# Tecartus® (brexucabtagene autoleucel) Alternative Therapies to Tocilizumab

Kite, a Gilead Company is providing this document to US Healthcare Professionals in response to your unsolicited request for medical information. Some of the information contained in this response may be outside of the US FDA-approved Prescribing Information. Kite does not intend to offer an opinion regarding the clinical relevance of these data nor the advisability of administering any drug in a manner inconsistent with its approved labeling. Please refer to the product labeling for complete product information.

**The full indication, important safety information, and boxed warnings for cytokine release syndrome, neurologic toxicities and secondary hematological malignancies are available at:**
**https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf**

## Alternative Therapies to Tocilizumab

As stated in the Tecartus US Prescribing Information (USPI), cytokine release syndrome (CRS) and neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving Tecartus.[1] Please refer to the Tecartus US Prescribing Information (Section 2.3) for the management of cytokine release syndrome (CRS) and neurologic events (NE) with tocilizumab and corticosteroids in patients receiving Tecartus.[1] Hospitals and their associated clinics must ensure that a minimum of 2 doses of tocilizumab are available on-site for each patient and are ready for immediate administration (within 2 hours of infusion).[1,2] The most up-to-date information on the YESCARTA and TECARTUS REMS program can be found at https://www.yescartatecartusrems.com.[2]

Kite, a Gilead Company, is committed to ensuring all providers have the resources they need to safely treat patients with chimeric antigen receptor (CAR) T-cell therapy [CAR T], including Tecartus. Certified healthcare facilities should follow their institutional guidelines regarding CAR T standard of care and inventory management of supportive care products.

Per the Tecartus USPI on managing CRS and NE, alternate immunosuppressants could be considered if no improvement is seen for patients with Grade 4 CRS, or Grade 4 NE with or without concurrent CRS.[1]

The use and selection of alternate immunosuppressants is at the discretion of the treating physician.

### Use of Tocilizumab Biosimilars

The Tecartus USPI refers to use and availability of “tocilizumab” for treatment of severe or life-threatening CRS for patients receiving Tecartus. The USPI is agnostic of a specific brand name for tocilizumab, however it should be noted that currently only ACTEMRA® (tocilizumab) has an approved indication for the treatment of CAR T-cell induced CRS, while other recently approved tocilizumab biosimilars do not.[3]

TYENNE® (tocilizumab-aazg) and TOFIDENCE® (tocilizumab-bavi) are US Food and Drug Administration (FDA) approved biosimilars to the reference product ACTEMRA®

(tocilizumab), and the US FDA considers both biosimilars to be highly similar to and have no clinically meaningful differences, in terms of safety or effectiveness, from the existing approved reference product. This means that health care professionals can prescribe either product instead of the original biologic.[3]

Of note, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Version 1.2025 – Management of CAR T-Cell-Related Toxicities states, "an FDA-approved biosimilar is an appropriate substitute for any recommended systemic biologic therapy in the NCCN Guidelines."[4] Use of tocilizumab biosimilars for the treatment of CAR T-cell induced CRS should be at the discretion of the treating physician.

## Clinical Studies

The pivotal ZUMA-2 phase 2 study (N=68) evaluated Tecartus in patients with relapsed/refractory mantle cell lymphoma.[5] In the ZUMA-2 study, one patient experienced Grade 4 cerebral edema that was confirmed by magnetic resonance imaging (MRI) of the brain.[6] This patient was intubated and treated with aggressive multimodality therapies including tocilizumab, siltuximab, high-dose steroids, intrathecal cytarabine (Ara-C) plus dexamethasone, ventriculostomy, and intravenous anti-thymocyte globulin (rabbit ATG).[6] This is the first reported use of ATG in treating CAR T cell-related toxicities. Additional data from ZUMA-2 on the use of alternative therapies for the management of CRS and/or NE is not available.

## Real World Evidence

A literature search conducted to identify primary evidence describing outcomes with alternate therapies to tocilizumab for the management of CRS and/or NE in patients treated with Tecartus yielded no relevant results.

The literature searched identified real-world evidence studies where alternate therapies for toxicity management were identified as being utilized. Please refer to the following publications for additional details:


- Gazeau N., Liang E.C., Wu Q.., et al Anakinra for Refractory Cytokine Release Syndrome or Immune Effector Cell-Associated Neurotoxicity Syndrome after Chimeric Antigen Receptor T Cell Therapy. Transplant. Cell. Ther 2023;29(7):430-437. Doi:10.1016/j.jtct.2023.04.001
- Gavriilaki E., Mallouri D., Bousiou Z., et al Molecular and Clinical Characteristics of Different Toxicity Rates in Anti-CD19 Chimeric Antigen Receptor T Cells: Real-World Experience. Cancers 2023;15(17):no pagination. Doi:10.3390/cancers15174253
- Shalhoub S.D., Tejeda J., Taylor B.J., Beitinjaneh P.A. Evaluation of Anakinra Use for CAR T-Cell Related Toxicities. Transplant. Cell. Ther 2023;29(2 Supplement):S212-S213. Doi:10.1016/S2666-6367%2823%2900344-5
- Kopmar N.E., Gooley T., Roloff G.W., et al Toxicity Profile of Brexucabtagene Autoleucel (brexu-cel; CD19-directed CAR T-cell therapy) in Adult Patients (pts) with Relapsed/Refractory (R/R) B-Cell Acute Lymphoblastic Leukemia (B-ALL): Results from a Multicenter Real-World Outcomes Study. Blood 2023;142(Supplement 1):522. Doi:10.1182/blood-2023-185107
- Wang Y., Jain P., Locke F., et al. Brexucabtagene Autoleucel for Relapsed/Refractory Mantle Cell Lymphoma in Routine Practice: Updated Report from the US Lymphoma CAR T Consortium. HemaSphere 2022;6(Supplement 3):2009-2010. Doi:10.1097/01.HS9.0000852292.38263.b8

- Wang Y., Jain P., Locke F.L., et al Brexucabtagene autoleucel for relapsed/refractory mantle cell lymphoma: Real world experience from the us lymphoma CAR T consortium. Blood 2021;138(SUPPL 1):744. Doi:10.1182/blood-2021-147563

Note that this is not a comprehensive list, and you are encouraged to search the published medical literature for additional citations on this topic. Please refer to the US Prescribing Information for alternate therapies identified and/or contact the respective manufacturers for additional information on these products.

Beyond the guidance included in the Tecartus USPI, the treatment of choice and sequence of use among the suggested alternate therapies is at the discretion of the treating physician.

# References


1. TECARTUS® (brexucabtagene autoleucel). Prescribing Information. Kite Pharma, Inc. Santa Monica, CA. 2024.
2. YESCARTA and TECARTUS Risk Evaluation and Mitigation Strategy (REMS). https://www.yescartatecartusrems.com/. Kite Pharma, Inc. 2024. Accessed February 20, 2025.
3. Data on File. Kite Pharma.
4. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities, Version 1.2025 – December, 20, 2024.
5. 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. https://doi.org/10.1056/nejmoa1914347. Accessed February 20, 2025.
6. Wang M, Munoz J, Goy A, et al. KTEX19, an Anti-CD19 Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Mantle Cell Lymphoma: Results of the Phase 2 ZUMA-2 Study. Oral presented at the American Society of Hematology (ASH) Annual Meeting; December 7-10, 2019; Orlando, FL. Abstract 754.


# Abbreviations

Ara-C=intrathecal cytarabine
ATG=anti-thymocyte globulin
CAR=chimeric antigen receptor
CRS=cytokine release syndrome
FDA=Food and Drug Administration
MRI=magnetic resonance imagine
NCCN=National Comprehensive Cancer Network
NE=neurologic event

# Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the TECARTUS® (brexucabtagene autoleucel) US Prescribing Information available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf.

# Follow Up

For any additional questions, please contact Kite Medical Information at:

☎1-844-454-KITE (1-844-454-5483) or ✉ medinfo@kitepharma.com

# Adverse Event Reporting

Please report all adverse events to:

Kite ☎ 1-844-454-KITE (1-844-454-5483)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

# Data Privacy

The Medical Information service at Kite, a Gilead Company, may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Kite or Gilead colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Kite or Gilead product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Kite's affiliates, business partners, service providers and regulatory authorities located in countries besides your own. Kite has implemented measures to protect the personal information you provide. Please see the Kite Privacy Statement (https://www.kitepharma.com/privacy-policy/) for more information about how Kite handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@kitepharma.com.