BlueCross BlueShield of North Carolina

An independent licensee of the Blue Cross and Blue Shield Association

Corporate Medical Policy

CAR-T Therapy

File Name:	car_t_therapy
Origination:	9/2017
Last P&T Review:	1/2021
Next P&T Review:	6/2021
Last Review:	4/2021

Description of Procedure or Service

Engineered T cell–based antitumor immunotherapy uses gene transfer of tumor antigen-specific T-cell receptors (TCR) or synthetic chimeric antigen receptors (CAR-T). CAR-T cells are prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The blood is sent to the manufacturer where the mononuclear cells are enriched for T cells. The T cells are expanded in cell culture, washed, and formulated into a suspension, which then is cryopreserved. This process may take several weeks. The product is then infused into the patient. This technique has shown very encouraging results in clinical trials for treatment of types of leukemias and lymphomas. However, CAR-T cells can persist more than 6 years in patients and can lead to severe adverse events shortly after infusion as well as at later times.

Cytokine-release syndrome (CRS) and other toxicities pose significant risks for patients. Providers develop toxicity management plans for patients undergoing CAR-T therapy. There are on-going clinical studies to determine the effectiveness of various toxicity management plans.

Kymriah™ (tisagenlecleucel) is a CD19-directed genetically modified autologous T cell immunotherapy used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that is either relapsing or refractory. In addition, tisagenlecleucel is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) no otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Yescarta® (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Tecartus™ (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Breyanzi® (lisocabtagene maraleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and follicular lymphoma grade 3B.

Abecma® (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the 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.

Related Policies:
Polatuzumab vedotin-piiq (Polivy™)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for CAR-T Therapy when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When CAR-T Therapy is covered

Tisagenlecleucel (Kymriah) may be considered medically necessary for the treatment of patients with refractory or second relapse B-cell precursor acute lymphoblastic leukemia (ALL) when the following criteria are met:

1. The patient has been diagnosed with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (ALL); **AND**

2. The patient is 25 years of age or younger; **AND**

3. The patient has a confirmed CD19 tumor expression; **AND**

4. The patient has not previously been treated with gene therapy or Kymriah; **AND**

5. If the patient has Philadelphia Chromosome positive (Ph+) ALL, they have tried and failed, is intolerant to, or has a contraindication to at least 2 tyrosine kinase inhibitors (TKI); **AND**

6. The patient will not be treated with more than 2.5×10^8 CAR-positive viable T cells; **AND**

7. If the patient is 50kg or less in weight, they will receive weight-based dosing at 0.2 to 5.0×10^6 CAR-positive viable T cells per kg of body weight; **AND**

8. The patient has received or will receive lymphodepleting chemotherapy [Fludarabine (30 mg/m^2 intravenous daily for 4 days) and cyclophosphamide (500 mg/m^2 intravenous daily for 2 days starting with the first dose of fludarabine)] within two weeks preceding Kymriah infusion; **AND**

9. The patient has been treated with 2 cycles of standard chemotherapy without a complete response or achieved a complete response and experienced multiple relapses following standard chemotherapy (at least 2 cycles); **AND**

10. The patient does not have active central nervous system (CNS) 3 acute lymphoblastic leukemia.

Tisagenlecleucel (Kymriah) may be considered medically necessary for the treatment of patients with relapsed or refractory B-cell lymphoma when the following criteria are met:

1. The patient has been diagnosed with relapsed/refractory B-cell lymphoma including any of the following:
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; **OR**
    b. High grade B-cell lymphoma; **OR**
    c. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma; **AND**

2. The patient is 18 years of age or older; **AND**

3. The patient has not previously been treated with gene therapy or Kymriah; **AND**

4. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; **AND**

5. Previous therapy included anthracycline chemotherapy agent and an anti-CD20 antibody; **AND**

6. The patient will be treated within a dosage range of 0.6 to 6.0 x 10^8 CAR-positive viable T cells; **AND**

7. The patient has received or will receive lymphodepleting chemotherapy [Fludarabine (25 mg/m^2 intravenous daily for 3 days) and cyclophosphamide (250 mg/m^2 intravenous daily for 3 days starting with the first dose of fludarabine), or alternate therapy with bendamustine 90 mg/m^2 intravenous daily for 2 days for patients unable to receive cyclophosphamide] within two weeks preceding Kymriah infusion, OR the patient is unable to receive lymphodepleting chemotherapy if WBC count is less than or equal to 1x10^9/L within one week prior to Kymriah infusion; **AND**

8. The patient does not have primary central nervous system lymphoma; **AND**

9. The patient does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression.

Axicabtagene ciloleucel (Yescarta) may be considered medically necessary when the following criteria are met:

1. The patient has been diagnosed with relapsed/refractory B-cell lymphoma including any of the following:
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; **OR**
    b. Primary mediastinal large B-cell lymphoma; **OR**
    c. High grade B-cell lymphoma; **OR**
    d. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma; **AND**

2. The patient is 18 years of age or older; **AND**

3. The patient has not previously been treated with gene therapy or Yescarta; **AND**

4. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; **AND**

5. Previous therapy included anthracycline chemotherapy agent and an anti-CD20 antibody; **AND**

6. The patient will not be treated with more than 2 x 10^8 CAR-positive viable T cells; **AND**

7. If the patient is under 100kg in weight, they will receive weight-based dosing 2 x 10^6 CAR-positive viable T cells; **AND**

8. The patient has received or will receive lymphodepleting cyclophosphamide 500mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously on the fifth, fourth, and third day before infusion of Yescarta; **AND**

9. The patient does not have primary central nervous system (CNS) lymphoma; **AND**

10. The patient does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression.

Axicabtagene ciloleucel (Yescarta) may be considered medically necessary for the treatment of patients with relapsed or refractory follicular lymphoma when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient has not previously received genetically modified T cell therapy or axicabtagene ciloleucel (Yescarta); **AND**
3. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; **AND**
4. Previous therapy included a combination of an anti-CD20 antibody and an alkylating agent; **AND**
5. The patient has received or will receive a lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously on the fifth, fourth, and third days before infusion of axicabtagene ciloleucel (Yescarta); **AND**
6. The patient will receive a target dose of 2 x 10^6 CAR-positive viable T cells per kg body weight; **AND**
7. The patient does not have does not have active infection including Hepatitis B, Hepatitis C, or human immunodeficiency virus (HIV), or any autoimmune disease requiring immune suppression.

Brexucabtagene autoleucel (Tecartus) may be considered medically necessary for the treatment of patients with relapsed or refractory mantle cell lymphoma (MCL) when the following criteria are met:

1. The patient has been diagnosed with relapsed/refractory mantle cell lymphoma (MCL); **AND**

2. The patient is 18 years of age and older; **AND**

3. The patient has been treated with ALL of the following:
    a. An anthracycline or bendamustine-containing chemotherapy; **AND**
    b. Anti-CD20 monoclonal antibody therapy (e.g., rituximab); **AND**
    c. A Bruton tyrosine kinase (BTK) inhibitor indicated for mantle cell lymphoma (e.g., acalabrutinib, ibrutinib); **AND**

4. The patient has disease progression after their last regimen or refractory disease to the most recent therapy; **AND**

5. The patient has not had a prior allogeneic hematopoietic stem cell transplant (HSCT); **AND**

6. The patient has received or will receive a lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously on each of the fifth, fourth, and third days before infusion of Tecartus; **AND**

7. The patient will not be treated with more than 2 x 10^8 CAR-positive viable T cells; **AND**

8. The patient has not previously received genetically modified T cell therapy or brexucabtagene autoleucel (Tecartus); **AND**

9. The patient does not have detectable malignant cells in the cerebrospinal fluid or brain metastases; **AND**

10. The patient does not have any history of central nervous system (CNS) lymphoma; **AND**

11. The patient does not have active infection including Hepatitis B, Hepatitis C, or human immunodeficiency virus (HIV).

Length of authorization for brexucabtagene autoleucel (Tecartus) is one (1) treatment course per lifetime.

Lisocabtagene maraleucel (Breyanzi) may be considered medically necessary for the treatment of patients with relapsed or refractory B-cell lymphoma when the following criteria are met:

1. The patient has been diagnosed with relapsed/refractory B-cell lymphoma including any of the following:
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma); **OR**
    b. High grade B-cell lymphoma; **OR**
    c. Primary mediastinal large B-cell lymphoma; **OR**
    d. Follicular lymphoma grade 3B; **AND**

2. The patient is 18 years of age or older; **AND**
3. The patient has not previously received genetically modified T cell therapy or lisocabtagene maraleucel (Breyanzi); **AND**
4. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; **AND**
5. Previous therapy included anthracycline chemotherapy agent and an anti-CD20 antibody; **AND**
6. The patient has received or will receive a lymphodepleting chemotherapy regimen of cyclophosphamide 300 mg/m^2/day intravenously and fludarabine 30 mg/m^2/day intravenously daily for 3 days before infusion of Breyanzi; **AND**
7. The patient will not be treated with more than 110 x 10^6 CAR-positive viable T cells (consisting of CD8 and CD4 components); **AND**
8. The patient does not have primary central nervous system (CNS) lymphoma; **AND**
9. The patient does not have active infection including Hepatitis B, Hepatitis C, or human immunodeficiency virus (HIV).

Length of authorization for lisocabtagene maraleucel (Breyanzi) is one (1) treatment course per lifetime.

Idecabtagene vicleucel (Abecma) may be considered medically necessary for the treatment of patients with relapsed or refractory multiple myeloma when the following criteria are met:

1. The patient has a diagnosis of relapsed or refractory multiple myeloma; AND
2. The patient is 18 years of age or older; AND
3. The patient has not previously received genetically modified T cell therapy or idecabtagene vicleucel (Abecma); AND

4. The patient has experienced disease progression following a trial of four or more lines of systemic therapy; AND
5. Previous therapy included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody; AND
6. The patient has received or will receive a lymphodepleting chemotherapy regimen of cyclophosphamide 300 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously daily for 3 days before infusion of idecabtagene vicleucel (Abecma); AND
7. The patient will NOT be treated with more than 460 x 10^6 CAR-positive viable T cells; AND
8. The patient has NOT had a prior allogeneic hematopoietic stem cell transplant (HSCT); AND
9. The patient does not have active infection including Hepatitis B, Hepatitis C, or human immunodeficiency virus (HIV).

Length of authorization for idecabtagene vicleucel (Abecma) is one (1) treatment course per lifetime.

When CAR-T Therapy is not covered

Tisagenlecleucel (Kymriah) is considered investigational for all other indications not listed above.

Axicabtagene ciloleucel (Yescarta) is considered investigational for all other indications not listed above.

Brexucabtagene autoleucel (Tecartus) is considered investigational for all other indications not listed above.

Lisocabtagene maraleucel (Breyanzi) is considered investigational for all other indications not listed above.

Idecabtagene vicleucel (Abecma) is considered investigational for all other indications not listed above.

Policy Guidelines

Tisagenlecleucel (Kymriah) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of patients up to 25 years if age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Kymriah is also indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Axicabtagene ciloleucel (Yescarta) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Brexucabtagene autoleucel (Tecartus) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Lisocabtagene maraleucel (Breyanzi) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma

(DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and follicular lymphoma grade 3B.

Research on CAR-T cell therapy is ongoing. Novartis manufactures tisagenlecleucel (Kymriah) and it was FDA approved in August 2017. Kite Pharmaceuticals manufactures axicabtagene ciloleucel (Yescarta), which received FDA approval in October 2017, and brexucabtagene autoleucel (Tecartus), which received FDA approval in July 2020. Bristol Myers Squibb manufactures lisocabtagene maraleucel (Breyanzi), which received FDA approval in February 2021.

There are warnings published by the FDA regarding administration of Kymriah, Yescarta, Tecartus, and Breyanzi:

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Kymriah, Yescarta, Tecartus, or Breyanzi. Do not administer these therapies to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab.

Neurological toxicities, which may be severe or life-threatening, can occur following treatment with Kymriah, Yescarta, Tecartus or Breyanzi, including concurrently with CRS. Monitor for neurological events after treatment with these therapies. Provide supportive care as needed.

Kymriah, Yescarta, Tecartus, and Breyanzi are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS Program, the YESCARTA and TECARTUS REMS Program, respectively, as well as the BREYANZI REMS Program.

Central nervous system (CNS) disease for B-cell acute lymphoblastic leukemia is defined by the following groups:

- CNS 1: Absence of lymphoblasts in the cerebrospinal fluid (CSF), regardless of the white blood cell (WBC) count
- CNS 2: WBC count of less than 5 leukocytes/μL in the CSF with the presence of blasts
- CNS 3: WBC count of 5 leukocytes/μL or more with the presence of blasts and/or clinical signs of CNS leukemia (e.g., facial nerve palsy, brain/eye involvement, hypothalamic syndrome

Longitudinal follow up of individual member's treatment outcomes may be needed to verify the effectiveness of therapy and the necessity for additional treatment. The various methods used to achieve this may include case management services, clinical registry data collection, evaluation of clinical trial eligibility, and/or requests for medical records.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0537T, 0538T, 0539T, 0540T, 0870, 0871, 0872, 0873, 0874, 0875, C9399, J3490, J3590, J9999, Q2041, Q2042, Q2053

Q2041 – Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR Positive Viable T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose
Q2042 – Tisagenlecleucel, up to 600 Million CAR Positive Viable T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose
Q2053 – Brexucabtagene Autoleucel, up to 200 Million Autologous Anti-CD19 CAR Positive Viable T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Hartmann J, Schüler-Lenz M, Bondanza A, Buchholz CJ. Clinical development of CAR T cells-challenges and opportunities in translating innovative treatment concepts. EMBO Mol Med. 2017 August 1. http://embomolmed.embopress.org/content/early/2017/07/31/emmm.201607485.long

https://www.cancer.gov/about-cancer/treatment/research/car-t-cells

Kymriah (tisagenlecleucel). Highlights of prescribing information. August 2017. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/kymriah.pdf

Medical Director review 9/2017

Yescarta (axicabtagene ciloleucel). Highlights of prescribing information. Available at: https://www.yescarta.com/wp-content/uploads/yescarta-pi.pdf

U.S. Food and Drug Administration (FDA). Available at: https://www.fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm581226.pdf

Medical Director review 4/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 4/12/2018

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Guidelines for Acute Lymphoblastic Leukemia. Version 1.2018. Fort Washington, PA: NCCN, 3/12/18. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed May 2018.

Maude SL, Laetsch TW, Buechner J, et al. Tisagenlecleucel in children and young adults with B-cell lymphoblastic leukemia. N Engl J Med. 2018;378(5):439-448. [PubMed 29385370]. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1709866. Accessed May 2018.

Medical Director review 5/2018

Kymriah (tisagenlecleucel). Highlights of prescribing information. May 2018. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/kymriah.pdf. Accessed June 2018.

Specialty Matched Consultant Advisory Panel 8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 7/12/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.01, 1/17/2019

Specialty Matched Consultant Advisory Panel 8/2019

Specialty Matched Consultant Advisory Panel 8/2020

Kite Pharma, Inc. Tecartus (brexucabtagene autoleucel) suspension for intravenous infusion. Highlights of prescribing information. July 2020. Available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf. Last accessed September 2020.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas, version 4.2020. Revised August 13, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Last accessed September 2020.

Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. N Engl J Med 2020;382:1331-42.

Medical Director review 9/2020

Blue Cross NC Pharmacy and Therapeutics Committee 1/2021

Bristol-Myers Squibb. Breyanzi (lisocabtagene maraleucel) suspension for intravenous infusion. Highlights of prescribing information. February 2021. Available at https://packageinserts.bms.com/pi/pi_breyanzi.pdf. Last accessed March 2021.

Celgene Corporation, a Bristol-Myers Squibb Company. Abecma (idecabtagene vicleucel) suspension for intravenous infusion. Highlights of prescribing information. March 2021. Available at: https://packageinserts.bms.com/pi/pi_abecma.pdf. Last accessed April 2021.

Policy Implementation/Update Information

9/29/17 New policy developed. CAR-T Therapy is considered medically necessary for the treatment of patients with refractory or second relapse B-cell precursor acute lymphoblastic leukemia (ALL) when the medical criteria and guidelines above are met. References added. (lpr)

11/28/17 Added Axicabtagene Ciloleucel (Yescarta) criteria as a covered indication. Added CPT codes Q2040 and 36511 to the Billing/Coding section. Reference added. (lpr)

12/15/17 Under "When Covered" section, corrected dosage under Yescarta from 2.5 to 2 in #6 and #7. No change to policy intent. Codes Q2040 and 36511 are effective 1/1/2018. (lpr)

3/29/18 Added CPT Q2041 and deleted CPT 36511 in Billing/Coding section for 4/1/2018 code update. (lpr)

4/27/18 Removed the following criterion from "When Covered" section for both Kymriah and Yescarta coverage: "The prescriber will submit documentation of response within 3 months following therapy as a follow up to the prior approval request." Added the following to "Policy Guidelines" section: "Longitudinal follow up of individual member's treatment outcomes may be needed to verify effectiveness of therapy and the necessity for additional treatment. The various methods used to achieve this may include case

management services, clinical registry data collection, evaluation of clinical trial eligibility, and/or requests for medical records." Other minor updates made to organization and wording of "Policy Guidelines" section for clarity. Removed codes C9399 and J3590 from Billing/Coding section, and added code descriptions for codes Q2040 and Q2041. References added. Medical Director review 4/2018. (krc)

5/25/18 Updated "When Covered" section for Kymriah to include criterion "The patient does not have active central nervous system (CNS) 3 acute lymphoblastic leukemia." Added definitions of CNS disease for B-cell acute lymphoblastic leukemia in Policy Guidelines section. References added. Medical Director review 5/2018. (krc)

6/29/18 Updated "When Covered" section for Kymriah to include medically necessary criteria for newly approved indication for diffuse large B-cell lymphoma (DLBCL). "Description" and "Policy Guidelines" sections updated to reflect additional DLBCL indication for Kymriah. Reference added. (krc)

10/12/18 Specialty Matched Consultant Advisory Panel review 8/22/2018. No change to policy statement. (krc)

12/31/18 Added HCPCS code Q2042 and associated description to Billing/Coding section, deleted code Q2040, and revised description of code Q2041, effective 1/1/19. (krc)

1/29/19 Added codes 0537T, 0538T, 0539T, and 0540T to Billing/Coding section effective 1/1/19. (krc)

10/1/19 Added reference to the following related policy: "Polatuzumab vedotin-piiq (Polivy™)". References added. Specialty Matched Consultant Advisory Panel review 8/21/2019. Added revenue codes 0870, 0871, 0872, 0873, 0874, and 0875 to Billing/Coding section. (krc)

9/22/20 Added brexucabtagene autoleucel (Tecartus) to policy to be considered medically necessary for the treatment of patients with relapsed or refractory mantle cell lymphoma (MCL) when specified medical criteria and guidelines are met. Updated Description and Policy Guidelines sections to include information relevant to brexucabtagene autoleucel. Other minor typographical edits made throughout policy for clarity. Added HCPCS codes C9399, J3490, J3590, and J9999 to Billing/Coding section. References added. Medical Director review 9/2020. (krc)

11/24/20 Specialty Matched Consultant Advisory Panel review 8/2020. No change to policy intent. (krc)

12/31/20 Added HCPCS code C9073 to Billing/Coding section effective 1/1/2021. (krc)

3/31/21 Added HCPCS code Q2053 and associated description to Billing/Coding section for Tecartus effective 4/1/2021 and deleted code C9073 termed 3/31/2021. Blue Cross NC Pharmacy and Therapeutics Committee 1/5/2021. (krc)

4/6/21 Added newly approved lisocabtagene maraleucel (Breyanzi) to policy to be considered medically necessary for the treatment of patients with relapsed or refractory large B-cell lymphoma, after two or more lines of system therapy, when specified medical criteria and guidelines are met. Updated Description and Policy Guidelines sections to include information relevant to lisocabtagene maraleucel. Added HCPCS codes C9399, J3490, J3590, and J9999 to Billing/Coding section for Breyanzi. Reference added. (krc)

4/20/21 Added new indication for Yescarta for relapsed/refractory follicular lymphoma with specific medical necessity criteria. Added newly approved Abecma (idecabtagene

vicleucel) to policy to be considered medically necessary for the treatment of patients with relapsed or refractory multiple myeloma when specified medical criteria and guidelines are met. Updated Description and Policy Guidelines sections to include information relevant to idecabtagene vicleucel. Added HCPCS codes C9399, J3490, J3590, and J9999 to Billing/Coding section for Abecma. Reference added. (krc)