CADTH

Budget Impact Analysis Protocol

A budget impact analysis will be conducted to address the financial impact of funding hybrid closed-loop (HCL) devices as the primary method of monitoring glucose and delivering insulin. Specifically, the budget impact analysis will compare a reference scenario, which includes technologies and devices currently being reimbursed by Canadian publicly funded health care systems, with a new device scenario, where the HCL device is also reimbursed. The patient population will be defined to reflect the current population that is eligible for HCL (i.e., patients with type 1 diabetes). Potential scenario analyses may be further conducted to explore the budget impact in subgroups (as identified by CADTH's clinical and implementation review). The time horizon in this analysis will reflect what is relevant to the budget holder (as per good research practices);[1] in this case, a one-year baseline period followed by a three-year forecast.

The primary perspective of the budget impact analysis will be that of a Canadian publicly funded health care system (i.e., ministry of health), and the costs captured in the budget impact analysis will reflect this analytical perspective. Specifically, the costs in the analysis will focus on the cost elements expected to differ between the options being evaluated. This may include costs related to glucose monitoring, insulin delivery devices and required accessories, and insulin. Should CADTH's clinical review find differences in the health care system resource use associated with HCL compared to other glucose and insulin delivery systems, these costs will be considered in the budget impact analysis as well. If Canadian-relevant costs are unavailable, costs will be estimated from the medical literature and, ideally, from comparable health systems. If necessary, costs will be adjusted to 2020 Canadian dollars using the Consumer Price Index. To ensure comparability between Canadian and international prices, where appropriate, international prices will be converted to Canadian dollars. Depending on the jurisdiction, some diabetes management costs are paid by different public programs; therefore, the budget impact analysis will also report total cost results disaggregated by type of expense.

Uncertainty in the structure and parameters of the budget impact analysis will be evaluated through scenario analyses. Assumptions and limitations will be identified and acknowledged in the report, and, where possible, these assumptions will be tested through scenario analyses.

The budget impact analysis will be conducted in accordance with the most recent good practice guidelines for budget impact analyses, published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)'s Task Force on Good Research Practices.[1]

Reference

1. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research*. 2014;17(1):5-14.