

CAR-T Cell Therapy

Policy Number: **M20180425008**
Effective Date: **6/1/2018**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: Internal External

Data Classification: Confidential Restricted Public

Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s): MediSource; MediSource Connect; Child Health Plus Essential Plan
- Medicare, if yes, which plan(s): MAPD; PDP; ISNP; CSNP
- Commercial, if yes, which type: Large Group; Small Group; Individual
- Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth Independent Health's clinical coverage guidelines for **Car-T Cell Therapy** utilizing **Kymriah (tisagenlecleucel)**, **Yescarta (axicabtagene ciloleucel)**, **Tecartus (brexucabtagene autoleucel)** **Breyanzi (lisocabtagene maraleucel)**, **Abecma (Idcabtagene Vicleucel)** or **Carvytki (ciltacabtagene autoleucel)**.

Policy:

Commercial and Self-Funded:

Kymriah (tisagenlecleucel) is considered medically necessary as single agent therapy for the treatment of patients with refractory or second relapsed 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. Patient does not have an active infection or inflammatory disorder; AND
4. The patient has a confirmed **CD19** tumor expression; AND
5. The patient has not previously been treated with gene therapy or Kymriah; AND
6. 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
7. 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
8. The prescriber will submit documentation of response to Kymriah within 3 months following therapy as a follow-up to the prior approval request.

Kymriah is considered medically necessary as single agent therapy for the treatment of patients with relapsed or refractory (r/r) large **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. Patient does not have an active infection or inflammatory disorder; AND
4. The patient has a confirmed CD19 tumor expression; AND
5. The patient has not previously been treated with gene therapy or Kymriah; AND
6. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; AND
7. The patient does not have primary central nervous system (CNS) lymphoma; AND
8. The patient does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression; AND
9. The prescriber will submit documentation of response to Kymriah within 3 months following therapy as a follow-up to the prior approval request.

Limitation of Use:

Kymriah is not indicated for treatment of patients with primary central nervous system lymphoma.

Yescarta (axicabtagene ciloleucel) is 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. Patient does not have an active infection or inflammatory disorder; AND
4. The patient has not previously been treated with gene therapy or Yescarta; AND
5. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; AND
6. Previous therapy included anthracycline chemotherapy agent and an anti-CD20 antibody; AND
7. The patient does not have primary central nervous system (CNS) lymphoma; AND
8. Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab, etc.) OR patient
9. previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; AND
10. Patient has an ECOG performance status of 0-1; AND
11. The patient does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression; AND
12. The prescriber will submit documentation of response to Yescarta within 3 months following therapy as a follow-up to the prior approval request.

Tecartus (brexucabtagene autoleucel) is considered medically necessary when the following criteria are met:

Mantle Cell Lymphoma:

1. The patient has been diagnosed with mantle cell lymphoma including:
 - a. Patient has relapsed or refractory disease; AND
 - b. Patient has at least one measurable lesion; AND
 - c. Patient must have received previous systemic therapy which included at least one agent from each of the following categories:
 - i. Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
 - ii. Anti-CD20 monoclonal antibody (e.g., rituximab)
 - iii. Anthracycline-OR bendamustine-containing chemotherapy
2. The patient is 18 years of age or older; AND
3. Patient does not have an active infection or inflammatory disorder; AND
4. Patient does not have a clinically significant active systemic infection or inflammatory disorder; AND
5. The patient does not have primary central nervous system (CNS) lymphoma; AND
6. Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT);
7. The patient does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression; AND

8. The prescriber will submit documentation of response to Tecartus within 3 months following therapy as a follow-up to the prior approval request.

Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL):

1. Patient has relapsed or refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) AND
2. Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab, etc.) OR patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; AND
3. Patient does not have CNS-3 disease or CNS-2 disease with neurological changes; AND
 - a. Patient has Philadelphia chromosome (Ph)-positive disease; AND
 - i. Disease is tyrosine kinase inhibitor (TKI) intolerant OR refractory to at least two (2) different TKIs; OR
 - b. Patient has Philadelphia chromosome (Ph)-negative disease

Breyanzi® (lisocabtagene maraleucel) is considered medically necessary when the following criteria are met:

1. The patient has been diagnosed with:
 - a. relapsed or refractory large B-cell lymphoma OR
 - b. diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), OR
 - c. high-grade B-cell lymphoma, OR
 - d. primary mediastinal large B-cell lymphoma, OR
 - e. follicular lymphoma grade 3B
2. The patient is 18 years of age or older; AND
3. The patient has not previously been treated with gene therapy or Breyanzi; AND
4. Patient does not have a clinically significant active systemic infection or inflammatory disorder; AND
5. The patient has experienced disease progression following a trial of two or more lines of systemic therapy; AND
6. The patient does not have primary central nervous system (CNS) lymphoma; AND
7. The prescriber will submit documentation of response to Breyanzi within 3 months following therapy as a follow-up to the prior approval request

Limitation of use:

Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma

Abecma (Idecabtagene Vicleucel) is considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; AND
2. The patient has a diagnosis of multiple myeloma; AND
3. Patient does not have an active infection or inflammatory disorder; AND
4. The patient has measurable disease defined by any of the following:
 - a. Serum monoclonal paraprotein (M-protein) level greater than or equal to 1 g/dL; OR
 - b. Urine M-protein level greater than or equal to 200 mg per 24 hours; OR
 - c. Serum immunoglobulin free light chain greater than or equal to 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio; AND

5. Individual has relapsed or refractory disease, defined as progression after four (4) or more lines of systemic therapy (which may or may not include therapy supported by hematopoietic stem cell transplant), AND prior therapy includes all of the following:
 - a. Anti-CD38 antibody (for example, isatuximab or daratumumab); AND
 - b. Proteasome inhibitor (for example, ixazomib, bortezomib, or carfilzomib); AND
 - c. Immunomodulatory drug (for example, thalidomide, pomalidomide, or lenalidomide); AND
6. Individual was refractory to the last treatment regimen; AND
7. Individual has adequate bone marrow reserve defined by all of the following:
 - a. Absolute neutrophil count (ANC) \geq 1000 cells/uL; AND
 - b. Platelet count \geq 50,000 cells/uL; AND
8. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; AND
9. Individual is using as a one-time, single administration treatment.

Carvytki (ciltacabtagene autoleucl) is considered medically necessary when the following criteria are met:

1. Individual is 18 years of age or older; AND
2. Individual has a diagnosis of multiple myeloma; AND
3. Individual has measurable disease defined by any of the following:
 - a. Serum monoclonal paraprotein (M-protein) level more than or equal to 1 g/dL; OR
 - b. Urine M-protein level greater than or equal to 200 mg per 24 hours; OR
 - c. Serum immunoglobulin free light chain greater than or equal to 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio; AND
4. Individual has relapsed or refractory disease, defined progression after four (4) or more lines of systemic therapy (which may or may not include therapy supported by hematopoietic stem cell transplant), or individual is double-refractory to proteasome inhibitor and immunomodulatory drug; AND prior therapy includes all of the following:
 - a. Anti-CD38 antibody (for example isatuximab or daratumumab); AND
 - b. Proteasome inhibitor (for example, ixazomib, bortezomib, or carfilzomib); AND
 - c. An immunomodulatory drug (for example, thalidomide, pomalidomide, or lenalidomide); AND
5. Individual has adequate bone marrow reserve defined by all of the following:
 - a. Absolute neutrophil count (ANC) \geq 1000 cells/uL; AND
 - b. Platelet count \geq 50,000 cells/uL; AND
6. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; AND
7. Individual does not have an active infection or inflammatory disorder; AND
8. Individual is using as a one-time, single administration treatment.

NOTE: Independent Health considers all other uses of Kymria, Yescarta, Tecartus, Breyanzi Abecma or Carvytki experimental and investigational.

NOTE: Independent Health considers repeat administration of Kymria, Yescarta, Tecartus, Breyanzi, Abecma or Carvytki experimental and investigational because the effectiveness of this approach has not been established.

NOTE: Kymria, Yescarta, Tecartus, Breyanzi, Abecma and Carvytki are available only through a Risk Evaluation and Mitigation Strategy (REMS) program to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

NOTE: The member's medical records submitted for review for all conditions should document that the above medical criteria are met, including office visit notes that contain the relevant history and physical and prior cancer treatment history.

NOTE: For medical necessity review for members receiving CAR T Cell therapy as part of a clinical trial, please refer to the Independent Health Clinical Trial Policy.

Medicare Advantage:

There is currently a National Coverage Determination for Car-T Cell therapy. Please refer to the link listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

Per NYS coverage criteria:

1. Kymria (tisagenlecleucel)

In accordance with FDA indications, Medicaid reimburses for tisagenlecleucel when the following criteria are met:

- a. The patient must have a diagnosis of B-cell precursor ALL;
- b. The patient must be 25 years of age (up to the end of the 25th year) or younger; and
- c. The ALL must be refractory or in second or later relapse.

OR

- d. The patient must have a diagnosis of 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 in adults;
- e. The patient is 18 years of age or older.

- ❖ **Note:** Hospitals administering tisagenlecleucel must be appropriately certified to do so. The list of currently authorized treatment centers may be viewed here: <https://www.us.kymria.com/treatment-center-locator/>

2. Yescarta (axicabtagene ciloleucel)

In accordance with FDA indications, Medicaid reimburses for axicabtagene ciloleucel when the following criteria are met:

- a. The patient must be an adult (18 years, 0 months and above);
- b. The patient must have a confirmed diagnosis of large B-cell lymphoma, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma; and

- c. The large B-cell lymphoma must be relapsed or refractory after two or more types of systemic therapy.

- ❖ **Note:** Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma

Hospitals administering axicabtagene ciloleucel must be appropriately authorized to do so. The list of currently authorized treatment centers may be viewed here:

<https://www.yescarta.com/find-a-treatment-center/>

3. Breyanzi (lisocabtagene maraleucel)

In accordance with FDA indications, Medicaid reimburses for lisocabtagene maraleucel when the following criteria are met:

- a. The patient must be an adult (18 years, 0 months and above);
- b. 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), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Note: Abecma (Idecabtagene Vicleucel) and Carvytki (ciltacabtagene autoleucel) are covered utilizing the Commercial criteria above.

Background:

CAR-T Cell therapy, also known as chimeric antigen receptor therapy, draws on the immune system's natural fighting ability to attack cancer. CAR-T Cells are prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The leukapheresis product 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 is then cryopreserved. The T cells are genetically engineered to produce receptors on their surface called CARs. These receptors allow the T cells to recognize and attach to a specific protein, or antigen, on tumor cells. This process may take many days but is typically complete within about 21 days. The product is then infused into the patient. The goal is for the engineered cells to further multiply in the patient's body, and with guidance from their engineered receptors, recognize and kill cancer cells that harbor the antigen on their surfaces.

Several CAR-T Cell therapies, Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel) Breyanzi (lisocabtagene maraleucel) Abecma (Idecabtagene Vicleucel) and Carvytki (ciltacabtagene autoleucel) have been approved by the Food and Drug Administration (FDA). Kymriah has been approved for refractory or relapsed B-cell precursor acute lymphoblastic leukemia. Yescarta has been approved for the treatment of relapsed or refractory large B-cell lymphoma after 2 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 has been approved for the treatment of relapsed or refractory mantle cell lymphoma (MCL) in adults. Breyanzi has been approved for 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), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. Abecma (Idecabtagene Vicleucel) was approved for multiple myeloma. Carvytki (ciltacabtagene autoleucel) was approved for multiple myeloma.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes No

Pre-authorization is required for this service.

Definitions

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.

Acute lymphoblastic leukemia (ALL) also called acute lymphoblastic leukemia, is a cancer that starts from the early version of white blood cells called lymphocytes in the bone marrow. Leukemia cells usually invade the blood fairly quickly, spreading to other parts of the body, including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testicles.

B-cell lymphoma is a type of cancer that forms in B Cells. B-cell lymphomas may be either indolent or aggressive. Most B-cell lymphomas are non-Hodgkin lymphomas, varieties of which include Burkitt lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), diffuse large B-cell lymphoma, follicular lymphoma, and mantle cell lymphoma. Prognosis and treatment depend on type and stage of the cancer.

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), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

CAR-T Cell Therapy is a type of treatment in which a patient's T cells from their own blood are changed in the laboratory, so they will attack cancer cells. A gene for a special receptor, also known as a chimeric antigen receptor (CAR) which binds to a certain protein on the patient's cancer cells is added in the laboratory. Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion.

Carvytki (ciltacabtagene autoleucel) 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 a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

CD19 is a protein coding gene. This gene encodes a cell surface molecule which assembles with the antigen receptor of B lymphocytes in order to decrease the threshold for antigen receptor-dependent stimulation.

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) which is either relapsing or refractory.

Mantle Cell Lymphoma (MCL) is a form of mature B cell non-Hodgkin lymphomas (NHL). The course of MCL is moderately aggressive and variable. Most patients with MCL have advanced stage disease at diagnosis (70 percent) and approximately 75 percent of patients initially present with lymphadenopathy.

Multiple myeloma is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

Philadelphia Chromosome is an abnormality of chromosome 22 in which part of chromosome 9 is transferred to it. Bone marrow cells that contain the Philadelphia chromosome are often found in chronic myelogenous leukemia and sometimes found in acute lymphocytic leukemia.

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).

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.

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Clinical Trial Policy, Policy No. M011011296

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes No

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
9/1/2023	Health Care Services	Revised
10/1/2022	Health Care Services	Revised
11/1/2021	Health Care Services	Revised
4/1/2021	Health Care Services	Revised

1/1/2021	Health Care Services	Revised
9/1/2020	Health Care Services	Revised
10/1/2019	Medical Management	Revised
7/1/2019	Medical Management	Revised
8/1/2018	Medical Management	Revised