

EUROCOVER-CLL

HPR232

Reimbursement and Accessibility for New Treatments in Relapsed/Refractory Chronic Lymphocytic Leukemia in Central and Eastern Europe

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BACKGROUND

Recent advancements in targeted therapies have expanded treatment options for patients with relapsed/refractory chronic lymphocytic leukemia (R/R CLL). However, access to these therapies varies across Central and Eastern European (CEE) countries due to differences in national reimbursement policies. This underscores the need to understand disparities in treatment access for R/R CLL patients in the region.

AIM

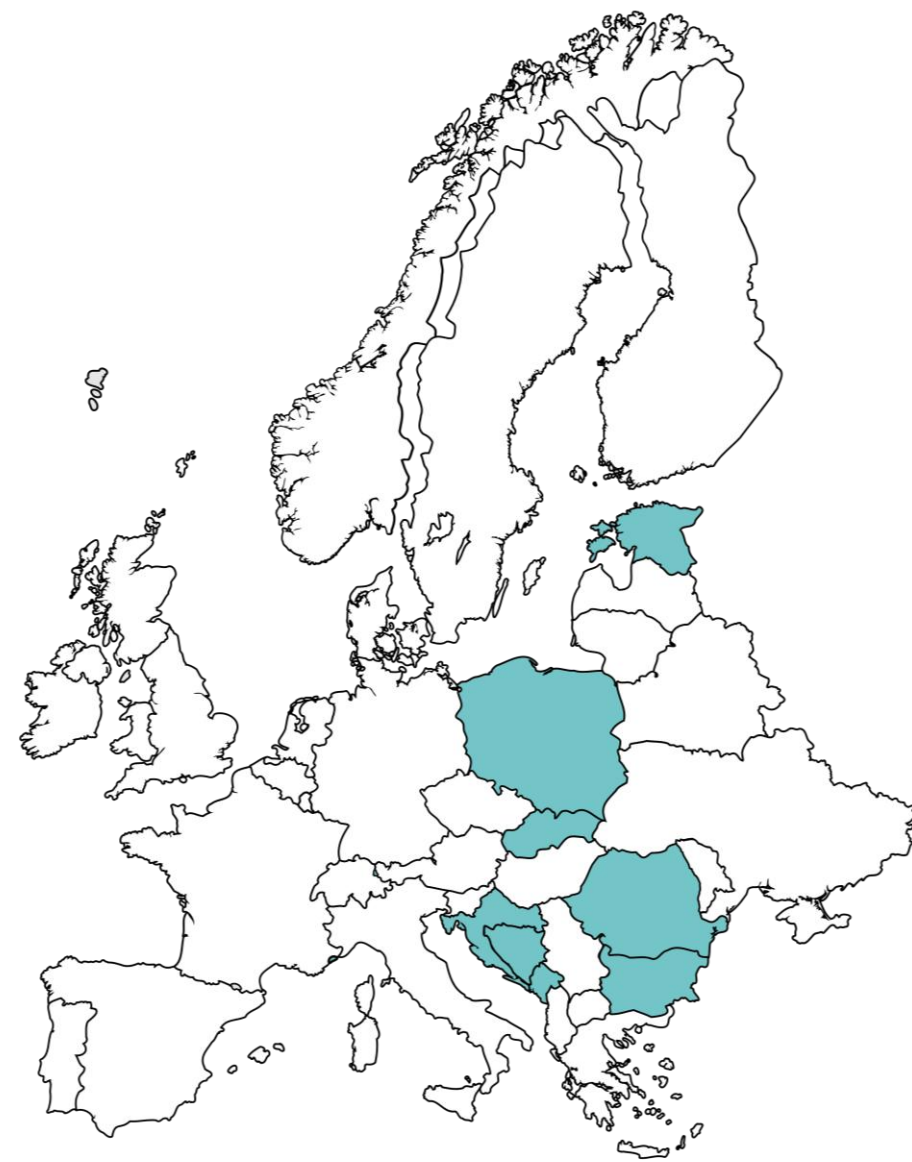
This study aims to explore the reimbursement landscape for novel targeted therapies across CEE countries, focusing on the following drugs:

- acalabrutinib,
- duvelisib,
- idelalisib,
- ibrutinib,
- venetoclax,
- and zanubrutinib.

METHODS

Reimbursement data were meticulously collected from eight CEE countries (Bosnia and Herzegovina, Bulgaria, Croatia, Montenegro, Estonia, Poland, Romania, and Slovakia). The authors gathered information from national databases using a detailed questionnaire covering aspects of reimbursement policy and HTA assessment for R/R CLL therapies. The survey focused on the general reimbursement status, target populations, costs, availability of cost-effectiveness analyses, and challenges in the reimbursement process. The data presented are current as of June 30, 2024.

This poster presents key insights into the reimbursement landscape for targeted therapies in R/R CLL across CEE countries. For more detailed data, including specific reimbursement indications and sources, please refer to the supplement accessible via the QR code.



RESULTS



REIMBURSEMENT SITUATION

Among the analyzed countries, Poland and Bulgaria have the most reimbursed therapies for R/R CLL, with four drugs each, while Montenegro has the fewest. The earliest reimbursement was for ibrutinib in Romania (December 2016), and the most recent was for zanubrutinib in Bulgaria and Poland (January 2024). None of the second-generation BTK inhibitors (acalabrutinib and zanubrutinib) are reimbursed in Bosnia and Herzegovina, Montenegro, or Slovakia. PI3K inhibitors (duvelisib and idelalisib) are not reimbursed in any of the studied countries.

In two countries (Bosnia and Herzegovina, Croatia), HTA assessments are not required for reimbursement. Other countries in the region conduct HTA assessments, but detailed cost-effectiveness data usually remains confidential.



TARGET POPULATION

In most countries, reimbursement indications allow treating the full population consistent with the registered indication for R/R CLL. However, exceptions exist in Croatia, Estonia, and Slovakia, where reimbursement excludes patients without cytogenetic abnormalities (e.g., del17p/mTP53) experiencing late relapses.

Data on the number of treated patients are significantly limited. In Bulgaria, Romania, and Slovakia, these data are not collected, making it challenging to assess drug accessibility. In other countries, available data may also include previously untreated patients, as seen in Poland. Particularly low numbers of treated patients were observed in Bosnia and Herzegovina, suggesting that reimbursement is obtained on a case-by-case basis.



REIMBURSEMENT COSTS

All analyzed drugs are fully reimbursed across the studied countries; however, in Estonia, patients pay an additional out-of-pocket cost of €2.50.

Acalabrutinib is most expensive in Poland (€5713.23) and Bulgaria (€5658.74) and cheapest in Romania (€4990.25). Ibrutinib costs are highest in Estonia (€6032.58) and Slovakia (€5705.70), while lowest in Montenegro (€4907.26). Venetoclax is priciest in Estonia (€6407.84) and cheapest in Bulgaria (€4394.57).

Since initial reimbursement, prices have varied. Acalabrutinib generally remained stable, with a 20% increase in Romania. Ibrutinib mostly decreased: -10% in Bosnia and Herzegovina, -12% in Croatia, -6% in Montenegro, and -5% in Poland. Venetoclax saw significant reductions: -25% in Bulgaria, -23% in Poland, and -22% in Romania, while remaining stable in other regions.






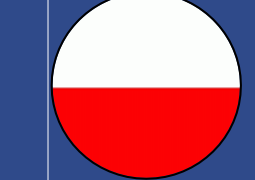
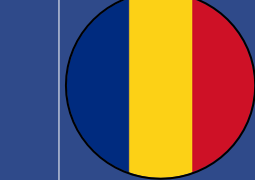



CHALLENGES AND BARRIERS

Main challenges in the reimbursement landscape include unequal access to treatments across regions, as seen in Bosnia and Herzegovina, where treatment availability varies.

In countries like Bulgaria and Romania, difficulties in accessing genetic diagnostics and biomarker assessments hinder precise CLL subtype or stage determination, affecting treatment decisions. Additionally, limitations in healthcare funding, as well as budgetary constraints, are notable barriers in Croatia and Estonia.

In countries where HTA assessments are required, there is often a lack of emphasis on unmet medical needs within evaluations. Furthermore, variations in reimbursement criteria interpretation across regions, especially in Romania, add complexity and inconsistency to the reimbursement process.

Drug	Country	 Bosnia and Hercegovina	 Bulgaria	 Croatia	 Estonia	 Montenegro	 Poland	 Romania	 Slovakia
Acalabrutinib		Not reimbursed	Reimbursed	Reimbursed	Reimbursed	Not reimbursed	Reimbursed	Reimbursed	Not reimbursed
• Reimbursement date		-	02-01-2022	05-11-2020	01-07-2022	-	01-01-2023	20-12-2020	-
• Reimbursed schemes		-	Only monotherapy	Only monotherapy	Only monotherapy	-	Only monotherapy	Only monotherapy	-
• Reimbursed indication		-	Full R/R population	Limited R/R population (del17p/mTP53- with late relapse not covered)	Limited R/R population (del17p/mTP53- or del11q-, late relapses not covered)	-	Full R/R population	Full R/R population	-
• Number of treated patients		-	2022: 2, 2023: 2	2022: 18	2022:15, 2023: 41	-	2023: 582	Data not publicly available	-
• Current official price		-	€5658,74^#	€4765,37*	€5463,00	-	€5713,23^	€4990,20^	-
Ibrutinib		Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
• Reimbursement date		05-07-2019	02-01-2017	01-01-2017	01-04-2017	29-12-2017	01-09-2017	27-12-2016	01-07-2022
• Reimbursed schemes		Only monotherapy	Monotherapy and combination with bendamustine+rituximab	Only monotherapy	Only monotherapy	Monotherapy and combination with bendamustine+rituximab	Only monotherapy	Monotherapy and combination with bendamustine+rituximab	Monotherapy and combination with bendamustine+rituximab
• Reimbursed indication		Full R/R population	Full R/R population	Limited R/R population (del17p/mTP53- with late relapse not covered)	Limited R/R population (del17p/mTP53- or del11q-, late relapses not covered)	Full R/R population	Full R/R population	Full R/R population	Limited R/R population (del17p/mTP53- with late relapse not covered)
• Number of treated patients		2022: 4; 2023:6	Data not publicly available	2017: 53, 2018: 61, 2019: 70, 2020: 80, 2021: 92, 2022: 106	2021: 82, 2022: 77, 2023: 67	Data not publicly available	2017: 0, 2018: 252, 2019: 494, 2020: 572, 2021: 711, 2022: 767, 2023: 1116	Data not publicly available	Data not publicly available
• Current official price		€5212,80	€4776,24^	€5377,00	€6032,58*	€4907,26**	€5365,47^	€5209,68**^	€5705,70*
Zanubrutinib		Not reimbursed	Reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Reimbursed	Not reimbursed	Not reimbursed
• Reimbursement date		-	01-01-2024	-	-	-	01-01-2024	-	-
• Reimbursed schemes		-	Only monotherapy	-	-	-	Only monotherapy	-	-
• Reimbursed indication		-	Full R/R population	-	-	-	Full R/R population	-	-
• Number of treated patients		-	Data not publicly available	-	-	-	Not available yet	-	-
• Current official price		-	€4939,07^	-	-	-	€5353,55^	-	-
Venetoclax		Reimbursed	Reimbursed	Reimbursed	Reimbursed	Not reimbursed	Reimbursed	Reimbursed	Reimbursed
• Reimbursement date		04-09-2020	01-01-2018	01-10-2017	01-07-2020	-	01-01-2019	11-07-2018	01-01-2019
• Reimbursed schemes		Monotherapy and combination with rituximab	Monotherapy and combination with rituximab	Monotherapy and combination with rituximab	Only combination with rituximab	-	Monotherapy and combination with rituximab	Only monotherapy	Monotherapy and combination with rituximab
• Reimbursed indication		Full R/R population	Full R/R population	Limited R/R population (late relapsed not covered)	Full R/R population	-	Full R/R population	Full R/R population	Limited R/R population (del17p/mTP53- with late relapse not covered)
• Number of treated patients		2020: 1, 2021: 2, 2022: 4, 2023: 7 (monotherapy); 2020: 9, 2021: 11, 2022: 12 2023: 18 (combination with rituximab)	Data not publicly available	2017: 4, 2018: 10, 2019: 20, 2021: 49, 2022: 82	2021: 40, 2022: 73, 2023: 82	-	2019: 70, 2020: 320, 2021: 644, 2022: 1388, 2023: 1749	Data not publicly available	Data not publicly available
• Current official price		€5150,88	€4394,57^	€5660,00	€6407,84	-	€4752,02^	€4584,88^	€5135,36
Duvelisib		Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed
Idelalisib		Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed	Not reimbursed

Legend: Unless otherwise indicated, official prices are given for Calquence 100 mg 60 hard capsules, Imbruvica 140 mg 90 hard capsules, Venclxyto 100 mg 112 tablets, Brukinsa 80 mg 120 hard capsules. The reimbursement indication refers to alignment with the regulatory approval indication. Patient numbers may include previously untreated populations due to the lack of data separation on publicly accessible websites. *Imbruvica 140 mg 3x30 tablets. **Maximum wholesale price. The official price of this preparation is subject to a special agreement, which cannot be displayed on the list of reimbursed drugs. #Calquence 100 mg 56 hard capsules. ^Calculated from the national currency to EUR using the average annual exchange rate.

CONCLUSIONS

Significant disparities in CLL therapy access remain across CEE countries, with many still lacking optimal coverage. Expanding reimbursement to include additional therapies and patient subpopulations is essential to ensure equitable access and improve outcomes. Harmonized policies could further support comprehensive and consistent treatment availability throughout the region.

SUPPORTIVE INFORMATION



<https://eurocover-cll.shinyapps.io/EUROCOVER/>