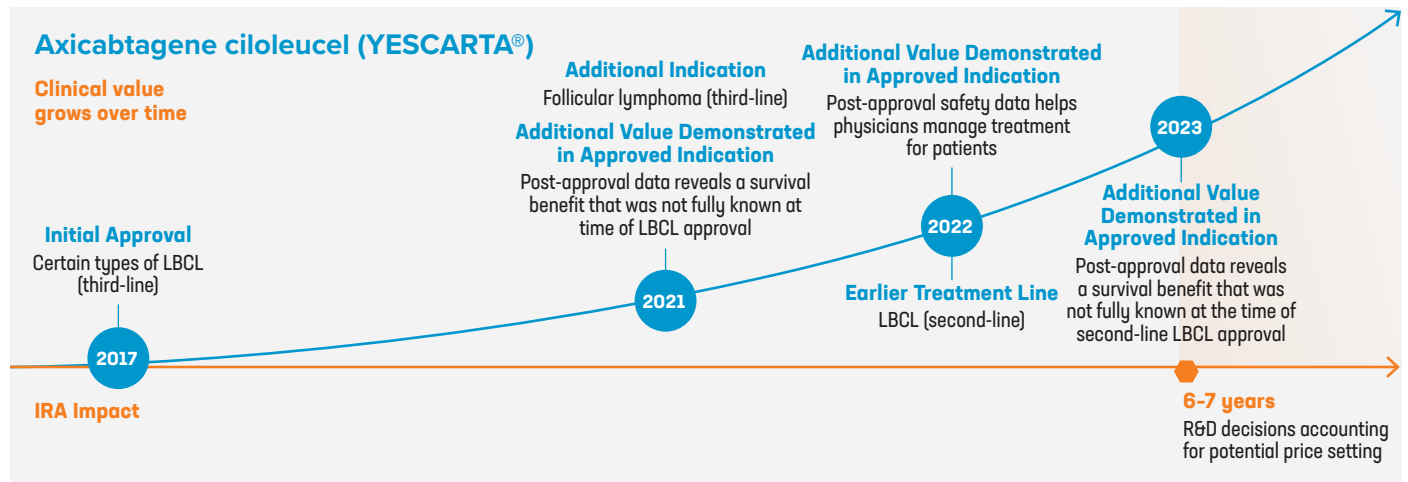


Axicabtagene ciloleucel | YESCARTA®

Axicabtagene ciloleucel stems from a promising class of immunotherapy known as chimeric antigen receptor (CAR) T-cell therapy, in which every dose is manufactured specifically for the patient. In the manufacturing process, a patient's T-cells are collected from the bloodstream and genetically modified to express an artificial receptor that allows T-cells to recognize cancer cells. Once returned to the body, the modified cells work by attacking cancer cells. CAR T-cell therapies are among the most promising areas in cancer treatment, often allowing patients to achieve long-term, cancer-free effects with a single administration.¹

In 2017, the FDA approved axicabtagene ciloleucel for patients with certain types of large B-cell lymphoma (LBCL) who have not responded to or have relapsed after at least two other lines of treatment.² In the study supporting initial approval, 72% of patients treated with a single dose of axicabtagene ciloleucel responded to therapy, and over half no longer showed signs of cancer.³ Ongoing research and clinical trials have revealed additional benefits and offered insights to optimize CAR T-cell therapy that were not recognized at the time of initial approval. Axicabtagene ciloleucel continues to be studied across a variety of other types of hematologic cancers.⁴



Additional Indication (March 2021): Granted accelerated approval for treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of therapy. The FDA granted priority review, orphan drug designation, and breakthrough therapy designation for this indication, and the approval was based on an overall response of 91%.⁵

Additional Value Demonstrated in Approved Indication (December 2021): Clinical evidence demonstrates long-term survival in certain patients with LBCL who had not responded to or relapsed after prior treatment. After five years of follow-up of these patients, clinical data showed a 5-year survival rate of 43%. Among those patients, 92% had received no additional treatment since their 1-time infusion of axicabtagene ciloleucel. These long-term outcomes showed a sustained survival benefit in this patient population, who previously had a life expectancy of just six months.⁶

Additional Value Demonstrated in Approved Indication (January 2022): Clinical trial data on axicabtagene ciloleucel in late stage LBCL helped support a safety management update of prophylactic corticosteroids. This addition to the label helps physicians manage and potentially prevent side effects. Without continued research efforts to optimize CAR T-cell therapy, this improvement in patient management may not have been realized.⁷

Expanded Use for Earlier Treatment Line (April 2022): Approved to treat adult patients with LBCL after first-line treatment. As the most common type of non-Hodgkin lymphoma, more than 18,000 people are diagnosed with LBCL in the US each year. In a Phase III global clinical trial considered the first and largest trial of its kind, 2.5 times more patients receiving axicabtagene ciloleucel were alive at two years versus standard-of-care. Only with continued clinical research were the survival benefits of axicabtagene ciloleucel fully realized, leading to the approval of the first LBCL treatment to improve upon the standard of care in this patient population in nearly 30 years.⁸ Most importantly, this expanded use earlier in the treatment line also allowed these patients to achieve these benefits without having to endure several prior lines of treatment.

Additional Value Demonstrated in Approved Indication (March 2023): Long-term clinical data showed that axicabtagene ciloleucel significantly improved survival for patients with LBCL after first-line treatment, demonstrating the importance of ongoing research to reveal the full clinical value of cancer treatments.⁹

Axicabtagene ciloleucel | YESCARTA® (continued)

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