Healthcare Resource Utilization and Costs among Elderly Medicare Beneficiaries Initiating Venetoclax vs. BTKis for Relapsed/Refractory Chronic Lymphocytic Leukemia: A Real-World Analysis

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OBJECTIVE

To examine real-world healthcare resource utilization (HRU) and costs associated with venetoclax vs. BTKis in the first year after initiation in older adults with relapsed/refractory (R/R) CLL

CONCLUSIONS

This national study represents the first direct, head-to-head comparison of HRU and costs in Medicare beneficiaries treated with venetoclax vs. BTKis.

Elderly adults with R/R CLL initiating venetoclax had lower risk-adjusted total all-cause and CLL-related costs than BTKi initiators in the first year after treatment initiation, largely driven by differences in prescription costs.

Our study illustrates the cost-savings afforded by venetoclax-based regimens, which can be a consideration for treatment selection to help avoid financial toxicity for patients and lessen healthcare burden on payers.

Future research should examine how these cost differences evolve over time given the fixed-duration nature of venetoclax treatment relative to the continuous treatment paradigm of BTKis.

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INTRODUCTION

- Novel oral agents such as BCL-2s (i.e., venetoclax) and BTKis (e.g., ibrutinib) have transformed treatment for chronic lymphocytic leukemia (CLL).
  - First BTKi ibrutinib approved for CLL in Feb 2014
  - Venetoclax first approved for relapsed/refractory CLL with 17p deletion in April 2016
- Few prior studies have assessed healthcare resource utilization (HRU) and costs among patients with CLL receiving BTKis or venetoclax.
  - Direct, head-to-head comparisons are sparse.
- Evidence is particularly lacking in the U.S. Medicare program, which represents a major gap in the literature and has major implications for real-world effectiveness:
  - CLL is most prevalent in the elderly population, who primarily receive coverage through the Medicare program.
  - Elderly patients are typically excluded from clinical trials owing to their comorbidities.

METHODS

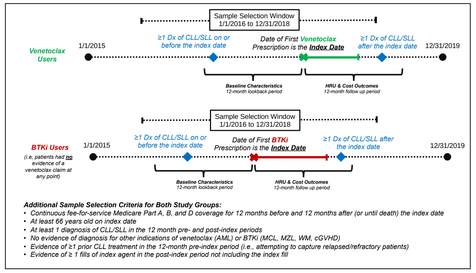
Study Design

- Retrospective cohort study using 2015-2019 100% Medicare claims data

Sample Selection

- All fee-for-service Medicare beneficiaries age ≥66 years newly initiating venetoclax between 1/1/2016 and 12/31/2018 were identified
- From the remaining individuals during the same time period, we also identified patients newly initiating a BTKi
- See **Figure 1** for additional sample selection criteria

Figure 1. Study Schematic



Outcomes

- All-cause and CLL-related HRU and costs in the 12-months after treatment initiation were examined.

Analysis

- Risk-adjusted outcomes controlling for differences in sociodemographic and clinical factors between the two groups were estimated using logistic regressions and generalized linear models (GLM) for key HRU and cost outcomes, respectively.
- Adjusted estimates using method of recycled predictions were produced for the key outcomes

RESULTS

- The final sample contained 711 and 1,566 mutually exclusive groups of beneficiaries initiating venetoclax and BTKis, respectively.
- Compared to the BTKi group, the venetoclax group tended to be slightly younger (median age 75.0 vs 77.0 years, p<0.001) but had poorer clinical characteristics (for example, 39.4% vs. 30.4% with ≥8 comorbidities, 15.8% vs.10.7% with ≥ 3 prior CLL agents and 51.5% vs. 42.5% with any hospitalization in the 12-months pre-index). (**Table 1**)

Table 1. Sample Characteristics

	Venetoclax Group	BTKi Group[a]	p-value
Characteristic			
N	711	1566	
Age, median[b]	75.0	77.0	<.0001
Male[b]	59.6%	59.5%	0.957
White[b]	>88.7%[i]	88.8%	0.8368
South	37.6%	37.4%	0.6252
Urban[b]	84.5%	78.9%	0.0017
Receiving Part D Low-Income Subsidy[b]	8.9%	14.6%	0.0001
Enhanced alternative Part D benefit	50.8%	47.8%	0.4316
Number of Elixhauser comorbidities[b,c]			0.0003
0	<1.5%[i]	1.3%	
1-2	9.7%	10.9%	
3-4	18.0%	21.9%	
5-7	>31.4%[i]	35.6%	
8-10	26.0%	22.1%	
11+	13.4%	8.3%	
CLL treatments around index drug initiation[d]			
None (i.e. venetoclax or BTKi only)	45.7%	68.9%	
Obinutuzumab	6.9%	4.2%	0.0069
Rituximab	23.1%	19.4%	0.0456
BTK Inhibitors	25.5%	N/A	
Other	11.1%	13.6%	0.0995
Number of prior CLL agents[c]			
1-2	84.2%	89.3%	
3-4	13.1%	9.2%	
5+	2.7%	1.5%	
All-cause hospitalization[e]	51.1%	42.5%	0.0001
All-cause medical costs[e], mean (SD)	$68,678 ($61,605)	$68,606 ($53,435)	0.9784
All-cause pharmacy costs[e,f], mean (SD)	$68,568 ($52,945)	$7219 ($17,338)	<.0001
CLL-related hospitalization[g]	46.7%	36.8%	
CLL-related medical costs[g], mean (SD)	$37,740 ($44,238)	$30,047 ($37,386)	<.0001
CLL-related drug costs[g,h], mean (SD)	$80,908 ($51,209)	$33,658 ($31,296)	<.0001
Index year[b]			<.0001
2016	10.1%	38.4%	
2017	29.0%	33.5%	
2018	60.9%	28.2%	
Died during follow-up[b]	21.8%	20.1%	0.3571

[a] BTKi group consisted almost exclusively of patients treated with ibrutinib, though some patients were using acalabrutinib
[b] Covariate included in regressions for all HRU and cost outcomes
[c] Assessed in 12-month pre-index period
[d] Assessed in the 4-week pre-index and 8-weeks post-index periods
[e] Covariate included in regressions for all-cause hospitalization and cost outcomes
[f] Includes only Part D prescription drug costs.
[g] Covariate included in regressions for CLL-related hospitalization and cost outcomes
[h] Includes Part D prescription drug costs and physician-administered Part B drug costs; hence CLL-related drug costs appear higher.
[i] Exact value cannot be reported per CMS policy because it represents a cell size <11 patients.

Figure 2. Unadjusted Healthcare Costs

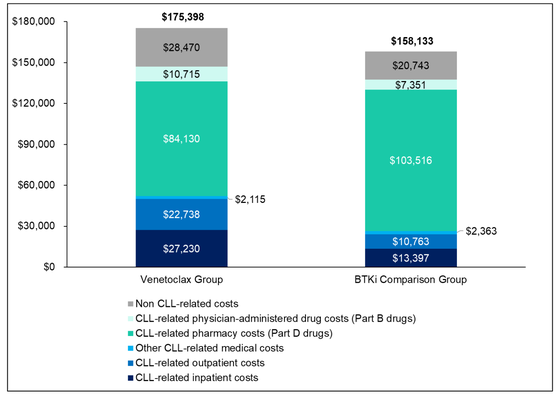


Table 2. Unadjusted Healthcare Resource Use

	Venetoclax Group	BTKi Comparison Group
N	711	1566
All-cause HRU		
Any hospitalization (%)	67.1%	48.9%
Any skilled nursing facility stay (%)	10.0%	11.1%
Any hospice care (%)	12.0%	11.8%
Any physician visits (%)	>98.5%[a]	>99.3%[a]
Number of visits, mean (SD)	24.5 (12.5)	20.9 (11.2)
CLL-related HRU		
Any hospitalization (%)	62.2%	43.0%
Any skilled nursing facility stay (%)	6.2%	6.5%
Any hospice care (%)	7.2%	7.0%
Any physician visits (%)	94.0%	95.2%
Number of visits, mean (SD)	13.0 (9.4)	10.8 (7.2)

[a] Exact value cannot be reported per CMS policy because it represents a cell size <11 patients.

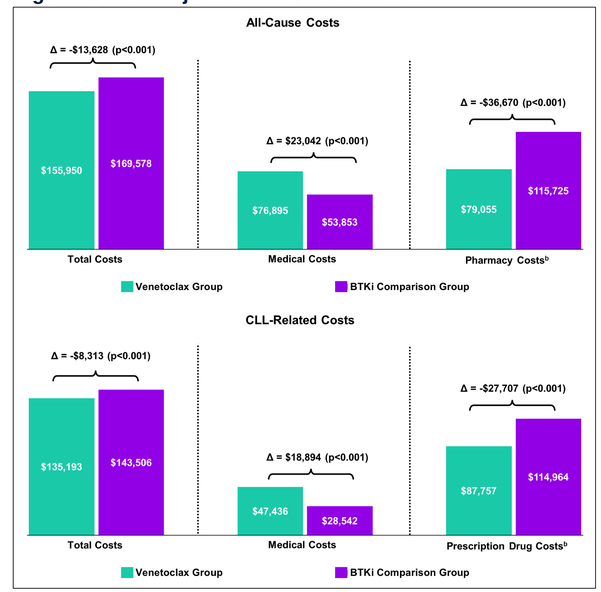
Unadjusted Results

- Total all-cause costs were $175,398 for venetoclax patients and $158,133 for BTKi patients (a difference of $17,265, p<0.001, **Figure 2**)
  - Over 80% of all-cause costs were CLL-related.
- Compared to BTKi patients, venetoclax patients had higher unadjusted CLL-related medical costs ($52,082 vs. $26,524) and lower unadjusted prescription drug costs ($94,845 vs. $110,867, **Figure 2**).
- The all-cause hospitalization rate was 67.1% for the venetoclax patients and 48.9% for the BTKi patients, a difference of 18.2% (p<0.001, **Table 2**)
  - Over 80% of the unadjusted all-cause HRU were CLL-related.
- Other than hospitalization, the samples did not differ on HRU measures. (**Table 2**)

Adjusted Results

- After risk-adjustment, venetoclax patients had lower all-cause total healthcare costs ($155,950) compared to BTKi patients ($169,578), resulting in an absolute difference of -$13,628 (p<0.001, **Figure 3**).
- Risk-adjusted CLL-related prescription costs were lower ($87,757 vs. $114,964, p<0.001) and CLL-related medical costs were higher ($47,436 vs. $28,542, p<0.001) for venetoclax patients relative to BTKi patients, respectively. (**Figure 3**)
- Overall, venetoclax patients had lower risk-adjusted CLL-related total costs compared to BTKi patients (-$8,313, p<0.001, **Figure 3**)
- The risk-adjusted rate of all-cause and CLL-related hospitalization was 63.7% and 60.2% for venetoclax patients and 50.9% and 43.9% for BTKi patients, respectively (p<0.001 for all).

Figure 3. Risk-Adjusted[a] Healthcare Costs



[a] Risk-adjusted rates estimated from multivariable logistic regressions using covariates identified in Table 1.
[b] All-cause pharmacy costs include self-administered Part D medications. CLL-related prescription drug costs includes self-administered Part D medications and physician-administered Part B drugs; hence, CLL-related prescription drug costs are higher than all-cause pharmacy costs.

LIMITATIONS

- Claims data lacks clinical information (e.g., disease stage) or medical chart notes.
- Follow-up was limited to 12 months after initiation of venetoclax or BTKi in R/R setting.
- Despite risk adjustment, there could still be unobserved confounders between the venetoclax and BTKi groups that could bias results
- Results are generalizable only to the fee-for-service Medicare Part D population