Teplizumab for delaying the onset of stage 3 type 1 diabetes in people 8 years and over with stage 2 type 1 diabetes [ID6259]

Confidential information redacted

Technology appraisal committee A [10 February 2026]

Chair: James Fotheringham

External assessment group: Kleijnen Systematic Reviews (KSR)

Technical team: Emma McCarthy, Caron Jones, Ian Watson

Company: Sanofi

Teplizumab (Tzield, Sanofi)

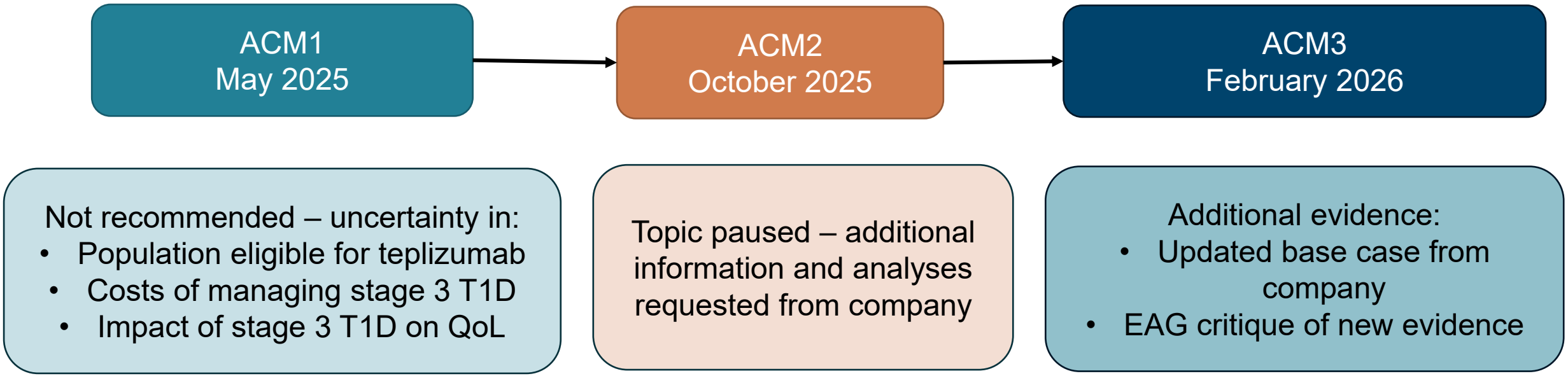
Marketing authorisation	Tzield is indicated to delay the onset of Stage 3 type 1 diabetes in adult and paediatric patients 8 years of age and older with Stage 2 type 1 diabetes (T1D). Granted August 2025
Mechanism of action	Binds to CD3, may involve deactivation of pancreatic beta-cell autoreactive T lymphocytes. Also increases regulatory T cells.
Administration	IV infusion, once daily for 14 consecutive days based on BSA: • Day 1: 65 mcg/m^2 • Day 2: 125 mcg/m^2 • Day 3: 250 mcg/m^2 • Day 4: 500 mcg/m^2 • Days 5 to 14: 1,030 mcg/m^2
Price	• List price - [redacted] per 14-vial treatment course • A simple patient access scheme discount applies for teplizumab

NICE

CD3, cluster of differentiation 3; BSA, body surface area-based dosing

Appraisal history

DG post ACM1 – Teplizumab should not be used for delaying the onset of stage 3 type 1 diabetes in people 8 years and over with stage 2 type 1 diabetes
Post ACM2 – Further evidence required to determine whether teplizumab should be recommended



Abbreviations: ACM, appraisal committee meeting; DG, draft guidance; T1D, type 1 diabetes, QoL, quality of lie

Latest committee preferred assumptions – issues for discussion

Issues discussed	Committee conclusion
Identifying the eligible population for teplizumab	Committee requested: • Cost-effectiveness estimates based on testing with population risk of 1 in 30 (for the first-degree relative population), and without testing • Blended cost-effectiveness estimates for the full population in the marketing authorisation, based on differing proportions of each of the 4 subpopulations eligible for teplizumab
Testing costs	Committee requested: • Testing costs based on the costs of additional services related to testing for T1D in addition to autoantibody testing, with more plausible costs for these services • Inclusion of these updated costs (including the full costs of testing) in the requested additional analyses that include testing costs (that is, using a risk proportion of 1 in 30 and blended cost effectiveness estimates)
Stage 2 disutility	Committee could not accept the inclusion of a stage 2 disutility without clear explanation of the rationale for and validity of applying a disutility to an asymptomatic stage of disease, and full information on the methods used
Generalisability of ELSA and health inequalities	Committee requested additional evidence on the generalisability of the ELSA study to the UK population, and to what extent disadvantaged groups are represented in the study
Carer disutility	Caregiver disutility of -0.04 should be applied up to the age of 25 for 1 caregiver only
Stage 3 T1D costs	Committee requested more suitable approach to model expected increase in costs beyond 20 years

T1D, type 1 diabetes; ECM, established clinical management

Other issues previously discussed

Equality considerations

- Company has submitted additional data on generalisability of ELSA study to address potential health inequality issues (see appendix)
- Company response to call for evidence raises new potential equalities issues on DKA and caregivers (see appendix for previously discussed issues)
  - DKA is associated with lower socioeconomic status
  - Diabetes distress in caregivers of adolescents with T1D is associated with deprivation and protected characteristics

Are there any additional equality issues that need to be considered?

DKA; diabetic ketoacidosis: T1D, type 1 diabetes

Key issues

Key issue	ICER impact
Identifying people with Stage 2 T1D and defining population eligible for teplizumab	Moderate
Testing costs	Moderate
Carer disutility	Moderate
Stage 2 disutility	Large
Estimation of stage 3 T1D costs	Large
Non-reference discount	Large

Other issues	ICER impact
Generalisability of ELSA	Unknown

T1D, type 1 diabetes; ICER, incremental cost effectiveness ratio

Key issue: Identifying people with Stage 2 T1D and defining population eligible for teplizumab

4 key populations that may be tested for and diagnosed with stage 2 T1D:

Population	Latest committee conclusions
Tested in research studies (e.g. ELSA)	Already identified in practice and funded separately to NHS testing – no additional testing costs
Tested because of clinical suspicions	Already identified in practice – testing costs cancelled out between treatment arms (so no additional testing costs)
First degree relatives of people with T1D	Expected increase in demand for ad-hoc autoantibody testing in FDRs if teplizumab was recommended – most additional funded tests in NHS likely to be for FDRs. Additional testing costs for FDRs should be captured in the model to account for this (in line with expected risk of 1 in 30).
All comers (i.e. people requesting antibody testing)	Unlikely that people in general population would be able to request autoantibody test in NHS practice – no additional testing costs

Committee requested:

- Cost-effectiveness estimates based on testing with population risk of 1 in 30 (for the first-degree relative population), and without testing
- Blended cost-effectiveness estimates for the full population in the marketing authorisation, based on differing proportions of each of the 4 subpopulations eligible for teplizumab

T1D; type 1 diabetes; FDRs, first degree relatives

Key issue: Identification of people with Stage 2 T1D and defining population eligible for teplizumab

Company

- Revised base case includes costs of additional testing for FDRs only, in line with a 1 in 30 population risk
- Assumes 13% of additional testing costs are applied to the NHS, based on UK PDU survey data (Swaby 2025) – with remaining proportion covered by research studies and testing for other clinical concerns
- Applies testing costs to both arms of model, since testing has additional benefits such as avoidance of DKA
- Inclusion of exploratory and confirmatory testing costs in modelling contradicts previous NICE appraisals in lung cancer, where diagnosis occurs before entering the model

EAG comments

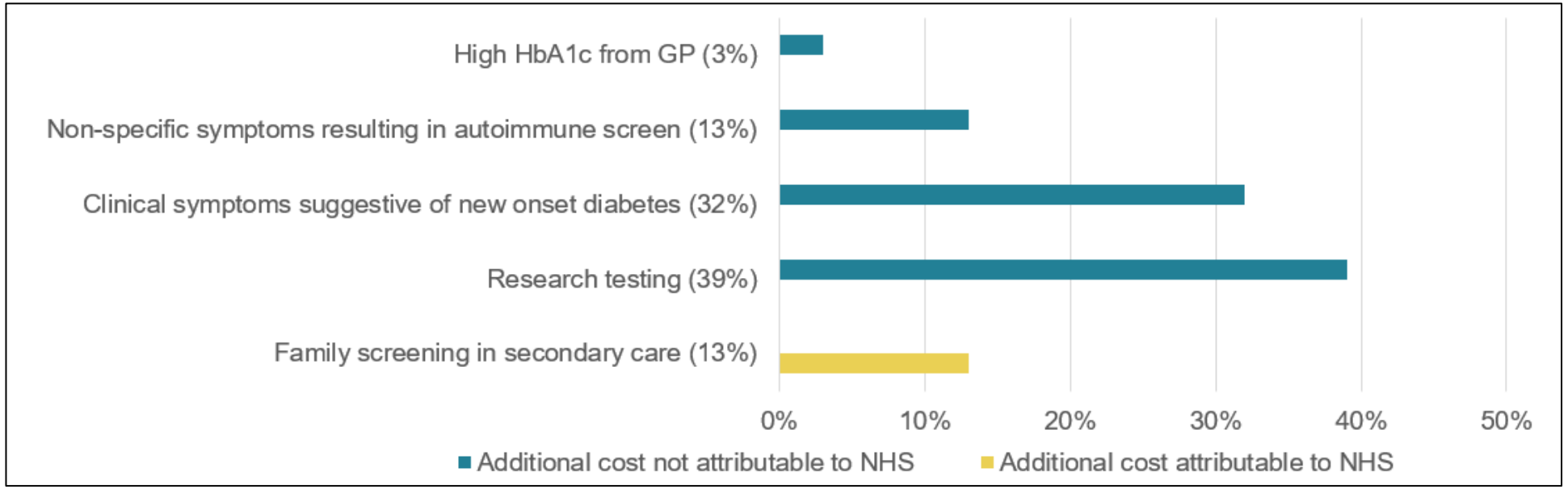
- Figure of 13% based on current testing figures – unclear how this would inform additional testing
  - Implies only 13% of testing to identify people eligible for teplizumab would be FDRs – contradicts company statement saying only FDR population will have increased need for testing
- EAG prefers to apply testing costs to teplizumab arm only - the introduction of teplizumab is the reason for additional testing, so additional cost to intervention needs to be captured
  - In previous NICE appraisals, if diagnostic pathway already in place, then introducing the intervention has no additional cost

FDR, first degree relatives; T1D, type 1 diabetes; PDU, paediatric diabetes units; DKA, diabetic ketoacidosis

Further statistics for T1D testing and staging

Key issue: Identification of people with Stage 2 T1D and defining population eligible for teplizumab

Reasons reported for autoantibody testing in children and young people in Swaby et al (2025), based on n=145 children and young people with early stage T1D



Company

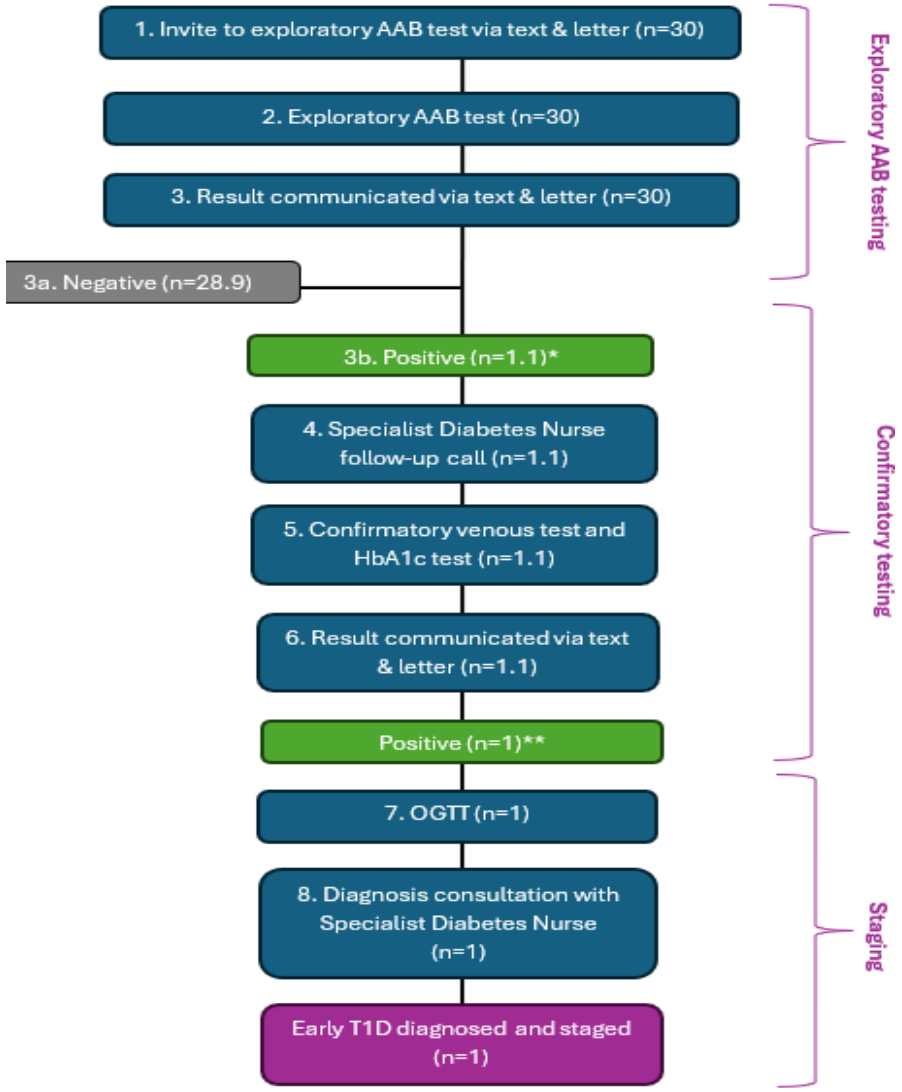
- Testing costs applied to NHS (13%) based on survey % tested due to family screening in secondary care
- Previous committee meetings, advisory boards and company's clinical experts – research studies expected to be primary route for identifying stage 2 T1D, while testing pathway is established

"How should additional testing costs be included in the model? What proportion of people eligible for teplizumab will be identified via additional FDR testing?
Should the additional testing costs be applied to both model arms, or the teplizumab arm only?

T1D, type 1 diabetes; FDR, first degree relative

Key issue: Testing costs

Company assumed testing pathway



Latest committee conclusion – committee requested

- Testing costs based on the costs of additional services related to testing for T1D in addition to autoantibody testing, with more plausible costs for these services
- Inclusion of updated costs (including full costs of testing) in requested additional analyses that include testing costs (using a risk proportion of 1 in 30 and blended cost effectiveness estimates)

Company

- Revised testing costs based on a 1:30 rate include the costs of exploratory autoantibody testing for 30 people, confirmatory testing in 1.1 individuals and diagnosis of 1 person with stage 2 T1D
- Total estimated costs = £1724.26 – with 13% of additional testing costs applied to NHS based on FDR proportion, blended cost of £224.15 used in base case
- Anticipated testing pathway based on NHS community clinic setting, agreed with company's clinical experts
  - Exploratory testing costs include 1 autoantibody test per person, 1 phlebotomy appointment, and sending test invites or results
  - Consultations (with specialist diabetes nurse) included only as part of confirmatory testing and diagnosis

NICE

Testing costs per pathway component

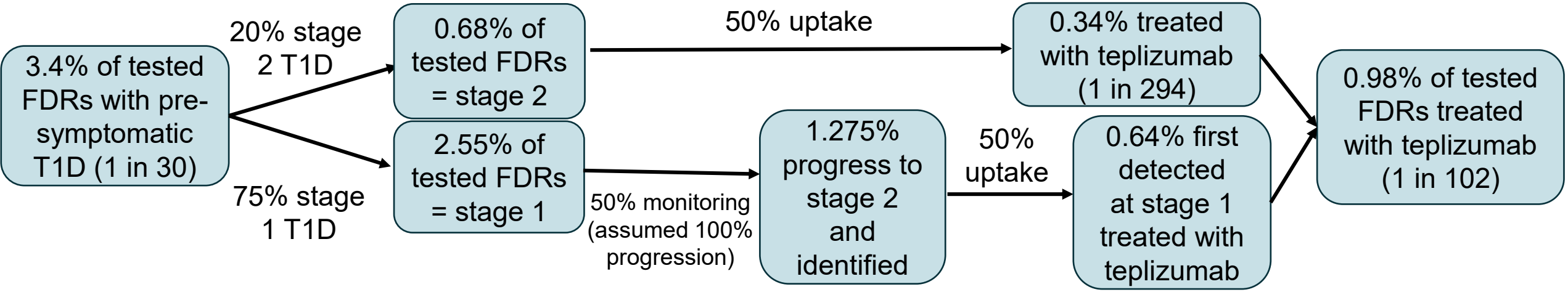
FDR, first degree relatives; T1D, type 1 diabetes;

Key issue: Testing costs

EAG comments

- Blended testing costs may be underestimated depending on the proportion who test positive for autoantibodies, how many people have stage 2 T1D vs stage 1, and uptake of teplizumab in people diagnosed with stage 2 T1D
- Additional expert communication (submitted in response to draft guidance consultation, with accompanying modelling input courtesy of the company) indicates that of the 3.4% (1 in 30) of FDRs tested and confirmed to have pre-symptomatic T1D, only 20% are stage 2 (with 75% at stage 1)
  - When accounting for this and assuming 50% uptake, 1 in 294 people tested would be treated with teplizumab
- When adding the proportion of FDRs confirmed as stage 1 and assuming 50% stage 1 monitoring (as in company clinical expert communication), and all progress to stage 2, then 1 in 102 people tested are treated
  - Costs of monitoring Stage 1 cases until progression to stage 2 not included in company model

EAG scenarios for detection rate – informed by expert communication:



Are the testing costs used suitable for decision making? Is a blended testing cost based on a detection rate of 1 in 30 (£224.15) appropriate?

FDR, first degree relatives; T1D, type 1 diabetes;

Key issue: Carer disutility

Company has provided additional data on secondary caregivers and revised base case

Committee conclusion at ACM2

Caregiver disutility of -0.04 should be applied up to the age of 25 for 1 caregiver only

Company

- Base case still applies caregiver disutility of -0.04 for 1.76 carers in people ≤ 25 years old, based on additional evidence showing multiple caregivers involved in caring for T1D in children and young people
- Additional data based on survey of caregivers of child or person ≤ 25 years old with T1D (average age [redacted]) shows secondary caregiver involvement in [redacted] of respondents ([redacted])
  - When 2 caregivers involved, contributions of secondary caregiver = [redacted] relative to primary caregiver time
- Caregiving activities reported consistently across respondents [redacted] included ordering supplies, attending appointments, liaising with education or recreational settings, checking glucose levels
  - Consistent involvement with care impacts work and causes significant mental strain

EAG comments

- Plausible that multiple caregivers are generally involved in care of a child or young person with T1D
- EAG prefers different number of caregivers ([redacted]), based on company survey data. Estimated by adding the proportion of time secondary caregivers spend on caregiving relative to primary caregivers, to the proportion of time spent providing care across all primary caregivers (including sole caregivers)

What size of carer disutility is appropriate? What number of caregivers should be used?

T1D, type 1 diabetes; ACM, appraisal committee meeting

Key issue: Stage 2 disutility

Committee conclusion at ACM2

Could not accept the inclusion of a stage 2 disutility without clear explanation of the rationale for and validity of applying a disutility to an asymptomatic stage of disease, and full information on the methods used

Company

- Further detail provided on vignette study used to derive stage 2 disutility (Guenther et al. 2025, conference poster), which assessed HRQoL perceptions of T1D progression in the UK (n=300 adults)
- There is a disutility associated with Stage 2 T1D due to psychological burden of being diagnosed with a chronic, progressive condition – impact on QoL would likely be reduced by availability of DMT
- Stage 2 disutility differs from stage 3 onset disutility, which involves adjustment to managing symptoms – clinically plausible that stage 2 disutility is larger due to earlier 'shock' of diagnosis
- Ongoing stage 2 disutility applied to both model arms (teplizumab = -0.049, ECM = -0.124)

EAG comments

- Company argument indicates this disutility is associated with initial impact on QoL but is applied constantly in company model – stage 2 disutility plausible but EAG prefers to apply for one cycle only (6 months)
- Magnitude of stage 2 disutility lacks face validity if applied continuously, since these values are higher than stage 3 disutility (-0.025 applied once following stage 3 onset, -0.0621 constant disutility, and time dependent decline of -0.0026 at <10 years at stage 3, or -0.0028 after 10 years at stage 3)

What is the impact of initial diagnosis of T1D at stage 2 on QoL?
Should a disutility associated with stage 2 T1D be applied in the model? If yes, is applying a treatment-specific disutility appropriate?
What size and duration of disutility should be applied?

T1D, type 1 diabetes; HRQoL, health related quality of life; ECM, established clinical management; QoL, quality of life; DMT, disease modifying therapy

Key issue: Estimation of stage 3 T1D costs

Committee conclusion at ACM2

- Request for more suitable approach to model the expected increase in costs beyond 20 years

Company

- Maintains approach of using Danish case control data with 19 year follow up, and linear regression model with quadratic term applied to data from 5-19 years to extrapolate long term costs past 19 years
  - Quadratic extrapolation had best fit for people with stage 3 T1D and healthy controls, and validated by company's clinical expert opinion – linear extrapolation likely underestimates costs
- Although T1D costs increase with duration spent in stage 3, the average per person cost of Stage 3 T1D in the model does not increase long term (since fewer people are alive to accrue costs and the model is cohort-based) – so cost effectiveness estimates not sensitive to stage 3 T1D duration
  - No cap on costs in base case, but scenario tested where costs are capped after 65 years in stage 3 T1D

Annual cost projections, assuming HCL uptake = 85% in company projections, 72% in EAG

Stage 3 T1D duration	% surviving at time point	Company projections for annual treatment cost (quadratic, no cost cap)	EAG projections for annual treatment cost (quadratic, 40-year cost cap)	EAG calibrated regression ACM1 (EAG scenario)*
20 years	[redacted]	[redacted]	[redacted]	[redacted]
40 years	[redacted]	[redacted]	[redacted]	[redacted]
60 years	[redacted]	[redacted]	[redacted]	[redacted]
80 years	[redacted]	[redacted]	[redacted]	[redacted]

*ACM1 calibration approach does not include costs of HCLs

T1D, type 1 diabetes; HCL, hybrid closed loops

Extrapolation graphs over time and monthly costs when accounting for survival

Key issue: Estimation of stage 3 T1D costs

Company (continued)

- Assumes 84% uptake of HCLs, and reduction in HbA1c of 0.5% for HCLs compared with non-HCL systems assumed over long term period based on communications with clinical expert from Jan 2026
  - Latest communication - uptake is currently 80% and expected to plateau at 84% by March 2026
- Cost savings associated with reduction in long term complications from T1D management with HCLs are applied to extrapolation (at year 10 = 11% reduction, by year 50 = 25% reduction), for 84% in model with HCL

EAG comments

- Model uses projected difference in costs between cases and controls based on Danish study data to model stage 3 T1D costs over time – but as controls develop comorbidities over time, their costs will increase and become closer to the T1D population, so the modelled T1D specific costs may be an overestimate
- Relevant annual diabetes costs of prevalent population from UK data (£4982.64 annually, from Hex et al 2024 and £3,280 from Stedman et al 2020) are significantly lower than company's projections
- Acknowledges non-linear increase in costs over time is most plausible – but other assumptions are still implausible, so a cap on long-term costs is reasonable in absence of more robust data
  - EAG prefers to cap Stage 3 T1D costs after duration of 40 years in stage 3 (compared with 65 years as in company scenario)
- Assumes 72% uptake of HCLs based on original uptake figure according to NHSE experts in the company's call for evidence submission

How should stage 3 T1D costs be modelled? Should a cap be applied to stage 3 T1D costs, and if so, at what time point? What % HCL uptake should be used?

Projections of Stage 3 T1D annual costs in company base case

T1D, type 1 diabetes; HCL, hybrid closed loops

Key issue: Non-reference discount

Company believes teplizumab meets criteria for 1.5% annual discount rate for health effects and costs

NICE manual - criteria for non-reference discount rate of 1.5% (all required to be met):

- The technology is for people who would otherwise die or have a very severely impaired life
- It is likely to restore them to full or near-full health
- The benefits are likely to be sustained over a very long period

Company

- T1D is a lifelong condition which usually starts in childhood, and relevant population in appraisal is based on a mean model starting age of 13.58 years (in line with TN-10 trial) – delaying stage 3 onset during key stage of development reduces disease burden over lifetime
- Long-term data shows people with early glycaemic control experienced lower rates of complications and mortality for prolonged period even after progression, in line with previous clinical expert comments at committee
- Teplizumab is expected to lead to significant long-term future health gains – a 1.5% discount is justified to appropriately capture this and modelled scenario significantly reduces cost effectiveness estimates
  - Base case company discount rate is still 3.5% for health effects and costs

EAG comments

- Does not consider all the criteria to be met for 1.5% discount rate to be applied

What discount rate for health benefits and costs should be used?

T1D, type 1 diabetes

Summary of company and EAG base case assumptions at ACM3

Assumption	Company base case ACM2	Revised company base case	Revised EAG base case
Proportion of testing costs attributed to NHS	N/A – no additional testing costs for identification included	13%	13%
Testing costs estimate	Confirmatory testing only – identification costs excluded	Blended - £224.15 (applied to both model arms)	Blended - £224.15 (teplizumab arm only)
Stage 2 disutility	Treatment-specific disutility (-0.049 for teplizumab, -0.124 for ECM), applied continuously	Treatment-specific disutility (-0.049 for teplizumab, -0.124 for ECM), applied continuously	Treatment-specific disutility (-0.049 for teplizumab, -0.124 for ECM), applied as one off
Costs of Stage 3 T1D	Values from Danish study, linear regression with quadratic term applied HCL costs included, no cap on costs	Values from Danish study, linear regression with quadratic term applied HCL costs included, no cap on costs (65-year cap in scenario)	Values from Danish study, linear regression with quadratic term applied HCL costs included, 40-year cap on costs
HCL% uptake	100%	84%	72%
Carer disutility	Based on 1.76 carers, up to age 25	Based on 1.76 carers, up to age 25	Based on [redacted] carers, up to age 25
Discount rate	3.5%	3.5% (1.5% in scenario)	3.5%

T1D, type 1 diabetes; ECM, established clinical management; HCL, hybrid closed loops

Cost-effectiveness results

All ICERs are reported in PART 2 slides

because they include confidential discounts for hybrid closed loops

With confidential discounts, company and EAG base case results are both over £30,000 per QALY

Key issues

Key issue	ICER impact	Slide
Identifying people with Stage 2 T1D and defining population eligible for teplizumab	Moderate	7-9
Testing costs	Moderate	10-11
Carer disutility	Moderate	12
Stage 2 disutility	Large	13
Estimation of stage 3 T1D costs	Large	14-15
Non-reference discount	Large	16

Other issues	ICER impact	Slide
Generalisability of ELSA	Unknown	31

T1D, type 1 diabetes; ICER, incremental cost effectiveness ratio

Teplizumab for delaying the onset of stage 3 type 1 diabetes in people 8 years and over with stage 2 type 1 diabetes [ID6259]

Supplementary appendix

NICE National Institute for Health and Care Excellence

Clinical trial results – TN-10

In primary and extended follow up analysis, teplizumab increases the median time to Stage 3 T1D onset compared with placebo

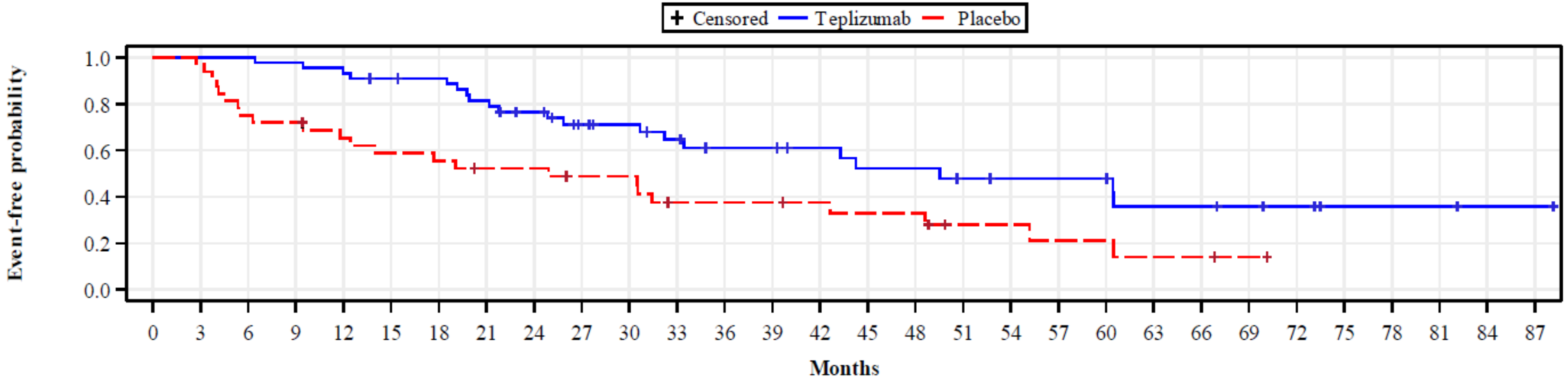
Outcome	Teplizumab (n=44)	Placebo (n=32)
Primary analysis (median follow up = 745 days)		
Median time from randomisation to Stage 3 T1D onset, months (95% CI)	49.5 (32.2, NE)	24.9 (9.5, 48.6)
Median difference in between arms, months (95% CI)	24.6 (NE, NE)	
Hazard ratio (95% CI); p-value	HR 0.41 (0.22 to 0.78); p=0.0066	
Extended follow up analysis (median follow up = 923 days)		
Median time from randomisation to Stage 3 T1D onset, months (95% CI)	59.6 [redacted]	27.1 [redacted]
Median difference between arms, months (95% CI)	32.5 [redacted]	
Hazard ratio (95% CI); p-value	0.457 (NR); p=0.01	

CI = confidence interval; HR = hazard ratio; NE = not estimable; NR = not reported; T1D = type 1 diabetes; KM, Kaplan-Meier

Clinical trial results –TN-10

In primary and extended follow up analysis, teplizumab increases the median time to Stage 3 T1D onset compared with placebo

KM curve for proportion of participants without Stage 3 T1D over time (TN-10; ITT population; primary analysis):



Number of Patients at Risk

Teplizumab	44	44	44	43	41	39	38	34	30	24	22	19	16	16	14	12	12	10	9	9	9	6	6	5	4	2	2	2	1	1
Placebo	32	31	24	23	20	18	17	15	15	13	13	9	9	9	8	7	7	4	4	3	3	2	2	1	0					

Number of Events

Teplizumab	0	0	0	1	3	4	4	8	10	12	12	14	15	15	15	17	17	18	18	18	18	20	20	20	20	20	20	20	20	20
Placebo	0	1	8	9	11	13	14	15	15	16	16	19	19	19	19	20	20	21	21	22	22	23	23	23	23					

KM; Kaplan-Meier; ITT; intention to treat; T1D = type 1 diabetes

Previous committee conclusions – not for discussion

Issues discussed	Latest committee preferred assumption
ECM as comparator	ECM is an appropriate comparator
Generalisability of teplizumab TN-10 trial population	Data from TN-10 suitable for decision making
General population mortality	Use 2017-18 life tables
Adverse events	Incidence rate of 4.6% for cytokine release syndrome in teplizumab model arm
Modelling of progression to stage 3 T1D	Teplizumab model arm: log normal distribution ECM model arm: gamma distribution
Stage 3 disutility	Company revised approach from ACM2 is appropriate for decision making

T1D, type 1 diabetes; ECM, established clinical management; CRS, cytokine release syndrome; ACM, appraisal committee meeting

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Equality considerations - ACM1

Teplizumab is being considered in within its anticipated marketing authorisation

Ethnicity

- Differences in clinical outcomes and CGM between ethnicities
- Clinical trials for teplizumab had mainly White populations - differences in disease progression across ethnic groups may influence treatment effectiveness

Age

- Teenagers and young adults at higher risk of more severe disease and premature death from T1D versus the general population – and poor glycaemic control frequently observed in teenagers
- Teplizumab could potentially be more cost effective in people under 18

Disability

- Some people may may find engaging with insulin therapy difficult (e.g. people who are neurodivergent or those with learning difficulties – delaying progression may be particularly beneficial in these groups)

Deprivation

- People living in more deprived areas may get greater benefit from teplizumab due to having fewer opportunities for participation in structured diabetes education and specialist diabetes services

Other issues

- Potential barriers to accessing teplizumab due to lack of national screening programme – particularly in areas with limited healthcare resources
- If only available to people identified through research trials, variation in access to trials may introduce inequalities (e.g. based on family history of T1D , geography, or education/knowledge of early-stage diabetes)
    - First-degree relatives of people with type 1 diabetes are more likely to have been screened for pancreatic islet autoantibodies
- 14-day infusion course of teplizumab could cause difficulties due to cost of travel and accommodation

NICE

CGM, continuous glucose monitoring; T1D, type 1 diabetes; ACM, appraisal committee meeting

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Equality considerations - ACM2

Additional potential equalities issues raised in consultation responses

Consultation comments

- Caregivers may have to reduce working hours or leave employment which may cause additional financial strain within households.
    - Uneven split between parents that may impact mother
- Separate consideration may be needed for visually impaired people (who may struggle to independently manage insulin), people with learning difficulties or children residing in care settings
- Access to insulin supplies and storage, and access to consistent healthcare, can be problematic for travelling communities and other nomadic groups

Treatment pathway and population eligible for teplizumab

Company positions teplizumab for people already diagnosed with stage 2 T1D – but no routine testing available in current practice

Stage 2 T1D:

Asymptomatic and not usually identified in routine practice – diagnosis mostly from research studies

Teplizumab

Established clinical management following diagnosis:

- monitoring blood glucose
- psychosocial support
- education

Stage 3 T1D:

Most people with T1D diagnosed at stage 3 following symptom onset and enter treatment pathway here

Stage 3 management includes:

- insulin
- blood glucose monitoring
- carbohydrate counting
- exercise

- **Key issue** – for teplizumab to be introduced into pathway, eligible population needs to be identified. But there is no national screening programme or standard pathway of care for pre-symptomatic T1D
- Some people with stage 2 T1D already identified through research studies or because of clinical suspicion of T1D, but no currently available treatment for delaying stage 3 T1D so demand for testing is low

T1D, type 1 diabetes

Key issue: Testing costs

Testing pathway and total estimated costs incurred by NHS to diagnose and stage early T1D

Step	Cost per person	Cost, total tested (n=30)	Key assumptions	Source of costs
Invite to exploratory autoantibody test	£1.44	£43.20	2 texts and 2 letters sent (£0.02 per text, £0.70 per letter)	NHS Notify
Exploratory autoantibody test	£44.76	£1,342.80	1 phlebotomy appointment (£15.00) based on 15-minute nurse appointment (with assumed uplift for additional time with children or young people), and 1 autoantibody test (£29.04)	15-minute nurse appointment costs from NHS GP website Antibody test cost based on GAD testing
Communicating result	£0.72	£21.60	1 text and 1 letter sent (£0.02 per text, £0.70 per letter)	NHS Notify

FDR, first degree relatives; T1D, type 1 diabetes;

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Key issue: Testing costs

Testing pathway and total estimated costs incurred by NHS to diagnose and stage early T1D

Step	Cost per person	Cost, total tested	Key assumptions	Source of costs
Confirmatory testing (for 1.1 people suspected to have ≥2 positive autoantibodies of 30 tested)				
Consultation	£22.00	£24.20	Community setting with specialist diabetes nurse; 1 appointment per positive individual (assumed 10 mins)	Salisbury 2017
Confirmatory testing	£118.24	£130.06	1 phlebotomy appointment (£15.00) based on 15-minute nurse appointment (with assumed uplift for additional time with children or young people), 1 confirmatory venous test and analysis (£97.52) and 1 HbA1c test (£5.00)	Phlebotomy appointment as in exploratory testing. Confirmatory venous test and HbA1c test costs – from data submitted in response to ACM1 DG
Sending result	£0.72	£0.79	1 text and 1 letter sent (£0.02 per text, £0.70 per letter)	NHS Notify
Staging and diagnosis (1 person per 30 tested)				
OGTT	-	£112.00	1 test assumed	Submitted data in response to ACM1 DG
Diagnosis consultation	-	£72.00	30 min appointment by secondary care team with specialist diabetes nurse; as per model submitted by clinical expert in response to ACM1 DG	Submitted data in response to ACM1 DG
Total costs	-	**£1,724.26**	Exploratory testing in 30 people, confirmatory testing in 1.1 individuals and staging in 1 individual	--

ACM; appraisal committee meeting; DG, draft guidance

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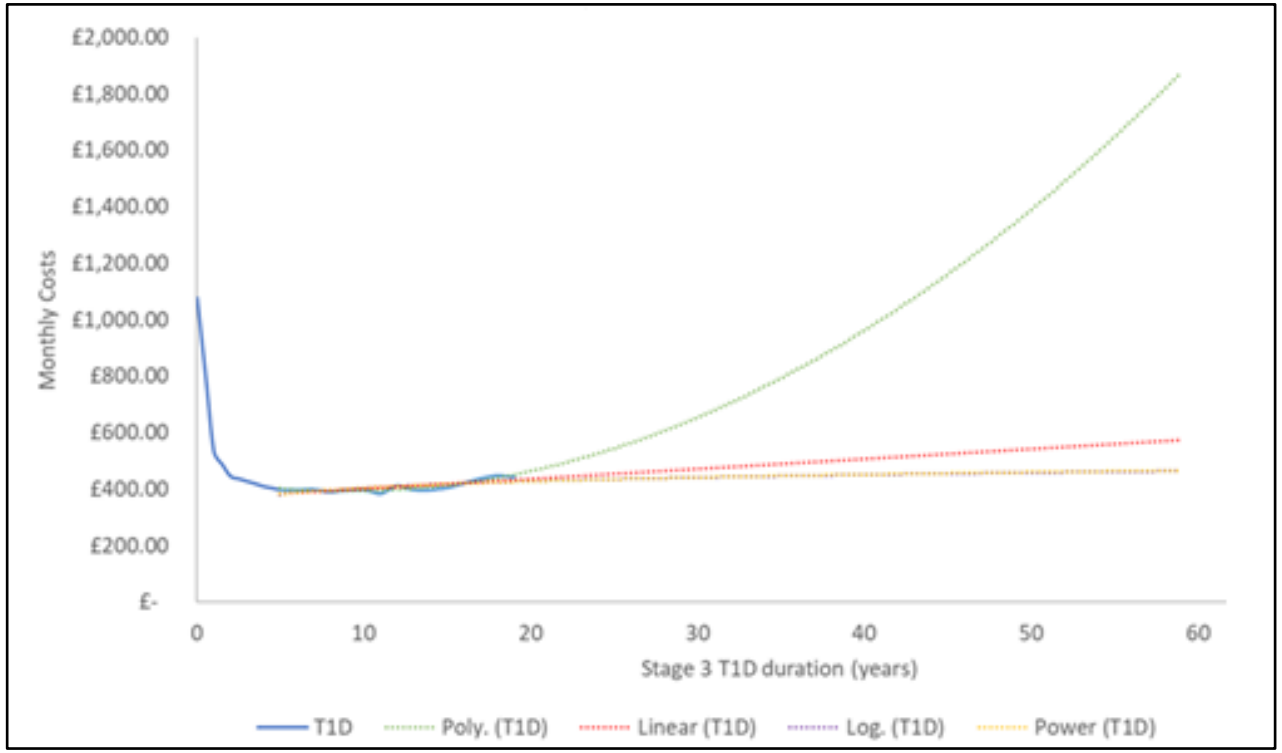
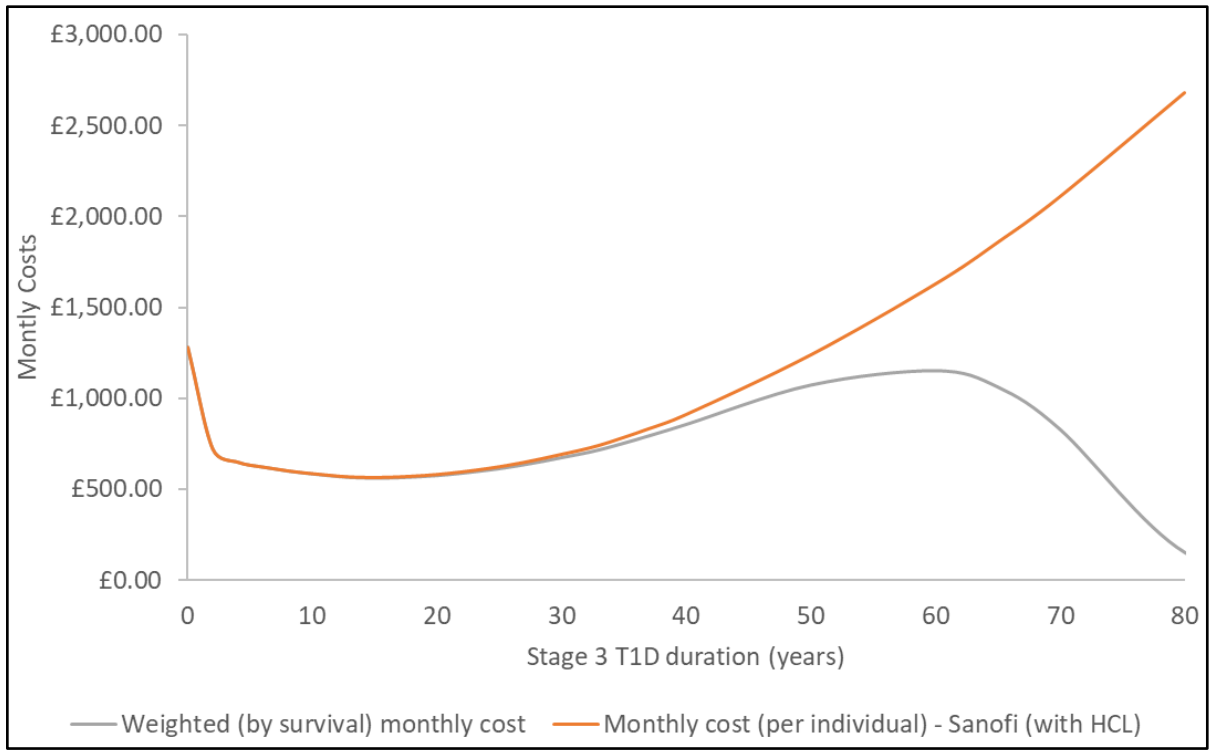
Key issue: Estimation of stage 3 T1D costs

Extrapolations for costs over time for people with stage 3 T1D



Company base case: monthly Stage 3 T1D costs when accounting and not accounting for survival



T1D, type 1 diabetes:

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Key issue: Estimation of stage 3 T1D costs

Projections of Stage 3 T1D annual costs in the company base case analysis

T1D, type 1 diabetes:

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Other issue: Generalisability of ELSA

Committee conclusion at ACM2

Committee requested additional evidence on the generalisability of the ELSA study to the UK population, and to what extent disadvantaged groups are represented in the study

Company

- Submitted data on demographics of ELSA relative to the general population
  - Black and Asian individuals and individuals from lower socio-economic backgrounds were slightly underrepresented
- ELSA study lead - recruitment across various settings (schools, GP, hospitals, community forums) supports recruitment from ethnic minority groups, those living in areas of high deprivation, and those without family history of T1D

Characteristic	ELSA (n=24,875)	UK General Population	UK reference
% Male	51.61%	49.00%	ONS 2022
Median age	8 years	-	
Reported ethnicity - White	80.96%	81.70%	ONS 2022
Reported ethnicity - Mixed	7.08%	2.90%	
Reported ethnicity - Asian	6.53%	9.30%	
Reported ethnicity - Black	2.09%	4.00%	
Reported ethnicity - Other	2.55%	2.10%	
Median IMD decile for English postcodes	6 (IQR 4–9)	5.5	GOV.UK 2019
Family history of T1D	32.47%	~10%	Sims 2022
Affected FDR (parent or sibling)	15.46%	~12%	Parkkola 2013

FDR, first degree relatives; T1D, type 1 diabetes; ONS, Office for National Statistics; IQR, interquartile range

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Further statistics for T1D testing and staging

- Estimated number of people with T1D – 310,187 (NHSE data submitted at DG consultation - no data available for specific staging)
    - Range of number eligible for FDR testing proposed by NHSE - 620,374 to 1,550,935 (based on either 2 or 5 FDRs being tested per person with T1D – no anticipated uptake data provided)
- ELSA study results (Quinn 2026)
    - 160/17,283 (0.93%) samples returned were positive for 2+ autoantibodies
    - Of 143 staged by OGTT, 105 (73.43%) were stage 1, 31 (21.7%) were stage 2, and 7 (4.89%) stage 3
    - Children with a FDR had a higher prevalence of multiple autoantibodies (3.75%) than those without (0.46%) ($p<0.001$)

FDR, first degree relatives; OGTT, oral glucose tolerance test; FDR, first degree relative; DG, draft guidance

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