA 125549/17	Trumenba	Meningococcal Group B Vaccine	Wyeth Pharmaceuticals LLC	3/27/2015	4/14/2016	12.6	two-dose schedule (a dose administered at 0 and 6 months) of Trumenba for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B	Converted	11/19/2021
BLA 125408/127	FLUCELVAX QUADRIVALENT	Influenza Vaccine	Seqirus Inc.	4/24/2015	5/23/2016	13.0	indicated for prevention of influenza in persons 4 years to <18 years of age	Converted	3/3/2021
BLA 125692/0	AUDENZ	Influenza A (H5N1) Monovalent Vaccine, Adjuvanted	Seqirus Inc.	2/1/2019	1/31/2020	12.0	For active immunization of influenza in persons 6 months through 17 years of age	Converted	11/17/2021
BLA 125109/0	CNJ-016	Vaccinia Immune Globulin Intravenous (Human)	Emergent BioSolutions Canada Inc.	11/1/2004	5/2/2005	6.0	conditions, which are complications resulting from smallpox vaccination:  Eczema vaccinatum Progressive vaccinia Severe generalized vaccinia	Not Yet Converted	
BLA 125546/0	Bexsero	Meningococcal Group B Vaccine	GlaxoSmithKline Biologicals	7/24/2014	1/23/2015	6.0	active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B. Meningococcal Group B Vaccine is approved for use in individuals 10 through 25 years of age.	Converted	8/19/2024
BLA 125510/0	FLUAD	Influenza Virus Vaccine, Adjuvated	Seqirus Inc.	11/25/2014	11/24/2015	12.0	For active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and B contained in the vaccine.	Not Yet Converted	
BLA 125586/0	Andexxa	coagulation factor Xa (recombinant), Inactivated-zhzo	AstraZeneca AB	12/18/2015	5/3/2018	28.5	For patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding	Not Yet Converted	
BLA 125510/143	Fluad Quadrivalent	Influenza vaccine, adjuvanted	Seqirus Inc.	1/22/2019	2/21/2020	13.0	for active immunization of persons 65 years of age and older against influenza disease caused by seasonal influenza virus subtypes A and types B	Not Yet Converted	
BLA 125508/868	GARDASIL 9	Human Papillomavirus 9-valent Vaccine, Recombinant	Merck Sharp & Dohme Corp	12/13/2019	6/12/2020	6.0	to add prevention of oropharyngeal and other head and neck cancers caused by Human Papillomavirus (HPV)	Not Yet Converted	
BLA 125643/248	Yescarta	axicabtagene ciloleucel	Kite Pharma, Inc.	9/3/2020	3/5/2021	6.0	a new indication for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	Not Yet Converted	
BLA 125731/0	Pprevnar 20	Pneumococcal 20-valent Conjugate Vaccine	Wyeth Pharmaceuticals LLC	10/8/2020	6/10/2021	8.0	prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.	Not Yet Converted	
BLA 125646/663	Kymriah	Tisagenlecleucel	Novartis Pharmaceuticals Corp	8/27/2021	5/27/2022	9.0	treatment of adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy	Not Yet Converted	
BLA 125755/0	Skysona	elivaldogene autotemcel	bluebird bio Inc.	10/18/2021	9/16/2022	10.9	indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD)	Not Yet Converted	
BLA 125781/0	Elevidys	delandistrogene moxeparovvec-rokl	Sarepta Therapeutics Inc.	9/28/2022	6/22/2023	8.8	treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene	Converted	1/31/2024
BLA 125777/0	IXCHIQ	Chikungunya Vaccine, Live	Valneva Austria GmbH	12/22/2022	11/9/2023	10.6	active immunization for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus	Not Yet Converted	
BLA 125773/0	Amtagvi	Lifileucel	Iovance Biotherapeutics, Inc.	3/27/2023	2/16/2024	10.7	treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor	Not Yet Converted	
BLA 125714/205	Breyanzi	Isocabtagene maraleucel	Juno Therapeutics, Inc. a Bristol-Myers Squibb Company	9/13/2023	3/14/2024	6.0	a new indication in relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma in patients who have received at least two prior lines of therapy including a Bruton's tyrosine kinase (BTK) inhibitor and a B-cell lymphoma-2 (BCL-2) inhibitor	Not Yet Converted	
BLA 125714/225	Breyanzi	Isocabtagene maraleucel	Juno Therapeutics, Inc. a Bristol-Myers Squibb Company	11/22/2023	5/15/2024	5.8	a new indication for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy	Not Yet Converted	
BLA 125814/0	CAPVAXIVE	Pneumococcal 21-valent Conjugate Vaccine	Merck Sharp & Dohme LLC	10/18/2023	6/17/2024	7.9	for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.	Not Yet Converted	
BLA 125781/34	Elevidys	delandistrogene moxeparovvec-rokl	Sarepta Therapeutics, Inc.	12/21/2023	6/20/2024	5.9	to expand the approved indication to individuals at least 4 years of age for the treatment of Duchenne muscular dystrophy (DMD) in patients who are non-ambulatory and have a confirmed mutation in the DMD gene.	Not Yet Converted	
BLA 125789/0	Telcelra	afamitresgene autoleucel	Adaptimmune LLC	12/5/2023	8/1/2024	7.8	for treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAG-EA4 antigen as determined by FDA-approved or cleared companion diagnostic devices.	Not Yet Converted	
BLA 125722/0	KEBILDI	eladocagene exuparovvec-tneq.	PTC Therapeutics	3/15/2024	11/13/2024	7.9	for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency	Not Yet Converted	
BLA 125820/0	VIMKUNYA	Chikungunya Vaccine, Recombinant.	Bavarian Nordic A/S	6/17/2024	2/14/2025	7.9	prevention of disease caused by chikungunya virus in individuals 12 years of age and older.	Not Yet Converted	