WE-ACCESS-CLL SURVEY:
Reimbursement and Access to Novel First-Line Treatments for Chronic Lymphocytic Leukemia in Poland and Western Europe

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Background

Advances in targeted therapies have significantly expanded first-line treatment (1L) options for patients with chronic lymphocytic leukemia (CLL). At the same time, access to these therapies still differs between Poland and Western European countries. Therefore, may still a better understanding of the factors underlying these regional disparities in access to targeted therapies is needed.

Aim

This study assessed the reimbursement landscape for novel targeted therapies used in 1L CLL across Poland and selected Western European countries, including ibrutinib, acalabrutinib, zanubrutinib, venetoclax + obinutuzumab, ibrutinib + venetoclax, acalabrutinib + obinutuzumab, ibrutinib + obinutuzumab, ibrutinib + rituximab, and idelalisib + rituximab.

Methods

Reimbursement data for Poland and selected Western European countries were collected using a structured questionnaire. Country-specific inputs were provided by local experts and were based on publicly available sources. The analysis captured reimbursement status, eligible populations, cost-related parameters, and key access barriers for 1L CLL therapies, using the most recent data available up to 31 March 2026.

Results

All analysed regimens were approved in the selected EU countries and the UK, with Switzerland being the only exception, where ZAN, IBR+VEN and IBR+OBI were not authorised. Reimbursement status varied across the analysed countries. The highest number of regularly reimbursed regimens was observed in France (8), followed by by Belgium (7), England and Scotland (6 each); Austria, Ireland, and Poland each reimbursed 5 regimens, while Switzerland reimbursed 4. The longest times between marketing authorisation and reimbursement approval were observed for IBR in Poland (2,994 days), followed by IDE+RTX in France (1,702 days), IBR+RTX in Switzerland (1,596 days), and VEN+OBI in Belgium (1,240 days). The fastest reimbursement approval was seen for IBR in Switzerland (57 days) and for ACA in Scotland (158 days) and England (167 days).

Population-based reimbursement restrictions were observed in all analysed countries, but they were more common for BTK inhibitor monotherapies, which in most markets were reimbursed only in selected patient subgroups. In contrast, IBR+VEN, IDE+RTX, and VEN+OBI were generally reimbursed in the label-consistent, full approved population where available. In most countries analysed, reimbursement provided full coverage with no patient copayment. The main exceptions were Ireland, with a capped monthly contribution of up to €80 per individual/family, and Switzerland, where patients paid a 10% copayment. The highest official prices per daily dose (DD) for single targeted therapies were reported in Poland for IBR (€207.24/day) and ACA (206.99/day) and in Belgium for for ACA and ZAN (€202.83/day). The lowest prices per DD were most consistently observed in France, at €143.00/day for IBR, ACA and ZAN, and €174.81/day for VEN.

No major limitations related to diagnostic testing availability were reported across countries. Overall, the main access barriers were linked to reimbursement restrictions and delays in implementation.

Country / Drug	EU jurisdiction					Non-EU jurisdiction		
	Austria	Belgium	France	Ireland	Poland	England	Scotland	Switzerland
IBRUTINIB (IBR)	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**
» Marketing approval date			21.10.2014			21.10.2014		05.03.2015
» First reimbursement date	01.08.2015	01.08.2015	05.08.2017	01.08.2016	01.01.2023	25.01.2017	08.08.2016	01.05.2015
» Current reimbursed indication	TN CLL: non-ICTH	TN CLL	TN CLL: del17p/ mTP53(+) and non-ICTH or TN CLL: non-FCR	TN CLL: del17p/ mTP53(+) and non-ICTH	TN CLL: del17p/ mTP53(+) or mIGHV(-)	TN CLL: del17p/ mTP53(+) and non-ICTH	TN CLL: del17p/ mTP53(+) and non-ICTH	1. TN CLL: del17p/ mTP53 (+) 2. TN CLL ≥65y and mIGHV(-) and non-FCR
» Current official price for DD [€]	193.87	192.67	143.00	190.15	207.24	178.97	178.97	171.32
ACALABRUTINIB (ACA)	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**
» Marketing approval date			05.11.2020			05.11.2020		04.03.2021
» First reimbursement date	01.03.2022	01.11.2021	02.04.2023	01.10.2021	01.01.2023	21.04.2021	12.04.2021	01.09.2023
» Current reimbursed indication	TN CLL	TN CLL: non-FCR	TN CLL: del17p/ mTP53(+) or del17p/ mTP53(-) and non-FCR	TN CLL: del17p/ mTP53(+) and non-ICTH	TN CLL	TN CL: del17p/ mTP53 (+) or del17p/ mTP53(-) and non-FCR, non-BR	1. TN CLL: del17p/ mTP53(+) and non-ICTH 2. TN CLL: del17p/mTP53 (-) and non-FCR	1. TN CLL: del17p/ mTP53(+) and ≥65 y or coexisting condition 2. TN CLL: IGHV(-) and ≥65 y or coexisting condition
» Current official price for DD [€]	196.72	202.83	143.00	196.66	206.99	196.88	196.88	168.83
ZANUBRUTINIB (ZAN)	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**
» Marketing approval date			15.11.2022			06.01.2023		NO MA
» First reimbursement date	01.08.2023	01.12.2023	16.01.2024	01.09.2023	01.01.2024	22.11.2023	09.10.2023	-
» Current reimbursed indication	TN CLL: non-ICTH	TN CLL: non-FCR	TN CLL: del17p/ mTP53(+) or del17p/ mTP53(-) and non-FCR	TN CLL: del17p(+) and / or mTP53(+)	TN CLL: non-FCR	TN CLL: del17p/ mTP53 (+) or del17p/ mTP53(-) and non-FCR, non-BR	TN CLL: non-ICTH	-
» Current official price for DD [€]	166.62	202.83	143.00	192.05	193.09	191.80	191.80	-
VENETOCLAX+OBINUTUZUMAB (VEN+OBI)	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**
» Marketing approval date			09.03.2020			09.03.2020		16.11.2023
» First reimbursement date	01.12.2020	01.08.2023	13.07.2023	01.03.2022	01.11.2021	09.12.2020	07.12.2020	01.10.2025
» Current reimbursed indication	TN CLL: non-ICTH	TN CLL	TN CLL: del17p/ mTP53(+) or del17p/ mTP53(-) and non-FCR	TN CLL	TN CLL	TN CLL	1. TN CLL: del17p/ mTP53(+) or del17p/ mTP53(-) and non-FCR 2. TN CLL: del17p/mTP53 (-) and FCR suitable	TN CLL: coexisting conditions
» Current official price for DD [€]	191.30 + [NA]	189.18 + [NA]	174.81 + [NA]	202.75 + 142.35	184.46 + 124.71	199.70 + 184.13	199.70 + 184.13	191.30 + 169.15
ACALABRUTINIB+OBINUTUZUMAB (ACA+OBI)	**NOT REIMBURSED**	**NOT REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**
» Marketing approval date			05.11.2020			05.11.2020		04.03.2021
» First reimbursement date	-	-	02.04.2023	-	-	-	-	-
» Current reimbursed indication	-	-	TN CLL: del17p/ mTP53(+) or del17p/ mTP53(-) and non-FCR	-	-	-	-	-
» Current official price for DD [€]	-	-	143.00 + [NA]	-	-	-	-	-
IBRUTINIB+VENETOCLAX (IBR+VEN)	**NOT REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**
» Marketing approval date			02.08.2022			02.08.2022		NO MA
» First reimbursement date	-	01.02.2024	09.03.2024	-	01.04.2024	31.05.2023	11.09.2023	-
» Current reimbursed indication	-	TN CLL	TN CLL: del17p/ mTP53(-) and non-FCR	-	TN CLL	TN CLL	TN CLL	-
» Current official price for DD [€]	-	192.67 + 189.18	143.00 + 174.81	-	207.24 + 184.46	178.97 + 199.70	178.97 + 199.70	-
IBRUTINIB+RITUXIMAB (IBR+RTX)	**NOT REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**REIMBURSED**
» Marketing approval date			28.08.2020			28.08.2020		17.12.2020
» First reimbursement date	-	01.12.2021	27.08.2021	-	-		-	01.05.2025
» Current reimbursed indication	-	TN CLL: del17p / mTP53(-)	TN CLL: del17p/mTP53(-) with FCR suitable	-	-		-	TN CLL: ≤70y and mIGHV(-) and non-FCR
» Current official price for DD [€]	-	192.67 + [NA]	143.00 + [NA]	-	-		-	171.32 + 83.35
IBRUTINIB+OBINUTZUMAB (IBR+OBI)	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**	**NOT REIMBURSED**
» Marketing approval date			02.08.2019			02.08.2019		NO MA
» First reimbursement date	-	-	-	-	-	-	-	-
» Current reimbursed indication	-	-	-	-	-	-	-	-
» Current official price for DD [€]	-	-	-	-	-	-	-	-
IDELALISIB+RITUXIMAB (IDE+RTX)	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**	**REIMBURSED**	**REIMBURSED**	**NOT REIMBURSED**
» Marketing approval date			18.09.2014			18.09.2014		22.01.2015
» First reimbursement date	01.06.2015	01.12.2015	17.05.2019	01.01.2017	-	28.10.2015	09.03.2015	-
» Current reimbursed indication	TN CLL: del17p/ mTP53(+) and non-other therapies	TN CLL: del17p/ mTP53(+) and initiated reimbursed idelalisib treatment before 1 August 2019	TN CLL: del17p/ mTP53(+) and non-other therapies	TN CLL: del17p/ mTP53(+) and non-other therapies	-	TN CLL: del17p/ mTP53(+)	TN CLL: del17p/ mTP53(+) and non-ICTH	-
» Current official price for DD [€]	141.86 + [NA]	134.27 + [NA]	111.97 + [NA]	132.84 + [NA]	-	121.21 + [NA]	121.21 + [NA]	-

** **Dark green colour** indicates reimbursement across the full scope of the approved indication **in 1L CLL; light green indicates** reimbursement with restrictions; **Red** indicates no reimbursement; * - ex-factory price; The reimbursement level is 100% (0% patient copayment), except in Ireland, where it is approximately 100%, with patients paying up to €80 per month per individual/family, and in Switzerland, where the reimbursement level is 90%, with a 10% patient copayment up to an annual cap of CHF 700; above this threshold, reimbursement increases to 100%.*

Abbreviations: *CLL – chronic lymphocytic leukemia; del17p(+) – deletion of the short arm of chromosome 17; del17p(–) – no deletion of the short arm of chromosome 17; FCR – treatment regimen consisting of fludarabine, cyclophosphamide, and rituximab; ICTH – immunochemotherapy; mIGHV(+) – mutated IGHV gene; mIGHV(–) – unmutated IGHV gene; mTP53(+) – presence of a mutation in the TP53 gene; mTP53(–) – no mutation in the TP53 gene; NA – data not publicly available; TN – treatment-naïve.*

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References

Conclusions

Despite broad regulatory approval, substantial differences remain in reimbursement scope and time to access to 1L CLL therapies across Europe. Access limitations are primarily driven by restrictive reimbursement criteria and delayed reimbursement decision rather than diagnostic capacity. However, for some therapies, such as ibrutinib+obinutuzumab or acalabrutinib+obinutuzumab, companies' market access strategies cannot be excluded. Greater alignment of reimbursement policies and broader population coverage may improve equity in access.