FREESTYLE LIBRE 2 FLASH GLUCOSE MONITORING SYSTEM: BUDGET IMPACT AND COST-UTILITY ANALYSES IN TYPE 1 DIABETES FROM THE ITALIAN NHS PERSPECTIVE

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PURPOSE

A Budget impact analysis (BIA) and a cost-utility analysis (CUA) were conducted from the perspective of Italian healthcare payer in order to understand the economic impact of the FreeStyle Libre 2 (FSL2) system's market placement in Italy for adults with type 1 diabetes (T1DM).

METHODS

- 3 analyses were developed in MS Excel: BIA, CUA, value-based pricing analysis.
- 4 glucose monitoring systems were included: self-monitoring of blood glucose (BGM), traditional continuous glucose monitoring (CGM), FreeStyle Libre (FSL), FSL2
- Annual costs included: glucose monitoring systems, physician appointments (set up and follow up), and healthcare resources consumption.
- Costs and utilities data came from the National Tariffs by the Italian Ministry of Health and the literature[1-4].
- The BIA reported net difference in costs, comparing two scenarios targeting the T1DM population: base scenario (without FSL2) and alternative scenario (FSL2 gradually placed on the market over a 3-year time horizon).
- The CUA determined the expected quality adjusted life years (QALYs) gained and the incremental cost-effectiveness ratio (ICER) for FSL2 compared to FSL, CGM, BGM over a 1-year time horizon. Efficacy of FSL2 on healthcare services utilization came from real-world evidence provided by the RELIEF study[5].
- The value-based price analysis was developed to calculate the maximum price gap between FLS2 and FSL capable of allowing an acceptable ICER for the innovative system.
- Sensitivity analyses for BIA and CUA were developed as well, changing the main input parameters by ± 20%, to assess the robustness of the results.

RESULTS

- Estimated total annual cost per patient was €1,306 with FSL2, €5,264 with CGM, €1,009 with BGM, and €1,176 with FSL, Figure 1.
- The BIA scenario with the placement of FSL2 (market shares 27%, 50% and 70% respectively after 1, 2, and 3 years) reported a potential cumulative saving of €145 million over 3 years (€21 million in year 1, €48 million in year 2, €76 million in year 3), Table 1.
- The CUA provided an ICER of €5,301 for FSL2 vs BGM, €7,116 vs FSL, Tables 2-3. Compared to CGM, the cost-minimization analysis reported an annual differential cost of €3,958 in favor of FSL2. T
- The sensitivity analyses demonstrated the robustness of the results, Figure 2. Value-based pricing analysis reported an acceptable cost-effectiveness profile for FSL2 (threshold of €25,000 per QALY) up to a sensor unit price increase of €16 vs FSL.

Figure 1. Total annual cost per patient related to glucose monitoring systems

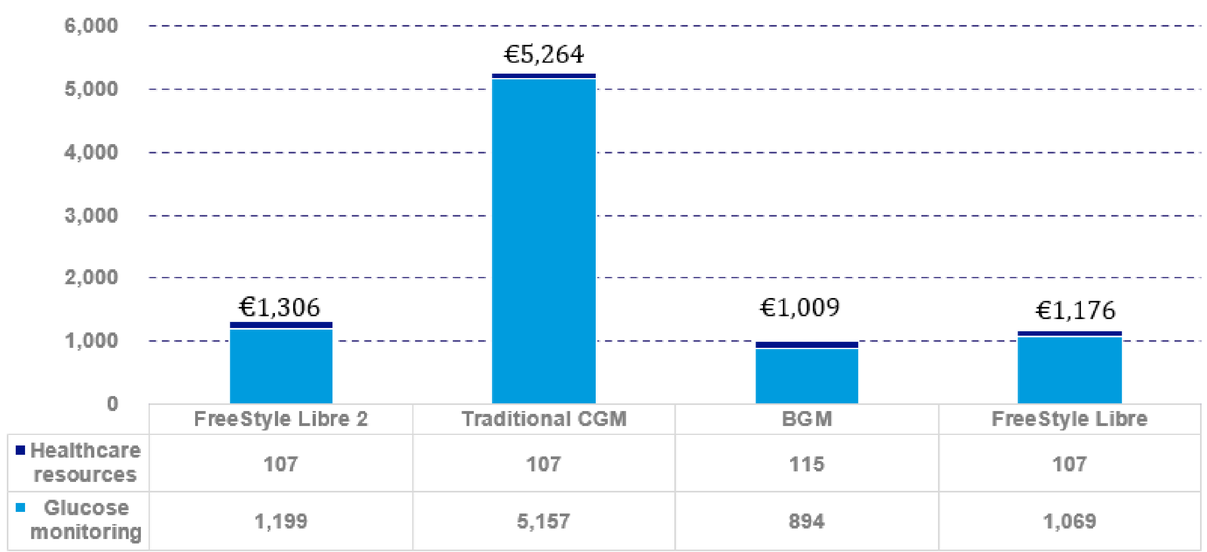

Figure 2. BIA and CUA sensitivity analysis results

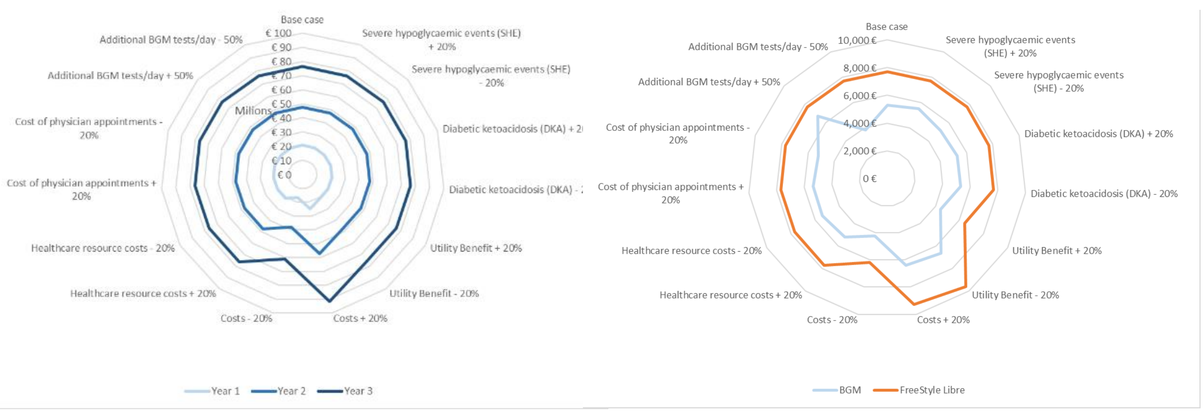

Table 1. BIA results (in million €): base scenario vs alternative scenario, time horizon 3 years

Base scenario	Year 1	Year 2	Year 3
FreeStyle Libre 2	€ 0	€ 0	€ 0
FreeStyle Libre	€ 98	€ 105	€ 110
CGM	€ 250	€ 302	€ 338
BGM	€ 46	€ 25	€ 8
Total	**€ 394**	**€ 432**	**€ 456**
Alternative scenario	**Year 1**	**Year 2**	**Year 3**
FreeStyle Libre 2	€ 62	€ 111	€ 151
FreeStyle Libre	€ 51	€ 22	€ 0
CGM	€ 215	€ 227	€ 220
BGM	€ 45	€ 24	€ 8
Total	**€ 373**	**€ 385**	**€ 380**
Total Budget impact	**- € 21**	**- € 48**	**- € 76**

Table 2. CUA results: FSL2 vs BGM, ICER, time horizon 1 year

Parameters	Monitoring System		Δ
	FSL2	BGM	
Total cost	€ 1,306	€ 1,009	-€ 297
Total QALYs	0.049	-0.007	-0.056
ICER			**€ 5,301**

Table 3. CUA results: FSL2 vs FSL, ICER, time horizon 1 year

Parameters	Monitoring System		Δ
	FSL2	FSL	
Total cost	€ 1,306	€ 1,176	-€ 130
Total QALYs	0.049	0.032	-0.017
ICER			**€ 7,716**

SUMMARY – CONCLUSIONS

Glucose monitoring is critical in the management of T1DM patients. Nowadays, there are several systems to achieve this goal, including FSL2, an updated version of FSL, equipped with optional alarms. FSL2 has proved a sustainable budget impact over a 3-year time horizon and has resulted in being cost effective compared to FSL and BGM.
FSL2 would also be far less expensive than CGM, the only other system providing alarms, thus entailing a considerable saving in the target population.
Reimbursement of FSL2 in Italy for adults with T1DM would result in a consequent decrease in total healthcare spending and would be considered cost-effective vs FSL with a sensor unit price increase of up to €16.

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DECLARATION OF INTEREST

Abbott provided funding for this study
Fleur Levrat-Guillen is an Abbott employee and stockholder

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