Tzield® (teplizumab)

INFORMATION & CONSIDERATIONS

for developing a TZIELD®▼ (teplizumab) infusion service

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 document is designed to provide information and considerations regarding the service requirements for delivery of TZIELD® infusions.

It aims to support clinicians and multidisciplinary teams wishing to deliver TZIELD infusions in framing and answering questions that might need to be addressed.

Content is based on:

- requirements set out in the Summary of Product Characteristics (SmPC) for TZIELD®
- expert feedback from Sanofi-funded advisory boards held to gather the views of clinicians, specialist nurses, pharmacists and service commissioners
- interviews with clinicians and a pharmacist with experience of delivering TZIELD though a Managed Access Programme in England

Providers will need to decide how delivery might best be achieved locally.

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 UKdrugsafety@sanofi.com

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Executive Summary

TZIELD is the first and only approved disease-modifying therapy to delay disease progression in Stage 2 autoimmune type 1 diabetes (T1D).[1-4] It is a single-course monoclonal antibody treatment delivered over 14 consecutive days' infusions.[1]

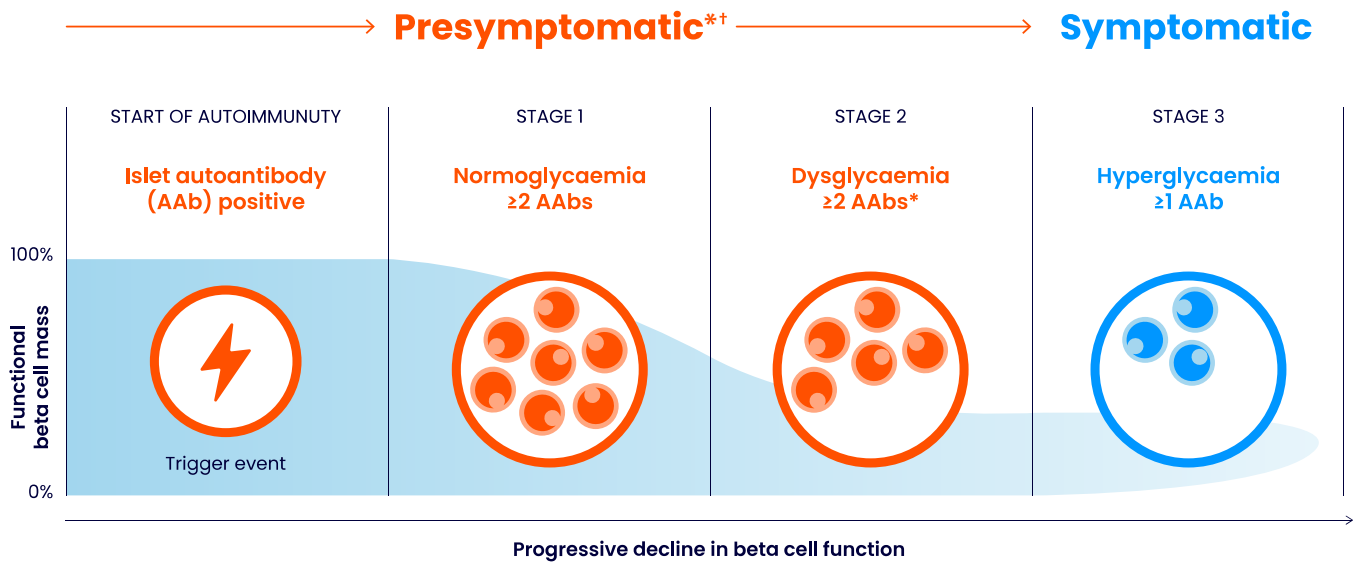
This poses some key logistical considerations for Trusts wishing to deliver a TZIELD infusion service.

This resource aims to provide information to support clinicians and multidisciplinary teams address these, including likely patient numbers, practicalities of how and where to deliver infusions, together with a checklist to help Trusts prepare for starting a service.

In addition to this resource, Sanofi have prepared an information pack to support healthcare professionals in completing formulary applications for TZIELD.

Background

T1D, characterised by an immune system attack and destruction of insulin-producing beta cells in the pancreas,[5] starts before symptoms arise.[6]



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.

Adults and paediatric patients aged 8 years of age and older with Stage 2 T1D may be eligible for TZIELD to delay the onset of Stage 3 T1D.[1]

†Early stage = presymptomatic Stage 1 and Stage 2.

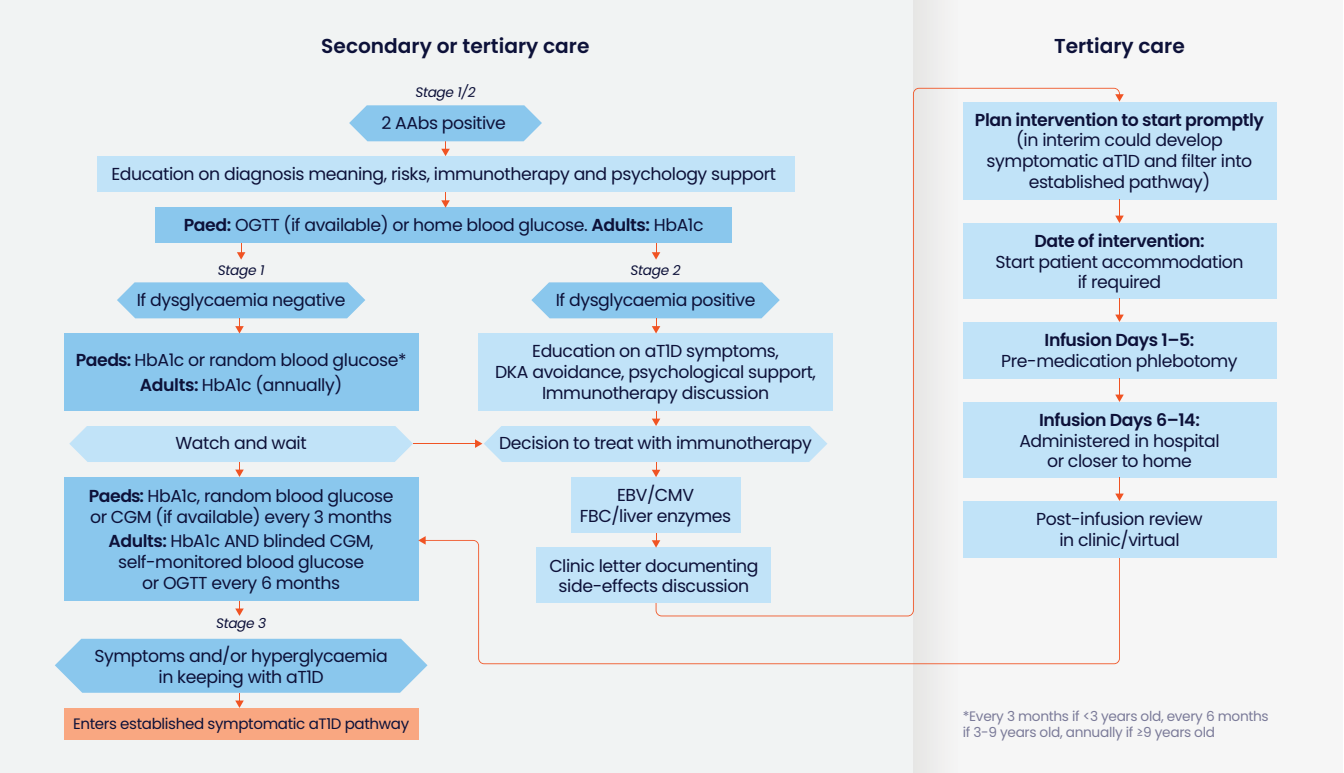
What are the key considerations for delivering TZIELD® locally?

TZIELD is the first and only approved disease-modifying therapy to delay disease progression in Stage 2 autoimmune type 1 diabetes (T1D).[1-4] It is a single-course monoclonal antibody treatment infused over 14 consecutive days.[1]

- What is the referral pathway for patients eligible for TZIELD?
- Where might infusions be delivered?
- What logistical elements of delivering infusions need to be considered?
- Can infusions be delivered within current service provision in the short term and might service development be required in the long term?

Patient pathway for TZIELD

Below is a suggested patient pathway for the management of early-stage T1D including the use of TZIELD in eligible patients.†



Based on BSPED best practice recommendations, ISPAD consensus guidance and expert opinions from a Sanofi-funded infusion service advisory board, April 2025.[7,8]

†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.

AAb: autoimmune antibody. aT1D: autoimmune type 1 diabetes. BPSED: British Paediatric Society for 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.

What are the key considerations for delivering TZIELD® locally?

Patient numbers and access to infusions

There is currently no national detection programme for patients with Stage 2 T1D. Patients eligible for TZIELD are either identified via research studies (ELSA for paediatrics and adolescents and T1DRA for adults)[*9] or when investigated for other reasons (incidentally/ad hoc) in diabetes clinics. A small number of patients may request tests for themselves or be a first-degree relative of patients with T1D.

There may also be existing patients in the system who have already been identified as eligible for TZIELD, but these numbers will differ by locality.

- **Patient numbers identified locally as eligible for, and wishing to have infusions, are therefore likely to be low** (~1 to 7 Stage 2 patients per 1 million population per year. **See** Appendix 1)
  - Utilising shared infusion services within Trusts that may exist for rheumatology/gastroenterology, for example, may be more suitable than bespoke infusion service provision initially
- **As treatment requires 14 consecutive infusion days, providers may want to consider practical solutions such as patient transport and accommodation to ensure timely and equitable access to care**
  - Consider discussing with ICB, patient transport services and local charities regarding provision over a 14-day period
  - Funding will be required for provision of patient transport

Where to deliver infusions

Staff with existing competence in delivering infusions are ideally placed to administer TZIELD. Infusion suite staff have experience in delivering monoclonal antibody infusions, most appropriate venous access, cannulation, monitoring patients and dealing with adverse reactions to treatment.

Staff require training and protocols relating to the use of TZIELD and management of adverse events.

- **Utilising existing infusion suites may be an effective way to deliver TZIELD, but there may be issues relating to capacity and weekend working**
  - Start discussions with the infusion service lead regarding the feasibility of infusing small numbers of patients with TZIELD with weekend working

*The ELSA and T1DRA aim to screen 20,000 people in each study.

What are the key considerations for delivering TZIELD® locally?

- **If the Trust has access to a Clinical Research Facility (CRF) or other clinical areas, e.g., research beds, cubicles, for delivery for the whole 14 days, or at weekends if the infusion suite only operates Monday – Friday, staff will be familiar with delivering infusions**
  - Discuss with CRF lead regarding the feasibility of infusing small numbers of patients with TZIELD in the short-term
- **Ambulatory Care Centres are an option for weekend delivery of infusions**
  - If weekend infusion provision is not possible via infusion suites or CRF, discuss logistical considerations for use of ambulatory care centres locally

Alternative options for delivering infusions may be available based on the considerations in this document and local service provision for existing infusions, e.g., homecare provision. If homecare is being considered, please speak to your Sanofi representative regarding this.

Practicalities of delivering TZIELD infusions

Pharmacy considerations

The Trust Chief Pharmacist, High Cost Drugs Pharmacist and Diabetes Specialist Pharmacist (where available), should ideally be involved in discussions with lead clinicians and infusion service providers around prescribing and dispensing of TZIELD from the outset. The drug will need to go through the Trust formulary process in order for pharmacy to be able to order stock.

The TZIELD recommended dosing schedule is based on body surface area (BSA) as below. Premedication is required prior to TZIELD infusion for the first five days of dosing with an NSAID or paracetamol, an antihistamine and/or emetic. Additional doses may be given if needed.

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.

*The dosing schedule in TN-10 was different to the recommended dosing schedule in the SmPC.[1]

What are the key considerations for delivering TZIELD® locally?

The following areas will need to be addressed to allow TZIELD to be prescribed and dispensed:

- **TZIELD needs to be added to the Trust Electronic Prescribing Record (EPR) system and dosing calculation built in**
  - If the EPR system does not allow for automated dosing calculation, a validated Body Surface Area (BSA) dosing calculator must be used and the process for checking the calculation agreed
- **An infusion monograph for TZIELD will need to be developed to provide all the necessary information nurses will need in order to safely prepare and administer the infusion**
  - The TZIELD SmPC can be used to populate the local Trust drug monograph template as per any standard operating procedure
- **Agree how prescription will be issued daily, including over weekends**
  - EPR systems may have the facility for advanced prescribing. If not available, consider how to ensure the full 14-day course is prescrbied in one go
- **Decide how doses will be dispensed over weekends and delivered to/collected by the infusion team**
  - If pharmacy does not operate 7 days a week, decide how pre-dispensed doses are collected and stored appropriately at site of administration
  - Prior to reconstitution, vials must be stored in a refrigerator at 2°C to 8°C[1] therefore cold chain must be maintained
- **Decide where the preparation of dispensed doses will take place safely**
  - If pharmacy does not carry out aseptic reconstitution or is not open over weekends, ensure infusion ward has appropriate area for reconstitution of TZIELD and staff are trained in aseptic preparation and dose preparation
  - Wherever the drug is reconstituted, polyvinylchloride (PVC) bags will need to be available in line with SmPC requirements[1]
  - If not used immediately, the diluted solution must be stored at room temperature (15°C to 30°C) and the infusion completed within 4 hours of preparation[1]
- **Ensure staff are aware of the contingency plan for missed doses**
  - If a planned infusion is missed, dosing should be resumed for all remaining consecutive days to complete the 14-day treatment course

What are the key considerations for delivering TZIELD® locally?

Pre-administration considerations

- **Agree how patients will be followed-up post-infusion, e.g., in which clinic setting, and monitored for disease progression**
- **Ensure adequate staffing is available, e.g., pharmacy, infusion nurses**

Local protocols will need to consider the logistics of delivering infusions in line with SmPC requirements:

- **Where appropriate, confirm that all age-appropriate vaccinations have been administered prior to starting TZIELD[1]:**
  - Administer live-attenuated (live) vaccines at least 8 weeks prior to treatment
  - Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment
  - Ensure sufficient time is allowed after vaccinations before commencing TZIELD, in line with SmPC, and schedule infusion time accordingly
  - Liaise with primary care to ensure vaccinations can be completed in sufficient time
- **Schedule the start of the 14-day infusion period to take account of the following:**
  - In clinical trials lymphocyte count decreased to a nadir on day 5
  - Take account of patient/carer responsibilities and ability to commit to 14-day infusion period. For example, considering scheduling around work and family commitments where possible for adults or for children in school holidays
  - Align scheduling with the local Trust practice for immunotherapy infusions
- **Ensure out-of-hours departments are aware of patients receiving TZIELD and have access to protocols for managing adverse events including anaphylaxis and severe infusion reactions**
- **Ensure the hospital laboratory is aware of the requirements for pre-infusion and ongoing monitoring timeframes, as per the infusion protocol**

What are the key considerations for delivering TZIELD® locally?

Administration considerations

- **Ensure full blood count and liver enzyme tests are completed and results received before infusion is due to start, during and after treatment, in line with SmPC (see Appendix 1)**
  - Inform the hospital laboratory of patients attending for infusion and timescales required for test results
- **Allocate sufficient chair time and staff to deliver the infusion and any required premedication**
  - An estimated 90 minutes of nurse time is required (not including pre-infusion consultation, blood tests or post-infusion follow-up)
  - The infusion is delivered over at least 30 minutes[1]
  - Consider total visit time when designing the service
- **Ensure staff are aware of how to manage adverse reactions** (see Appendix 3)
- **Ensure the infusion is completed within 4 hours of TZIELD preparation**[1]
  - Staff trained in aseptic technique should prepare TZIELD for infusion no more than 2 hours before it is to be administered, ideally after blood test results have confirmed that day's infusion can go ahead. This may require planning and support from a clinical pharmacist
  - Local protocols for checking should be in place
- **Once the 14-day course is completed, agree how patients will be monitored for progression of T1D**
  - Liaise with administrative team around provision of clinic appointment time for patient follow-ups
  - Inform the patient's GP about course completion and ongoing follow-up requirements. Code as 'Pre-symptomatic type 1 diabetes mellitus' (SNOMED CT code 1290118005)

Checklist when preparing a TZIELD® infusion delivery service

Planning and governance

- [ ] **Engage key stakeholders including:**
  - Infusion lead
  - Chief pharmacist
  - High-cost drugs pharmacist
  - Diabetes Specialist Pharmacist
  - Operational team
  - Formulary committee
  - Multidisciplinary diabetes team
  - Commissioner
  - Finance and contracting
- [ ] **Establish risk management protocols for infusion reactions and escalation,** which covers out-of-hours advice/esclaation
- [ ] **Agree and issue vaccination guidance**

Logistics

- [ ] **Infusion delivery location for weekdays and weekends agreed**
- [ ] **Plan chair time and staffing requirements**
- [ ] **Process for ongoing follow-up post-infusion course agreed**

Checklist when preparing a TZIELD® infusion delivery service

Patient scheduling

- [ ] Confirm eligible patient population estimate including where the referral boundaries are, e.g., local or regional
- [ ] Create scheduling guidance
- [ ] Agree patient transport and accommodation provision if required

Pharmacy

- [ ] Complete Trust formulary inclusion processes
- [ ] Infusion monograph and administration protocols produced
- [ ] TZIELD added to EPR system and dosing calculator confirmed
- [ ] Prescribing process agreed, including for weekends
- [ ] Confirm drug storage, dispensing process, aseptic process and availability of PVC bags
- [ ] Agree contingency plans for missed doses

Checklist when preparing a TZIELD® infusion delivery service

Workforce

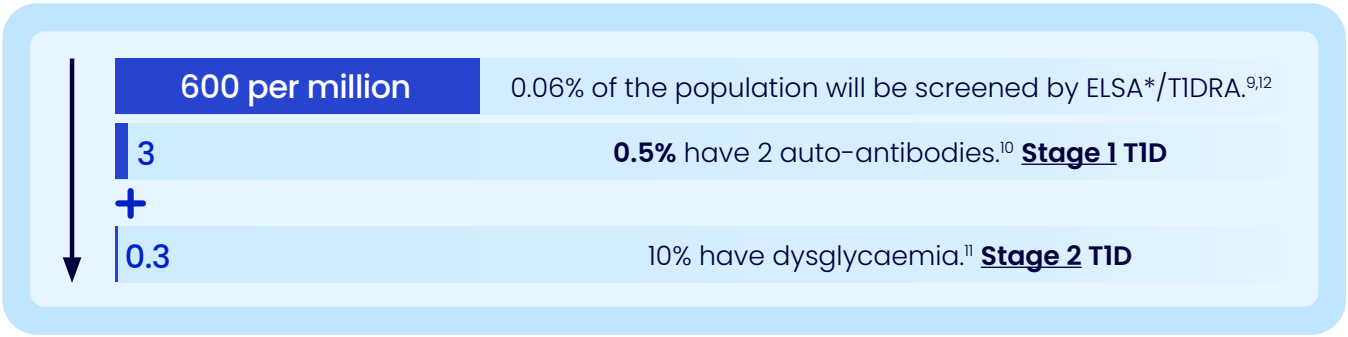
- [ ] Train pharmacy, multidisciplinary teams (MDTs) and infusion teams about TZIELD including preparation, administration and adverse event management
- [ ] Out-of-hours departments, hospital laboratory and primary care informed about infusion
- [ ] Confirm staff availability for 14-day infusion periods – infusion teams, clinicians, pharmacy

Appendix 1:
Patient numbers

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**. This depends on uptake and continuation of ELSA/T1DRA studies*† and the extent of first-degree relative testing locally and retesting of Stage 1 patients. There may also be existing patients in the system who may be eligible for TZIELD, but numbers will vary by locality.

The following tables illustrate the potential numbers of patients eligible for TZIELD who may be identified through current research trials (blue boxes) and through ad-hoc testing of first-degree relatives of patients with T1D (orange boxes).

The numbers of patients identified with Stage 1 and Stage 2 using reference sources are shown in the first of the two tables for each cohort. The second table shows the cumulative effect of continuing to identify new patients each year, adding in those with Stage 1 that progress to Stage 2 annually.



*Based on 40,000 tests currently available and UK total population of 67,602,800 in mid-2023.[9,12]

Based on the above table, expected number of people who may be eligible for teplizumab **per 1 million population** via screening 600 people in **research studies:**

Year	Stage 1 people detected cumulative[13]	Stage 2 people detected EACH year (10% of Stage 1)[11]	Stage 1 people detected who will PROGRESS to Stage 2 EACH year (21%)[14]	Total number of people in Stage 2 each year
1	**~3**	0.3		**0.3**
2	3+3=**6**	0.3	6x21%=**1.3**	0.3+1.3=**1.6**
3	3+6=**9**	0.3	9x21%=**1.9**	0.3+1.9=**2.2**
4	3+9=**12**	0.3	12x21%=**2.5**	0.3+2.5=**2.8**
5	3+12=**15**	0.3	15x21%=**3.2**	0.3+3.2=**3.5**

†ELSA (EarLy Surveillance for Autoimmune diabetes) and T1DRA (Type 1 Diabetes Risk in Adults) are UK based research studies to identify people at risk of developing T1D.[9]

Appendix 1:
Patient numbers

100	Example figure of 100 first degree relatives being tested in an area
3	**2.6%** have 2 auto-antibodies.[13] **Stage 1 T1D**
+	
0.3	10% have dysglycaemia.[11] **Stage 2 T1D**

Based on the above table, expected number of people who may be eligible for teplizumab **per 1 million population**, if 100 people with a **first-degree relative** were auto-antibody tested via ad-hoc testing by clinical teams:

Year	Stage 1 people detected cumulative[13]	Stage 2 people detected EACH year (10% of Stage 1)[11]	Stage 1 people detected who will PROGRESS to Stage 2 EACH year (21%)[14]	Total number of people in Stage 2 each year
1	**~3**	0.3		**0.3**
2	3+3=**6**	0.3	6x21%=**1.3**	0.3+1.3=**1.6**
3	3+6=**9**	0.3	9x21%=**1.9**	0.3+1.9=**2.2**
4	3+9=**12**	0.3	12x21%=**2.5**	0.3+2.5=**2.8**
5	3+12=**15**	0.3	15x21%=**3.2**	0.3+3.2=**3.5**

Appendix 2:
Laboratory testing before and during treatment with TZIELD[1]

Prior to initiating, and on each day during TZIELD infusion period, obtain a full blood count (FBC) and liver enzyme tests. Use of TZIELD is not recommended in patients with:

- Lymphocyte count less than 10^9 lymphocytes/L
- Haemoglobin less than 100 g/L
- Platelet count less than 150 x 10^9 platelets/L
- Absolute neutrophil count less than 1.5 x 10^9 neutrophils/L
- Elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN
- Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- Active serious infection or chronic active infection other than localised skin infections

Appendix 3:
Management of adverse reactions[1]

Cytokine Release Syndrome (CRS)

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 times the upper limit of normal (ULN) or bilirubin >3 times 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.

Lymphopenia

- Monitor white blood cell counts during the 2-week treatment period
- If prolonged lymphopenia (<500 cell/microlitre, lasting one week or longer) develops, discontinue TZIELD

Serious Infections

- Monitor patients for signs and symptoms of infection during and after TZIELD treatment. If serious infection develops, treat appropriately, and discontinue TZIELD

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