Costs of First-Line Treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma With Bruton Tyrosine Kinase Inhibitors: Simulation of the Impact of the Inflation Reduction Act

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OBJECTIVE

To compare total healthcare costs and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)–related pharmacy costs for patients with CLL/SLL receiving first-line (1L) ibrutinib versus other covalent Bruton tyrosine kinase inhibitors (cBTKis; acalabrutinib or zanubrutinib) after an Inflation Reduction Act price reduction for ibrutinib

CONCLUSIONS

Post–maximum fair price effectuation modeling projected meaningful total cost savings for ibrutinib versus other cBTKis, driven by pharmaceutical costs

Findings suggest reductions in overall plan-level expenditures with the use of ibrutinib for 1L treatment of CLL/SLL

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BS, **SB**, **AD**, **EF**, and **KS** are employees of and own stock with AbbVie. **BE**, **JM**, **EH**, **GW**, and **SZ** are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to AbbVie.

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INTRODUCTION

- Covalent Bruton tyrosine kinase inhibitors (cBTKis), including ibrutinib,[1] acalabrutinib,[2] and zanubrutinib,[3] are standard-of-care first-line (1L) treatment for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)[4]
- The 2022 Inflation Reduction Act (IRA) is a federal law aimed at lowering prescription drug costs, expanding access to affordable healthcare, and improving Medicare's ability to negotiate drug prices
- Per the IRA Drug Price Negotiations, ibrutinib became the first cBTKi with a negotiated maximum fair price (MFP) in Initial Price Applicability Year 2026[5]
- To inform payer decision making, it is critical to understand current healthcare costs and to estimate the impact of the IRA pricing on the total cost of care for patients with CLL/SLL receiving 1L treatment with cBTKis

METHODS

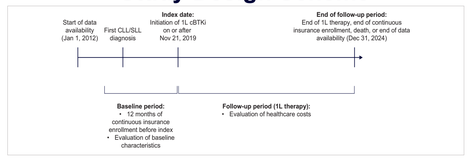
DATA SOURCE

- This study used administrative health claims data from Optum Clinformatics™ Data Mart (January 1, 2012–December 31, 2024)
- Data included information on medical and pharmacy claims for >20 million commercially insured patients and Medicare Advantage beneficiaries across all census regions in the United States
- Data were de-identified and comply with the Health Insurance Portability and Accountability Act

Study Design and Population

- A retrospective cohort study was conducted
- Patients with CLL/SLL were included if they initiated 1L monotherapy with ibrutinib or other cBTKis on or after November 21, 2019 (date of acalabrutinib approval)
- Patients were required to have continuous insurance eligibility, a CLL/SLL diagnosis, no diagnoses associated with other cBTKi indications, and no evidence of CYP3A4 (cytochrome P450 3A4) inhibitor or inducer use or history of stem cell transplant

Study Design Scheme



- Patients were stratified into mutually exclusive cohorts based on the receipt of ibrutinib or other cBTKis (acalabrutinib or zanubrutinib) as 1L treatment (**Supplement**)
  - Analyses were conducted in the overall population and in subgroups by insurance type (commercially insured patients or Medicare Advantage beneficiaries)

Outcomes and Statistical Analyses

- Overlap weighting based on propensity scores was used to balance cohorts overall and by insurance type
- Total per-patient-per-month (PPPM) healthcare costs (2024 US dollars [USD]) were assessed during 1L therapy (ie, from the index date to end of the follow-up period)
- Adjusted regression models were used to estimate mean PPPM cost differences between cohorts with bootstrapped 95% CIs
- Based on Wholesale Acquisition Cost mirroring of the published 38% price reduction per the IRA MFP, a 41% ibrutinib price reduction was applied to simulate costs post-MFP effectuation, holding all other parameters constant

RESULTS

Baseline Characteristics in the Overall Population Post-Weighting Were Well Balanced

Characteristic	Ibrutinib n=767	Other cBTKis[a] n=1330	Standardized Difference (%)
Mean ± SD (median) age at index date, years	74.2 ± 8.3 (75.0)	74.6 ± 8.5 (75.0)	5.1
Female, n (%)	307 (40.0)	532 (40.0)	0.0
Year of index date,[b] n (%)			
2019	21 (2.8)	3 (0.2)	21.1
2020	265 (34.5)	77 (5.8)	76.7
2021	232 (30.3)	163 (12.3)	45.1
2022	136 (17.7)	243 (18.3)	1.5
2023	55 (7.1)	365 (27.5)	55.8
2024	59 (7.7)	479 (36.0)	73.1
US region, n (%)			
South	289 (37.7)	501 (37.7)	0.0
West	200 (26.1)	347 (26.1)	0.0
Midwest	178 (23.3)	309 (23.3)	0.0
Northeast/unknown	99 (13.0)	172 (13.0)	0.0
Race/ethnicity, n (%)			
White	548 (71.5)	951 (71.5)	0.0
Black	86 (11.2)	149 (11.2)	0.0
Other	133 (17.3)	230 (17.3)	0.0
Mean ± SD (median) time between first CLL/SLL diagnosis and index date, months	31.0 ± 30.4 (21.4)	31.0 ± 30.6 (21.2)	0.0
Mean ± SD (median) Quan-CCI	4.3 ± 2.4 (4.0)	4.3 ± 2.4 (4.0)	0.0
Cardiovascular conditions, n (%)			
Hypertension	547 (71.3)	949 (71.3)	0.0
Congestive heart failure	98 (12.8)	170 (12.8)	0.0
Atrial fibrillation	74 (9.7)	129 (9.7)	0.0
Mean ± SD (median) PPPM all-cause total healthcare costs at baseline, USD			
Medical costs	2595 ± 3586 (1305)	2595 ± 3340 (1465)	0.0
Pharmacy costs	263 ± 1589 (41)	263 ± 1002 (56)	0.0
Mean ± SD (median) PPPM all-cause HRU at baseline			
Inpatient admissions	0.02 ± 0.05 (0.00)	0.02 ± 0.05 (0.00)	0.0
Days with ED visit	0.05 ± 0.10 (0.00)	0.05 ± 0.09 (0.00)	0.0
Days with outpatient visit	1.90 ± 1.35 (1.58)	1.88 ± 1.30 (1.58)	1.4
Days with other services[c]	0.50 ± 0.59 (0.33)	0.50 ± 0.62 (0.33)	0.0

ED, emergency department; HRU, healthcare resource utilization; Quan-CCI, Quan–Charlson Comorbidity Index; SD, standard deviation.

[a]Acalabrutinib or zanubrutinib. [b]Year of index date was adjusted for as a categorical variable in the regression model used to evaluate cost differences. [c]Other services were defined as all services that were not identified as inpatient, ED, or outpatient visits.

Study Sample and Baseline Characteristics

- Among 2097 patients with CLL/SLL who initiated a 1L cBTKi, 10.9% (n=228) were commercially insured and 89.1% (n=1869) were Medicare Advantage beneficiaries
- In total, 767 patients initiated ibrutinib and 1330 patients initiated other cBTKis (acalabrutinib, n=886; zanubrutinib, n=444)
- Baseline characteristics were well balanced between cohorts after weighting

Total Healthcare Costs Post-IRA Price Reduction

- In the overall population, PPPM all-cause and CLL-related total healthcare costs (USD) were lower for ibrutinib than for other cBTKis

Weighted PPPM All-Cause and CLL-Related Total Healthcare Costs for Ibrutinib Were Lower Than Other BTKis Post-IRA Price Reduction

Mean ± SD (median) PPPM Costs, USD	Overall	Medicare Advantage	Commercial
All-cause total healthcare costs			
Ibrutinib	12,075 ± 10,216 (10,798)	11,964 ± 10,228 (10,776)	12,411 ± 9666 (11,051)
Other cBTKis[a]	15,960 ± 8144 (16,032)	15,915 ± 8151 (16,008)	16,493 ± 8623 (16,107)
Acalabrutinib	15,422 ± 8141 (15,864)	15,358 ± 8339 (15,729)	16,056 ± 5922 (16,077)
Zanubrutinib	17,065 ± 8048 (16,393)	17,020 ± 7664 (16,368)	17,494 ± 13,345 (16,569)
CLL-related total healthcare costs			
Ibrutinib	10,244 ± 8787 (10,003)	10,180 ± 9138 (9923)	10,425 ± 5153 (10,418)
Other cBTKis[a]	14,101 ± 6928 (15,060)	14,029 ± 7038 (14,988)	15,078 ± 6177 (15,720)
Acalabrutinib	13,663 ± 7265 (14,888)	13,540 ± 7457 (14,749)	15,006 ± 5165 (15,507)
Zanubrutinib	15,003 ± 6115 (15,422)	14,997 ± 6037 (15,274)	15,242 ± 8329 (15,999)
CLL-related pharmacy costs[b]			
Ibrutinib	6898 ± 3596 (7737)	6731 ± 3618 (7198)	8268 ± 3185 (9603)
Other cBTKis[a]	11,568 ± 5029 (13,832)	11,417 ± 5050 (13,639)	12,963 ± 4462 (14,796)
Acalabrutinib	11,089 ± 5247 (13,450)	10,830 ± 5267 (13,094)	13,316 ± 4086 (14,796)
Zanubrutinib	12,551 ± 4411 (14,501)	12,581 ± 4382 (14,444)	12,154 ± 5281 (14,907)

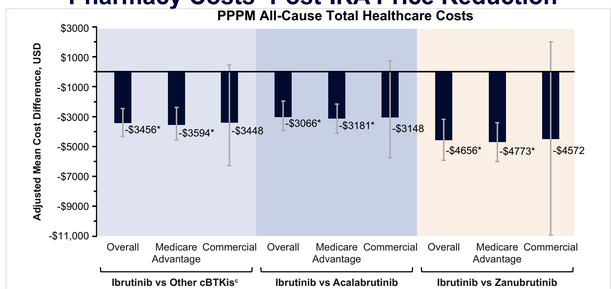
[a]Acalabrutinib or zanubrutinib. [b]Costs for filled BTKi prescriptions.

- After adjusting for the remaining imbalance in the year of the index date, ibrutinib demonstrated significant cost savings compared with other cBTKis in the overall population and among Medicare Advantage beneficiaries
  - Among commercially insured patients, ibrutinib demonstrated numerical cost savings but did not reach statistical significance

Limitations

- Claims data may contain omissions and inaccuracies, but these were expected to equally affect all cohorts and thus should not impact conclusions
- Although analyses were adjusted, residual confounding may remain
- Although there was a ≥12-month washout period for antineoplastic agents before initiation of 1L therapy, patients who previously received fixed-duration regimens may have had a treatment-free interval lasting >12 months; therefore, second-line therapy may have been misclassified as 1L therapy in the current study
- Drug acquisition costs were calculated based on the assumption of complete adherence for all treatments
- Results may not be generalizable to patients with other types of insurance or uninsured patients

Ibrutinib Demonstrated Cost Savings in PPPM All-Cause Total Healthcare Costs and CLL-Related Pharmacy Costs[a] Post-IRA Price Reduction[b]



*Indicates statistical significance (P<0.05).

[a]Costs for filled BTKi prescriptions.
[b]Mean cost differences of <0 indicate that patients receiving ibrutinib had lower costs than those receiving other cBTKis.
[c]Acalabrutinib or zanubrutinib.

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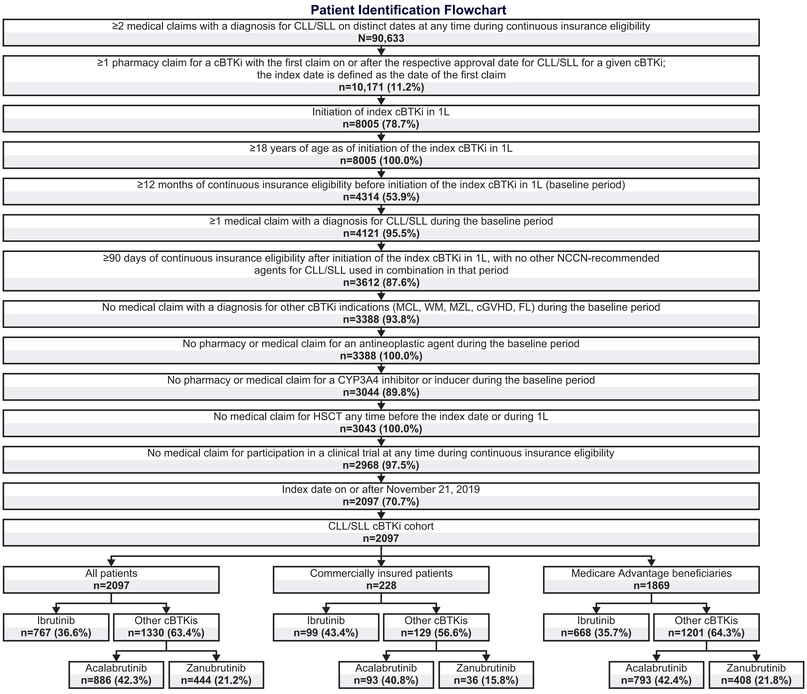
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SUPPLEMENTAL RESULTS

Patient Identification Flowchart



1L, first-line; cBTKi, covalent Bruton tyrosine kinase inhibitor; cGVHD, chronic graft-versus-host disease; CLL, chronic lymphocytic leukemia; CYP3A4, cytochrome P450 3A4; FL, follicular lymphoma; HSCT, hematopoietic stem cell transplant; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; NCCN, National Comprehensive Cancer Network; SLL, small lymphocytic lymphoma; WM, Waldenström macroglobulinemia.

Baseline Characteristics Post-Weighting Were Well Balanced Among Commercially Insured Patients and Medicare Advantage Beneficiaries

Characteristic	Commercial			Medicare Advantage		
	Ibrutinib n=99	Other cBTKis[a] n=129	Standardized Difference (%)	Ibrutinib n=668	Other cBTKis[a] n=1201	Standardized Difference (%)
Mean ± SD (median) age at index date, years	60.6 ± 7.6 (61.0)	60.5 ± 7.8 (61.0)	1.2	76.0 ± 6.5 (76.0)	76.4 ± 6.8 (76.0)	6.7
Female, n (%)	25 (25.3)	33 (25.3)	0.0	279 (41.7)	501 (41.7)	0.0
Year of index date,[b] n (%)						
2019	1 (1.3)	0 (0.0)	16.0	19 (2.8)	3 (0.2)	20.9
2020	47 (47.7)	5 (3.6)	117.1	221 (33.0)	72 (6.0)	72.7
2021	25 (25.5)	25 (19.4)	14.5	209 (31.2)	137 (11.4)	49.8
2022	17 (17.4)	22 (16.8)	1.4	116 (17.4)	218 (18.1)	1.9
2023	6 (6.1)	43 (33.7)	73.8	48 (7.2)	321 (26.8)	54.0
2024	2 (2.1)	34 (26.4)	74.2	56 (8.3)	450 (37.4)	73.8
US region, n (%)						
South	38 (38.7)	50 (38.7)	0.0	253 (37.8)	454 (37.8)	0.0
Midwest	34 (34.5)	45 (34.5)	0.0	147 (21.9)	263 (21.9)	0.0
West	16 (15.7)	20 (15.7)	0.0	181 (27.1)	325 (27.1)	0.0
Northeast/unknown	11 (11.1)	14 (11.1)	0.0	88 (13.2)	158 (13.2)	0.0
Race/ethnicity, n (%)						
White	59 (59.8)	77 (59.8)	0.0	489 (73.1)	878 (73.1)	0.0
Black	9 (9.4)	12 (9.4)	0.0	78 (11.6)	139 (11.6)	0.0
Other	30 (30.7)	40 (30.7)	0.0	102 (15.3)	183 (15.3)	0.0
Mean ± SD (median) time between first CLL/SLL diagnosis and index date, months	26.3 ± 30.6 (15.6)	26.3 ± 25.2 (18.3)	0.0	31.8 ± 30.3 (22.2)	31.8 ± 31.2 (21.7)	0.0
Mean ± SD (median) Quan-CCI	3.3 ± 2.1 (3.0)	3.3 ± 1.8 (3.0)	0.0	4.4 ± 2.4 (4.0)	4.4 ± 2.4 (4.0)	0.0
Cardiovascular conditions, n (%)						
Hypertension	52 (52.6)	68 (52.6)	0.0	489 (73.3)	880 (73.3)	0.0
Congestive heart failure	3 (2.8)	4 (2.8)	0.0	92 (13.8)	166 (13.8)	0.0
Atrial fibrillation	1 (1.2)	1 (1.2)	0.0	71 (10.7)	128 (10.7)	0.0
Mean ± SD (median) PPPM total healthcare costs, USD						
Medical costs	2155 ± 2843 (1105)	2155 ± 2396 (1492)	0.0	2625 ± 3643 (1322)	2625 ± 3411 (1440)	0.0
Pharmacy costs	215 ± 1220 (21)	215 ± 553 (27)	0.0	230 ± 1014 (45)	230 ± 576 (58)	0.0
Mean ± SD (median) PPPM HRU						
Inpatient admissions	0.02 ± 0.04 (0.00)	0.02 ± 0.04 (0.00)	0.0	0.02 ± 0.05 (0.00)	0.02 ± 0.05 (0.00)	0.0
Days with ED visit	0.05 ± 0.11 (0.00)	0.05 ± 0.11 (0.00)	0.0	0.05 ± 0.09 (0.00)	0.05 ± 0.09 (0.00)	0.0
Days with outpatient visit	1.44 ± 0.90 (1.25)	1.43 ± 0.92 (1.25)	1.3	1.95 ± 1.38 (1.58)	1.93 ± 1.33 (1.66)	1.5
Days with other services[c]	0.34 ± 0.44 (0.25)	0.34 ± 0.33 (0.25)	0.0	0.52 ± 0.60 (0.33)	0.52 ± 0.66 (0.33)	0.0

ED, emergency department; HRU, healthcare resource utilization; PPPM, per patient per month; Quan-CCI, Quan–Charlson Comorbidity Index; SD, standard deviation; USD, United States dollar.

[a]Acalabrutinib or zanubrutinib. [b]Year of index date was adjusted for as a categorical variable in the regression model used to evaluate cost differences. [c]Other services were defined as all services that were not identified as inpatient, ED, or outpatient visits.