Corporate Medical Policy

CAR-T Therapy

File Name: car_t_therapy
Origination: 9/2017
Last CAP Review: NA
Next CAP Review: 9/2018
Last Review: 9/2017

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.

***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) is 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:
CAR-T Therapy

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 x 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 x 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/m2 intravenous daily for 4 days) and cyclophosphamide (500 mg/m2 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 prescriber will submit documentation of response to Kymriah within 3 months following therapy as a follow-up to the prior approval request.

When CAR-T Therapy is not covered

Tisagenlecleucel (Kymriah) 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 of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

Research on CAR-T cell therapy is ongoing. Novartis manufactures Tisagenlecleucel (Kymriah) and it was FDA approved in August 2017. Kite Pharmaceuticals is currently working on Axicabtagene (Ciloleucel), however, it is not FDA approved at this time.

There are warnings published by the FDA regarding administration of Kymriah:

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving KYMRIAH. Do not administer KYMRIAH 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, including concurrently with CRS. Monitor for neurological events after treatment with KYMRIAH. Provide supportive care as needed.

KYMRIAH is available only through a restricted program under a Risk Evaluation and Mitigation
CAR-T Therapy

An Independent Licensee of the Blue Cross and Blue Shield Association

Strategy (REMS) called the KYMRIAH REMS.

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 website at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: C9399, J3590

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


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


Medical Director review 9/2017

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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.