THE **NEXT ERA** IN TYPE 1 DIABETES

INDICATION: Tzield®▼ (teplizumab) 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)[1]

Tzield Prescribing Information can be accessed by clicking **here**, or by scanning the QR code below. This promotional material has been produced by Sanofi and is intended for healthcare professionals in the United Kingdom (UK).

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com

Tzield®▼ (teplizumab)

MAT-XU-2502760 (v4.0) | November 2026

In the short term an autoimmune type 1 diabetes (T1D) diagnosis may have a sudden emotional and physical impact on people[2,4-6]

Newly diagnosed patients may need to **start insulin immediately**[2,3]

Patients will be dealing with the shock of their diagnosis as well as:[4]

Injecting & monitoring[2]

Starting insulin, glucose monitoring

Emotional impact[4,5,6]

Shock, fear, depression, distress, feeling alone

Diet & lifestyle adjustments[2,5]

Physical activity, daily routine changes & dietary changes

Risk of hypo- or hyperglycaemia[2]

While learning to adjust insulin

~25% of children

are diagnosed with T1D only when they present with **diabetic ketoacidosis (DKA)**[7]

In the long term, a person with autoimmune type 1 diabetes may experience:

135%

higher mortality risk in people living with T1D than those of the same age without it[8]

11-15 years

reduction in life expectancy in the UK due to T1D[8]

DKA: diabetic ketoacidosis. T1D: type 1 diabetes.

25% of children are diagnosed with type 1 diabetes only when they present with diabetes ketoacidosis (DKA).[7] DKA is a medical emergency and acute complications may require hospitalisation[2,9]

In the UK, the cost of one DKA episode is **estimated to be £2,064 in adults and £1,387 in adolescents** (11–18 years of age)[10]

Over the longer term, a population health management approach is required to manage autoimmune type 1 diabetes, where per 1 million total UK population results in the following complications:



~153
cases of end-stage renal failure‡[8,11]

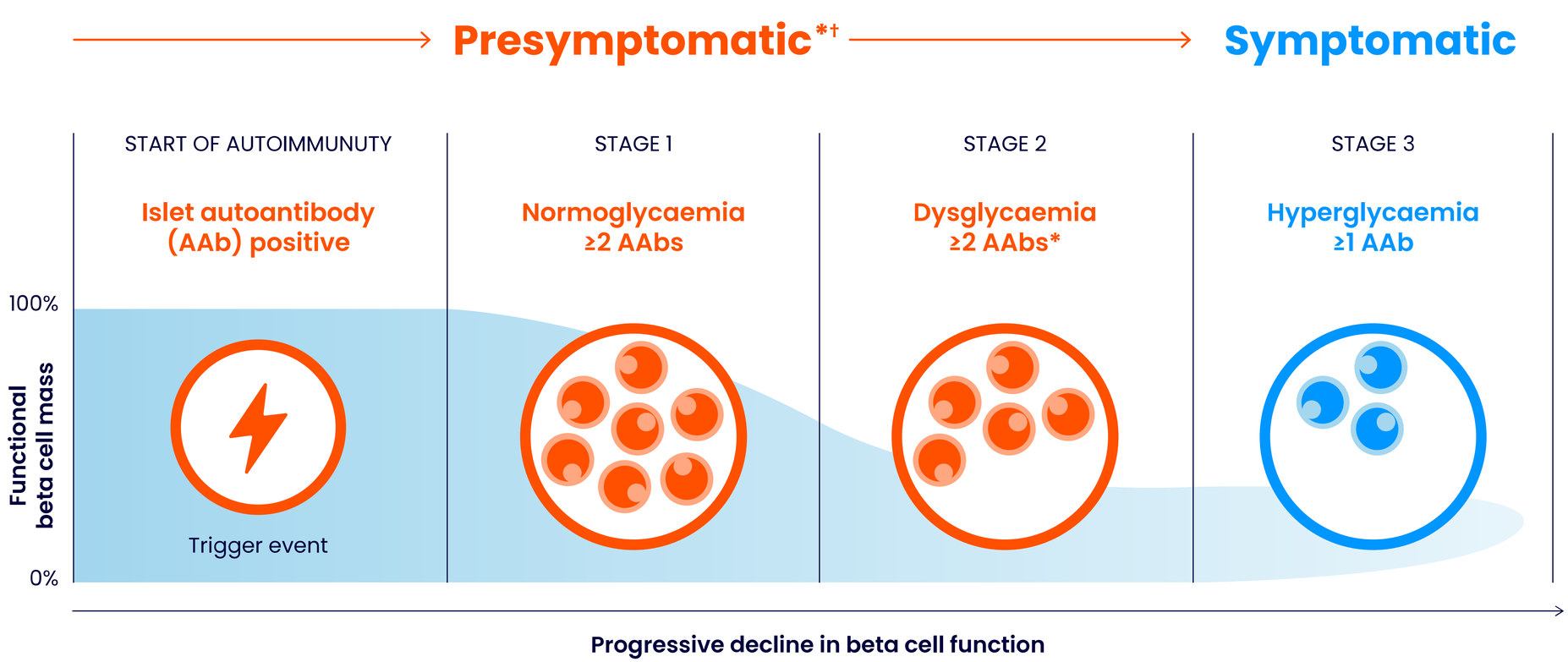
~125
leg, toe or foot amputations each year‡[8,11]

~50%
of people with T1D have some form of retinopathy[8]

‡Complications of T1D in the UK: at least 10,350 people have end-stage renal failure, and there are more than 8,500 leg, toe or foot amputations per year. UK population: 67,602,800 (mid-2023).[11]
DKA: diabetic ketoacidosis. T1D: type 1 diabetes.

Autoimmune type 1 diabetes is characterised by an immune system attack on and destruction of insulin-producing beta cells in the pancreas[12]

People with autoimmune type 1 diabetes progress through 3 clinically distinct stages as their beta cells are destroyed[13-15]



Adapted from: Sims EK, et al. Diabetes. 2022;71(4):610-623 and Phillip M, et al. Diabetes Care. 2024;47(8):1276-1298.

*Some people with confirmed persistent prior multiple autoantibody positivity may revert to single autoantibody status or negative status.
†Early stage T1D = presymptomatic Stage 1 and Stage 2.
AAbs: autoantibodies.

Progression rates to symptomatic Stage 3 type 1 diabetes vary depending on the sub population:

~100% lifetime risk of symptomatic T1D in children at Stage 1[13,16]

~15% of adults with multiple / ≥2 AAbs will progress to Stage 3 within 5 years[17]

75% of people with a first-degree relative with T1D at Stage 2 will progress to Stage 3 **within 4-5 years**[13]

A window of opportunity exists to intervene before patients become clinically symptomatic with type 1 diabetes[13]

DELAY PROGRESSION → TIME TO PREPARE → CHANGE TRAJECTORY

Offering additional years free from the social stigma, and lifestyle disruptions associated with autoimmune T1D[18-21]

To learn how to achieve **optimal glycaemic control** before insulin initiation[2,3]

Slowing the progression of autoimmune T1D **offers the potential to change the disease**[22,23]

T1D: type 1 diabetes. AAbs: autoantibodies.

Delaying autoimmune type 1 diabetes may align to NHS priorities including:[24-27]



Prevention Agenda

Enabling people living with T1D to **prepare** for the later stages of the condition **for longer**[24,25]

Proactive detection may reduce the likelihood of DKA, a medical emergency, and may enable a smoother transition to life with symptomatic autoimmune T1D (Stage 3)[7,15,28,29]



Productivity Agenda

Moving from **reactive** to **proactive** management of T1D may potentially impact local NHS **productivity targets**[26]

Delaying the onset of T1D may allow services to reallocate capacity and develop new proactive models of care



Population Health Management

Scaling up from a largely reactive system to a more **systematic proactive one** for T1D may help meet the aims of population health management[27]

Proactive management of autoimmune T1D may require service evolution, facilitating equitable access to TZIELD

DKA: diabetic ketoacidosis. T1D: type 1 diabetes.

TZIELD (teplizumab) is NICE recommended[30]

TZIELD is recommended by the National Institute for Health and Care Excellence (NICE), within its marketing authorisation,[1] as an option for delaying the onset of stage 3 T1D in people 8 years and over with stage 2 T1D, subject to the commercial arrangement as outlined in the NICE guidance.[1,30]



What does this mean?

Within the recommended population, NICE have determined TZIELD provides benefit and value for money[30]

Testing/Screening context

- Stage 2 T1D requires both AAb testing (≥2 islet AAbs) and evidence of dysglycaemia for identification[15]
  - Currently, patients are identified through research studies (such as ELSA & T1DRA), clinical assessment, first-degree relative screening, or patient request
- The NICE guidance acknowledges that new NHS testing pathways will need to be established to support TZIELD implementation. Importantly, the relevant real-world costs of testing eligible FDR have already been accounted for within the confidential net price agreed for TZIELD[30]
- NICE's economic model reflects the expected FDR testing activity required to identify people eligible for treatment, based on up to 43 FDRs tested for every 1 person treated with TZIELD.[30] This means FDR testing should not be viewed as a separate, unfunded activity sitting outside the NICE recommendation – it is part of the funded implementation pathway, and **NHS funding is available** to cover both TZIELD treatment and the associated **FDR testing costs**
- The availability of TZIELD is expected to incrementally increase the number of people that come forward to NHS-funded AAb testing, but the most likely cost-effectiveness estimates are within the range NICE considers an acceptable use of NHS resources[30]
- **First-degree relatives** of people with type 1 diabetes represent the primary population for testing, as they have significantly higher risk compared to general population.[7] **Healthcare professionals should feel able to discuss and request AAb testing for eligible FDR and their families, in line with the testing activity already recognised and funded within the NICE recommendation[30]**

+ Learn more: Click here to read NICE Final Guidance in full

AAbs: autoantibodies. ELSA: EarLy Surveillance for Autoimmune diabetes. FDR: first-degree relatives. T1D: type 1 diabetes. T1DRA: The type 1 diabetes risk in adults study.

TZIELD is the first and only approved disease modifying therapy to delay disease progression in stage 2 autoimmune type 1 diabetes[1,18,23,24]

TZIELD is a humanised **anti-cluster of differentiation 3 (CD3)** monoclonal antibody **designed to target and modulate the autoimmune process** involved in beta cell destruction*[1,18,31]

TZIELD helps to **preserve beta cell function and insulin production** in the pancreas thereby delaying progression from presymptomatic Stage 2 to symptomatic Stage 3 autoimmune T1D*[1,23]

As a result, a patient can experience

2x more time in Stage 2 autoimmune T1D with TZIELD vs placebo[1]

Median time to diagnosis of Stage 3 autoimmune T1D:

TZIELD: 48.4 months

Placebo: 24.4 months

(N=76; hazard ratio (HR) 0.41; 95% CI, 0.22–0.78; P=0.0066 by an adjusted Cox proportional-hazards model stratified by age and OGTT status at randomisation).[1,18] Median follow-up time: 745 days (range: 74–2,683 days)[18] Primary efficacy endpoint: Time from randomisation to diagnosis of Stage 3 clinical T1D†[1]

In TN-10, Stage 3 T1D was diagnosed in 20 (45%) patients treated with TZIELD and 23 (72%) patients treated with placebo.[1]

- TN-10 was a phase 2, randomised, double-blind, event-driven, placebo-controlled study in 76 patients, 8-49 years of age with Stage 2 T1D and who had a relative diagnosed with Stage 3 T1D‡[1,18]
- Median follow-up time: 745 days (range 74-2,683 days)[18]
- Patients were followed in a blinded fashion until 40 patients had developed Stage 3 clinical T1D†[18]

*The mechanism of action for TZIELD is not fully understood. It may involve partial agonistic signalling and deactivation of pancreatic beta cell autoreactive T lymphocytes.[1]

†Criteria for Stage 3 T1D were based on glucose testing or the presence of unequivocal hyperglycaemia or hyperglycaemic crisis.[32]

‡Stage 2 is defined as having two or more pancreatic islet AAbs (GADA, IAA, ICA, IA-2A, and ZnT8A) and dysglycaemia on OGTT[1]

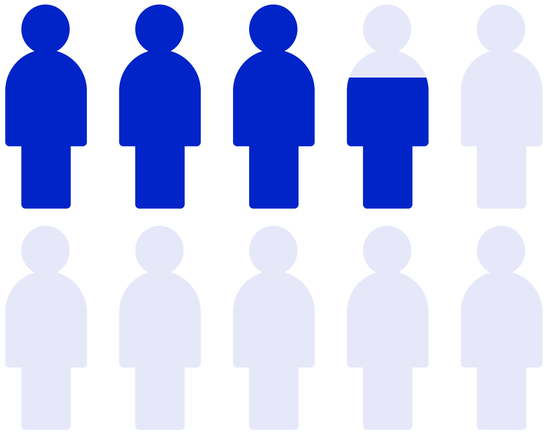
CI: confidence interval. OGTT: oral glucose tolerance test. T1D: type 1 diabetes.

TN-10 extended follow-up analysis

In a TN-10 extended follow-up analysis, 1 in 3 TZIELD-treated patients remained undiagnosed with Stage 3 T1D[33]

In an extended analysis of TN-10, after a median follow-up time of 7 years*

36.4% of TZIELD-treated patients (n=16/44)

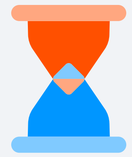


vs

12.5% of placebo-treated patients (n=4/32)



remained undiagnosed with Stage 3 autoimmune T1D (P=0.03 Fisher's exact test)[33]



The median time to Stage 3 T1D was ~4 years in the TZIELD group vs ~2 years in the placebo group (P=0.0026)†[33]

The TN-10 study was relatively small at the start, and patient numbers decreased throughout follow-up.[1,18] Therefore, definitive conclusions cannot be derived from these data. Patient results may vary.

*The median follow-up time was 80.46 months.[33]
†The median time to Stage 3 T1D was ~4 years [52.2 months (95% CI, 30.5–86.7)] with TZIELD and ~2 years [27.3 months (95% CI, 9.5–48.4)] in the placebo group; P=0.0026 log-rank test.[33]
T1D: type 1 diabetes.

The safety profile of TZIELD has been evaluated in a pool of adult and paediatric patients who participated in five controlled clinical studies*[1]

Adverse reactions occurring in ≥5% of patients in the pooled safety analysis of clinical studies[1]

	Frequency		
System organ class	**Very common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Not known†**
Infections and infestations		Infections**	Epstein-Barr virus reactivation
Blood and lymphatic system disorders	Lymphopenia, Leukopenia, Neutropenia, Decreased haemoglobin, Thrombocytopenia		
Immune system disorders		Cytokine release syndrome (CRS)	
Nervous system disorders	Headache		
Respiratory, thoracic and mediastinal disorders		Nasopharyngitis	
Gastrointestinal disorders	Nausea	Diarrhoea	Vomiting
Skin and subcutaneous tissue disorders	Rash, Pruritus	Urticaria	Rash pruritic
General disorders and administration site conditions	Pyrexia	Chills	Fatigue, Pain, Illness
Investigations	Increased alanine aminotransferase (ALT), Increased aspartate aminotransferase (AST), Decreased blood bicarbonate, Decreased blood calcium		

Lymphopenia, leukopenia, neutropenia, decreased blood bicarbonate, and rash were the most frequently reported adverse reactions, which occurred at a higher frequency in the TZIELD group compared to the control group*[1]

No drug interaction studies have been performed[1]

Adapted from TZIELD (teplizumab) UK SmPC.[1]

Refer to the Summary of Product Characteristics for full safety information

*Adverse reactions were evaluated in a pool of adult and paediatric patients across one phase 2 study in patients with Stage 2 autoimmune T1D (TN-10), three placebo-controlled studies in an unapproved population (Stage 3 T1D), and one open-label standard-of-care controlled study of TZIELD in an unapproved population (Stage 3 T1D).[1]

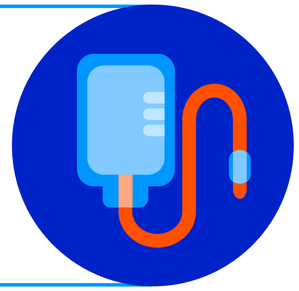
**Reported as serious

†Cannot be estimated from available data.

ALT: alanine aminotransferase. AST: aspartate aminotransferase. T1D: type 1 diabetes.

TZIELD is a single-course treatment infused over 14 consecutive days[1]

TZIELD is administered by intravenous infusion
over a minimum of 30 minutes, using BSA-based dosing[1]



Recommended dosing schedule‡[1]

Day	1	2	3	4	5-14
Dose micrograms/m²	65	125	250	**500**	**1,030**

Refer to section 6.3, section 6.4, and section 6.6 of the SmPC for information on storage and preparation for intravenous administration of TZIELD.

Premedication is required prior to administering TZIELD for the first five days of dosing with a non-steroidal anti-inflammatory drug (NSAID) or paracetamol, an antihistamine, and/or an antiemetic. Administer additional doses of premedication if needed.[1]

Please consult the TZIELD SmPC for full details on premedication and administration before prescribing.

‡The dosing schedule in TN-10 was different to the recommended dosing schedule in the SmPC.[1]
BSA: body surface area.

Administration of TZIELD: Treatment pathway

Prior to TZIELD initiation

Blood test[1]
Complete blood count and liver enzyme tests*[1]

Vaccines[1]
Administer all age-appropriate vaccinations†[1]

Viral load
Test for active EBV or CMV§[1]

Treatment days 1-14
Options: Weekdays: in hospital; Weekends: care closer to home

Daily premedication‡[1]

Days 1-5; continue as necessary

- NSAID or paracetamol
- antihistamine and/or antiemetic

Monitoring‡[1]

- Liver enzymes and bilirubin‡
- Signs & symptoms of infection§
- White blood cell counts**
- Adverse reactions

Infusion preparation[1]

- Each vial is for a single dose only
- Based on BSA dosing, more than one vial may be needed; ensure the complete dose for each day is contained in one infusion bag or syringe

Administration[1]

- Administer TZIELD by IV infusion over at least 30 minutes‖

Infusion preparation	1.5 hours	3 hours	4.5 hours	6 hours

Time at room temperature since infusion preparation started

Staffing time

- Estimated 90 minutes††

††Sanofi has consulted with experts on potential infusion settings and time commitment for healthcare professionals. The estimated time does not include pre-infusion consultations and blood tests or post-infusion follow-up.

‖Please see SmPC for details regarding the storage and shelf life for TZIELD prior to administration.

IV: intravenous.

Safety information for treatment pathway

*Use of TZIELD is not recommended in patients with:[1]

- Lymphocyte count <10^9 lymphocytes/L
- Haemoglobin <100 g/L
- Platelet count <150 x 10^9 platelets/L
- Absolute neutrophil count <1.0 x 10^9 neutrophils/L in those of African descent, and <1.5 x 10^9 neutrophils/L in all other groups
- Elevated ALT or AST >2 x ULN or bilirubin >1.5 x ULN
- Laboratory or clinical evidence of acute infection with EBV or CMV
- Active serious infection or chronic active infection other than localised skin infections

†Administer live-attenuated vaccines at least 8 weeks prior to treatment. Administered inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.[1]

‡To mitigate CRS:

- Premedicate with antipyretics, antihistamines and/or antiemetics prior to TZIELD treatment
- Monitor liver enzymes and bilirubin during treatment. Discontinue TZIELD treatment in patients who develop elevated ALT or AST >5 x ULN or bilirubin >3 x ULN
- Treat symptoms of CRS with antipyretics, antihistamines and/or antiemetics. If severe CRS develops, consider temporarily pausing dosing for 1-2 days (and administer the remaining doses to complete the full 14-day course on consecutive days) or discontinuing treatment

§Bacterial and viral infections have occurred in patients treated with TZIELD. In clinical trials, patients treated with TZIELD had a higher rate of serious infections (3.5%) than patients in the control group (2%), including gastroenteritis, cellulitis, pneumonia, abscess and sepsis. Epstein-Barr virus (EBV) reactivation may occur in patients treated with TZIELD. In patients with co-morbid conditions predisposing them to significant immunocompromise, clinical course of EBV reactivation may present with increased severity. Patients should be tested for active EBV and CMV infection prior to starting treatment. Use of TZIELD is not recommended in patients with active serious infection, laboratory or clinical evidence of acute infection with EBV or CMV, or chronic infection other than localised skin infections. Lymphocyte count monitoring requirements and discontinuation recommendations should be followed.

Monitor patients for signs and symptoms of infection, including viral reactivation, during and for at least 2 months after the last TZIELD treatment dose. If viral reactivation is suspected, viral load should be assessed (e.g., PCR). If serious infection or viral reactivation develops, treat appropriately. If these infections occur during treatment discontinue TZIELD.

**In clinical trials, 80% of patients treated with TZIELD developed lymphopenia compared to 17% of patients in the control group. For most patients treated with TZIELD who experienced lymphopenia, lymphocyte levels began to recover after the fifth day of treatment and returned to pre-treatment values within two weeks after treatment completion and without dose interruption. Severe lymphopenia (<0.5 x 10^9 cells/L) lasting 1 week or longer occurred in 0.9% of patients treated with TZIELD, and 0.5% of patients treated with TZIELD permanently discontinued TZIELD because of lymphopenia. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia (<0.5 x 10^9 cells/L lasting 1 week or longer) develops, discontinue TZIELD.

Please refer to section 4.4 of the SmPC for full information on special warnings and precautions for use.

ALT: alanine aminotransferase. AST: aspartate aminotransferase. CMV: cytomegalovirus. CRS: cytokine release syndrome. EBV: Epstein-Barr virus. ULN: upper limit of normal.

There is currently no national screening programme for people with Stage 1 or 2 autoimmune type 1 diabetes, therefore most will be unknown to your clinicians

Patients eligible for TZIELD are identified via research studies or when investigated for other reasons (incidentally/ad hoc) in diabetes clinics. A small number of patients may request tests themselves or for a first-degree relative of patients with T1D. Those people who are known and are potentially appropriate for TZIELD will most likely have been identified via two routes:

Ad hoc testing of first-degree relatives of people with T1D by clinical teams

Patients identified incidentally

UK research studies – ELSA (paeds) and T1DRA (adults)

Known potentially appropriate population for treatment with TZIELD

100	Example figure of 100 first degree relatives being tested in an area
3	**2.6%** have 2 auto-antibodies[15] **Stage 1 T1D**
+	
0.3	10% have dysglycaemia[34] **Stage 2 T1D**

600 per million	0.06% of the population will be screened by ELSA*/T1DRA[11,35]
3	**0.5%** have 2 auto-antibodies[36] **Stage 1 T1D**
+	
0.3	10% have dysglycaemia[34] **Stage 2 T1D**

Modelling would suggest between **~1 to 7** Stage 2 patients per 1 million population per year could be identified over the next 1-5 years

- Depends on uptake and continuation of ELSA/T1DRA studies
- Depends on extent of first-degree relative testing locally and retesting of Stage 1 patients

*Based on 40,000 tests currently available and UK total population of 67,602,800 in mid-2023.[11,35]

ELSA: EarLy Surveillance for Autoimmune diabetes. T1D: type 1 diabetes. T1DRA: The type 1 diabetes risk in adults study.

Proactive management may include early detection and delaying the onset of Stage 3 T1D

Proactive early detection of autoimmune type 1 diabetes may reduce the likelihood of an emergency and may enable a smoother transition to life with symptomatic autoimmune type 1 diabetes (Stage 3)[7,15,28,29,37]

Early detection and monitoring in children may help avoid DKA at diagnosis[15,38]

Early detection and monitoring of autoimmune T1D:

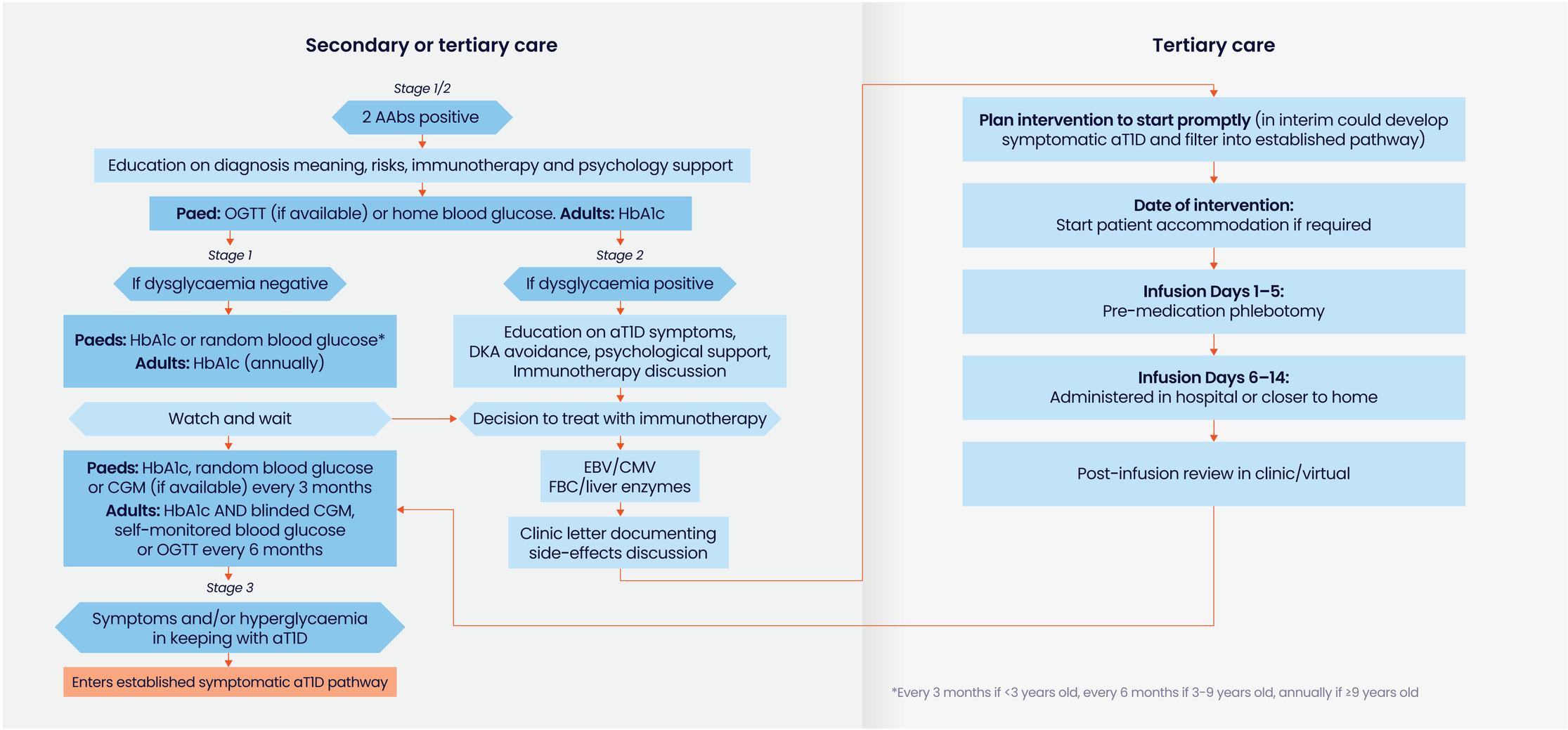
Provides time for proactive education and support[15,28,39]

Facilitates access to treatment for eligible patients with presymptomatic Stage 2 autoimmune T1D[1,15]

DKA: diabetic ketoacidosis. T1D: type 1 diabetes.

Proactive management of autoimmune T1D may require service evolution

Patient pathway prototype



†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.

Based on BSPED best practice recommendations, ISPAD consensus guidance and expert opinions from a Sanofi-funded infusion service advisory board, April 2025.[14,40]

AAb: autoimmune antibody. aT1D: autoimmune type 1 diabetes. BSPED: British Society for Paediatric Endocrinology and Diabetes. CGM: continuous glucose monitoring. CMV: cytomegalovirus. DKA: diabetic ketoacidosis. EBV: Epstein–Barr virus. FBC: full blood count. HbA1c: glycated haemoglobin. ISPAD: International Society for Pediatric and Adolescent Diabetes OGTT: oral glucose tolerance test.

TZIELD offers an opportunity to reduce the burden to patients and the NHS of autoimmune T1D for the first time[1,18,22]



Prioritise access to TZIELD

How will you ensure TZIELD is **available for all eligible** patients?



Prioritise adult and paediatric service provision

How will you **evolve services** to incorporate administration of TZIELD to help protect patients from early progression to Stage 3 T1D?



Prioritise proactive management

How will you **identify patients** who may benefit from TZIELD to prolong the time before starting insulin in Stage 3 T1D?

T1D: type 1 diabetes.

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