CLL-144

Real-World Healthcare Costs Among Patients with Chronic Lymphocytic Leukemia Receiving First-Line Treatment with Venetoclax + Obinutuzumab versus Bruton's Tyrosine Kinase Inhibitors

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Summary

This study assessed **real-world healthcare costs** in primarily commercially insured patients with chronic lymphocytic leukemia (CLL) in the United States (US) receiving first-line (1L) treatment with venetoclax-obinutuzumab (VenO) and Bruton's tyrosine kinase inhibitors (BTKis; ibrutinib or acalabrutinib)

Real-world monthly costs among primarily commercially insured patients with CLL were **reduced by over 70% beyond 12 months of fixed-duration VenO** compared with ibrutinib or acalabrutinib

This study highlights the substantial **economic benefit of fixed-duration VenO relative to BTKis**

Monthly costs associated with VenO after the fixed-duration treatment period were **over $8,000 lower** than costs associated with ibrutinib or acalabrutinib

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Background

- VenO and BTKis have become the two main treatment modalities for patients with CLL in the 1L setting
  - VenO is a fixed-duration treatment (prescribed for ~12 months [12 cycles])
  - BTKis are prescribed as a continuous treatment until progression or intolerance.
- Fixed-duration treatment, with a treatment-free remission period, has the potential advantage of lowering healthcare costs by avoiding continuous exposure.
- This study aims to assess real-world healthcare costs in primarily commercially insured patients with CLL in the US receiving 1L treatment with VenO and BTKis (ibrutinib or acalabrutinib).

Methods

- This was a retrospective observational cohort study, using the IQVIA PharMetrics® Plus database, conducted between January 1, 2015 and June 30, 2023.
- Patients diagnosed with CLL/small lymphocytic lymphoma (SLL) between January 1, 2018 and December 31, 2022 were included (**Figure 1**).
- The index date was the date of first treatment claim with VenO, ibrutinib, or acalabrutinib between January 1, 2018 (or their respective Food and Drug Administration [FDA] approval date) and June 30, 2023.
- The baseline period was 36 months pre-index (with only the presence of other CLL therapies being assessed), and the follow-up period was ≥6 months post-index, for up to 24 months.

Figure 1. Study cohort criteria.

Inclusion criteria

- Aged ≥18 years at index with confirmed CLL/SLL diagnosis between January 1, 2018 and December 31, 2022
  - Confirmed CLL/SLL diagnosis defined as ≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart.
- ≥1 claim for venetoclax, ibrutinib, or acalabrutinib on or after CLL/SLL diagnosis claim
  - Patients initiating venetoclax should also have a claim for obinutuzumab 4 weeks pre- to 8 weeks post-venetoclax starter pack claim.
- Continuously enrolled in medical and pharmacy benefits 36 months pre- and 6 months post-index.

Exclusion criteria

- Participated in a clinical trial any time during the continuous enrollment period.
- ≤6 months of follow-up.
- Index date before the index treatment FDA approval date.
- Other primary cancer diagnosis or received stem cell transplant within 6 months pre-index.
- Claim for other CLL therapies during the baseline period (within 36 months pre-index).

Study outcomes

- Healthcare per-patient per-month (PPPM) costs, adjusted to 2023 US dollars using the Cost Performance Index, included all-cause total (sum of medical and pharmacy), medical (outpatient, inpatient, and emergency room costs), and pharmacy costs.
- Costs were computed among patients that met the follow-up duration criteria for each respective time period:
  - Months 0–12 (VenO [~12-month fixed duration therapy] on-treatment period)
  - Months 13–18 (VenO off-treatment period)
  - Months 19–24 (VenO off-treatment period).

Statistical analysis

- Multivariable generalized linear models (Gaussian distribution and identity link) and bootstrapping were used to generate predicted PPPM costs by treatment, cost differentials and 95% confidence intervals (CI).
- Costs were adjusted for age, sex, region, payer type, product type, Charlson Comorbidity Index (CCI) at 12-months pre-index, and total costs at 12 months pre-index.
  - CCI and healthcare resource utilization (HCRU) variables were computed over the 12-months pre-index period as they were the most relevant for controlling confounders proximal to the index date.

Results

Baseline demographics and clinical characteristics

- A total of 997 patients were included; 177 received VenO, 614 received ibrutinib, and 206 received acalabrutinib (**Table 1**)
  - Patients treated with VenO were younger and were more likely to be commercially insured than patients receiving ibrutinib or acalabrutinib
  - Patients treated with ibrutinib had a longer follow-up time compared with patients receiving VenO or acalabrutinib
  - At 12 months pre-index, total costs were lowest for patients treated with acalabrutinib, while costs were generally similar between patients receiving VenO and ibrutinib.

Table 1. Baseline demographics and clinical characteristics.

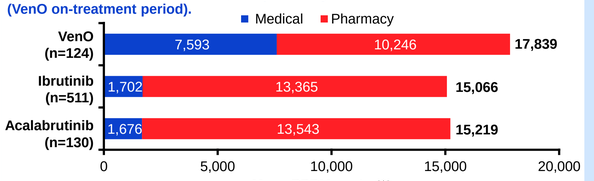
	Overall (N=997)	VenO (n=177)	Ibrutinib (n=614)	Acalabrutinib (n=206)	p-value
Age (years), mean (SD)	63.6 (9.0)	61.1 (9.4)	64.0 (8.8)	64.7 (8.7)	0.001*
Sex, n (%)					
Female	341 (34.2)	61 (34.5)	212 (34.5)	68 (33.0)	0.92†
Male	656 (65.8)	116 (65.5)	402 (65.5)	138 (67.0)	
Region, n (%)					
Northeast	175 (17.6)	32 (18.1)	105 (17.1)	38 (18.4)	
Midwest	298 (29.9)	52 (29.4)	189 (30.8)	57 (27.7)	0.5†
South	345 (34.6)	70 (39.5)	205 (33.4)	70 (34.0)	
West	179 (18.0)	23 (13.0)	115 (18.7)	41 (19.9)	
Payer type, n (%)					
Commercial	513 (51.5)	108 (61.0)	298 (48.5)	107 (51.9)	0.019†
Self-insured	279 (28.0)	47 (26.6)	175 (28.5)	57 (27.7)	
Other	205 (20.6)	22 (12.4)	141 (23.0)	42 (20.4)	
Product type, n (%)					
HMO	163 (16.3)	21 (11.9)	103 (16.8)	39 (18.9)	0.16†
Non-HMO	834 (83.7)	156 (88.1)	511 (83.2)	167 (81.1)	
Follow-up time for HCRU assessment (months), mean (SD)	18.5 (6.3)	17.1 (6.4)	20.0 (5.9)	15.4 (6.1)	<0.001*
CCI, mean (SD)‡	3.0 (1.6)	3.1 (1.6)	3.0 (1.6)	2.8 (1.5)	0.2*
Total costs per month ($), mean (SD)‡	2,941.4 (3,878.7)	3,103.7 (2,882.4)	3,271.3 (4,397.6)	1,818.7 (2,553.1)	<0.001*

*Kruskal-Wallis rank sum test; †Pearson's Chi-squared test; ‡Assessed at 12 months pre-index.
HMO, health maintenance organization; SD, standard deviation.

Predicted total, medical and pharmacy costs (Months 0–12; VenO on-treatment period)

- During Months 0–12 (VenO on-treatment period), total PPPM costs with VenO were ~$2,700 higher than ibrutinib and acalabrutinib (**Figure 2**)
  - This was likely due to the increased medical cost of initiating venetoclax with intravenous obinutuzumab.

Figure 2. Predicted total, medical, and pharmacy costs PPPM in Months 0–12 (VenO on-treatment period).



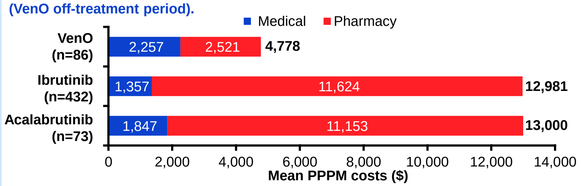
	Difference: VenO versus ibrutinib	Difference: VenO versus acalabrutinib
Total	**2772**	**2620**
Medical	5891	5917
Pharmacy	–3119	–3298

Results

Predicted total, medical and pharmacy costs (Months 13–18; VenO off-treatment period)

- During Months 13–18, (VenO off-treatment period), total PPPM costs for VenO decreased to $4,778, while costs were ~$13,000 for both ibrutinib and acalabrutinib (**Figure 3**)
  - Costs for VenO were ~$8,000 lower compared with ibrutinib and acalabrutinib due to the reduction in pharmacy costs associated with VenO in the off-treatment period compared with the on-treatment period.

Figure 3. Predicted total, medical, and pharmacy costs PPPM in Months 13–18 (VenO off-treatment period).

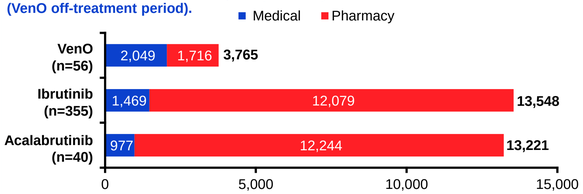


	Difference: VenO versus ibrutinib	Difference: VenO versus acalabrutinib
Total	**–8203**	**–8223**
Medical	900	409
Pharmacy	–9103	–8632

Predicted total, medical and pharmacy costs (Months 19–24; VenO off-treatment period)

- During Months 19–24 (VenO off-treatment period), similar cost patterns were observed as those across Months 13–18 (**Figure 4**)
  - Total monthly costs associated with VenO remained low ($3,765), compared with costs associated with ibrutinib and acalabrutinib (~$13,000)
  - While the monthly medical costs associated with VenO were $600–$1000 higher than BTKis during this period, monthly pharmacy costs continued to be ~$10,000 higher for BTKis compared with VenO.

Figure 4. Predicted total, medical, and pharmacy costs PPPM in Months 19–24 (VenO off-treatment period).



	Difference: VenO versus ibrutinib	Difference: VenO versus acalabrutinib
Total	**–9783**	**–9456**
Medical	580	1072
Pharmacy	–10,363	–10,528

Conclusions

- Real-world monthly costs among primarily commercially insured patients with CLL in the US were reduced by over 70% beyond 12 months of fixed-duration VenO; this finding was largely driven by lower pharmacy costs compared with medical costs in the off-treatment period
  - During Months 13–18, monthly predicted total PPPM costs declined by 73% for VenO (from $17,893 to $4,778), but was only reduced by 14% for both ibrutinib (from $15,066 to $12,981) and acalabrutinib (from $15,219 to $13,000)
  - Similarly, during Months 19–24, monthly predicted total PPPM costs were substantially lower for VenO ($3,765) compared with ibrutinib ($13,548) and acalabrutinib ($13,221).
- This decline was not observed with ibrutinib or acalabrutinib, highlighting the economic benefit of fixed-duration VenO compared with treat-to-progression BTKis.

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Disclosures

AR: employee at the time of study (Genentech, Inc.); stock ownership (F. Hoffmann-La Roche Ltd); **AP:** current employment (Genentech/Roche); ended employment in the past 24 months (GSK); stock ownership (Genentech/Roche); **TT:** current employment (Genentech, Inc.); stock ownership (Genentech, Inc.); **SL:** current employment (Genentech, Inc.); stock ownership (Genentech, Inc.); **SH:** honoraria (Medscape); consulting or advisory role (Janssen, Genentech, Inc., AbbVie, Inc. Flatiron Health, BeiGene, AstraZeneca, ADC Therapeutics, Epizyme, Merck, Seattle Genetics, TG Therapeutics, Tyme, Pharmacyclics, and Arvinas).