



Tecartus® (brexucabtagene autoleucel) – New indication

- On October 1, 2021, [Gilead announced](#) the FDA approval of [Tecartus \(brexucabtagene autoleucel\)](#), for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
- Tecartus is also approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).
- The approval of Tecartus for the new indication was based on ZUMA-3, an open-label, single-arm study in adult patients with relapsed or refractory B-cell precursor ALL. Treatment consisted of lymphodepleting chemotherapy followed by a single intravenous infusion of Tecartus. The efficacy endpoints included overall complete remission (OCR) and complete remission (CR). The evaluable efficacy population was 54 patients.
 - In the efficacy evaluable patients, the OCR rate was 64.8%. The CR rate was 51.9%. The duration of remission was 13.6 months (95% CI: 9.4, not estimable).
- Tecartus carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities.
- The most common non-laboratory adverse reactions ($\geq 20\%$) with Tecartus use for ALL were fever, CRS, hypotension, encephalopathy, tachycardia, nausea, chills, headache, fatigue, febrile neutropenia, diarrhea, musculoskeletal pain, hypoxia, rash, edema, tremor, infection with pathogen unspecified, constipation, decreased appetite, and vomiting.
- Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy. Refer to the Tecartus drug label for dosing and administration recommendations.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.