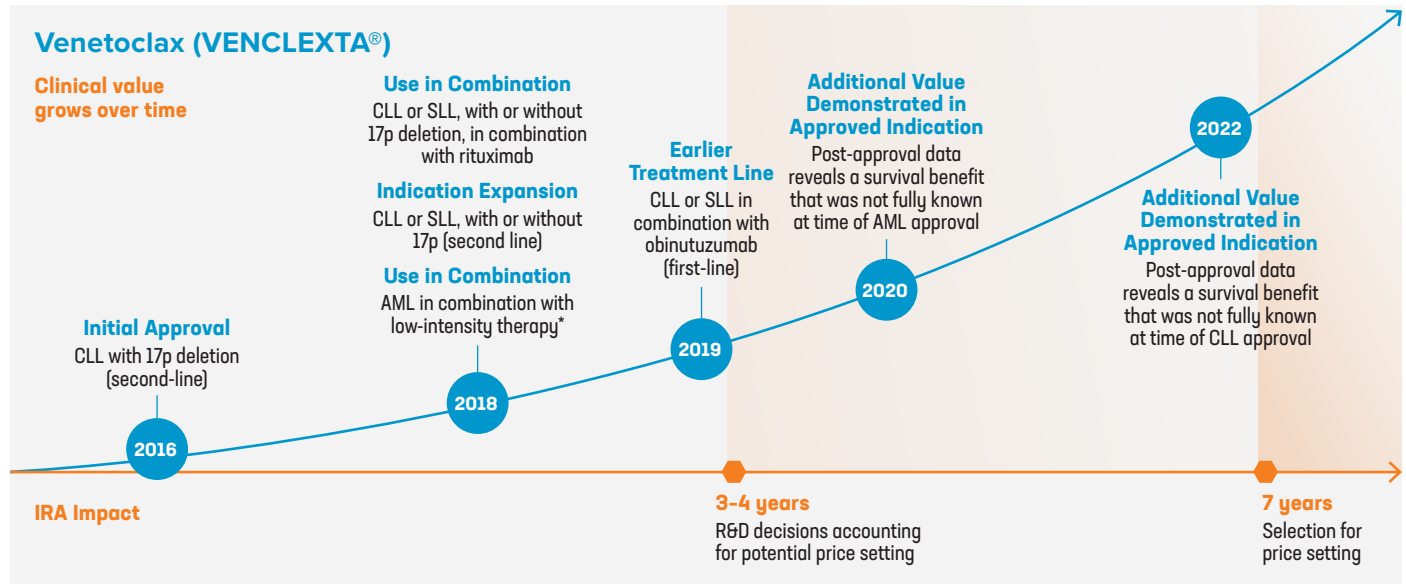


Venetoclax | VENCLEXTA®

In 2016, FDA granted venetoclax, a targeted oral therapy, accelerated approval to treat patients with hard-to-treat chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy.¹ CLL is the most common leukemia in adults, and the 17p deletion is a genetic abnormality associated with poor prognosis.^{1,2} Venetoclax is a B-cell lymphoma 2 (BCL-2) inhibitor, designed to selectively block a protein that is overexpressed in many cancers and helps restore the process in which cancer cells self-destruct.^{1,3} After initial approval for CLL 17p deletion, venetoclax was researched further, including in combination with other treatments and across numerous cancers, revealing additional benefits that were not recognized at the time of initial approval.



Use in Combination, Indication Expansion (June 2018):

Approved in combination with rituximab to treat CLL or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. In a clinical trial, the combination was shown to reduce the risk of disease progression or death by 81% compared to the prior standard of care in CLL. The FDA also granted venetoclax traditional approval for the initial indication as a single agent for hard-to-treat CLL and SLL, and expanded the indication to include patients with or without 17p deletion.⁴

Use in Combination, Additional Indication (November 2018):

Granted accelerated approval in combination with low-intensity therapy* to treat newly-diagnosed acute myeloid leukemia (AML) in adults at least 75 years of age or who cannot be treated with intensive chemotherapy. Many of these patients cannot tolerate the standard chemotherapy required to achieve optimal results in this aggressive form of leukemia.⁵

Use in Combination, Earlier Treatment Line (May 2019):

Approved in combination with obinutuzumab for the treatment of people with newly diagnosed CLL or SLL. This was the first chemotherapy-free fixed-duration treatment for patients with CLL allowing newly diagnosed patients to go off therapy after just one year. The 12-month treatment reduced the risk of disease progression or death by 67% compared to a prior standard of care.⁶

Additional Value Demonstrated in Approved Indication

(October 2020): Granted traditional approval in combination with low-intensity therapy* to treat newly diagnosed AML in adults at least 75 years of age or who cannot be treated with intensive chemotherapy. This approval was based on additional data, including demonstrated superior overall survival versus chemotherapy.⁷ At the time of initial approval for this indication, clinical data on survival outcomes was not available; only through the ongoing collection of evidence was this benefit demonstrated.

Additional Value Demonstrated in Approved Indication

(June 2022): New CLL clinical trial results with long-term follow-up show a majority of patients treated with one year of venetoclax in combination with obinutuzumab remain without relapse after four years off treatment. This ongoing research reinforced the clinical benefit of the venetoclax-based combination treatment that has helped transform the therapeutic landscape for patients with this disease.⁸

*Approved in combination with azacitidine, decitabine, or low-dose cytarabine

Venetoclax | VENCLEXTA® (continued)

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- 3 U.S. Food and Drug Administration. "FDA approves new drug for chronic lymphocytic leukemia in patients with a specific chromosomal abnormality." <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-chronic-lymphocytic-leukemia-patients-specific-chromosomal-abnormality>. Published April 11, 2016. Accessed June 12, 2023.
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- 8 AbbVie. "New Data Demonstrates AbbVie's VENCLYXTO®/VENCLEXTA® Combination Sustained Progression-Free Survival in Chronic Lymphocytic Leukemia Patients After Four Years Off Treatment." <https://news.abbvie.com/news/press-releases/new-data-demonstrates-abbvies-venclaxtovenclaxta-combination-sustained-progression-free-survival-in-chronic-lymphocytic-leukemia-patients-after-four-years-off-treatment.htm>. Published June 10, 2022. Accessed June 13, 2023.