BUDGET IMPACT ANALYSIS OF THE INCORPORATION OF IBRUTINIB FOR THE TREATMENT OF RELAPSED/REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVE

The advent of novel targeted therapies, such as ibrutinib, has altered the treatment paradigm for Chronic Lymphocytic Leukemia (CLL) in the recent years. The aim of this study was to estimate the budget impact of ibrutinib, a first-in-class once daily Bruton’s Tyrosine Kinase inhibitor, for the treatment of relapsed/refractory (R/R) CLL in the Brazilian private healthcare system (BHPS).

METHODS

A budget impact analysis (BIA) was developed to project investments over the years from 2016 to 2019. An approach based on Brazilian age-adjusted incidence rate (IR) for R/R CLL patients was used to estimate the population eligible for analysis. Two scenarios were simulated: (1) current setting, in which patients are treated either with fludarabine-cyclophosphamide-rituximab (FCR) or ofatumumab monotherapy; (2) proposed setting, with introduction of ibrutinib monotherapy. Annual treatment costs were calculated following doses/intervals defined in the guidelines. Final costs were calculated considering drug acquisition costs and prices were gathered from the official Brazilian government website (MED-ANIHS). Expected ibrutinib adoption rates were assumed over ofatumumab.

RESULTS

Based on projected Brazilian total population (2016-2019) and employing proportion of patients in BHPS (24.70%), the BIA estimated eligible patient cohort with R/R CLL ranging from 158 (2016) to 166 (2019). Considering that all drugs would be considered tax-exempt, incorporation of ibrutinib would incur higher expenses for the treatment of R/R CLL, a budget impact of R$7,400,062 in 2016 and R$15,656,728 in 2019 and cumulative budget impact of R$45,801,929 (2016-2019). Considering the present population in BHPS, incorporation of ibrutinib would produce budget impact ranging from R$0.012 to R$0.025 per month, per life insured (table 4, Figure 1).

CONCLUSIONS

In this BIA, the introduction of ibrutinib in BHPS as an option for R/R CLL patients would bring a small budget impact for private payers over the next 4 yrs, albeit with potentially superior outcomes over traditional chemotherapy as shown in studies of relapsed CLL.

INTRODUCTION

Although chronic lymphocytic leukemia (CLL) is the most common type of leukemia in adults (22-30% of total leukemia cases)1, it is still considered a rare disease with low incidence rates. In the US, the numbers of new cases and deaths represent 4.5/100,000 and 1.4/100,000 per year, respectively2. However, although low incidence rates, costs of healthcare for CLL patients represents significant budget impact. In Germany it is estimated that the annual cost of treating patients with CLL are between 9,753 and 10,819 euros1, and in the US the estimated total cost per patient is $87,1511. The advent of novel targeted therapies, such as ibrutinib, has altered the treatment paradigm for Chronic Lymphocytic Leukemia (CLL) in the recent years.

The aim of this study was to estimate the budget impact of ibrutinib, a first-in-class once daily Bruton’s Tyrosine Kinase inhibitor, for the treatment of relapsed/refractory (R/R) CLL in the Brazilian private healthcare system (BHPS).

METHODS

A budget impact analysis (BIA) was developed to project investments over the years from 2016 to 2019. An approach based on Brazilian age-adjusted incidence rate (IR) for R/R CLL patients was used to estimate the population eligible for analysis (table 1). Two scenarios were simulated: (1) current setting, in which patients are treated either with fludarabine-cyclophosphamide-rituximab (FCR) or ofatumumab monotherapy; (2) proposed setting, with introduction of ibrutinib monotherapy (table 2). Annual treatment costs were calculated following doses/intervals defined in the guidelines. Final costs were calculated considering drug acquisition costs and prices were gathered from the official Brazilian government website (MED-ANIHS). Both fludarabine and ibrutinib received regulatory and commercial approvals in 2015. In this model, additional costs based on Brazilian patient characteristics (age, sex, stage and type of lymphoma) were calculated for ofatumumab and FCR were calculated based on market assumption.

LIMITATIONS

• In this study, incidence rates of patient starting treatment for CLL were used rather than prevalence rate;
• Incidence rates of patient starting treatment for CLL were calculated based on Government administrative claims database (Datasus);
• Patients may have more than one line of treatment per year

CONCLUSIONS

In this BIA, the introduction of ibrutinib in BHPS as an option for R/R CLL patients would bring a small budget impact for private payers over the next 4 yrs, albeit with potentially superior outcomes over traditional chemotherapy as shown in studies of relapsed CLL.