Estimation of the Patient Population Eligible for Pirtobrutinib and the Budget Impact of Pirtobrutinib for Patients with Mantle Cell Lymphoma After Covalent Bruton Tyrosine Kinase Inhibitor Discontinuation in the United States

EPH131

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BACKGROUND & OBJECTIVE

- Pirtobrutinib is a highly selective, non-covalent (reversible) Bruton tyrosine kinase inhibitor (BTKi).
- It is FDA-approved for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL), after at least two lines of systemic therapy, including a BTK inhibitor.
- MCL is diagnosed in less than 3,341 people per year in the United States (US)[1] and accounts for 5 to 7% of all lymphomas.[2]
- Objective one: to estimate the annual population of patients with R/R MCL who may be eligible for treatment with pirtobrutinib in US commercial and Medicare health plans
- Objective two: to estimate the budget impact of introducing pirtobrutinib as a treatment option to a payer's formulary (US commercial or Medicare) over a 5-year time horizon

METHODS

Population Funnel

- A funnel (Figure 1) was constructed to narrow a US health plan population to those patients eligible for treatment with pirtobrutinib. Input data are outlined in Table 1.
- Health plan size was assumed as 1,000,000 members.
- For the Medicare population, all patients were assumed to be 65+ years of age.
- The percentage of adult patients aged 18-64 years for the commercial population was estimated using US Census Bureau data (2021).[3]
- The age-dependent incidence of MCL was estimated using the Surveillance, Epidemiology, and End Results Program of the National Cancer Institute.[4]
- Real-world data from US electronic medical records were analyzed to estimate the percentage of patients who received a prior cBTKi-containing regimen[5] and the percentage of patients who received more than 2 lines of systemic therapy.[6]

METHODS

Budget Impact (Model in Microsoft Excel)

- The population funnel identified the number of patients eligible for pirtobrutinib treatment.
- Alternative treatment options were identified from ConcertAI electronic health record data.
  - rituximab +/- bendamustine, lenalidomide +/- rituximab, venetoclax +/- cBTKi, cBTKi monotherapy, chimeric antigen receptor T-cell therapy (CAR T), and standard chemotherapy
- Costs included in the model were drug acquisition (WAC[7] and ASP[8]), drug administration,[9] monitoring,[9,10] and treatment of adverse events.[10]
- Costs were incurred for the duration of time on treatment, estimated from the BRUIN trial[12] and Flatiron Health Electronic Medical Record data.[6]
- Market share estimates and pirtobrutinib uptake projections over the modeled time horizon (39% in year 1 to 62% in year 5) were assumptions.

RESULTS

Budget Impact

- Medicare perspective
  - The budget impact of the introduction of pirtobrutinib was negligible with incremental per-member per-month (PMPM) costs ranging from $0.003 to $0.006 over the 5 years modeled.
  - Net budget impact was approximately $33,000 to $67,000 over the 5 years modeled (Figure 2).
- Commercial perspective
  - PMPM budget impact was less than $0.001 for each year modeled.
  - Net budget impact was approximately $2,100 to $4,400 over the 5 years modeled (Figure 3).
- One-way sensitivity analyses showed that budget impact was most sensitive to the time on treatment for pirtobrutinib and the monthly acquisition cost of pirtobrutinib.

RESULTS

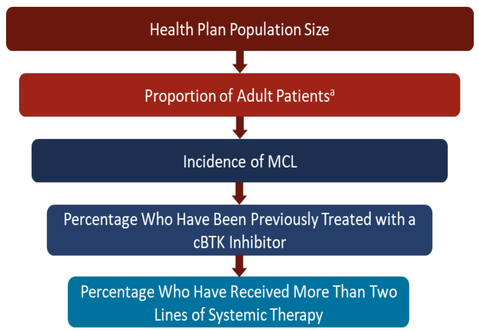
Population Funnel

- If pirtobrutinib were to claim 100% of the market share for these patients, 0.4 and 5.7 patients per million would receive pirtobrutinib in the commercial and Medicare populations, respectively.
- With projected market share estimates, < 1 to < 4 patients would receive pirtobrutinib in the commercial and Medicare populations, respectively.

CONCLUSIONS

- Pirtobrutinib was estimated to result in a negligible budget impact for each of the 5 years observed from both the Medicare and commercial perspectives.
- This impact was due to a shift in market share to pirtobrutinib from less expensive regimens.

Figure 1. Population Funnel



a. For the commercial perspective, patients are aged 18-64 years. For the Medicare perspective, patients are aged 65+ years.

Table 1. Funnel Input Parameters and Estimated Number of Patients Eligible for Pirtobrutinib

Parameter	Input - Medicare	Input - Commercial	Source
Health plan population size	1,000,000	1,000,000	Assumption.
Percentage of adult patients	100.0%	61.0%	Medicare: Assumption. Commercial: US Census Bureau (2021).
Incidence of MCL (per 100,000)	4.5	0.5	SEER (2017).
Percentage who received a cBTKi-containing regimen	21.4%	21.4%	Hess et al. (2022).
Percentage who received more than two lines of systemic therapy[a]	59.0%	59.0%	Lilly data on file (2022).
Estimated number of patients with MCL eligible for pirtobrutinib	5.7	0.4	

a.The data considered to calculate this value are a general estimate of the number of lines of therapy and do not account for the timing of cBTKi treatment. Therefore, the eligible population may be overestimated.

Figure 2. Annual Budget Impact of Introduction of Pirtobrutinib From a Medicare Perspective: Incremental Total Costs

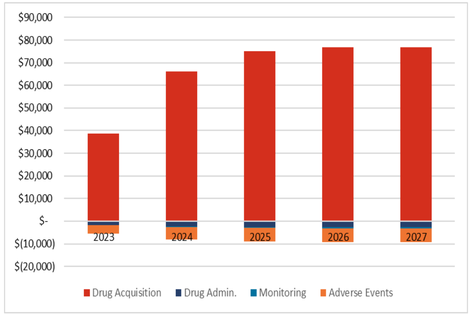
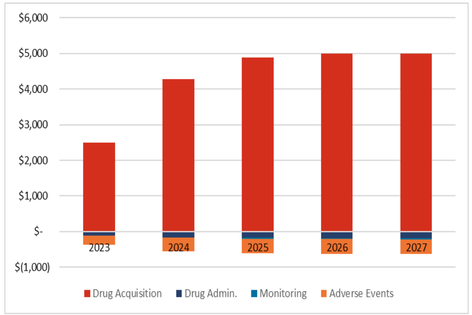


Figure 3. Annual Budget Impact of Introduction of Pirtobrutinib From a Commercial Perspective: Incremental Total Costs



Limitations

- With low MCL 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 costs within that time window.
- Pirtobrutinib market share estimates are assumptions and may not reflect actual use in patients with R/R MCL.

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