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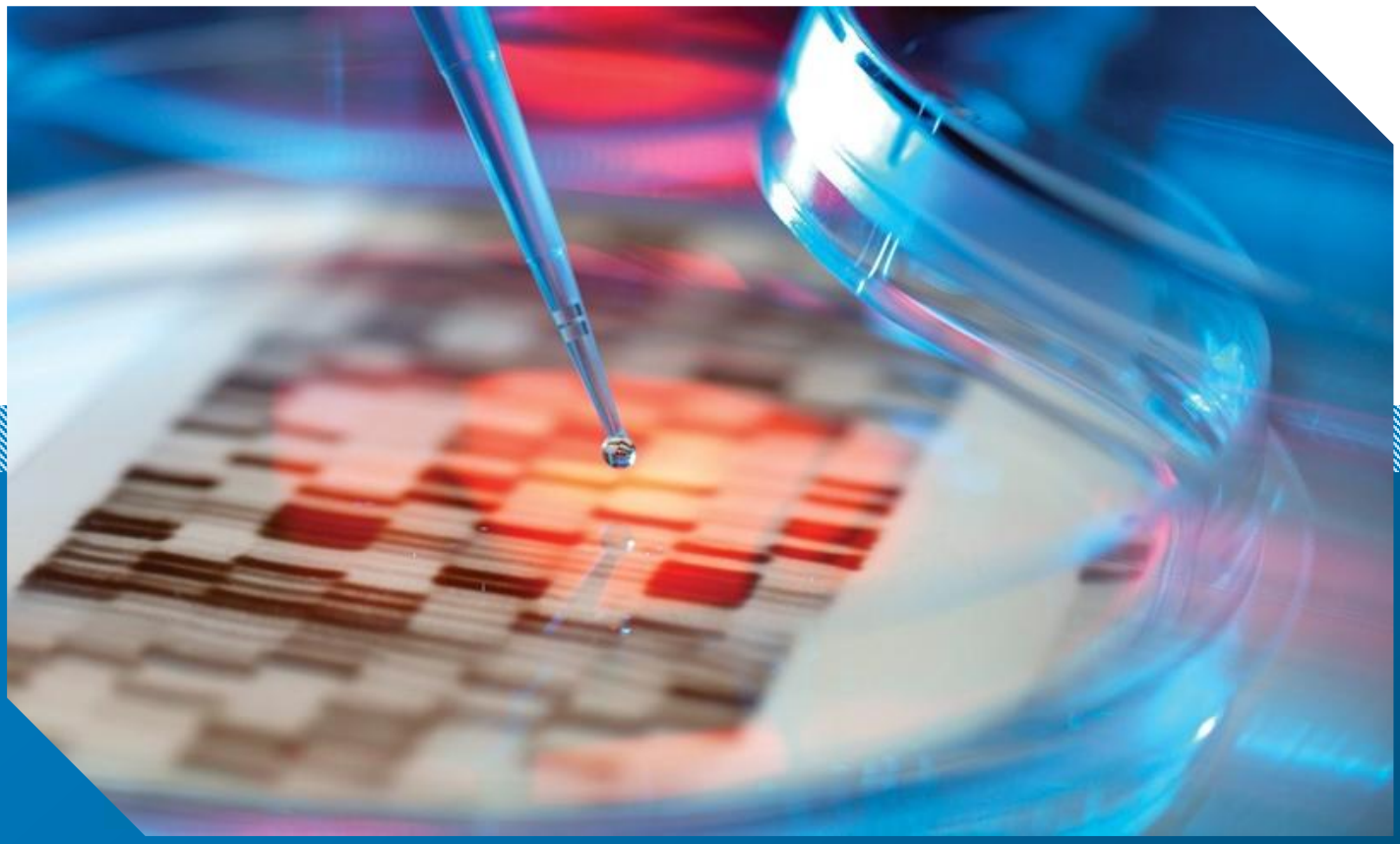

When Innovation Outpaces Access:

Closing the Gap in CLL Care

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Table of Contents

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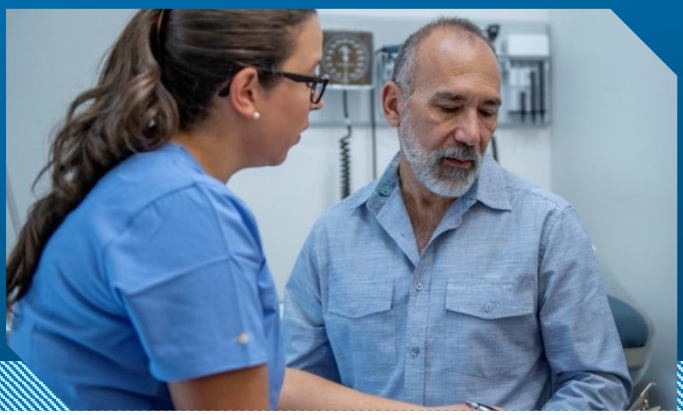
Executive Summary



Chronic lymphocytic leukemia (**CLL**) is the most common leukemia among older adults and, increasingly, a disease that can be managed through personalized, guideline-directed care. Over the past two decades, **targeted therapies** have transformed **CLL** care by increasing five-year survival rates to nearly 90% and improving quality of life. Today, healthcare providers can tailor treatment based on genetic risk factors, age, comorbidities, and treatment goals.

But while the innovation landscape continues to advance, many **CLL** patients still do not fully benefit from newer, targeted **CLL** therapies. Access to **biomarker testing** and guideline-recommended treatments remains inconsistent due to geographic and socioeconomic access barriers. Insurance barriers, including **utilization management** (**UM**), **prior authorization**, and **step therapy**, can delay or restrict access to treatments. Failure to evaluate all patient risk factors as part of treatment remains an issue. Additionally, patients can face financial hardship from medical and insurance bills.

Federal and state policymakers have taken steps to address these challenges, including expanding **biomarker testing** coverage, extending telehealth flexibilities, reforming **UM** policies, and limiting **copay accumulator programs**. The **CLL** community also has expanded education and financial programs to support patients and their families. However, gaps remain.

Drawing on policy evidence and stakeholder input, this report examines barriers to CLL care and recommends five actions to help ensure every patient receives the right treatment at the right time:

1. Expand access to comprehensive biomarker testing.

Ensure that all patients have timely access to clinically appropriate **biomarker testing**, regardless of insurance or location, and reduce administrative barriers that delay testing.

2. Provide education on the latest treatments.

Promote guideline-concordant care pathways with healthcare providers, increase access to **CLL** expertise, and provide patients with accessible information to support informed treatment decisions.

3. Improve care coordination for timely access to specialists.

Expand access to blood cancer expertise through telehealth, strengthen rural cancer infrastructure, and reduce geographic barriers that limit access to the latest care.

4. Reform UM policies.

Reform **step therapy** and **prior authorization** requirements that can delay access to guideline-preferred therapies and create significant barriers for patients and healthcare providers.

5. Increase transparency and promote responsible artificial intelligence (AI) in cancer care.

Advance responsible use of AI to help patients access trusted, evidence-based education and resources, require health plans to disclose when AI is used in coverage decisions, and require qualified clinician oversight of care denial determinations.

Recent innovative advances have created new opportunities for patients with **CLL** to live longer and healthier lives. Realizing the full benefits of these innovations will require addressing persistent barriers across the **CLL** treatment journey to ensure that more patients have access to personalized, evidence-based treatment.

1. Introduction

Chronic lymphocytic leukemia (**CLL**) is primarily a disease of older adults with a median diagnosis age of 70 to 72 years.[1] **CLL** patients can have multiple comorbidities, including cardiovascular disease, hypertension, renal impairment, and other chronic conditions, at the time of diagnosis that can complicate treatment selection and tolerability. **CLL** is not the same in every patient, with outcomes influenced by genetic risk factors such as IGHV status and TP53 mutations.[2] Many patients are initially managed under an "active surveillance" approach before requiring therapy, adding further complexity.[3] Together, these factors make individualized, guideline-directed treatment essential to improving patient outcomes, **overall survival** (**OS**), and quality of life.

For decades, **CLL** treatment relied on chemotherapy, which was associated with severe side effects and lower efficacy relative to today's targeted treatments.[4] In the 2010s, the **standard of care** evolved to early **immunotherapies** often used in combination with chemotherapy.[5] While these therapies improved survival, side effects (e.g., fatigue and immunosuppression) were profound and left patients vulnerable to infections.[6] There were few biomarker or risk-targeted options, especially if patients had comorbidities. Median **progression-free survival** (**PFS**) was four to five years and only two to three years for high-risk patients.[7]

New, more efficacious **CLL** treatments were introduced following the Food and Drug Administration (FDA) approval of oral treatments: the first Bruton's tyrosine kinase inhibitor (BTKi) in 2014 and the first B-cell lymphoma 2 inhibitor (BCL2i) in 2016. These **targeted therapies** attack cancer cells while minimizing damage to healthy cells and have drastically improved patient outcomes.[8] The first-generation **BTKi** extended **PFS** by 7.6 years compared with chemotherapy alone.[9] Second-generation **BTKis** built on these survival gains and improved selectivity and tolerability, increasing three-year **PFS** in **relapsed/refractory CLL** from 54% to 66% compared with first-generation **BTKis**.[10] Some next-generation treatments have demonstrated exceptional long-term survival benefits over chemotherapy, increasing 78-month PFS from 31% to 72% compared with **chemoimmunotherapy**

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[1] William G. Wierda et al., "NCCN Guidelines® Insights: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," *Journal of the National Comprehensive Cancer Network* 20 (2022): 622–634; American Cancer Society, "Key Statistics for Chronic Lymphocytic Leukemia (CLL)," last modified January 13, 2026, https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/about/key-statistics.html.

[2] Stephan Stilgenbauer, "Selection of Initial Therapy for Symptomatic or Advanced Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," *UpToDate*, April 23, 2026, 5–12.

[3] Stephan Stilgenbauer, "Overview of the Treatment of Chronic Lymphocytic Leukemia," *UpToDate*, June 3, 2025, https://www.uptodate.com/contents/overview-of-the-treatment-of-chronic-lymphocytic-leukemia#H5.

[4] Mayo Clinic, "Innovative Therapies Shape the Future of Chronic Lymphocytic Leukemia Treatment," December 9, 2025, https://www.mayoclinic.org/medical-professionals/cancer/news/innovative-therapies-shape-the-future-of-chronic-lymphocytic-leukemia-treatment/mac-20592646; Stefano Molica and David Allsup, "Chronic Lymphocytic Leukemia Care and Beyond: Navigating the Needs of Long-Term Survivors," *Cancers* 17, no. 119 (2025): 2.

[5] Mayo Clinic, "Innovative Therapies Shape the Future of Chronic Lymphocytic Leukemia Treatment"; Anna Lewandowska et al., "Quality of Life of Cancer Patients Treated with Chemotherapy," *International Journal of Environmental Research and Public Health* (2020): 1, Table 2; Jeffrey Bryan and Gautam Borthakur, "Role of Rituximab in First-Line Treatment of Chronic Lymphocytic Leukemia," *Therapeutics and Clinical Risk Management* 7, no. 1 (2010); Eugen Tausch et al., "Advances in Treating Chronic Lymphocytic Leukemia," *F1000 Prime Reports* 6, no. 65 (2014): 1; Jennifer A. Woyach and Amy J. Johnson, "Targeted Therapies in CLL: Mechanisms of Resistance and Strategies for Management," *Blood* 126, no. 4 (2015): 471; Michele Ghielmini et al., "Panel Members of the 1st ESMO Consensus Conference on Malignant Lymphoma. ESMO Guidelines Consensus Conference on Malignant Lymphoma 2011 Part 1: Diffuse Large B-Cell Lymphoma (DLBCL), Follicular Lymphoma (FL) and Chronic Lymphocytic Leukemia (CLL)," *Annals of Oncology* 24, no. 3 (2013): 561–576.

[6] Stefano Molica, "Progress in the Treatment of Chronic Lymphocytic Leukemia: Results of the German CLL8 Trial," *Expert Review of Anticancer Therapy* 11, no. 9 (2011): 1333–1340; ecancer, "New Combination Treatment to Show Improved Overall Survival in Patients with Chronic Lymphocytic Leukaemia," October 1, 2010, https://ecancer.org/en/news/1250-new-combination-treatment-to-show-improved-overall-survival-in-patients-with-chronic-lymphocytic-leukaemia; Lisa Astor, "The Battle for the Front Line in CLL Moves Away from Chemoimmunotherapy," *Targeted Therapies in Oncology* 13, no. 9 (2020).

[7] Sonya Collins, "10 Years in CLL: Top Advances from 2012–2022," *Targeted Therapies in Oncology* 6 (2022).

[8] Mayo Clinic, "Innovative Therapies Shape the Future of Chronic Lymphocytic Leukemia Treatment"; Matthew S. Davids et al., "First-Line Treatment for CLL in the Era of Targeted Therapy," *Blood Cancer Journal* 16, no. 19 (2026): 9.

[9] CLL Society, "What's New in CLL Therapies at ASH 2024," January 24, 2025, https://CLLsociety.org/2025/01/whats-new-in-CLL-therapies-at-ash-2024/; Jan A. Burger et al., "Final Analysis of the RESONATE-2 Study: Up to 10 Years of Follow-Up of First-Line Ibrutinib Treatment for CLL/SLL," *Blood* 146, no. 18 (2025): 2168–2176.

[10] Constantine Tam and Philip A. Thompson, "BTK Inhibitors in CLL: Second-Generation Drugs and Beyond," *Blood Advances* 8, no. 9 (2024): 2300–2309; Brian Koffman, "Zanubrutinib Extends Remission Time vs. Ibrutinib in CLL / SLL," CLL Society, February 29, 2024, https://CLLsociety.org/2024/02/zanubrutinib-extends-remission-time-vs-ibrutinib-in-CLL-sll/.

alone, underscoring the importance of durable long-term data in treatment decision-making.[11] **Fixed-duration** treatments may offer the promise of treatment-free intervals for some patients, depending on the specific characteristics of their disease.[12]

These advances now allow healthcare providers to tailor treatment based on a patient's unique risk factors and treatment goals, including:[13] genetic risk, comorbidities, age factors, concomitant medications and patient preferences.[14] However, not all **CLL** patients have access to the treatment options that may give them the greatest opportunity for survival and the best quality of life.[15] **Clinical guidelines** must continually evolve to reflect the latest data and best clinical practice, yet they are not always updated or consistently followed, with some patients still initiated on chemotherapy instead of targeted oral therapies.[16] Insurance coverage may lag behind **clinical guidelines** with **utilization management (UM)** policies like **step therapy** requiring patients to fail on less efficacious therapies before accessing newer therapies. [17]

In this report, we synthesize perspectives from the academic and policy literature and from the broader blood cancer community through interviews to assess the gaps between innovation and access in **CLL** care. Only when the impact of access barriers is understood and reduced can patients fully benefit from innovative medicines. As **CLL** is a common type of **B-cell malignancy,** identifying treatment gaps for this disease may also inform broader needs.[18] **Box 1** describes the key definitions used in this report.

[11] CLL Society, "Long-Term Follow-Up of First-Line Zanubrutinib for CLL," May 5, 2025, https://cllsociety.org/2025/05/long-term-follow-up-of-first-line-zanubrutinib-for-cll/; Results presented by BeOne Medicines at American Society of Clinical Oncology 2026 Annual Meeting.

[12] *AbbVie, Venclexta (venetoclax), prescribing information, revised February 2026, https://www.rxabbvie.com/pdf/venclexta.pdf. Fixed duration treatments are administered for a definite period of time, and patients are monitored for signs of worsening disease after completing a fixed duration treatment course (see Sara Youngblood Gregory, "Chronic Lymphocytic Leukemia (CLL): Understanding the Difference Between Fixed Duration and Continuous Treatment," Mayo Clinic, March 28, 2025, https://mcpress.mayoclinic.org/managing-CLL/chronic-lymphocytic-leukemia-CLL-understanding-the-difference-between-fixed-duration-and-continuous-treatment/).*

[13] Stilgenbauer, "Selection of Initial Therapy for Symptomatic or Advanced Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma"; Wierda et al., "NCCN Guidelines® Insights"; Tycho Baumann et al., "Chronic Lymphocytic Leukemia in the Elderly: Clinico-Biological Features, Outcomes, and Proposal of a Prognostic Model," *Haematologica* 99, no. 10 (2014): 1599–1604.

[14] Arliene Ravelo et al., "Patient Preferences for Chronic Lymphocytic Leukemia Treatments: A Discrete-Choice Experiment," *Future Oncology* 20, no. 28 (2024): 2063.

[15] CLL Society, "Access," accessed May 18, 2026, https://CLLsociety.org/access-CLL-societys-policy-institute/; HealthTree Foundation, "What's Keeping Patients from the Best First-Line CLL Treatments?," June 16, 2025, https://healthtree.org/CLL/community/articles/eha25-disparities-recommended-first-CLL-treatments.

[16] Julie Ehlers, "Many CLL Patients Are Not Receiving Recommended First-Line Treatment," Hematology Advisor, December 31, 2023, https://www.hematologyadvisor.com/reports/chronic-leukemia-CLL-patients-not-receiving-recommended-first-line-treatment/; Jacob D. Soumerai et al., "Consensus Recommendations from the 2024 Lymphoma Research Foundation Workshop on Treatment Selection and Sequencing in CLL or SLL," *Blood Advances* 9, no. 5 (2025).

[17] See, for example, UnitedHealthcare, "UnitedHealthcare Pharmacy Clinical Pharmacy Programs," July 1, 2026, https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/step-therapy/Step-Therapy-Brukinsa.pdf.

[18] Nitin Jain et al., "Chronic Lymphocytic Leukaemia," *Lancet* 404, no. 10453 (2024): 694–706.

2. Innovation and Treatment Landscape

Prior to 2014, **CLL** patients had few treatment options beyond chemotherapy and **immunotherapy**.[19] The **CLL** treatment paradigm then radically shifted with the approval of the first **BTKi** for **CLL** in 2014 and the first **BCL2i** for **CLL** in 2016.[20]

CLL is often detected through routine blood tests and treatment is initiated after symptoms develop. Innovation in **CLL** enables healthcare providers to tailor treatment decisions based on a patient's unique risk factors and treatment goals, including the following:[21]

- Genetic risk (e.g., IGHV mutations, Del(17p), and TP53) assessed through **biomarker testing**
- Comorbidities (e.g., cardiovascular disorders, hypertension, bleeding risk, liver function, and kidney impairment)
- Age factors (median age at **CLL** diagnosis is 72; patients over 70 often present with more advanced disease)
- Concomitant medications (e.g., warfarin, nephrotoxic drugs, and CYP3A inhibitors)
- Patient preferences (e.g., type of treatment [oral vs. intravenous], survival outlook, side effects) and treatment goals

[19] Danielle F. James and Thomas J. Kipps, "Rituximab in Chronic Lymphocytic Leukemia," *Advances in Therapy* 28 (2011): 534–554; Tausch et al., "Advances in Treating Chronic Lymphocytic Leukemia."

[20] Mayo Clinic, "Innovative Therapies Shape the Future of Chronic Lymphocytic Leukemia Treatment"; CLL Society, "New Options for Treatment-Resistant CLL," December 17, 2024, https://CLLsociety.org/2024/12/new-options-for-treatment-resistant-CLL/.

[21] Stilgenbauer, "Selection of Initial Therapy for Symptomatic or Advanced Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma"; Wierda et al., "NCCN Guidelines® Insights"; Baumann et al., "Chronic Lymphocytic Leukemia in the Elderly"; Ravelo et al., "Patient Preferences for Chronic Lymphocytic Leukemia Treatments."

Updated treatment pathways now recommend targeted therapies over chemotherapy. The **CLL** treatment pathway, when adherent to current **clinical guidelines**, may look as follows:

1. Active Surveillance

CLL is often found after an abnormal result on a routine blood test.[22] Since **CLL** progresses slowly,[23] many patients are managed under "**active surveillance**" until symptoms develop.[24]

2. Biomarker Testing

Before starting a new treatment, **CLL** patients should have three biomarker tests—fluorescence in situ hybridization ("FISH"), tumor protein 53 ("TP53"), and immunoglobulin variable heavy chain ("IGHV")—which can predict how a patient may respond to treatment.[25]

3. First-line Treatment

In accordance with current National Comprehensive Cancer Network ("NCCN") guidelines, the two most common **CLL** treatment strategies are **continuous treatment** using a **BTKi** or **fixed-duration treatment** using a **BCL2i** combined with an anti-CD20 monoclonal antibody and/or a **BTKi**.[26] Each treatment choice comes with unique benefits and risks, highlighting the need for personalized treatment. For example, treatment using a **BTKi** is highly effective but may result in cardiac toxicities, such as atrial fibrillation and arrhythmias, and bleeding risk.[27] Likewise, treatment using a **BCL2i** is also highly effective and may allow for time off therapy but requires frequent intravenous infusions and monitoring.[28]

4. Second-line and Later Treatment

As with **first-line treatment**, later lines of treatment need to be individualized based on prior therapy, patient and tumor characteristics, patient preference, and treatment goals. Later lines of therapy may include: a covalent or noncovalent **BTKi**, a **BCL2i**, a phosphoinositide 3-kinase (PI3K) inhibitor, an anti-CD20 monoclonal antibody, and/or CAR-T cell therapy.[29] Guidelines may change to reflect treatments in development, such as BTK degraders, next-generation **BCL2is**, and bispecific monoclonal antibodies that could help patients with **relapsed/refractory CLL**.[30]

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[22] American Cancer Society, "Can Chronic Lymphocytic Leukemia (CLL) Be Found Early?," March 20, 2025, https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/detection-diagnosis-staging/detection.html.

[23] American Cancer Society, "Treating Chronic Lymphocytic Leukemia (CLL)," accessed June 2026, https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/treating.html.

[24] American Cancer Society, "Treating Chronic Lymphocytic Leukemia (CLL)"; Stilgenbauer, "Overview of the Treatment of Chronic Lymphocytic Leukemia."

[25] Ann Liu, "First-Line Therapies and Biomarker Testing in Patients with CLL," CLL Society, April 20, 2026, https://CLLsociety.org/2026/04/first-line-therapies-and-biomarker-testing-in-patients-with-CLL/; Scott Huntington, "Navigating Dramatic Changes and Using Novel Therapies in CLL Management," Cancer Network, October 9, 2025, https://www.cancernetwork.com/view/navigating-dramatic-changes-and-using-novel-therapies-in-CLL-management.

[26] Cure Today, "Moving Beyond Chemotherapy: How Biomarker Testing is Changing Cancer Care," February 27, 2025, https://www.curetoday.com/view/moving-beyond-chemotherapy-how-biomarker-testing-is-changing-cancer-care; Brian T. Hill, "Continuous Versus Fixed-Duration Treatment for Frontline Chronic Lymphocytic Leukemia," *The Hematologist* 23, no. 1 (2026).

[27] Jason P. Ng et al., "Cardiovascular Adverse Effects of Novel Bruton Tyrosine Kinase Inhibitors: What All Cardiologists Should Know," American College of Cardiology, August 16, 2023, https://www.acc.org/latest-in-cardiology/articles/2023/08/15/16/45/cv-adverse-effects-of-novel-bruton-tyrosine-kinase-inhibitors.

[28] Hill, "Continuous Versus Fixed-Duration Treatment for Frontline Chronic Lymphocytic Leukemia."

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[30] Andrea Eleazar, "The Next Wave of **CLL** Therapies to Target Resistance," *Targeted Oncology*, April 4, 2026, https://www.targetedonc.com/view/the-next-wave-of-**CLL**-therapies-to-target-resistance; Kyle Doherty, "Lisaftoclax Wins Chinese Approval in Pretreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," *OncLive*, July 11, 2025, https://www.onclive.com/view/lisaftoclax-wins-chinese-approval-in-pretreated-chronic-lymphocytic-leukemia-small-lymphocytic-lymphoma.

Targeted therapies, such as **BTKis** and **BCL2is**, have enabled **CLL** patients to live longer.[31] In the mid-2000s, the median **PFS** for **CLL** patients on chemotherapy was less than one year. After the approval of **chemoimmunotherapies**, median **PFS** increased to four to five years and two to three years for high-risk patients.[32] Data on **BTKis** suggest that the median **PFS** may now be eight years.[33]

Fixed-duration CLL treatments may enable time off therapy or potentially fewer office visits later on. **Fixed-duration treatments** offer the promise of treatment-free intervals for some patients, depending on specific characteristics of their disease. Emerging fixed-duration treatments have the potential to shift the treatment paradigm but only if fixed-duration therapies elicit a more durable response, demonstrate sustained PFS, carry a reduced infection risk compared with continuous BTKi therapy, and offer more convenient administration. Likewise, oral therapies that can be taken at home reduce the number of doctor visits required.[34] As a result of these gains in survival and quality of life, **targeted therapies** are preferred over **chemoimmunotherapy** in most **CLL** patients. **Chemoimmunotherapy** is generally only considered when access to **targeted therapies** is limited as it is not appropriate for most **CLL** patients.[35]

But these innovations and treatments are only valuable if patients can access them. Access barriers created by insurer **UM** policies, such as **step edits** and **prior authorization**, and inconsistent adherence to **clinical guidelines** may both prevent patients from benefiting from recent innovation in **CLL**. The next few sections of this report will describe the evidence of key gaps in accessing the latest **CLL** treatments and identify solutions and policies that can address these access gaps.

[31] CLL Society, "What's New in CLL Therapies at ASH 2024."

[32] Collins, "10 Years in CLL."

[33] Collins, "10 Years in CLL."

[34] Othman Al-Sawaf et al., "Fixed-Duration Versus Continuous Treatment for Chronic Lymphocytic Leukemia," *New England Journal of Medicine* 394, no. 11 (2025): 1085; Blood Cancer United, "People with CLL Are Living Longer Than Ever Before, and Cures Are on the Horizon," January 30, 2025, https://bloodcancerunited.org/resources/blog/people-CLL-are-living-longer-ever-and-cures-are-horizon.

[35] Stilgenbauer, "Selection of Initial Therapy for Symptomatic or Advanced Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," p. 30.

Evolution of CLL Treatment (1950-2026)

1950-1990

Treatment: Chemotherapy-based[1]
Treatment did not significantly extend overall survival (OS)[2]

1990-2000

Treatment: Combinations of **chemotherapy** drugs
Improved PFS compared to chemo alone but with high toxicity and immunosuppression[3]

2000-2012

Treatment: Immunotherapy used in combination with chemotherapy
Improved PFS by 23.9 months compared to chemo alone, but with high toxicity
Efficacy limited by comorbidities, age, patient health, and certain mutations[4]

2013

Treatment: Next-generation anti-CD20 antibody approved in combination with chemotherapy
Improved PFS by 8.7 months compared to chemo alone[4]

2014

Treatment: First BTKi and **PI3K inhibitor** approved
First-generation BTKis improved PFS by 7.6 years compared to chemo alone[5]

2016

Treatment: First BCL2i (first fixed-duration treatment) approved
Improved PFS by 39.8 months for untreated CLL compared to chemo alone and by 37.7 months for relapsed CLL compared to chemoimmunotherapy[6,7]

2019-2023

Treatment: Multiple **second-generation BTKis** approved
Improved side effect profiles
Overall response rate increased to 85.6% compared to first-generation BTKis at 75.4%[8]

2024

First CAR-T therapy approved for relapsed/refractory CLL
Improved OS by 18.8 months compared to standard of care[9]

2026

Treatment: First all-oral, fixed duration **BCL2i and BTKi combination** approved without major comorbidities
Reduced risk of disease progression by 35% compared to chemoimmunotherapy[10]

Future of CLL Treatment

BTK degraders, second-generation BCL2is, and **bispecific monoclonal antibodies** are being studied in CLL[11,12, 13]

Advances in CLL treatment have created new opportunities for effective, personalized care, but only if care is guided by patient risk factors, preferences, and treatment goals.

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3. Hallek, Michael et al., "Immunochemotherapy with Fludarabine (F), Cyclophosphamide (C), and Rituximab (R) (FCR) Versus Fludarabine and Cyclophosphamide (FC) Improves Response Rates and Progression-Free Survival (PFS) of Previously Untreated Patients (pts) with Advanced Chronic Lymphocytic Leukemia (CLL)," Blood, 112 (11), 2008, p. 325.
4. Scheffold A. and Stilgenbauer S. "Revolution of Chronic Lymphocytic Leukemia Therapy: the Chemo-Free Treatment Paradigm," Curr Oncol Rep., 2020, 22(2), p. 16.
5. Burger, Jan A. et al., "Final analysis of the RESONATE-2 study: up to 10 years of follow-up of first-line ibrutinib treatment for CLL/SLL," Blood, 146(18), 2025, pp. 2168-2176.
6. Al-Sawaf et al., "Venetoclax-obinutuzumab for previously untreated chronic lymphocytic leukemia: 6-year results of the randomized phase 3 CLL14 study," Blood, 144(18), 2024, pp. 1924-1935.
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9. William G. Wierda et al., "Comparison of outcomes for patients (pts) with R/R chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) previously treated with Bruton tyrosine kinase inhibitor (BTKi) and venetoclax from the TRANSCEND CLL 004 study versus a matched cohort of real-world (RW) pts," J Clin Oncol, 43, 2025, p.7039.
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11. Doyle, Chase, "BTK Degraders and CELMoDs: Novel Mechanisms Overcoming Resistance in Hematologic Malignancies," The ASCO Post, August 25, 2024, https://ascopost.com/issues/august-25-2024/btk-degraders-and-celmods-novel-mechanisms-overcoming-resistance-in-hematologic-malignancies/.
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3. Key Access Gaps in CLL Treatment

CLL patients can face significant challenges in getting the right treatment at the right time throughout their care journey.

Biomarker Testing

Biomarker testing is not consistently done for **CLL** patients, often resulting in suboptimal treatment selection.[36] Many patients are not tested to understand their genetic risk factors even though more than one-half of all patients are high risk and may benefit more from certain types of treatments (e.g., **continuous therapy**) than others.[37] Biomarker test results, when considered alongside a patient's age and comorbidities, may indicate an even higher level of risk.[38] In addition, the gaps in access to **biomarker testing** are significant. For example, a study of Medicare patients with **CLL** and small lymphocytic lymphoma (SLL) found that less than 15% of patients were tested for the three most common biomarkers.[39]

Accessing Clinically Recommended Treatments

Clinical guidelines must continually evolve to reflect the latest data and best clinical practice, yet they are not always updated or consistently followed, with some patients still initiated on chemotherapy instead of targeted oral therapies.[40] For example, a study found that minority **CLL** patients were less likely to receive preferred treatments and more likely to receive older treatments, such as **chemoimmunotherapy**, compared with white patients.[41] The gap between guidelines and clinical practice[42] could be due to site of service inequities where large hospitals have greater access and familiarity with the latest treatment options compared with smaller healthcare providers or rural treatment centers.[43] As a result, access can depend heavily on geography with patients in rural or underserved areas often lacking access to **CLL** specialists[44] and having to travel farther to receive

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[36] Tariqa Ackbarali et al., "3662 Systems-Based Care Improvements to Optimize BTK Inhibitors in Chronic Lymphocytic Leukemia Vary in the Community Setting," American Society of Hematology, December 8, 2024; Association of Cancer Care Centers, "Regional Disparities in Chronic Lymphocytic Leukemia: A GPS for Cancer Care," June 22, 2023, https://www.accc-cancer.org/view/regional-disparities-in-chronic-lymphocytic-leukemia-a-gps-for-cancer-care.

[37] Liu, "First-Line Therapies and Biomarker Testing in Patients with CLL"; Imbruvica, "Genetic Testing," accessed June 2026, https://www.imbruvica.com/CLL/what-is-CLL/genetic-testing; CLL Society, "Zanubrutinib Shows Strong Six-Year Efficacy in Frontline CLL," May 7, 2026, https://CLLsociety.org/2026/05/zanubrutinib-shows-strong-six-year-efficacy-in-frontline-CLL/; Andrea Park, "New BeiGene Campaign Encourages Biomarker Testing Before Treatment for CLL Patients," Fierce Pharma, December 4, 2024, https://www.fiercepharma.com/marketing/new-beigene-campaign-encourages-biomarker-testing-treatment-CLL-patients.

[38] Eugen Tausch et al., "Risk-Stratification in Frontline CLL Therapy: Standard of Care," *Hematology American Society of Hematology Education Program* 2024, no. 1 (2024): 457–466; Stefano Molica et al., "Chronic Lymphocytic Leukemia International Prognostic Index: A Systematic Review and Meta-Analysis," *Blood* 131, no. 3 (2018): 365–368.

[39] Liu, "First-Line Therapies and Biomarker Testing in Patients with CLL."

[40] Ehlers, "Many CLL Patients Are Not Receiving Recommended First-Line Treatment"; Soumerai et al., "Consensus Recommendations from the 2024 Lymphoma Research Foundation Workshop on Treatment Selection and Sequencing in CLL or SLL."

[41] CLL Society, "Prescription of Novel Therapies for CLL Varies by Race," March 19, 2026, https://CLLsociety.org/2026/03/prescription-of-novel-therapies-for-CLL-varies-by-race/.

[42] Soumerai et al., "Consensus Recommendations from the 2024 Lymphoma Research Foundation Workshop on Treatment Selection and Sequencing in CLL or SLL."

[43] National Comprehensive Cancer Network, "Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," December 22, 2025, CSLL-1, CSLL-4, CSLL-5, CSLL-D; Soumerai et al., "Consensus Recommendations from the 2024 Lymphoma Research Foundation Workshop on Treatment Selection and Sequencing in CLL or SLL," Figure 2; Mayo Clinic Laboratories, "Complex Testing Offers Answers and Guidance About a Lifelong Illness," accessed May 18, 2026, https://news.mayocliniclabs.com/2021/06/14/complex-testing-offers-answers-and-guidance-about-a-lifelong-illness/.

[44] Association of Cancer Care Centers, "Regional Disparities in Chronic Lymphocytic Leukemia: A GPS for Cancer Care," June 22, 2023, https://www.accc-cancer.org/view/regional-disparities-in-chronic-lymphocytic-leukemia-a-gps-for-cancer-care.

treatment.[45] Due to the older median age of **CLL** patients, transportation support costs can be a barrier to care.[46] Newer, oral **CLL** treatments can significantly alleviate this burden on patients by enabling patients to take their treatments at home.[47]

Insurance Barriers and UM

Even when healthcare providers prescribe guideline-preferred therapies, insurance coverage policies, determined by large health insurers and **pharmacy benefit managers** (**PBMs**), particularly in the highly concentrated Medicare market, can create additional barriers to treatment.[48] Insurance companies often require patients to go through **prior authorization** and **step therapy,** where patients are required to demonstrate intolerance, have a contraindication, or otherwise be an inappropriate candidate for older, potentially less efficacious treatments first before accessing newer treatments recommended by NCCN guidelines.[49] For example, one large health insurer requires patients who have been prescribed a second-generation **BTKi** to have a contraindication, history of intolerance, inappropriate clinical status, or comorbidities for a first-generation **BTKi** or an older second-generation **BTKi**, even though second-generation **BTKis** can have superior selectivity and reduced cardiovascular side effects compared with first-generation **BTKis** and are preferred in NCCN guidelines.[50] Depending on a patient's treatment history and clinical circumstances, **step therapy** requirements may mean that the patient has to cycle through multiple therapies before being able to access a healthcare provider's preferred treatment.[51]

UM policies often cause significant delays and administrative burdens.[52] A national survey of independent community oncology practices found that, in general, **UM** policies delay oncology treatment, interfere with doctors' care decisions, and increase administrative and financial burdens on oncology practices. A survey of community oncologists found that 91% think that insurance companies or **PBM** policies do not align with clinical recommendations and 97% said that insurance policies interfere with patients' access to the treatments recommended by their doctors.[53]

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[45] OncLive, "Dr. Burke on CLL Treatment Challenges in Community vs Academic Health Care Settings," May 30, 2025, https://www.onclive.com/view/dr-burke-on-CLL-treatment-challenges-in-community-vs-academic-health-care-settings.

[46] Association of Cancer Care Centers, "Regional Disparities in Chronic Lymphocytic Leukemia: A GPS for Cancer Care."

[47] Sydney George et al., "EE410 Real-World Treatment Patterns, Clinical Outcomes, and Healthcare Resource Utilization of Patients with Chronic Lymphocytic Leukemia Treated with Fixed Duration Therapy in a First-Line Setting in Alberta, Canada," *Value in Health* 28, no. 6 (2025): S137–S138.

[48] Dima Qato et al., "Pharmacy Benefit Manager Market Concentration for Prescriptions Filled at US Retail Pharmacies," *JAMA* 332, no. 15 (2024): 1298–1299.

[49] National Organization for Rare Disorders, "Step Therapy (Fail First)," accessed June 2026, https://rarediseases.org/policy-issues/step-therapy-fail-first/; UnitedHealthcare, "UnitedHealthcare Pharmacy Clinical Pharmacy Programs Brukinsa (Zanubrutinib)."

[50] UnitedHealthcare, "UnitedHealthcare Pharmacy Clinical Pharmacy Programs Brukinsa (Zanubrutinib)"; Tam and Thompson, "BTK Inhibitors in CLL"; Mazyar Shadman, "Indirect Comparison of the Efficacy of Zanubrutinib vs Ibrutinib and Acalabrutinib in Treatment-Naive Chronic Lymphocytic Leukemia: 6-Year Follow-Up," OncLive, June 29, 2026, https://www.onclive.com/view/indirect-comparison-of-the-efficacy-of-zanubrutinib-vs-ibrutinib-and-acalabrutinib-in-treatment-naive-chronic-lymphocytic-leukemia-6-year-follow-up; National Comprehensive Cancer Network, "NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," December 22, 2025, https://www.nccn.org/professionals/physician_gls/pdf/CLL.pdf.

[51] American Cancer Society Cancer Action Network, "Step Therapy in Medicare Part D Oncology Drugs," May 21, 2024, https://www.fightcancer.org/sites/default/files/acs_can_part_d_formulary_analysis_final.pdf.

[52] Becker's Hospital Review, "When 'Fail First' Fails Patients: Why Step Therapy Exception Requests Matter More Than Ever," April 13, 2026, https://www.beckershospitalreview.com/finance/revenue-cycle-management/when-fail-first-fails-patients-why-step-therapy-exception-requests-matter-more-than-ever/.

[53] Community Oncology Alliance, "National Survey Shows Insurer Utilization Management Interferes with Cancer Treatment Decisions," February 19, 2026, https://mycoa.communityoncology.org/press-releases/news-updates/2026-utilization-management-survey.

[54] Sucharu Prakash, "Stop Insurers from Denying Cancer Care," *Washington Times*, March 23, 2026, https://www.washingtontimes.com/news/2026/mar/23/stop-insurers-denying-cancer-care/.

Provider Perspective: "Insurers and their pharmacy benefit managers wield extraordinary power to delay, deny, and dictate care. **Step therapy** protocols force physicians to prescribe treatments they know are inferior, waiting for patients to fail before insurers will approve what should have been prescribed initially. **Prior authorizations** that should take hours routinely take four to six weeks."[54]

Patient Affordability Barriers

CLL patients often face high insurance **copays** or **coinsurance** for treatment and can face significant travel costs to receive treatment.[55] Patients also face the financial strain of lost income due to the inability to work.[56] Additionally, like other oncology patients, **CLL** patients tend to experience financial hardship that can lead to debt, bankruptcy, and property foreclosures due to medical bills, with 42% of oncology patients depleting their life savings within two years of diagnosis.[57]

4. Current Policy Landscape for CLL Access and Remaining Challenges

At both the federal and state levels, policymakers have sought to improve cancer treatment access and reduce the financial hardship of a cancer diagnosis, but there is evidence that significant gaps persist in accessing and being able to afford the right treatment.

Insurance Coverage for Biomarker Testing

Federal and state policymakers have taken steps to expand coverage for **biomarker testing**, recognizing its importance in guiding treatment selection for oncology patients. The Centers for Medicare & Medicaid Services' (CMS) local coverage determinations provide coverage for certain biomarker tests considered necessary for **CLL** patients.[58] At the state level, as of July 2026, 19 states require **biomarker testing** coverage for all state-regulated plans, five states require **biomarker testing** coverage for certain types of plans (e.g., state-regulated private plans, Medicaid plans, or state employee health plans), and nine states introduced legislation on **biomarker testing** coverage requirements in 2026.[59]

Despite these policy advances, coverage remains fragmented. For example, while CMS issued national and local coverage determinations that increased access to **biomarker testing** for Medicare

[55] Rena M. Conti et al., "Observational Survey of Financial Difficulties Among Patients with Multiple Myeloma and Chronic Lymphocytic Leukaemia Treated at US Community Oncology Clinics (Alliance A231602CD)," *BMJ Open* 15 (2025): 2, 13.

[56] Conti et al., "Observational Survey of Financial Difficulties Among Patients with Multiple Myeloma and Chronic Lymphocytic Leukemia Treated at US Community Oncology Clinics."

[57] National Cancer Institute, "Financial Toxicity (Financial Distress) and Cancer Treatment (PDQ®)–Patient Version," updated June 6, 2024, https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-pdq; Advisory Board, "42% of Cancer Patients Spent Entire Life Savings in 2 Years After Diagnosis, Study Finds," November 1, 2018, https://www.advisory.com/daily-briefing/2018/11/01/financial-toxicity.

[58] CMS, "Biomarkers for Oncology," April 24, 2025, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35396; CMS, "Billing and Coding: Biomarkers for Oncology," April 24, 2025, https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52986l; CMS, "Billing and Coding: Molecular Pathology Procedures," July 15, 2026, https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56199. According to CMS, the "reasonable and necessary" biomarkers for CLL are BIRC3, BTK, PLCG2, NOTCH1, and SF3B1. TP53 is considered "reasonable and necessary" for other diseases (e.g., acute myeloid leukemia and myeloproliferative diseases) but not CLL. According to a local coverage determination from CMS revised in April 2025, covered biomarkers for CLL include IGH, TP53, BTK, PLCG2, BIRC3, NOTCH1, and SF3B1. Effective July 2026, CMS considers IGH testing and TP53 testing to be medically necessary for CLL (of B-cell type) that has not achieved remission, is in remission, or is in relapse, and BTK testing and PLCG2 testing are to be covered if documentation supports medical necessity.

[59] American Cancer Society Cancer Action Network, "Access to Biomarker Testing," updated September 8, 2026, https://www.fightcancer.org/what-we-do/access-biomarker-testing.

beneficiaries, other plan types are not bound by the same requirements.[60] Likewise, many state **biomarker testing** laws only apply to state-regulated plans, leaving significant gaps.[61] Even when **biomarker testing** is covered, patients may face **prior authorization** and high out-of-pocket costs.[62]

Geographic and Socioeconomic Barriers

Federal policies have sought to address geographic and socioeconomic barriers to treatment access, including increased telehealth flexibilities and the Rural Health Transformation Program. Medicare telehealth flexibilities, which support access to oncology care in rural areas, have been extended to allow Medicare patients to receive telehealth services through December 31, 2027.[63] As a reaction to the hundreds of rural hospitals that have closed or have reduced oncology services due to financial problems over the last decade, the Rural Health Transformation Program has provided funding to approved states through 2030 to prevent closures and increase oncology care in rural areas.[64] This includes remote monitoring, teleconsultations for follow-up care, and sharing of information and education.[65] Further support for telehealth and rural health policies could help enable greater access to **CLL** specialists and cancer care teams as **CLL** is often managed in community settings with limited access to **CLL** specialists and 20% of **CLL** patients report not being treated by a cancer care team.[66]

UM and Patient Affordability Barriers

Federal and state policymakers have tried to reform **UM** policies, such as **prior authorization** and **step therapy**.

Within Medicare Advantage (MA), plans are required to comply with national coverage determinations, local coverage determinations, and general coverage conditions included in traditional Medicare.[67] CMS requires that coordinated care plan **prior authorization** policies only be used to confirm diagnoses or ensure medical necessity and that approval of a **prior authorization** request be valid for as long as medically reasonable and necessary.[68] States have similarly adopted protections. For example, in New Jersey, when a **step therapy** exception is granted by a managed care organization, coverage must be authorized for at least 180 days or the duration of therapy.[69]

However, changes in the structure of Medicare Part D resulting from the Inflation Reduction Act's (IRA) changes to plan cost sharing have incentivized insurers to increasingly use **UM** policies to

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[60] Matt Devine, "State Legislation Requiring Coverage of Biomarker Testing Gains Momentum," Association of Cancer Care Centers, September 30, 2022, https://www.accc-cancer.org/view/state-legislation-requiring-coverage-of-biomarker-testing-gains-momentum.

[61] Clarisa Blattner, "State Biomarker Legislation Is Accelerating—But Operational Complexity Remains," HealthCareBusiness News, June 12, 2026, https://www.dotmed.com/news/story/66340.

[62] Devine, "State Legislation Requiring Coverage of Biomarker Testing Gains Momentum."

[63] National Consortium of Telehealth Resource Centers, "The Telehealth Policy Cliff: Preparing for October 1, 2025," September 26, 2025, https://telehealthresourcecenter.org/resources/the-telehealth-policy-cliff-preparing-for-october-1-2025/; Telehealth.HHS.gov, "Telehealth Policy Updates," updated February 5, 2026, https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates.

[64] Cicilia Brown and Laura Litwin, "Interruption, Fragmentation, and Adaptation: How Rural Hospital Closures Are Impacting Oncology Nursing Care Across the Nation," Cancer Nursing Today, May 28, 2026, https://www.cancernursingtoday.com/post/interruption-fragmentation-and-adaptation-how-rural-hospital-closures-are-impacting-oncology-nursing-care-across-the-nation; CMS, "Rural Health Transformation (RHT) Program," accessed June 2026, https://www.cms.gov/initiatives/rural-health-transformation-rht-program/overview.

[65] Community Oncology Alliance, "COA Position Statement on Telehealth in Cancer Care," March 24, 2025, https://mycoa.communityoncology.org/publications/position-statements/coa-position-statement-on-telehealth-in-cancer-care.

[66] Association of Cancer Care Centers, "Regional Disparities in Chronic Lymphocytic Leukemia"; CLL Society, "A Charter for Improving Care for Those Living with CLL," August 14, 2025, https://cllsociety.org/2025/08/a-charter-for-improving-care-for-those-living-with-cll/.

[67] CMS, "2024 Medicare Advantage and Part D Final Rule (CMS-4201-F)," April 5, 2023, https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f.

[68] CMS, "2024 Medicare Advantage and Part D Final Rule (CMS-4201-F)."

[69] New Jersey Legislature, "P.L. 2025, CHAPTER 50," May 8, 2025, https://pub.njleg.gov/Bills/2024/AL25/50_.HTM.

control plan costs.[70] As **CLL** patients are increasingly prescribed oral **targeted therapies**, the burden of **UM** for **CLL** patients is only expected to increase.[71]

Many pharmaceutical manufacturers provide **copay** assistance for commercially insured patients, which has traditionally counted toward a patient's annual out-of-pocket maximums or deductibles, but under insurer **copay accumulator programs**, this **copay** assistance does not count toward a patient's annual out-of-pocket maximums or deductibles. Some states have taken steps to regulate or prohibit **copay accumulator programs**.[72] For example, Virginia and West Virginia were the first states to ban **copay accumulator programs** for state-regulated plans in 2019, with 26 states banning or limiting **copay accumulator programs** as of 2026.[73]

Despite attempts to lower patient out-of-pocket costs for cancer treatment, costs have increased in recent years as insurers have responded to the increasing costs of newer treatments by adjusting benefit designs. For example, insurers have switched from flat **copays** to **coinsurance**, significantly increasing patient costs.[74]

Artificial Intelligence, Transparency, and Care Denials

Cancer patients, including those with **CLL**, are increasingly turning to AI for information about their diagnosis and treatment. While AI can help patients better understand their **CLL** diagnosis and treatment options in accessible language, patient advocates have raised concerns that patients may receive outdated or inaccurate treatment recommendations, potentially influencing them to pursue treatments that are not recommended by their physicians. For example, a recent study found that one-third of treatments recommended by an AI chatbot were misaligned with NCCN treatment guidelines.[75] To help **CLL** patients and their physicians navigate treatment decisions, NCCN has developed the NCCN Guidelines Navigator, a digital version of the NCCN Guidelines that incorporates AI-powered search capabilities to improve accessibility.[76] Similarly, the CLL Navigator provides digital tools for **CLL** patients, including resources that explain how they can best leverage AI in treatment discussions with their physicians.[77] While the NCCN Guidelines Navigator and CLL Navigator are important resources for patients navigating a **CLL** diagnosis, additional tools and safeguards are needed, as patients often turn to general AI chatbots before seeking out cancer or **CLL**-specific resources.

Insurers are also increasingly using AI in the **UM** process, including evaluating **prior authorization** requests. Patient advocates and physicians have voiced concerns that patients may be inappropriately denied recommended treatments through AI-assisted review of **prior authorization** requests without ever knowing that AI contributed to the decision.[78] For example, a 2025 American Medical Association survey found that a majority of physicians were concerned that health plans' use

[70] CLL Society, "CLL Society Joins Growing Number of Groups Calling for Patient Protections from Medicare Part D Plan Utilization Management Under New IRA Kickoff," June 25, 2025, https://CLLsociety.org/2025/06/CLL-society-joins-growing-number-of-groups-calling-for-patient-protections/.

[71] James T. Kenney Jr., "Payers' Management of Oncology Drugs: Opportunities and Challenges," *American Health & Drug Benefits* 7, no. 3 (2014): 123–124.

[72] Joseph Cantrell, "State Copay Accumulator Legislation: An Overview," The Rheumatologist, June 25, 2024, https://www.the-rheumatologist.org/article/state-copay-accumulator-legislation-an-overview/.

[73] Clarivate, "Virginia and West Virginia Ban Copay Accumulators. What's Next?," April 10, 2019, https://clarivate.com/life-sciences-healthcare/blog/virginia-west-virginia-ban-copay-accumulators-whats-next/; The Coalition for Hemophilia, "New Jersey Joins Growing List of States Passing Copayment Accumulator Bans," January 13, 2026, https://www.hemob.org/resource-library/01-13-2026.

[74] Caroline F. Pearson, "Part D Plans Moving from Copayments to Coinsurance," Physicians for a National Health Program, March 10, 2016, https://pnhp.org/news/part-d-plans-moving-from-copayments-to-coinsurance/.

[75] S. Chen et al., "Use of Artificial Intelligence Chatbots for Cancer Treatment Information," *JAMA Oncology* 9, no. 10 (2023): 1459–1462.

[76] National Comprehensive Cancer Network, "NCCN Guidelines Navigator," NCCN, accessed June 2026, https://www.nccn.org/guidelines/nccn-guidelines-navigator.

[77] CLL Navigator, "Using AI to Prepare for CLL Care Conversations," accessed June 2026, https://cllnavigator.com/chronic-lymphocytic-leukemia/using-ai-to-prepare-for-cll-care-conversations/.

[78] Austin Littrell, "Physicians Warn That AI Will Undermine Judgment, Increase Prior Authorization Denials," Medical Economics, February 26, 2025, https://www.medicaleconomics.com/view/physicians-warn-that-ai-will-undermine-judgement-increase-prior-authorization-denials.

of AI is increasing prior authorization denials and may lead to avoidable patient harm.[79] In response to these concerns, insurers are facing lawsuits over alleged failures to disclose the use of AI in care denial decisions.[80] States are likewise increasingly prohibiting the use of AI as the sole basis for care denials (with seven states enacting such laws in 2026), and at least four states require insurers to disclose the use of AI in care decisions.[81] Increasing transparency around the use of AI in care decisions and requiring human oversight of AI-generated denial decisions are emerging as legislative priorities at both the state and federal levels.

5. Targeted Recommendations to Help Every CLL Patient Get the Right Treatment at the Right Time

Drawing on the gaps noted above, in addition to existing proposals and suggestions from the blood cancer community, this report recommends five actions that could help ensure that treatment decisions are driven by clinical evidence and patient needs, helping more patients receive the right treatment at the right time.

1. Expand access to comprehensive biomarker testing.

a. Biomarker coverage should be expanded across different plan types as follows:

   i. **Biomarker testing** coverage requirements should be passed in all states to require state-regulated plans to cover medically necessary biomarker tests for **CLL**.[82]

   ii. **Biomarker testing** coverage requirements should be passed by Congress for self-funded employee health plans that are federally regulated under the Employee Retirement Income Security Act (ERISA) to cover biomarker tests that CMS decides are medically necessary for cancer treatment, including for **CLL** treatment.

b. As proposed in the Safe Step Act (H.R. 5509) and Improving Seniors' Timely Access to Care Act (H.R. 3514), Congress should require federally regulated plans (e.g., MA plans, ERISA plans) to modernize and streamline their **prior authorization** process, with real-time approvals for routinely approved services and approvals within 72 hours for standard requests.[83]

2. Provide education on the latest treatments.

a. Healthcare systems should implement a guideline-concordant **CLL** care pathway that is refreshed after guideline updates and requires **biomarker testing** before treatment decisions and access to blood cancer expertise at key decision points, potentially facilitated by continued telehealth flexibilities in Medicare.

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[79] American Medical Association, "Physicians Concerned AI Increases Prior Authorization Denials," February 24, 2025, https://www.ama-assn.org/press-center/ama-press-releases/physicians-concerned-ai-increases-prior-authorization-denials.

[80] Jakob Emerson, "UnitedHealth, Cigna Face Lawsuits over Alleged Automated Claims Denials," Becker's Payer Issues, November 27, 2023, https://www.beckerspayer.com/uncategorized/unitedhealth-cigna-face-lawsuits-over-alleged-automated-claims-denials/.

[81] Jakob Emerson, "7 AI Health Insurance State Laws Passed in 2026," Becker's Payer Issues, July 28, 2026, https://www.beckerspayer.com/policy-updates/7-ai-health-insurance-state-laws-passed-in-2026/; Tshedimoso Makhene, "Which States Require Disclosure of AI Use in Treatment?," Paubox, December 23, 2025, https://www.paubox.com/blog/which-states-require-disclosure-of-ai-use-in-treatment.

[82] American Cancer Society Cancer Action Network, "Access to Biomarker Testing."

[83] Jesse Pines, "Prior Authorization Reform Is Here—And It Could Change How Millions Get Care," *Forbes*, April 13, 2026, https://www.forbes.com/sites/jessepines/2026/04/13/prior-authorization-reform-is-here-and-it-could-change-how-millions-get-care/; Gabrielle M. Grasso, "Congress Reintroduces Safe Step Act to Amend Step Therapy Policies," Healio, October 21, 2025, https://www.healio.com/news/dermatology/20251021/congress-reintroduces-safe-step-act-to-amend-frustrating-step-therapy-policies; Congress.gov, "H.R. 5509 - Safe Step Act," September 19, 2025, https://www.congress.gov/bill/119th-congress/house-bill/5509; Congress.gov, "H.R. 3514 - Improving Seniors' Timely Access to Care Act of 2025," May 20, 2025, https://www.congress.gov/bill/119th-congress/house-bill/3514.

3. Improve care coordination for timely access to specialists.

a. Congress should continue to extend telehealth flexibilities in Medicare to expand the use of telehealth in oncology, particularly for patients in rural and underserved communities.[84]

b. Congress should increase investments in programs such as the Rural Health Transformation Program to help financially sustain rural hospitals and health systems that have reduced oncology services due to financial constraints.[85]

4. Reform UM policies.

a. As proposed in the Safe Step Act (H.R. 5509), Congress should reform **UM** policies of ERISA plans by 1) ensuring plans offer a process for **step therapy** exceptions so that patients with a history of prior failures or adverse events can access newer therapies without having to fail on older, less efficacious ones first, 2) requiring plans to respond within 72 hours to an exception request, and 3) establishing circumstances where exceptions should be granted.[86]

b. Require Medicare Part D prescription drug plans and MA plans to document where **step therapy** is embedded into **prior authorization** requirements so that patients and healthcare providers can quickly understand the barriers to **CLL** care within different plans.[87] Additionally, CMS should exercise greater oversight over Medicare Part D formularies, requiring plans to provide clinical justification for **UM** restrictions in alignment with current **clinical guidelines** and evidence, to help ensure access to clinically appropriate therapies within a protected class.[88]

c. Similar to state laws requiring state-regulated health plans to cover oral cancer therapies on a "no less favorable" basis than infusion therapies, ERISA plans should be required to cover oral cancer therapies on a no less favorable basis than infusion therapies. In practice, coverage on a no less favorable basis would mean 1) similar cost sharing for the oral and infusion therapies and 2) no additional **prior authorization** hurdles for the oral therapies compared with the infusion therapies. Additionally, plans should not be able to cost-shift and increase the cost of the infusion therapy for patients to avoid having to reduce patient cost sharing on the oral therapy.[89]

5. Increase transparency and promote responsible AI in cancer care.

a. Support the responsible use of AI by patient advocacy organizations, healthcare institutions, and professional societies to help patients access trusted, evidence-based information about their disease, treatment options, and care journey.

b. Similar to state laws requiring insurers to disclose if AI was used in a care decision and as proposed in the Protecting Patients from Automated Denials Act (H.R.9734), MA plans and ERISA plans should be required to disclose whether AI was used in care decisions.[90] These disclosures should be provided to patients and physicians in a clear and accessible manner and should identify the role AI played in the decision-making process.

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[84] Robin T. Zon, "Telehealth in Oncology: ASCO Standards and Practice Recommendations," *JCO Oncology Practice* 17, no. 9 (2021): 546–646.

[85] CMS, "Rural Health Transformation (RHT) Program."

[86] Congress.gov, "H.R. 5509 - Safe Step Act."

[87] Avalere Health, "Part D Prior Authorization Policies May Include Step Therapy," April 15, 2025, https://advisory.avalerehealth.com/insights/part-d-prior-authorization-policies-may-include-step-therapy.

[88] CMS, "Medicare Modernization Act Final Guidelines—Formularies CMS Strategy for Affordable Access to Comprehensive Drug Coverage," 2005, https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/formularyguidance.pdf.

[89] America's Health Insurance Plans, "Oral Chemotherapy Parity Benefit Mandates: Summary of State Requirements," July 21, 2017, https://house.mi.gov/Document/?DocumentId=40074&DocumentType=CommitteeTestimony.

[90] Congress.gov, "H.R. 9734 - Protecting Patients from Automated Denials Act," accessed June 2026, https://www.congress.gov/bill/119th-congress/house-bill/9734/text/ih#xd_co_f=ZjJkNmUwNTQtNDdlZi00NTY4LWFkMWQtZGNkNGJhZDAxZDgy~.

c. Similar to state laws requiring human oversight of care denial decisions and as proposed in the Protecting Patients from Automated Denials Act (H.R.9734), MA plans and ERISA plans should be required to provide proof that a qualified clinician evaluated the care decision before a care denial was issued.[91] This would prevent AI or algorithmic tools from serving as the sole basis for denying, delaying, or limiting coverage or care.

6. Conclusion

Science has transformed what is possible for people living with **CLL**, offering more personalized, effective, and tolerable treatment options than ever before. Yet too many patients remain unable to fully benefit from these advances because of inconsistent access to comprehensive **biomarker testing**, barriers to guideline-concordant treatment, **UM** policies that delay treatment, and lack of affordable coverage.

The evidence-based recommendations outlined in this report provide a clear roadmap to translate scientific innovation into meaningful patient access. Expanding access to **biomarker testing**, modernizing **UM**, strengthening care coordination, improving access to blood cancer expertise, and ensuring affordable coverage would help align healthcare policy with today's standard of care for **CLL**.

Ensuring that treatment decisions are guided by clinical evidence, and not administrative barriers or insurance design, is essential to improving outcomes for people living with **CLL**. By acting on these recommendations, payors, healthcare providers, patient advocates, and policymakers can help strengthen a healthcare ecosystem that keeps pace with innovation and ensures every patient has timely access to the right treatment at the right time, regardless of where they live or the type of insurance they have.

[91] Congress.gov, "H.R. 9734 - Protecting Patients from Automated Denials Act."

BOX 1

Active surveillance: Period of time after a CLL diagnosis before symptoms develop and treatment is necessary, also known as "watch and wait," in which patients are monitored for symptoms.[92]

B-cell lymphoma 2 inhibitor (BCL2i): Medicines that target the B-cell lymphoma 2 family of proteins, which are especially abundant in certain types of cancer cells.[93] BCL2is are approved by the FDA to treat CLL.[94]

B-cell malignancies: Group of blood cancers that arise when B cells, a type of white blood cell responsible for producing antibodies, behave abnormally, leading to diseases such as leukemia, lymphoma, and multiple myeloma.[95]

Biomarker testing: Lab tests that look for certain genes, proteins, hormones, etc. to provide detailed information about an individual's cancer.[96] Clinical guidelines recommend that biomarker testing be used to inform CLL treatment decisions.[97]

Bruton's tyrosine kinase inhibitor (BTKi): Medicines that block the enzyme Bruton's tyrosine kinase. Covalent BTKis shut down the BTK protein by attaching to it permanently, whereas noncovalent BTK inhibitors attach more flexibly and can continue to be effective even when the cancer mutates in ways that prevent covalent BTKis from binding effectively.[98] BTKis are approved by the FDA to treat certain white blood cell cancers.[99]

Chemoimmunotherapy: Chemotherapy combined with immunotherapy.[100]

Chronic lymphocytic leukemia (CLL): The most common type of blood cancer in adults, which often progresses slowly, and occurs when white blood cells change into cancer cells.[101] As CLL is largely incurable, CLL treatment focuses on managing symptoms, extending PFS, and improving quality of life.[102] Many patients can live with CLL for years.[103]

Clinical guidelines: Systematically developed recommendations issued by organizations on the diagnosis and treatment of specific clinical circumstances.[104] Clinical guidelines often describe the level of evidence for each recommendation and provide additional details on the line of therapy (e.g., first-line, second-line) and considerations for specific patient risk factors.[105]

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103 Lindsay Modglin, "CLL Prognosis By Age: Information for Patients and Caregivers," Patient Power, updated May 7, 2026, https://www.patientpower.info/chronic-lymphocytic-leukemia/cll-prognosis-by-age; American Cancer Society, "Living as a Chronic Lymphocytic Leukemia Survivor," updated March 20, 2025, https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/after-treatment/follow-up.html.

104 National Center for Complementary and Integrative Health, "Clinical Practice Guidelines," accessed June 2026, https://www.nccih.nih.gov/health/providers/clinicalpractice.

105 Wierda et al., "NCCN Guidelines® Insights."

Coinsurance: When a patient's out-of-pocket expense is based on a percentage of a drug's list price.[106] Coinsurance is typically only applied to high-cost specialty drugs, but is increasingly being used for non-specialty drugs.[107]

Continuous treatment: Treatment that is administered until disease progression or discontinuation due to side effects or other factors.[108] BTKis are an example of continuous treatment in CLL.[109]

Copay: A fixed fee paid by a patient for a covered medical expense.[110] A patient's copay may vary based on the formulary tier of a prescription drug, with drugs on higher formulary tiers having higher patient copayments.[111]

Copay accumulator programs: When an insurer does not count copay assistance toward a patient's deductible or out-of-pocket maximum.[112]

First-line treatment: The first treatment for a disease, often accepted as the best treatment among a standard set of treatments.[113]

Fixed-duration treatments: Treatments that are administered for a certain amount of time and then stopped until there are signs of worsening disease or recurrence, which may allow for time without treatment.[114] Fixed-duration treatment regimens often last for one to two years.[115]

Formulary: A health insurance plan's list of approved drugs, which often specifies tiers and restrictions (e.g., prior authorization, step therapy, and quantity limits).[116] Tiers typically determine cost levels (e.g., Tier 1 [generics with lowest copay], Tier 2 [preferred brand-name drugs], Tier 3 [nonpreferred brand drugs with higher copay], and Tier 4 [high-cost or specialty medications]).[117]

Immunotherapy: A type of therapy that stimulates or suppresses the immune system to fight cancer.[118]

Overall survival (OS): The length of time a patient remains alive after a cancer diagnosis or treatment initiation.[119]

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[117] MMIT Network, "Formulary Coverage."

[118] National Cancer Institute, "Immunotherapy," accessed June 2026, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunotherapy.

[119] National Cancer Institute, "Overall Survival," accessed June 2026, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/overall-survival.

Pharmacy benefit managers (PBMs): Organizations that manage prescription drug plan benefits for insurers and employers. PBMs' functions include negotiating rebates with drug manufacturers, managing formularies, adjudicating claims, assembling retail pharmacy networks, and conducting UM.[120]

Prior authorization: A UM policy where a payor must review and approve a prescribed treatment, service, or medicine before coverage is granted.[121]

Progression-free survival (PFS): The amount of time between treatment initiation and a cancer progressing or worsening in a patient.[122]

Refractory CLL: CLL that does not have a lasting response to treatment.[123] One study found that the overall survival of CLL patients who are refractory to both BTKis and BCL2is was 2.2 years.[124]

Relapsed CLL: CLL that reappears after a period of remission.[125] Patients often relapse multiple times.[126]

Second-line treatment: A treatment that is used after a first-line treatment stops working or a patient develops intolerance.[127]

Standard of care: The treatment for a disease that is accepted by medical experts and widely used by health care professionals.[128]

Step therapy: A UM policy, sometimes known as the "fail first" approach, in which a payor requires a patient to try a specific medicine (that is often lower cost and older) before covering a higher-priced medicine.[129]

Targeted therapies: Medicine that treats cancer by targeting specific genes or molecules, such as molecules on the surface of cancer cells.[130]

Utilization management (UM): Tools used by payors to manage health care costs and utilization by directing patients toward treatment options preferred by the payor, including prior authorization, step therapy, quantity limits, formulary restrictions or tiering, and mandatory generic substitution.[131]

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