Medicare Part D Out-of-Pocket (OOP) Costs for Venetoclax-Obinutuzumab vs. BTKis in Frontline CLL: Modeling the Benefits of Fixed-Duration Treatment and Changes Under the Inflation Reduction Act (IRA)

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OBJECTIVE

To model the Medicare Part D prescription drug OOP costs before and after completion of the fixed-duration treatment period for venetoclax-obinutuzumab (VEN) relative to continuous BTKis (ibrutinib or acalabrutinib) for first-line CLL, with and without an annual OOP maximum.

CONCLUSIONS

In this modeling study, Medicare beneficiaries with CLL treated with VEN had lower OOP costs in both the on- and off-treatment periods compared to continuous BTKis prior to the IRA.

The institution of the annual OOP maximum of $2000 from 2025 onwards will lower OOP costs for VEN and BTKi patients, but VEN patients will continue to have lower OOP costs over time compared to BTKi patients due to the fixed duration of VEN treatment.

Our study highlights the substantial OOP savings for beneficiaries prescribed VEN relative to treat-to-progression therapies like BTKis and carries implications for treatment decision-making.

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INTRODUCTION

- Venetoclax-obinutuzumab (VEN) and BTK inhibitors (BTKi) such as ibrutinib (IBR) and acalabrutinib (ACAL) have become key chemotherapy-free treatment options for patients with chronic lymphocytic leukemia (CLL) in the front-line (1L) setting[1]
  - VEN in combination with obinutuzumab is a 12-month fixed-duration therapy
  - BTKi treatment is indicated for use until disease progression or intolerance
- However, out-of-pocket (OOP) costs may impede utilization of these novel oral therapies among Medicare Part D beneficiaries with CLL, despite the Inflation Reduction Act's recent introduction of a $2,000 annual OOP maximum effective January 1, 2025
  - In this respect, fixed-duration VEN treatment may offer an advantage over treat-to-progression BTKis
- No study has assessed OOP costs for Medicare beneficiaries with CLL since the introduction of fixed-duration VEN-based combination therapies
- Evidence is particularly lacking in the U.S. Medicare program, which represents a major gap in the literature and has major implications:
  - CLL is most prevalent in the elderly population, who primarily receive coverage through the Medicare program
  - Elderly patients typically have limited financial means and are therefore more susceptible to financial toxicity
  - Prior studies have shown increased OOP costs to be associated with prescription abandonment and delayed initiation of novel oral anticancer agents[2]

METHODS

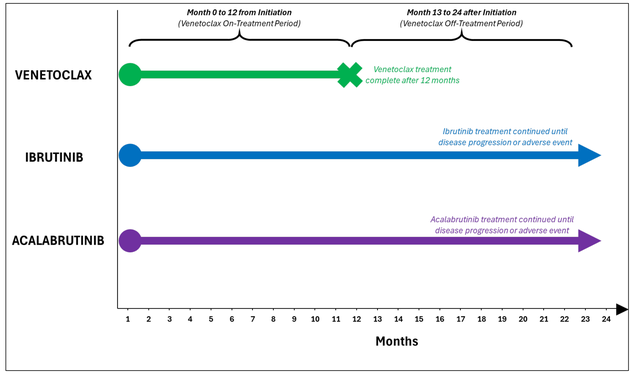
Study Design

- Modeling study using Medicare Part D prescription drug benefit

Outcomes

- Mean cumulative OOP costs were simulated for VEN and BTKi users over two fixed time periods (see **Figure 1**):
  - Months 0 to 12 from initiation (i.e. proxy for on-treatment period for VEN)
  - Months 13 to 24 after initiation (i.e. proxy for off-treatment period for VEN)
- Out-of-pocket costs were summed across each benefit phase (e.g., deductible, initial coverage, coverage gap, catastrophic, see **Figure 2**)

Figure 1. Fixed-Duration vs. Continuous Treatment Paradigm per FDA Treatment Label

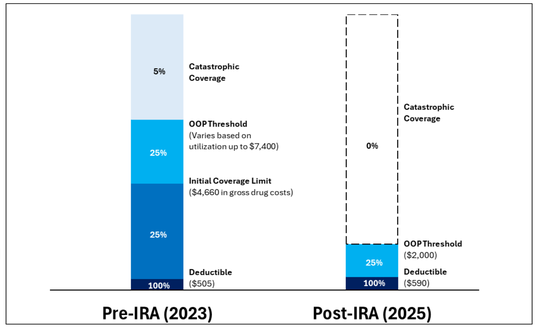


METHODS (cont.)

Analysis

- OOP costs were modeled for each of the three agents (VEN, IBR, ACAL) using the Medicare Part D benefit structure (see **Figure 2**)
  - 2023 Medicare Part D benefit (pre-IRA w/ no annual OOP maximum)
  - 2025 Medicare Part D benefit (post-IRA w/ a $2,000 annual OOP maximum)
- Model assumptions:
  - Patients initiated treatment on January 1 (i.e., at the beginning of the first phase of the Part D benefit)
  - Patients received treatment according to the FDA label over the entire expected on-treatment period (i.e., 12 months for VEN vs. continuously for BTKis) and did not cease treatment (for instance, due to adverse events or disease progression)
  - Patients were only receiving a single Part D therapy (VEN, IBR, or ACAL) and no other Part D medications for CLL or other conditions
  - Patients were enrolled in standard Part D benefit
  - For all analyses, drug prices[3] remained at 2023 levels, though Part D thresholds for the deductible/coverage gap were adjusted

Figure 2. Patient OOP Cost Liability* Across Medicare Part D Benefit Phases, Pre- and Post-IRA

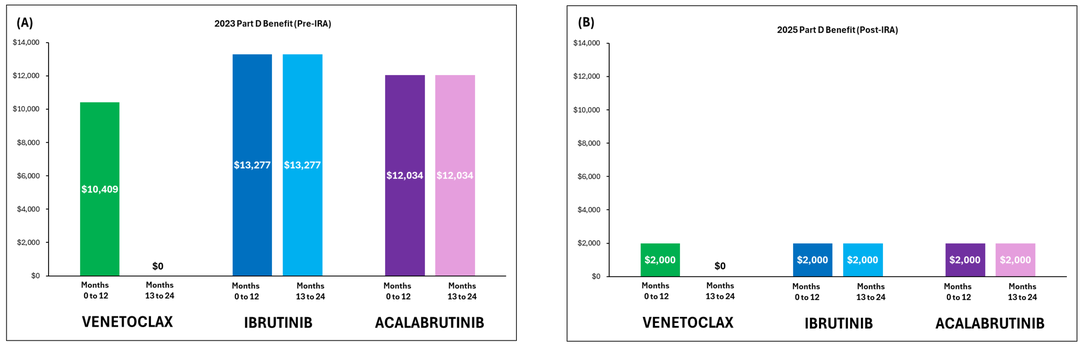


***Note:** Percentages correspond to coinsurance (i.e., OOP liability) per beneficiary in each Medicare Part D benefit phase.*

RESULTS

- In 2023, mean cumulative OOP costs for VEN ($10,409) were lower in Months 0-12 compared to IBR ($13,277) and ACAL ($12,034) (**Figure 3a**)
  - Further, OOP costs for VEN dropped to $0 in Months 13-24 whereas OOP costs remained the same amount for BTKis
- In 2025, OOP costs between Months 0-12 will be the same at $2,000 for all three agents given the annual OOP maximum (**Figure 3b**)
  - However, during Months 13-24 the OOP costs for VEN will drop to $0 whereas BTKi users would continue to incur $2000

Figure 3. Mean Cumulative Out-of-Pocket Costs for Fixed-duration Venetoclax vs. Continuous Ibrutinib and Acalabrutinib under the Medicare Part D Benefit (Pre- and Post-IRA)



LIMITATIONS

- Results from this modeling analysis will need to be confirmed using real-world data
- Analysis focused solely on novel oral cancer therapies; in reality, many patients will be receiving additional medications, some of which could have significant OOP costs of their own
- OOP costs for VEN did not include costs for obinutuzumab, a therapy received under Medicare Part B; however, most Medicare beneficiaries will have supplemental insurance to cover Medicare Part B cost sharing
- Analysis assumed patients would remain on treatment per FDA label; in the real-world setting, early discontinuation (particularly of the BTKis) is a common occurrence

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