Cost-Effectiveness and Budget Impact Analyses Using Real World Data from Brazilian Health Care Insurance Companies in the Treatment of Iron Deficiency in Patients with Heart Failure

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INTRODUCTION

- Iron deficiency (ID) is a frequent comorbidity in anemic and non-anemic heart failure (HF) patients [1~2]. The prevalence of HF in developed countries is less than 2 per cent in the population under 60 years of age and rises sharply to 15 per cent in people aged 60 to 80[2].

- An analysis of five cohorts in Europe showed that approximately 50% of all HF patients are iron deficient[1]. Reduced absorption is an important factor in the cause of iron deficiency in HF, as it may explain why intravenous (IV) iron works to replenish iron stores, while specific oral preparations do not[3 -5].

- The economic burden of heart disease in Brazil was evaluated. Health system costs for HF were BRL 14.5 million. Absenteeism was estimated at 12.66 days for those with New York Heart Association (NYHA) III/IV and 3.04 days per year for those with NYHA I/II. This loss of productivity resulted in a cost of BRL 7.6 million. The total cost of HF was BRL 22.1 million[6].

OBJECTIVES

- The objective was to conduct a cost-effectiveness analysis (CEA) and budget impact analysis (BIA) of ferric carboxymaltose (FCM) compared to placebo in the treatment of ID in HF, NYHA class II and III, using real-world data (RWD) to define the costs from the Brazilian private payer perspective (BPPP).

METHODS

- Data derived from clinical trials (CONFIRM–HF) was used to develop a model for predicting HF hospitalization rates and NYHA class distribution over a 52-week time horizon[2]. A Markov cycle length of 1 week was chosen for baseline analysis[7]. (**Table 1**)

- Real World Data from BPPP was used to estimate risk of hospitalization and specific costs. An algorithm was used to cluster all patients (n = 4,246,930) and the following prognostic characteristics: age, hospitalization rates, hospital readmission, cardio-intensive care unit rates, New York Heart Association (NYHA) class, outpatient medication rate and inpatient rates.

- CEA and BIA were carried out considering a time horizon of 52 week and five years, respectively. Data was used, as for target population to be treated, in terms of medical direct costs and drug costs.

- Sensitivity analysis for CEA was conducted to check the robustness of the results.

RESULTS

- Improvements in NYHA class and decrease in related health resource use as well as avoided hospitalizations due to HF worsening define both budget impact and cost-effectiveness analysis.

- The weekly inpatient cost was NYHA I (BRL 72,51), NYHA II (BRL 219,94), NYHA III (BRL 337,57) and NYHA IV (BRL 530,24). The weekly outpatient cost was NYHA I (BRL 81,01), NYHA II (BRL 84,20), NYHA III (BRL 302,88) and NYHA IV (BRL 269,36)

- The use of FCM compared to placebo yields an incremental QALY of 0.3 per patient and average cost-saving of BRL 815 per patient. FCM proves to be a dominant strategy with a higher effectiveness at a lower cost. (**Table 2**)

- The estimation of the target population in Brazil was based on published references. On the basis of a gradual introduction of FCM, a potential total cost-saving of 39 million BRL was estimated over 5 years. (**Table 3, 4 & 5)**

CONCLUSIONS

- A gradual introduction of FCM for the treatment of HF with ID may bring about potential cost-savings by decreasing health care resource use.

- FCM may be a dominant option in Brazil with higher efficacy at a lower total cost explained by improvements in NYHA class and avoided hospitalizations.

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Figure 1. **Markov model schematic representation of the general structure.**

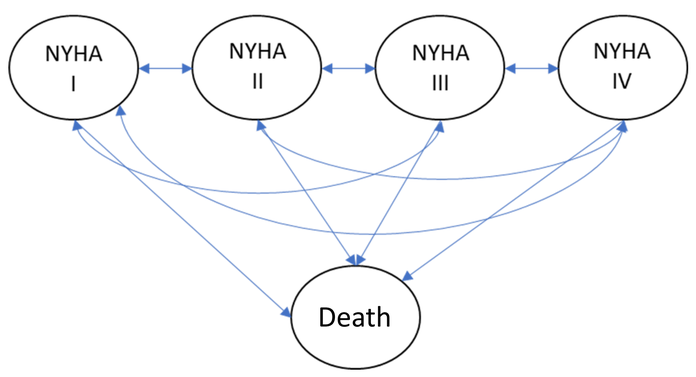

Table 1. **Distribution of patients over time according to the different NYHAs**

	Placebo (%)					FCM (%)				
NYHA Class	I	II	III	IV	Death	I	II	III	IV	Death
Baseline	0	33	67	0	0	0	33	67	0	0
Week 4	0.1	30.1	65.6	4	0.2	0.9	51.6	46	1.4	0.1
Week 12	0.4	35.9	57.2	4.2	2.2	5.1	55.9	36.4	1.3	1.3
Week 24	0.5	43.3	45.8	6.3	4.1	5.4	63.1	27.3	1.9	2.3
Week 36	0.7	41.1	45.1	6.6	6.5	5.8	63.2	25.2	2	3.8
Week 52	0.9	39.2	44.2	6.9	8.9	6.1	63.1	23.5	2.1	5.2

Table 2. **The Incremental Cost Effectiveness Ratio (ICER).**

	FCM	Placebo	Incremental
Average cost per patient	BRL 9’679.17	BRL 10’494.49	BRL -815.32
Average QALY gained per patient	4.19	3.88	0.31
Incremental Cost Effectiveness Ratio (ICER)			Dominance

Figure 2. **Scatter plot Sensitivity analysis.**

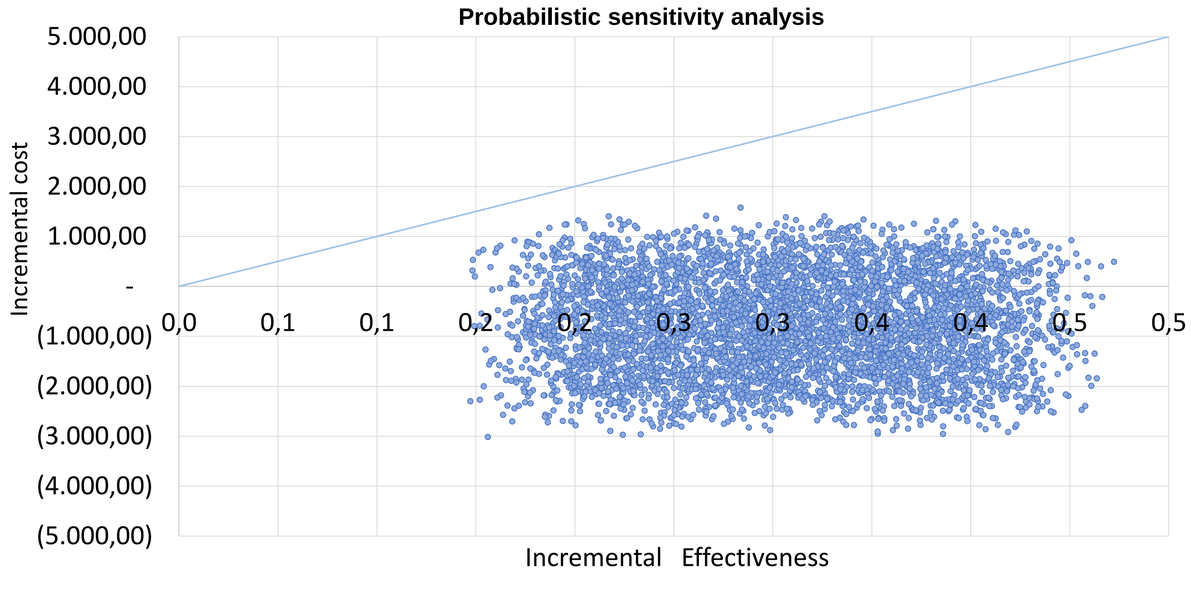

Table 3. **Estimation of the target population in Brazil.**

HF Incidence	0.20%[8]	ANS population	50’281’473
HF - Reduced Ejection Fraction	59%[9]	HF Incidence	100’563
NYHA II	29.8%[10]	HF - Reduced Ejection Fraction	59’332
NYHA III	25%[10]	NYHA II	17’681
NYHA II & III with ID	50%[11]	NYHA III	14’833
		NYHA II & III with ID	16’257

Table 4. **Expected growth of target population and market share of FCM**.

	2023	2024	2025	2026	2027
Growth of target population	16’257	16’363	16’464	16’561	16’654
Gradual uptake Ferinject®	10%	40%	60%	80%	100%

Table 5. **Budget impact of introducing FCM for the treatment of HF with ID**.

	Without FCM (BRL)	Gradual Uptake of FCM (BRL)	Budget Impact (BRL)
2023	170’608’985	169’283’519	-1’325’466
2024	171’717’943	166’381’616	-5’336’327
2025	172’782’594	164’728’476	-8’054’118
2026	173’802’012	162’999’828	-10’802’184
2027	174’775’304	161’196’959	-13’578’345
Total			-39’096’440

(*1 USD$ = 5.13 BRL; 1 Euro € = 5.37 BRL)