# Budget Impact of Pirtobrutinib for Patients with Mantle Cell Lymphoma (MCL) or Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) in the United States (US)

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## Background

- Pirtobrutinib is a non-covalent (reversible) BTK inhibitor (BTKi) with FDA approval for patients with relapsed or refractory (R/R) MCL after at least two lines of systemic therapy, including a BTKi, and for patients with CLL/SLL who have received at least two prior lines of therapy, including a BTKi and a BCL-2 inhibitor (BCL2i).
- Accelerated approvals were based on the single-arm BRUIN trial (NCT03740529, LOXO-BTK-18001).[13]
- Population estimates and budget impact of pirtobrutinib for MCL alone were presented previously.[1] Here, we expand this work to include the recent CLL/SLL indication.

### Objective

To estimate the budget impact of introducing pirtobrutinib as a treatment option for patients with R/R MCL or CLL/SLL to a payer's formulary (US commercial or Medicare) over a 5-year time horizon

## Methods

### Population eligible for pirtobrutinib (patient funnel)

| Parameter | Number of Patients | | |
|---|---|---|---|
| | Medicare | Commercial | Source/Notes |
| Plan population size | 1,000,000 | 1,000,000 | Assumption |
| Number of adult patients | 1,000,000 | 610,215 | Assumed Medicare 100%. Commercial 61.0% US Census Bureau (2021).[2] |
| **CLL/SLL** | | | |
| • Incident CLL/SLL model population | 228.0 | 13.4 | Calculated. Age-based incidence from SEER Stat (2021).[3] |
| • Patients who received both a cBTKi and BCL2i | 4.9 | 0.3 | Calculated. Lilly data on file from ConcertAI.[6] |
| • Patients who received post-dual therapy | **2.9** | **0.2** | Calculated. Lilly data on file of ConcertAI.[6] |
| **MCL** | | | |
| • Incident MCL model population | 45.0 | 2.4 | Calculated. Age-based incidence from SEER Stat (2021).[3] |
| • Patients who received a cBTKi | 9.6 | 0.5 | Calculated. Hess et al (2022).[14] |
| • Patients who received > 2 lines of systemic therapy | **5.7** | **0.3** | Calculated. Lilly data on file from Flatiron Health.[7] |
| **Total Population** | **8.6** | **0.5** | Calculated sum of CLL/SLL and MCL eligible patients. |

[a]The study used a curated dataset of deidentified, longitudinal, patient-level electronic health record data from ConcertAI.
[b]The study used the nationwide, longitudinal Flatiron Health electronic health record-derived, deidentified database, comprising patient-level data originated from ~280 cancer clinics (~800 sites; primarily community oncology settings) and curated via technology-enabled abstraction.[4,5]

### Treatment Options

- Market share for pirtobrutinib was assumed to be 39% in year 1 (year of pirtobrutinib approval) and 50% for years 2-5 (post approval).
- Alternative treatment options were identified from ConcertAI[a] data (MCL) or Flatiron Health[b] data (CLL/SLL).[6,7]
- MCL: rituximab +/- bendamustine, lenalidomide +/- rituximab, venetoclax +/- cBTKi, cBTKi monotherapy, chimeric antigen receptor T-cell therapy (CAR-T), and standard chemotherapy
- CLL/SLL: bendamustine + rituximab, cBTKi +/- obinutuzumab, anti-CD20 +/- venetoclax, PI3K inhibitor, and chemo-immunotherapy

### Costs

- Costs included in the model were drug acquisition (WAC[8] and ASP[9]), drug administration,[10] healthcare monitoring,[10,11] and treatment of grade 3/4 adverse events.[12]
- Costs were incurred for the duration of time on treatment, estimated from the BRUIN trial[13] and Flatiron Health data.[7]
- Total and per-member-per-month (PMPM) costs were estimated over a 5-year period per million members.

### Sensitivity analysis

- Robustness of findings was evaluated with one-way sensitivity analyses (OWSA), using bounds of +/- 20%.

## Results

### Medicare perspective

- The combined MCL and CLL/SLL budget impact of pirtobrutinib resulted in incremental PMPM costs ranging from $0.011 to $0.032 over the 5 years modeled.
- The net incremental budget impact ranged from $121,663 to $366,602 over the 5 years modeled (Figure 1).
- OWSA showed that duration of pirtobrutinib treatment and monthly acquisition costs had the greatest impact on results (Figure 3).

### Commercial perspective

- The combined MCL and CLL/SLL budget impact resulted in incremental PMPM costs ranging from <$0.001 in years 1-3 to $0.002 in years 4-5.
- The net incremental budget impact ranged from $5,970 to $18,894 over the 5 years modeled (Figure 2).
- OWSA showed consistent parameters of greatest impact as seen with Medicare (data not shown).

**Figure 1. Annual Budget Impact of Pirtobrutinib From a Medicare Perspective: Incremental Total Costs**

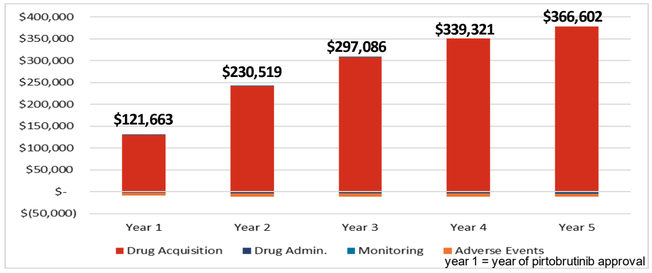



**Figure 2. Annual Budget Impact of Pirtobrutinib From a Commercial Perspective: Incremental Total Costs**

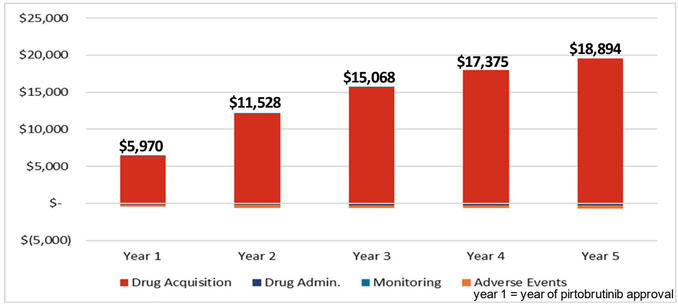
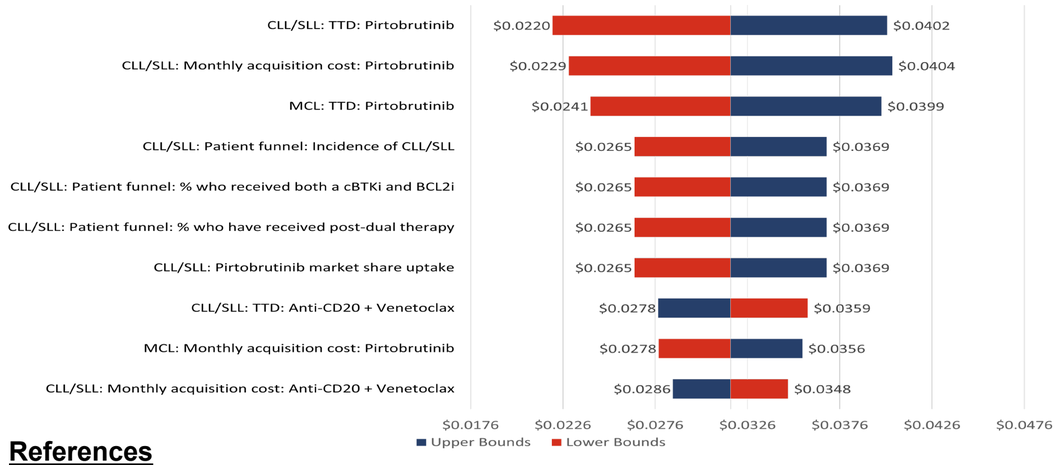



**Figure 3. One-Way Sensitivity Analysis: Top 10 Parameters (Medicare)**




## Conclusion

This model demonstrates the minimal budget impact of pirtobrutinib for patients with MCL or CLL/SLL, largely due to small patient populations eligible for treatment.

### Limitations

- With low incidence and thus few patients eligible in a 1,000,000-member plan, budget-impact results calculated using average expected value costs may not reflect those of a single plan.
- Only one line of therapy was modeled so budget impact is limited to patient costs within that time window.
- Published drug acquisition costs were used, which may not reflect actual price paid by all US payers.
- Market share estimates are assumptions and may not reflect actual use in clinical practice.

### References

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