

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 Number | 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 for the prevention of influenza in adults 18 years and older  | Converted                    | 6/21/2007                                |
| BLA 125127/0       | Fluarix                         | Influenza Virus Vaccine  | GlaxoSmithKline Biologicals                            | 5/25/2005          | 8/31/2005                 | 3.2   |   | 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       | Corfact                         | 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     | Prevnar 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 influenza 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 (HSN1) 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 conditions, which are complications resulting from smallpox vaccination:   | 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   | Eczema vaccinatum<br>Progressive vaccinia<br>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, Adjuvanted                                  | 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       | Prevnar 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 or 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                        | delandistrogen moxeparvovec-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                        | lisocabtagene 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                        | lisocabtagene 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                        | delandistrogen moxeparvovec-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 MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. | Not Yet Converted            |  |
| BLA 125722/0       | KEBILIDI                        | eladocagene exuparvovec-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 (AAADC) 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            |  |