

STN: BLA 125736

Proper Name: idecabtagene vicleucel Tradename: ABECMA

Manufacturer: Celgene Corporation, a Bristol-Myers Squibb Company

Indications:

Treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

STN: BL 125643

Proper Name: axicabtagene ciloleucel Trade Name: YESCARTA

Manufacturer: Kite Pharma Inc.

Indication:

For the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma

STN: 125646

Proper Name: Tisagenlecleucel Tradename: KYMRIA

Manufacturer: Novartis Pharmaceuticals Corporation

Indication:

KYMRIA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of therapy

STN: BL 125703

Proper Name: brexucabtagene autoleucel Tradename: TECARTUS

Manufacturer: Kite Pharma, Inc.

Indication:

Adult patients with relapsed or refractory mantle cell lymphoma (MCL). New Indication for this supplement: Adult patients with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukemia (ALL)

STN# BLA 125714

Proper Name: lisocabtagene maraleucel Tradename: BREYANZI

Manufacturer: Juno Therapeutics, Inc., a Bristol-Myers Squibb Company

Indication:

For treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:

- Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
- Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
- Relapsed or refractory disease after two or more lines of systemic therapy.

Limitations of Use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma

STN:125746

Proper Name: ciltacabtagene autoleucl Tradename: CARVYKTI

Manufacturer: Janssen Biotech, Inc.

Indications:

Treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

STN: BLA 125772

Proper Name: etranacogene dezaparvovec-drlb Tradename: HEMGENIX

Manufacturer: CSL Behring LLC

Indication:

HEMGENIX is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

STN: BLA 125700

Proper Name: nadofaragene firadenovec-vncg Tradename: ADSTILADRIN

Manufacturer: Ferring Pharmaceuticals A/S

Indication:

For the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors

STN: 125610

Proper Name: voretigene neparvovec-rzyl Trade Name: LUXTURNA

Manufacturer: Spark Therapeutics, Inc.

Indication:

For the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

STN: BL 125413

Proper Name: HPC, Cord Blood Trade Name: ALLOCORD

Manufacturer: SSM Cardinal Glennon Children's Medical Center

Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: BL 125603

Proper Name: Autologous Cultured Chondrocytes on a Porcine Collagen Membrane

Tradename: MACI

Manufacturer: Vericel Corporation

Indication

Indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI is an autologous cellularized scaffold product.

STN: BL 125197

Proper Name: sipuleucel-T Tradename: PROVENGE

Manufacturer: Dendreon Corporation

Indication:

For the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

STN: 125685

Proper Name: allogeneic processed thymus tissue–agdc Tradename: RETHYMIC

Manufacturer: Enzyvant Therapeutics GmbH

Indication:

For immune reconstitution in pediatric patients with congenital athymia.

STN: 125755

Proper Name: elivaldogene autotemcel Tradename: SKYSONA

Manufacturer: bluebird bio, Inc.

Indication:

To slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD).

STN: 125730

Proper Name: allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat Tradename: STRATAGRAFT

Manufacturer: Stratatech Corporation

Indication:

For the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

STN: BL 125594

Proper Name: HPC, Cord Blood Trade Name: Clevecord

Manufacturer: Cleveland Cord Blood Center

Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: BL 125407

Proper Name: HPC, Cord Blood Trade Name: Ducord

Manufacturer: Duke University School of Medicine

Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: BL 125397

Proper Name: HEMACORD (HPC, Cord Blood) Trade Name: Hemacord

Manufacturer: New York Blood Center, Inc

Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment

STN: BL 125391

Proper Name: HPC, Cord Blood                      Trade Name: None  
Manufacturer: Clinimmune Labs, University of Colorado Cord Blood Bank  
Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: BL 125657

Proper Name: HPC, Cord Blood                      Trade Name: None  
Manufacturer: MD Anderson Cord Blood Bank  
Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment

STN: BL 125432/0

Proper Name: HPC, Cord Blood                      Trade Name: None  
Manufacturer: LifeSouth Community Blood Centers, Inc.  
Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: 125585

Proper Name: HPC, Cord Blood                      Trade Name: None  
Manufacturer: Bloodworks  
Indication:

For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

STN: 125518

Proper Name: talimogene laherparepvec    Tradename: IMLYGIC  
Manufacturer: Amgen Inc.  
Indication:

IMLYGIC is a genetically modified oncolytic viral therapy. For the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of use: IMLYGIC has not been shown to improve overall survival or have an effect on visceral metastases.

STN: BL 125348

Proper Name: Azficel-T

Trade Name: LAVIV

Manufacturer: Fibrocell Technologies, Inc.

Indication:

Indicated for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults.

STN: 125717

Proper Name: betibeglogene autotemcel

Tradename: ZYNTEGLO

Manufacturer: bluebird bio Inc.

Indication:

For treatment of adult and pediatric patients with  $\beta$ -thalassemia who require regular red blood cell (RBC) transfusions

TN: 125694

Proper Name: onasemnogene abeparvovec

Trade Name: ZOLGENSMA

Manufacturer: Novartis Gene Therapies, Inc.

Indication:

Treatment of Spinal Muscular Atrophy (Type I)

