

THE VISION HORIZON SCANNING MODEL: PREDICTING THE EVOLUTION OF DIRECT NHS EXPENDITURE FOR TYPE 1 DIABETES IN ITALY UP TO 2028



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INTRODUCTION AND OBJECTIVES

Type 1 diabetes (T1D) is a chronic autoimmune condition characterized by the destruction of pancreatic β -cells, leading to permanent insulin deficiency¹. It accounts for up to 10% of all diabetes cases, representing the most prevalent diabetes form in the pediatric population². If not adequately controlled, T1D onset may result in diabetic ketoacidosis, a potentially life-threatening condition, especially in children³. Other serious complications include organ damage and represent micro and macro cardiovascular events, contributing to increased hospitalization rates³.

In Italy, current T1D management relies solely on chronic insulin therapy administration². However, the T1D landscape is expected to evolve with the upcoming implementation of pediatric screening pursuant to Law n.130/2023⁴, broader adoption of high-technology medical devices (MDs), and the potential launch of disease progression modifying therapies (DMTs) to delay T1D onset. Additionally, one new insulin brand has entered the market⁵, another one is set to lose market exclusivity⁶ and enable biosimilar entry, and the whole insulin product class is expected undergo price renegotiations with AIFA by 2028⁷.

In this evolving landscape, the VISION study aimed to assess the evolution of direct T1D-related expenditure from the perspective of the Italian National Health Service (NHS), evaluating system sustainability ahead of future DMT launches, with a focus on pharmaceutical treatments, high-technology MDs, and screening initiatives.

MATERIALS AND METHODS

A cost-calculator horizon scanning (HS) model with a 7-year time horizon (2021–2028) was developed in Microsoft Excel. The model integrates clinical data (screened individuals, total T1D cases, treatment distributions) and economic data (therapy costs for insulins, DMTs, MDs, and screening budget *per* Law n.130/2023⁴).

Model inputs and assumptions were retrieved from both quantitative sources (two national IQVIA databases, *i.e.* Longitudinal Patient Data and Database on Consumptions and Sales, and regional public procurement adjudications for CGMs and insulin pumps^{8–10}) and qualitative sources (scientific literature^{11–18}, guidelines², association reports^{19–21}, and expert interviews with 4 clinicians and 2 payers).

The baseline scenario used: (1) quarterly patient data (2021–2023) on insulin regimens (basal-bolus, short-acting only, pre-mixed) and brands, stratified by adult and pediatric populations²² (2) reported MDs usage prevalence, also stratified by age^{15,22}, (3) insulin therapy costs, adjusted for mandatory price reductions and estimated brand discount²³, (4) average net NHS cost for MDs therapies^{9–10}.

Expenditure projections (2024–2028) accounted for trends in T1D prevalence and insulins and MDs usage. The model incorporated assumptions on pediatric screening uptake from 2026⁷, new insulin launches, patent expiries, price renegotiations, and future DMTs reimbursement timelines, target populations, and costs. Inputs were informed by past trends, analogue analyses, market insights, and two rounds of individual interviews with experts. DMT projections were informed by pivotal trial timelines, EMA approval expectations, and a dynamic funnel model estimating eligible patients based on screening rates, disease staging, and progression^{17,18}. Model robustness was assessed via deterministic sensitivity analysis (DSA) and results were validated in a final expert roundtable.

RESULTS

Total NHS expenditure for T1D pharmaceutical therapies, MDs, and screening was estimated at €636 million in 2021 and is projected to reach €887 million by 2028, with a compound annual growth rate (CAGR) of +4.86% (Figure 1). High-cost medical devices represent the highest expenditure, totaling €528M in 2021 and up to €797M in 2028 (CAGR +6.07%), while pharmaceutical expenditure is significantly lower and decreasing, from €108M estimated in 2021 to €87 in 2028 (CAGR -3.14%) (Figure 1).

The increase in the number of registered T1D cases (CAGR +0.15%) is only a small component of this expenditure increase, which is mainly driven by a higher pro-capita expenditure (CAGR +4.70%) (Figure 2), linked to both an expanded use of high-technology MDs and to a switch towards costlier close loop systems (integrated CGM-insulin pump). Per-patient pharmaceutical expenditure is projected to continue its downward trend (CAGR -3.28%) (Figure 2), driven by insulins tendering dynamics, price re-negotiations and biosimilar entry. These events are estimated to overall offset the additional expenditure that teplizumab may bring, as it is considered the only DMT to be reimbursed by 2028 for delaying the onset of T1D, limited to Stage 2 patients identified by antibody testing. Average per-patient expenditure for pharmaceutical therapy is aligned across age classes, while average expenditure per medical device user is higher for pediatric patients, due to higher insulin pump use (Table 1).

DSA confirmed model robustness and indicated a higher variation in total expenditure under exploratory assumptions of increased or decreased MDs yearly cost (Figure 3).

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ISPOR Europe 2025 | 9-12 November 2025 | Glasgow, Scotland, EU

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Funding: The study was sponsored by Sanofi Italy. Analysis and editorial assistance was provided by IQVIA Italy and was funded by Sanofi Italy.

Conflict of interest: BF, PS, PB, SR, MA, RM received honoraria from Sanofi Italy to participate in the study. CA, LMP, TA have served as consultant for IQVIA Italy and have received consulting fee from Sanofi Italy related to this study. PA, AG, TC are Sanofi Italy employees.

FIGURE 1. Overall NHS T1D expenditure, 2021–2028

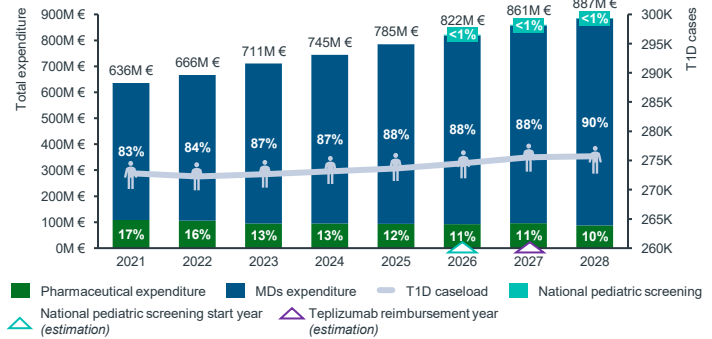


FIGURE 2. Average pro-capita T1D NHS expenditure, 2021–2028

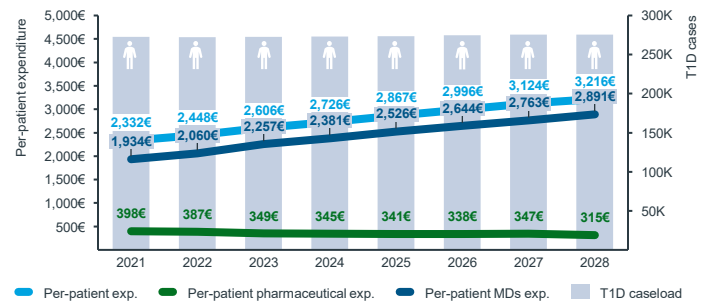
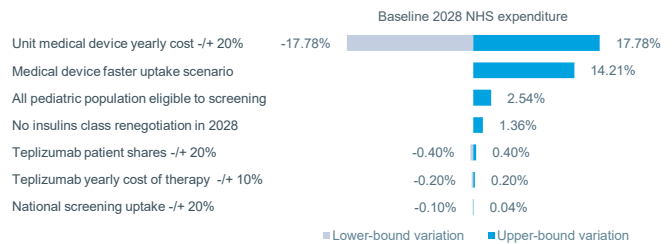


TABLE 1. Average per-user T1D NHS expenditure by age, 2021 vs 2028

Medical devices	2021	2028	Pharmaceutical treatment	2021	2028
Adult	2.689 €	2.916 €	Adult	398 €	295 €
Pediatric	4.864 €	6.704 €	Pediatric	388 €	550 €

FIGURE 3. Deterministic sensitivity analysis, from 2028 baseline



CONCLUSIONS

The VISION study suggests that, by 2028, overall pharmaceutical expenditure for T1D will slightly decline, despite the reimbursement of the first DMT. This decrease, is foreseen due to competitive tendering dynamics and price renegotiations of insulins.

However, the chronic nature of T1D treatment entails a largest and growing cost component driven by medical devices, which are indispensable for the correct administration of insulin and for achieving glycemic control with precision, following a treat-to-target approach. These new generation medical devices represent predicted to drive overall T1D expenditure increase.

The VISION horizon scanning model is a first-in-a-kind analysis of expenditure in the T1D area from the Italian NHS perspective, offering an original outlook that encompasses both drug and MD-related expenditure. Insights on drivers of expenditure evolution may represent a key tool for decision makers in preparing the NHS for the upcoming therapeutic and technological innovations.

Further studies might expand on the present analysis, investigating the economic impact of DMTs in terms of hospitalizations, comorbidities, and quality of life.