PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable – CAR-T) – Tecartus Prior Authorization Policy
- Tecartus® (brexucabtagene autoleucel intravenous infusion – Kite Pharma)

REVIEW DATE: 08/24/2022

OVERVIEW

Tecartus, a CD19-directed genetically modified autologous T cell immunotherapy, is indicated for the treatment of adults with relapsed or refractory:

- **B-cell precursor acute lymphoblastic leukemia**.
- **Mantle cell lymphoma**. This indication was approved under accelerated approval based on the overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Tecartus is supplied in infusion bag(s) containing frozen suspension of genetically modified autologous T cells in human serum albumin.[1] Each bag is supplied in a metal cassette stored in the vapor phase of liquid nitrogen. Store Tecartus frozen in the vapor phase of liquid nitrogen and thaw prior to administration.

Guidelines

Tecartus is addressed in National Comprehensive Cancer Network guidelines:

- **Acute lymphoblastic leukemia:** Guidelines (version 1.2022 – April 4, 2022) recommend Tecartus for the treatment of relapsed or refractory acute lymphoblastic leukemia.[3,4]
- **B-cell lymphomas:** Guidelines (version 5.2022 – July 12, 2022) recommend Tecartus for the third-line treatment of relapsed or refractory mantle cell lymphoma, following treatment with chemoimmunotherapy and Bruton tyrosine kinase inhibitor therapy.[2,3]

Safety

Tecartus has a Boxed Warning regarding cytokine release syndrome and neurological toxicities. Due to these risks, Tecartus is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Tecartus REMS.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tecartus. All approvals for therapy are provided for the approval duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tecartus as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecartus to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tecartus is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve a single dose if the patient meets all of the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has B-cell precursor disease; AND
   - **C)** Patient has relapsed or refractory disease; AND
   - **D)** Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; AND
   - **E)** Patient has not been previously treated with CAR-T therapy; AND
     Note: Examples of CAR-T therapy include Tecartus, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel intravenous infusion).
   - **F)** Tecartus is prescribed by or in consultation with an oncologist.

2. **Mantle Cell Lymphoma.** Approve a single dose if the patient meets all of the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has previously received the following (i and ii):
     - **i.** Chemoimmunotherapy; AND
       Note: Examples of chemoimmunotherapy include bendamustine + rituximab, DHAP (dexamethasone, cisplatin, cytarabine) + rituximab, DHAX (dexamethasone, cytarabine, oxaliplatin) + rituximab.
     - **ii.** A Bruton tyrosine kinase inhibitor; AND
       Note: Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules and tablets).
   - **C)** Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; AND
   - **D)** Patient has not been previously treated with CAR-T therapy; AND
     Note: Examples of CAR-T therapy include Tecartus, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel intravenous infusion).
   - **E)** Tecartus is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecartus is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tecartus® intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; October 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2022 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 15, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 15, 2022. Search term: brexucabtagene.
4. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 15, 2022.