Tzield® ▽
(teplizumab)

Testing and **monitoring handbook**

A comprehensive guide to early detection of autoimmune T1D

INDICATION: TZIELD is indicated to delay the onset of Stage 3 T1D in adult and paediatric patients 8 years of age and older with Stage 2 T1D.[1]

This material is intended for healthcare professionals in the United Kingdom (UK).

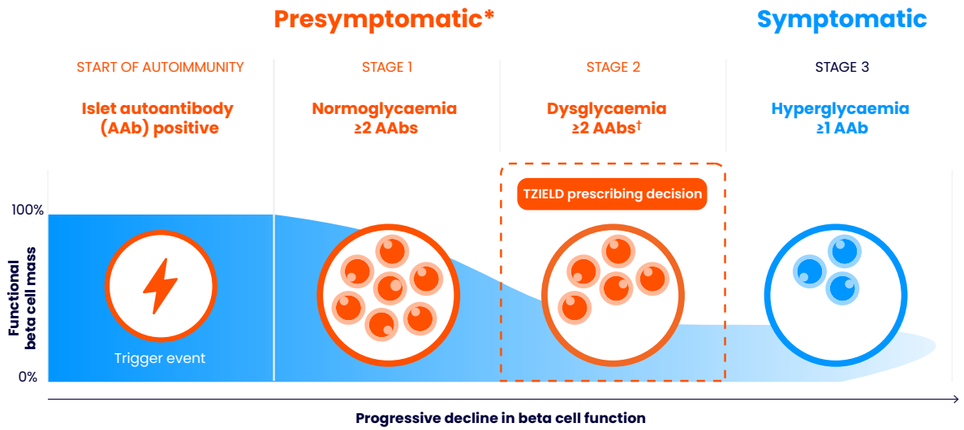
▽ Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com

The prescribing information can be accessed at the end of this document.

sanofi

Autoimmune T1D can start long before symptoms arise[2]

People with autoimmune T1D progress through three clinically distinct stages as their beta cells are destroyed[2–4]



Adapted from Sims EK, et al. 2022.[3]

The **lifetime risk** of progressing from early T1D (Stages 1 and 2) to symptomatic autoimmune T1D (Stage 3) approaches **100% in children** screened at birth[2]

*Presymptomatic Stages 1 and 2 may be collectively referred to as early-stage T1D.[4]
†Reversion to single AAb or negative status can occur in some people with previously confirmed multiple AAb positivity.[4]

Glycaemic parameters to look for in autoimmune T1D[5–7]

BSPED, ISPAD, and WHO outline the following diagnostic tests and glycaemic parameters for the stages of T1D[5–7]

Blood test	Stage 1 Normoglycaemia	Stage 2 Dysglycaemia	Stage 3 Hyperglycaemia
Fasting plasma glucose (FPG)	<5.6 mmol/L	5.6–6.9 mmol/L	≥7.0 mmol/L
120-min oral glucose tolerance test (OGTT)	<7.8 mmol/L	7.8–11.0 mmol/L	≥11.1 mmol/L
Glycated haemoglobin (HbA1c)	<39 mmol/mol (<5.7%)	39–47 mmol/mol (5.7–6.4%)	≥48 mmol/mol (≥6.5%)

Adapted from Besser REJ, et al. 2025.[6]

The number of AAbs detected, glycaemic status, and age may be used to guide frequency of monitoring[8]

Who is at risk and may be suitable for autoimmune T1D testing?

Relatives of patients with autoimmune T1D[9]

People with a first-degree relative with autoimmune T1D have up to

~15x HIGHER LIFETIME RISK

of developing the condition compared to the general population

Those with certain autoimmune diseases[10–12]

Coeliac disease and autoimmune thyroid diseases **are associated with increased risk of autoimmune T1D***

Those misdiagnosed with T2D[13]

~40% of adults with autoimmune T1D are **initially misdiagnosed**†

Of these, 77% are **misdiagnosed with T2D**†

Self-reported patient data†

~90% of **new diagnoses** occur in **people without a first-degree relative** with autoimmune T1D‡[14]

*While autoimmune conditions like coeliac disease and autoimmune thyroid disease are associated with increased risk of autoimmune T1D, the risk of developing additional autoimmune conditions is particularly elevated in individuals already diagnosed with autoimmune T1D.[10-12]
†In a retrospective online survey of people with autoimmune T1D and caregivers of people with autoimmune T1D in the US, a diagnosis of autoimmune T1D was missed in 38.6% (n=330/856) of those diagnosed at ≥18 years of age. Of those people, 76.8% (n=253/330) were initially diagnosed with T2D.[13]
‡From a population-based observational study of 57,371 young people with autoimmune T1D across Germany, Austria, Switzerland and Luxembourg, using data from the Diabetes Prospective Follow-up Registry between 1995 and 2018. 93.4% had no first-degree relative with T1D vs 6.6% who had a first-degree relative with T1D.[14]

Proactive testing can identify autoimmune T1D before symptoms appear[3,15]

Early T1D (Stages 1 and 2) can be identified through testing for AAbs in the blood[3,15]

The four AAb tests recommended by BSPED are:[6]

GADA (Glutamic acid decarboxylase 65 AAb)

IA-2A (Insulinoma-associated antigen 2 AAb)

IAA (Insulin AAb)

ZnT8A (Zinc transporter 8 AAb)

Collection of a blood sample for testing can be done by a simple finger prick[5]

AAb testing can help to avoid a misdiagnosis of T2D in adult patients with autoimmune T1D[16]

Early detection can help avoid DKA and give your patients time to prepare

DKA is a medical emergency associated with high morbidity[17]

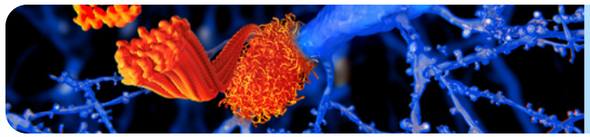
DKA at diagnosis can have significant consequences over time, including:*

- Hospitalisation[18,19]
- Neurocognitive impairments[19–21]
- Sustained negative effects on glycaemic control[22]

Preparation time

Early detection of autoimmune T1D:

- Creates a valuable window for proactive education and support[3,23–26]
- Facilitates access to treatment for eligible patients with early T1D (Stage 2)[1,3]
- Offers the potential to delay progression to symptomatic disease (Stage 3)[1,3]



Early detection and monitoring of autoimmune T1D can reduce rates of DKA at Stage 3 T1D diagnosis†[3,19,27]

*Independent of other variables.
†Compared to those diagnosed without early detection of T1D.

Screening and monitoring for autoimmune T1D in the UK

Most screening initiatives for early T1D (Stages 1 and 2) are being performed in the context of research, but may become standard of care in parts of the world[5]

In the UK, adults and children can be screened for autoimmune T1D through enrolment in research studies:[28,29]

For further information, please follow the links to the T1DRA and ELSA study websites.

By following the links above, you will be directed to independent websites which Sanofi has no control over. Sanofi accepts no responsibility for the content or availability of the websites.

T1DRA
Adults aged 18–70 years old

ELSA
Children and adolescents aged 2–17 years old

Not actual patients.

Testing should be coupled with education and ongoing monitoring for those identified with islet AAbs[4–6]

UK (BSPED) and international (ISPAD) guidance for adult and paediatric patients recommend regular glycaemic monitoring in all patients who have tested positive for islet AAbs[4–6]

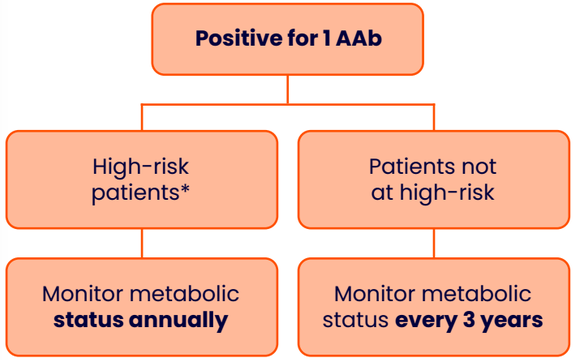
TZIELD is indicated to delay the onset of Stage 3 T1D in adult and paediatric patients 8 years of age and older with Stage 2 T1D.[1]

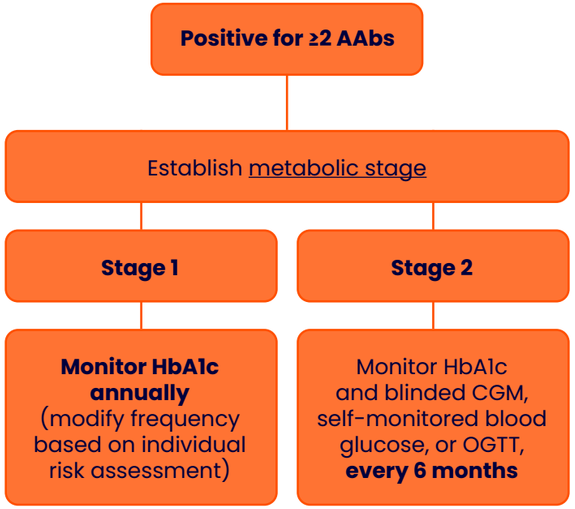
ISPAD guidance for monitoring **adult patients** (≥18 years) with detected AAb positivity[4]

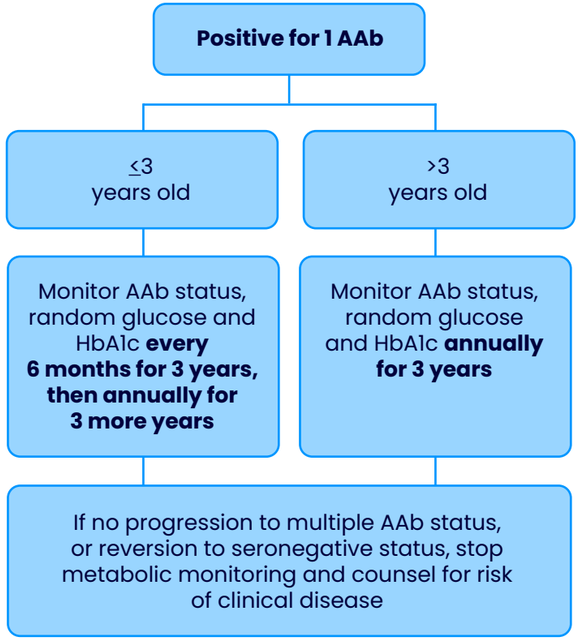
BSPED guidance for monitoring **paediatric patients** (≤17 years) with detected AAb positivity[6]

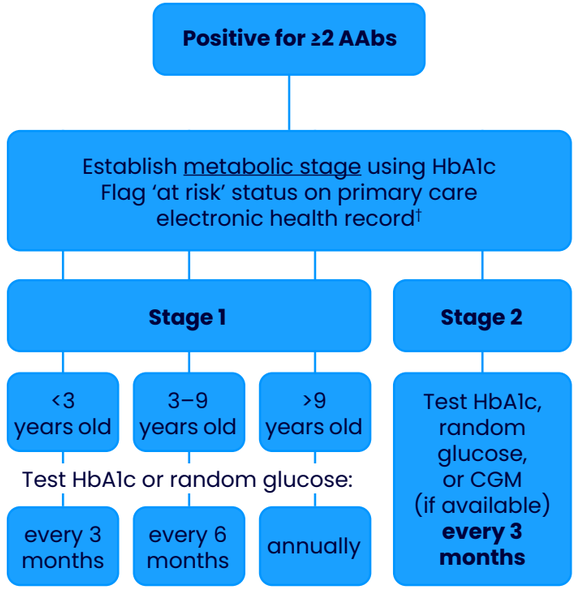
For patients who test positive for single or multiple AAbs:[4–6]

- Confirm AAb positivity on two different assays from two separate samples
- Provide education on diabetes symptoms, DKA awareness, and importance of glycaemic monitoring









TZIELD is indicated to delay the onset of Stage 3 T1D in adult and paediatric patients 8 years of age and older with Stage 2 T1D.[1]

Adapted from the 'Consensus Guidance for Monitoring Individuals With Islet Autoantibody-Positive Pre-Stage 3 Type 1 Diabetes', endorsed by ISPAD. Please refer to the full Consensus Guidance for additional information on monitoring.
*High-risk patients are patients with one or more of the following: first-degree relative with T1D, elevated genetic risk for T1D if tested, dysglycaemia (e.g. impaired fasting glucose or impaired glucose tolerance), or history of stress hyperglycaemia.[4]

Adapted from 'UK best practice recommendations for children and young people <18 years with pre-stage 3 type 1 diabetes', developed by BSPED. Please refer to the full guidance for additional information on monitoring.
†Early T1D (Stages 1 and 2) can be captured on a patient's electronic health record using a unique SNOMED (Systematized Nomenclature of Medicine) code 1290118005.[6,30]

AAb, autoantibody; **BSPED**, British Society for Paediatric Endocrinology and Diabetes; **CGM**, continuous glucose monitor; **DKA**, diabetic ketoacidosis; **ELSA**, Early Surveillance for Autoimmune diabetes study; **FPG**, fasting plasma glucose; **GADA**, glutamic acid decarboxylase 65 autoantibodies; **HbA1c**, glycated haemoglobin; **IAA**, insulin autoantibody; **IA-2A**, insulinoma-associated antigen 2 antibody; **ISPAD**, International Society for Pediatric and Adolescent Diabetes; **OGTT**, oral glucose tolerance test; **SNOMED**, Systematized Nomenclature of Medicine; **T1D**, Type 1 diabetes; **T1DRA**, Type 1 Diabetes Risk in Adults study; **T2D**, Type 2 diabetes; **UK**, United Kingdom; **WHO**, World Health Organization; **ZnT8A**, zinc transporter 8 autoantibody.

1. TZIELD (teplizumab) UK Summary of Product Characteristics. **2**. Insel RA, et al. Diabetes Care. 2015; 38(10): 1964–1974. **3**. Sims EK, et al. Diabetes. 2022; 71: 610–623. **4**. Phillip M, et al. Diabetes Care. 2024; 47(8): 1276–1298. **5**. Haller MJ, et al. Horm Res Paediatr. 2024; 97(6): 529–545. **6**. Besser REJ, et al; BSPED. Diabet Med. 2025; 42(11): e70117. **7**. World Health Organization. Classification of diabetes mellitus. 2019. Available at: https://www.who.int/publications/i/item/classification-of-diabetes-mellitus. Accessed May 2026. **8**. Simmons KMW, et al. Diabetes Technol Ther. 2023; 25(11): 790–799. **9**. Besser REJ, et al. Pediatr Diabetes. 2022; 23(8): 1175–1187. **10**. Barker JM, et al. Clin Endocrinol Metab. 2006; 91(4): 1210–1217. **11**. Ludvigsson JF, et al. Diabetes Care. 2006; 29(11): 2483–2488. **12**. Skov J, et al. Eur J Endocrinol. 2022; 186(6): 677–685. **13**. Muñoz C, et al. Clin Diabetes. 2019; 37(3): 276–281. **14**. Karges B, et al. Diabetes Care. 2021; 44(5): 1116–1124. **15**. Ospelt E, et al. Clin Diabetes. 2024; 42(1): 17–26. **16**. Diabetes UK. Autoantibody testing can help to diagnose diabetes type correctly. Available at: https://www.diabetes.org.uk/about-us/news-and-views/starting-right-diabetes-diagnosis. Accessed May 2026. **17**. Wolfsdorf JI, et al. Pediatr Diabetes. 2018; 19(Suppl 27): 155–177. **18**. Tomic D, et al. Diabet Med. 2024; 41(1): e15218. **19**. Besser REJ, et al. Arch Dis Child. 2022; 107(9): 790–795. **20**. Cameron FJ, et al. Diabetes Care. 2014; 37(6): 1554–1562. **21**. Ghetti S, et al. Diabetes Care. 2020; 43(11): 2768–2775. **22**. Duca LM, et al. Diabetes Care. 2017; 40(9): 1249–1255. **23**. Narendran P. Diabetologia. 2019; 62(1): 24–27. **24**. Hummel S, et al. Diabetologia. 2023; 66(9): 1633–1642. **25**. Quinn LM, et al. Br J Gen Pract. 2023; 73(726): 36–39. **26**. Moore DJ, et al. Int J Gen Med. 2024; 17: 3003–3014. **27**. Ziegler AG, et al. JAMA. 2020; 323(4): 339–351. **28**. The ELSA Study. Available at: https://www.elsadiabetes.nhs.uk/. Accessed May 2026. **29**. The Type 1 Diabetes Risk in Adults (T1DRA) Study. Available at: https://t1dra.bristol.ac.uk/. Accessed May 2026. **30**. University of Birmingham. Launch of new international medical code for presymptomatic type 1 diabetes. 2024. Available at: https://www.birmingham.ac.uk/news/2024/launch-of-new-international-medical-code-for-presymptomatic-type-1-diabetes. Accessed May 2026.

The Prescribing Information can be accessed **Here**

sanofi | Tzield® (teplizumab)