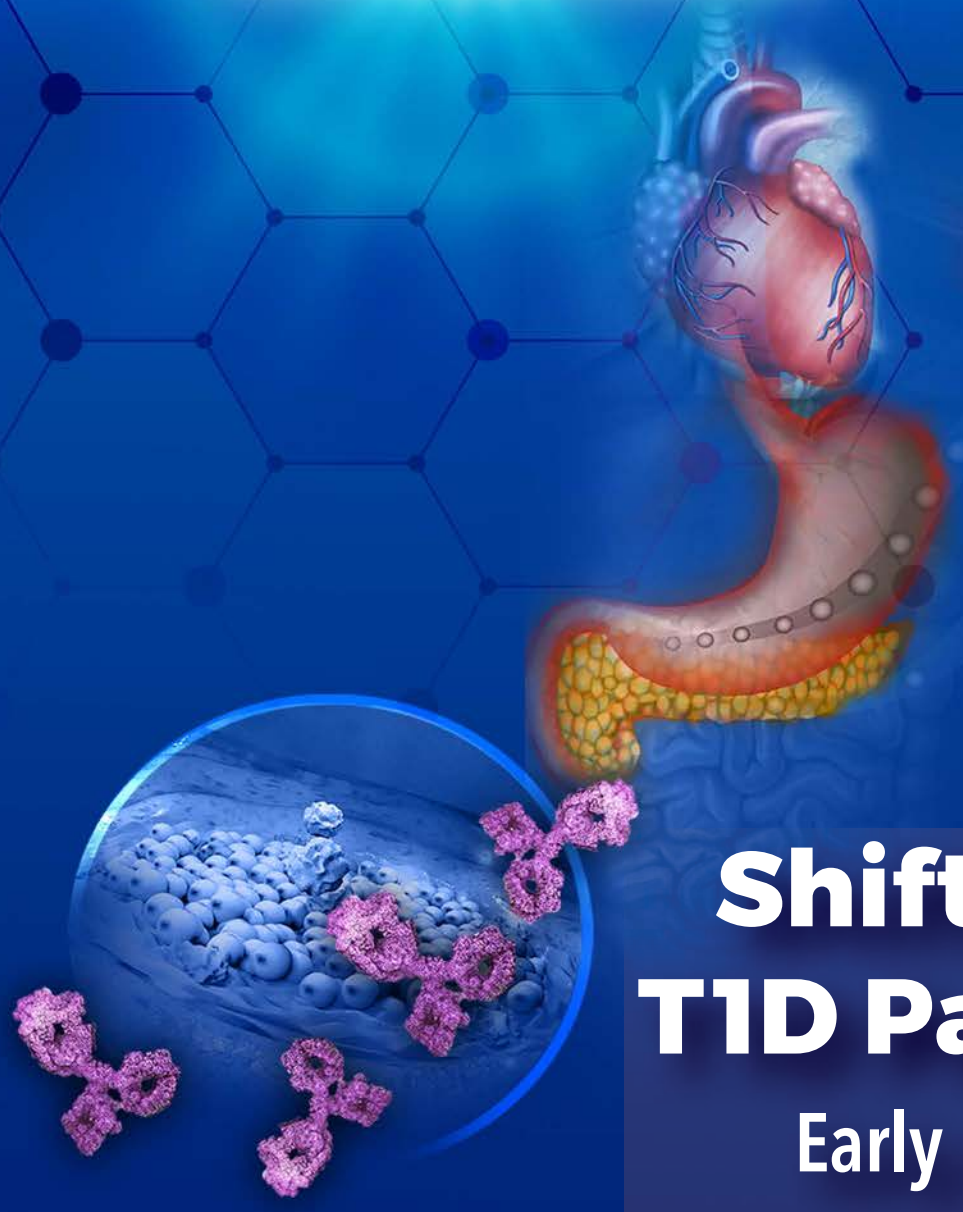
DETECT 1D



Shifting the T1D Paradigm:

Early Detection, Disease Modification, and Beta Cell Preservation

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This activity is provided by Med Learning Group.
This activity is supported by an educational grant from Sanofi US.

DETECT 1D

Shifting the T1D Paradigm:

Early Detection, Disease Modification, and Beta Cell Preservation

Agenda	
5 mins	**Introduction and Housekeeping**
5 mins	**The Paradigm Shift in T1D: Screening for Presymptomatic Disease**
5 mins	**T1D Epidemiology, Pathophysiology and Staging**
15 mins	**Caregiver Perspective & Panel discussion: Screening for T1D**
10 mins	**How and Whom to Screen**
15 mins	**Case #1 & Group Breakout Discussion**
5 mins	**Follow-up & monitoring after T1D screening**
15 mins	**Caregiver Perspective & Panel discussion: Follow-up After Screening Results**
10 mins	**Delaying Progression to Stage 3 T1D: Review of Data & Rationale**
15 mins	**BREAK**
15 mins	**The Future is Now: The Importance of Beta Cell Preservation in New-Onset (Stage 3) T1D**
5 mins	**Considerations for the use of teplizumab in clinical practice**
15 mins	**Patient Perspective & Panel discussion: Treatment With Disease Modifying Therapies for T1D**
15 mins	**Case #2 & Group Breakout Discussion**
5 mins	**Conclusions & Practice Takeaways**
15 mins	**Audience Q & A and Concluding Remarks**

Shifting The T1D Paradigm: Early Detection, Disease Modification, and Beta-Cell Preservation

PROGRAM CO-CHAIRS

Lucia M. Novak MSN, CRNP, ANP-BC, BC-ADM
President, Diabesity LLC, North Bethesda, Maryland
Co-Executive Director, Capital Health and Metabolic Center, Capital Diabetes and Endocrine Associates, Silver Spring, Maryland
Diabetologist, Stability Health, Worcester, Massachusetts

Kim Pfotenhauer DO, FACOFP, DABOM
Assistant Professor of Family Medicine
Assistant Dean for Clerkship Education
Michigan State University College of Osteopathic Medicine
East Lansing, Michigan

SPEAKING FACULTY

Daniel Moore, PhD, MD
Associate Professor Pediatrics and
Pathology, Microbiology, and Immunology
Vanderbilt University Medical Center
Nashville, Tennessee

Charles Vega, MD
Clinical Professor
UC Irvine Department of Medicine
Irvine, California

PATIENT AND PATIENT ADVOCATE

Marissa Loginow and Daughter Claire
Maryville, Tennessee

PROGRAM OVERVIEW

The DETECT-T1D Live Summit series will provide a practical overview of early detection and disease-modifying therapies across the type 1 diabetes (T1D) continuum. Insights from multidisciplinary expert faculty, paired with a powerful patient perspective, will aim to translate emerging evidence into actionable strategies for clinical practice. The program will cover evidence and guidance for identifying presymptomatic T1D, applying therapies that can delay disease progression, as well as exploring emerging strategies to preserve beta-cell function in new onset T1D. In addition, the program will feature dynamic discussions between the faculty and the patient advocate, interactive case-based learning, and peer-to-peer discussions, as well as an opportunity to access a learning gallery featuring additional educational tools and resources.

TARGET AUDIENCE

This activity is designed to meet the educational needs of multidisciplinary clinicians who refer, treat, or see patients with or at high risk for T1D is needed, including primary care clinicians, pediatricians, pediatric and adult endocrinologists, diabetes educators, infusion professionals, and other allied health care professionals.

LEARNING OBJECTIVES

Upon completion of this activity, attendees will have improved ability to:

- Implement risk-based screening approaches to facilitate timely identification of presymptomatic T1D
- Analyze T1D screening results to determine disease stage and inform appropriate monitoring and referral decisions
- Develop individualized treatment strategies that incorporate disease-modifying therapies to delay T1D progression in eligible patients
- Recognize the importance of beta cell preservation on T1D prognosis and outcomes
- Review emerging approaches aimed at beta cell preservation and their potential future application in new-onset T1D

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Faculty Member	Disclosures
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Kim Pfotenhauer DO, FACOFP, DABOM	Consulting Fees: Novo Nordisk Stock: ROMTech Advisory Board: Boehringer Ingelheim
Marissa Loginow	Has nothing to disclose
Daniel Moore PhD, MD	Consulting Fees: Sanofi; Ownership Interest: Metaphore Biotechnology
Charles Vega, MD	Consulting Fee: GSK, Boehringer Ingelheim, Exact Sciences

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Shifting the T1D Paradigm: From Early Detection to Beta Cell Preservation

Daniel Moore, MD, PhD
Associate Professor
Pediatrics and Pathology, Microbiology, and Immunology
Vanderbilt University Medical Center
Nashville, Tennessee

Chuck Vega, M.D.
Clinical Professor
UC Irvine Department of Medicine
Irvine, California

Marissa Loginow and her daughter Claire
T1D Patient
Maryville, TN

1

2

DETECT 1D

RECEIVE CME/CNE CREDIT

Pre-Test

Post-Test

3

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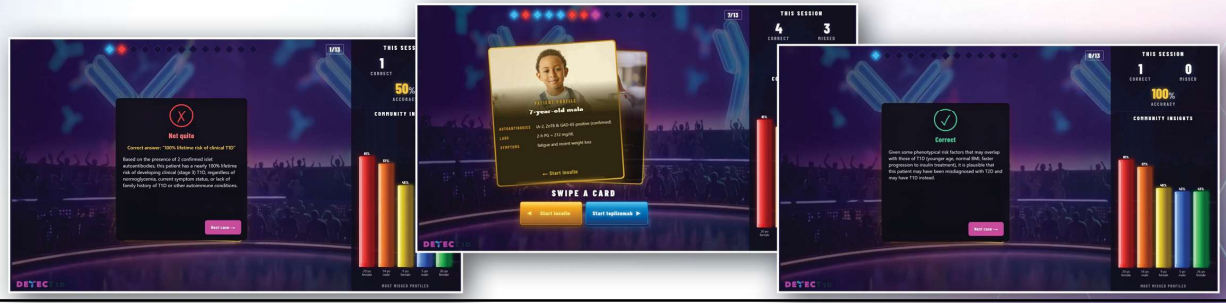
DETECT 1D

SWIPE OR MISS: T1D DECISIONS

Sign up

Swipe left or right to answer the case question

Live leaderboards



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- **Dr. Moore** discloses that he has received consulting fees from Sanofi Advisory Board and has stock in Metaphor Biotechnology.
- **Dr. Vega** discloses that he has received consulting fees from GSK, Boehringer Ingelheim, and Exact Sciences.
- **Marissa Loginow** has nothing to disclose.

During this lecture the faculty may mention the use of medications for both US Food and Drug Administration (FDA)-approved and non-FDA-approved indications.

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Learning Objectives

- Implement risk-based screening approaches to facilitate timely identification of presymptomatic T1D.
- Analyze T1D screening results to determine disease stage and inform appropriate monitoring and referral decisions.
- Develop individualized treatment strategies that incorporate disease-modifying therapies to delay T1D progression in eligible patients.
- Recognize the importance of beta-cell preservation on T1D prognosis and outcomes.
- Review emerging approaches aimed at beta cell preservation & their potential future application in new-onset T1D

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The Paradigm Shift in T1D: Screening for Presymptomatic Disease

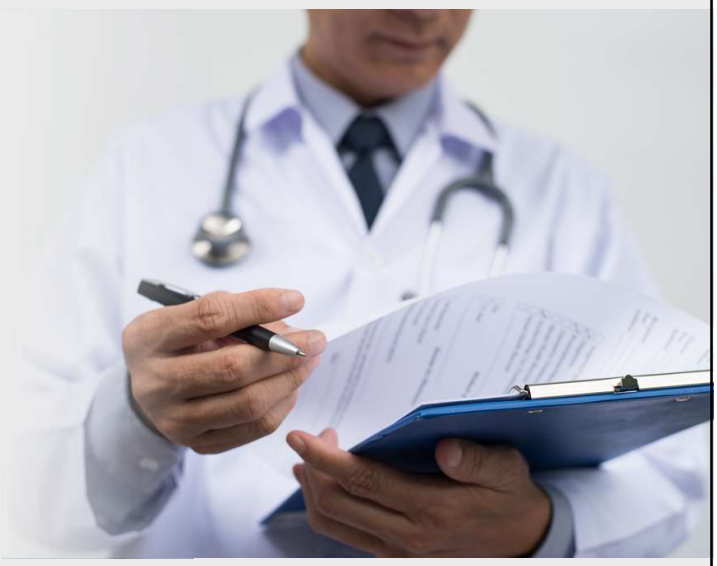
8

The Screening Gap in T1D

Recent research shows that while clinician believe they are proactively screening patients for T1D, **current practice may not always reflect this**.

Most clinicians are attentive to the **signs and symptoms of T1D** -- like polydipsia, polyuria, and hyperglycemia.

What's less widely recognized, however, is that by the time these symptoms appear, **patients are already at later stages of the disease!**



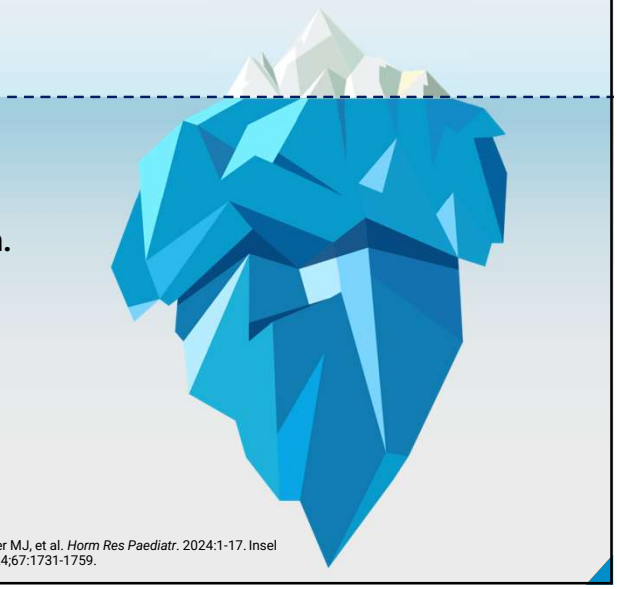
Shubrook JH et al. *Diabetes, Obesity, and CardioMetabolic CARE*. Submitted May 2026.

9

The Revolution in our understanding of T1D

Previously, T1D was defined as a clinical disease **diagnosed at the onset of symptomatic hyperglycemia requiring exogenous insulin therapy**.

Now, T1D is defined as **a staged disease that can begin years before symptoms appear — before hyperglycemia or dependence on exogenous insulin.**



American Diabetes Association (ADA) Professional Practice Committee. *Diabetes Care*. 2026;49(suppl 1):S27-S49. Haller MJ, et al. *Horm Res Paediatr*. 2024:1-17. Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Phillip M, et al. *Diabetologia*. 2024;67:1731-1759.

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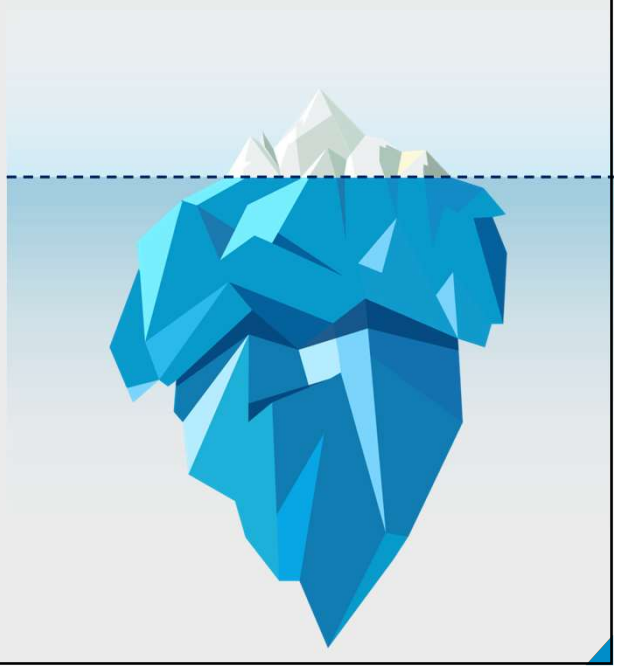
Early T1D detection

When we detect hyperglycemia using glucose testing, we are not catching the disease early – **we are catching it late!**

Early detection relies on a different set of tools **that can detect islet autoantibodies that are detectable years before hyperglycemia.**

Patients with normoglycemia can now be positively diagnosed with T1D when they test positive for **two or more islet autoantibodies.**

Opportunities to intervene early with disease-modifying therapy to **delay disease progression and protect β-cells**



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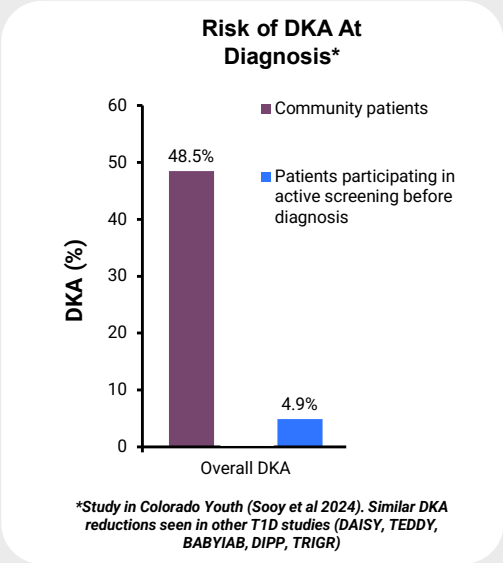
11

Why take early T1D screening seriously?

1. DKA prevention – asymptomatic screening and ongoing monitoring have been shown to reduce the number of patients who are first diagnosed with T1D in a state of DKA from ~49% to <5%!
   - Reduce hospitalizations
   - Improve long-term patient outcomes



Barker JM, et al. *Diabetes Care*. 2004;27:1399-1404. Elding Larsson H, et al. *Pediatr Diabetes*. 2014;15:118-126. Winkler C, et al. *Pediatr Diabetes*. 2012;13:308-313. Hekkala AM, et al. *Pediatr Diabetes*. 2018;19:314-319. Nakhla M, et al. *JAMA Pediatr*. 2021;175:518-520. Sooy M, et al. *Diabetes Care.* 2024;110:e80-e86.

12

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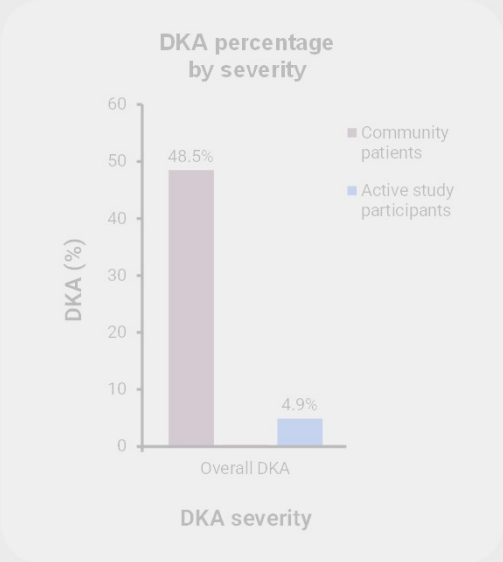
   - Reduce hospitalizations
   - Improve long-term patient outcomes

2. Early diagnosis allows patients and family members to emotionally prepare for the onset of symptoms and develop stronger self-efficacy earlier
   - Improved glycemic control
   - Reduced risk of long-term complications



13

Why take early T1D screening seriously?

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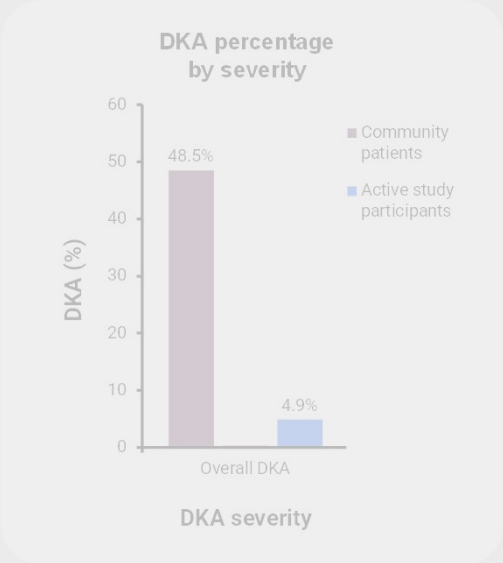
   - Reduce hospitalizations
   - Improve long-term patient outcomes

2. Early diagnosis allows patients and family members to emotionally prepare for the onset of symptoms and develop stronger self-efficacy earlier
   - Improved glycemic control
   - Reduced risk of long-term complications

3. Identify patients who may benefit from approved therapies to delay progression or for beta cell preservation, or want to enroll in clinical trials



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Roadmap for today

In today's session we will:

1. Review T1D epidemiology and pathophysiology
2. Breakdown of how and who to screen
3. Look at best practices in follow-up monitoring after screening
4. Review the data and rationale for delaying disease progression of T1D
5. Consider the practical aspects of providing disease modifying therapy for T1D
6. Look ahead to the use of disease modifying therapy for beta cell preservation

Throughout the session, we will hear from a patient advocate to understand the real-world experience of early screening and treatment for T1D.

And we will discuss examples of specific patient scenarios together in the room.

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T1D Epidemiology, Pathophysiology and Staging

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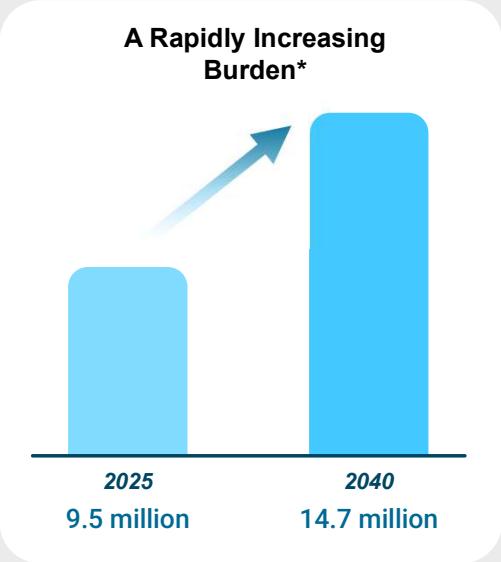
The Burden of T1D Is Growing



*projected increase in global prevalence

Ogle GD, et al. *Diabetes Res Clin Pract*. 2025;225:112277.

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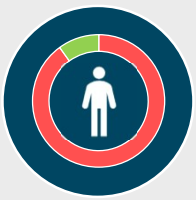
Family history is important, but most new cases don't have a family history

Up to 15x higher risk of developing T1D in first-degree relatives



~ 90% of people diagnosed with T1D don't have a family history

Increased risk in those with personal or family history of other autoimmune conditions (e.g. celiac or thyroid disease)

Ogle GD, et al. *Diabetes Res Clin Pract*. 2025;225:112277. Muñoz C, et al. *Clin Diabetes*. 2019;37:276-281. Turtinen M, et al. *Diabetologia*. 2019;62:2025-2039. Sims EK, et al. *Diabetes*. 2022;71:610-623. Edelman SV, et al. *Diabetes Obes Metab*. 2025;27:4229-4238.

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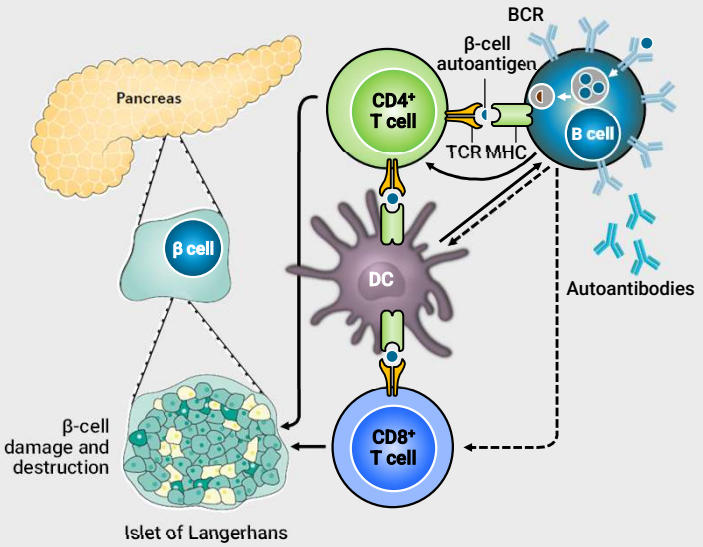
T1D Is a Chronic Autoimmune Disease



- Characterized by T-cell mediated destruction of pancreatic β-cells,
- Both genetic and environmental factors drive the immune attack of β-cells
- Autoantibodies are markers of this attack; by measuring them we can detect autoimmunity before symptoms develop

APC = antigen-presenting cell; BCR = B-cell receptor; DC = dendritic cell; IAb = islet autoantibody; MHC = major histocompatibility complex; TCR = T-cell receptor.

Atkinson MA, Mirmira RG. *Cell Metab.* 2023;35:1500-1518. Katsarou A, et al. *Nat Rev Dis Primers.* 2017;3:17016.

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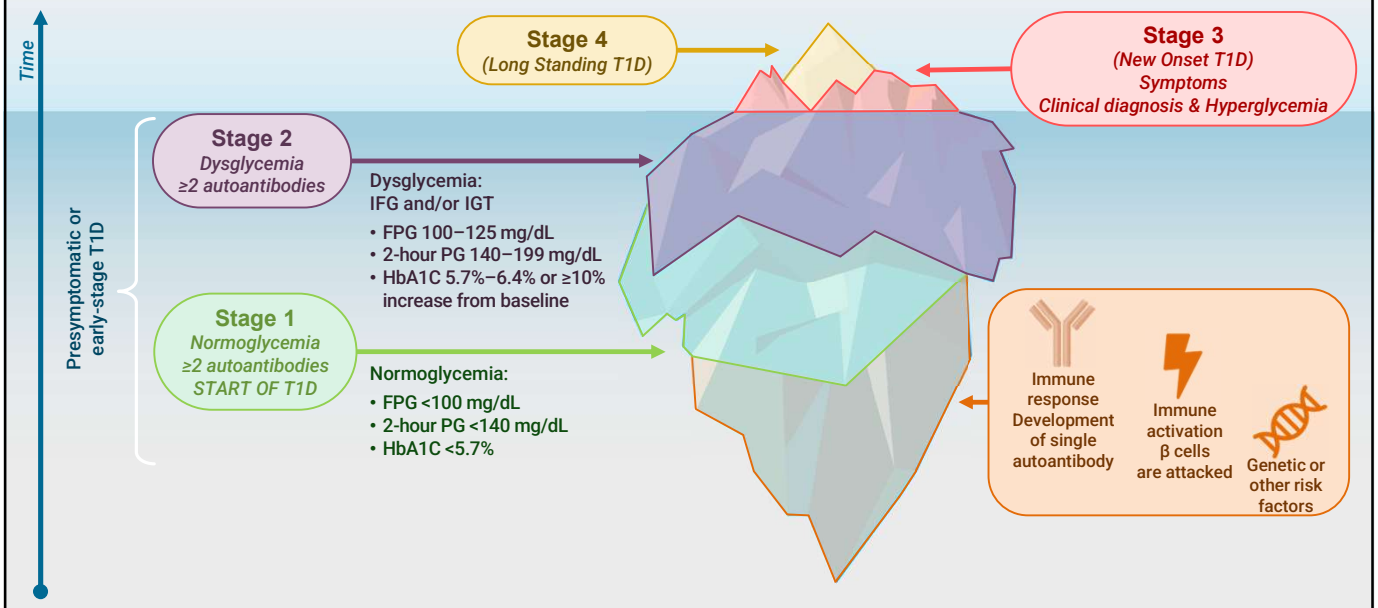
T1D develops in predictable and detectable stages



FPG = fasting plasma glucose; HbA1C = glycosylated hemoglobin; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; PG = plasma glucose; RPG = random plasma glucose.

American Diabetes Association (ADA) Professional Practice Committee. *Diabetes Care.* 2026;49(suppl 1):S27-S49. Haller MJ, et al. *Horm Res Paediatr.* 2024:1-17. Insel RA, et al. *Diabetes Care.* 2015;38: 1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Phillip M, et al. *Diabetologia*. 2024;67:1731-1759.

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Patient Perspective and Panel Discussion: Screening for T1D

Marissa and Claire

T1D Caregiver and Patient

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How and Who to Screen

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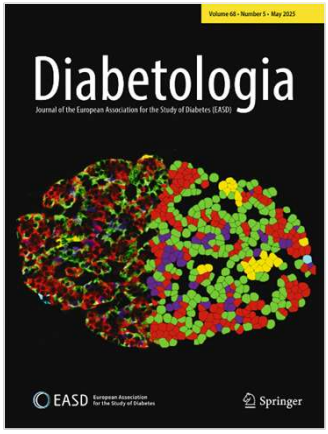
Presymptomatic T1D Screening with Islet Autoantibodies Is ADA Standard of Care



Guidelines recommend testing for four autoantibodies

Screening for all four autoantibodies increases the chance of detecting and diagnosing early-stage T1D

Test for the following:

- IAA
- GAD65/GADA
- IA-2A
- ZnT8A

ADA Professional Practice Committee. *Diabetes Care.* 2026;49(suppl 1):S27-S49. .Philip M, et al. *Diabetes Care*. 2024;47:1276-1298.

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Who to Screen

ADA recommended

A — **Family history**
First- or second-degree relative with diagnosed T1D
(or those with elevated genetic risk scores – if available)

B — **Autoimmune disease or diabetes**
Personal or family history of autoimmune diseases (eg, celiac disease, Hashimoto's)
Diagnosis of prediabetes or diabetes*

C — **General population**
Can combine with other tests
(eg, hemoglobin testing) in pediatrics;
population screening in organized programs

Highest Priority

*For patients without typical features of T2D.
Modified from Leichter SB, et al. *J Clin Endocrinol Metab.* 2025;dgaf194. ADA Professional Practice Committee. *Diabetes Care.* 2026;49(suppl 1):S27-S49

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Mythbusting

Myth: Screening for T1D onset is primarily a pediatric matter

Reality: T1D Can Develop At Any Age

Epidemiological fact

Globally, 62% of all new T1D cases occurred in people ≥20 years old, with a median age of 36

Most people who develop T1D are adults.

Clinical fact

>40% of those developing T1D after age 30 years are initially treated as T2D.

Misdiagnosis can lead to DKA due to prescribing the wrong therapy.

Muñoz C, et al. *Clin Diabetes*. 2019;37:276-281

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IAbs for Disease Classification

The AABBCC approach can be useful clinically for distinguishing T1D, however, no single clinical feature confirms T1D—not age, not body mass index, not DKA

Islet autoantibody testing is recommended to classify diabetes in adults whose features overlap with T1D — e.g. younger age, lean body habitus, unintentional weight loss, DKA, or rapid progression to insulin. A personal or family history of autoimmune disease heightens suspicion.

American Diabetes Association.

Age	<35 years
Autoimmunity	Personal or family history
Body habitus	BMI <25 kg/m^2
Background	Family history of T1D
Control	Level of glucose control with current treatment
Comorbidities	Immune checkpoint inhibitors for cancer & other cancer treatments

DKA = diabetes-related ketoacidosis.

Thomas NJ, et al. Diabetes Care. 2023;46:1156-1163. Gregory GA, et al. Lancet Diabetes Endocrinol. 2022;10:741-760. ADA Professional Practice Committee. Diabetes Care. 2026;49(suppl 1):S27-S49. Leslie RD, et al. Diabetes Care. 2021;44:2449-2456.

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Clinical Pathways for T1D Screening

Clinical Laboratory Codes for Screening	
Quest Diagnostics, LabCorp, ARUP, or Mayo Clinic Laboratories	All ages, HCP order required. CPT codes* ▪ 86341 (GAD65, IA-2, ZnT8 antibodies) ▪ 86337 (insulin antibody)

Relevant ICD10 Codes for Diagnosing Presympotmatic T1D	
Z83.3	Family history of T1D
Z86.2	History of autoimmune disease
Z83.2	Family history of autoimmune disease
E10.A0	T1D, Presymptomatic, Unspecified
E10.A1	T1D, Presymptomatic, Stage 1
E10.A2	T1D, Presymptomatic, Stage 2

Not a comprehensive list of available screening programs; may be subject to change.
*CPT codes may be subject to change, and specific codes may differ between laboratories. Not all antibodies may be available under a specific laboratory or under a CPT code.

CPT = Current Procedural Terminology; HCP = healthcare provider.
ASK (https://www.askhealth.org). TrialNet. Pathway to prevention (https://www.trialnet.org/our-research/risk-screening). Breakthrough T1D (formerly JDRF) (https://www.breakthrought1d.org/early-detection/). Ask the Experts (https://www.asktheexperts.org/for-providers). URLs accessed 6/4/2026. Leichter SB, et al. *J Clin Endocrinol Metab*. 2025;110:2371-2382.

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Research Pathways to T1D Screening

Research-based screening programs

	Age to participate
ASK (Autoimmunity Screening for Kids)	Children and adults aged 1–99 years (no family history of T1D required)
Type 1 Diabetes TrialNet	Aged 2–45 years with a parent, brother/sister, or child with T1D; or have tested positive for ≥ 1 T1D autoantibody outside of TrialNet ***OR*** Aged 2–20 years with aunt/uncle, cousin, grandparent, niece/nephew, or half-sibling with T1D

Not a comprehensive list of available screening programs; may be subject to change.
*CPT codes may be subject to change, and specific codes may differ between laboratories. Not all antibodies may be available under a specific laboratory or under a CPT code.

ASK (https://www.askhealth.org). TrialNet. Pathway to prevention (https://www.trialnet.org/our-research/risk-screening). Breakthrough T1D (formerly JDRF) (https://www.breakthrought1d.org/early-detection/). Ask the Experts (https://www.asktheexperts.org/for-providers). URLs accessed 6/4/2026. Leichter SB, et al. *J Clin Endocrinol Metab*. 2025;110:2371-2382.

28

Who Is Responsible for Presymptomatic T1D Screening and Process Considerations

Process Considerations

Communication

- Benefits of screening
- Differences between T1D and T2D
- Options for screening, monitoring, and treatment
- Consent for screening
- Cost(s)

Reaching family members

- Discuss screening of family members with T1D patients
- Provide informational handout about screening options, including information on free IAb screening through research programs

Timing of screening

- From 9 months of age
- Can combine with other routine testing, such as:

  1 to 2 years — hemoglobin
  4 to 6 years — vaccinations
  9 to 11 years — lipid screening

Phillip M, et al. *Diabetes Care*. 2024;47:1276-1298. Phillip M, et al. *Diabetologia*. 2024;67:1731-1759. Leichter SB, et al. *J Clin Endocrinol Metab*. 2025;110:2371-2382.

29

Polling Question

In your current practice, who do you typically screen with islet autoantibodies?

Select all that apply.

- **A** First-degree relatives
- **B** Second-degree relatives
- **C** High-risk patients (clinical suspicion)
- **D** Patients with a personal or family history of other autoimmune conditions, regardless of symptoms or glycemic status
- **E** General population
- **F** Not currently screening

30

Polling Question

If you are screening with islet autoantibodies, how are you currently doing it in your practice?

- **A** Refer for research-based screening (e.g. TrialNet or ASK)
- **B** Clinical labs
- **C** A combination of both

31

Polling Question

What are your biggest barriers in screening with islet autoantibodies?

Select all that apply.

- **A** Knowing who to screen
- **B** Knowing when to screen
- **C** Knowing how to screen
- **D** Interpreting results
- **E** Cost of screening
- **F** Patient/caregiver anxiety

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Case #1 and Group Breakout Discussion

33

Case 1 | Introduction: Emma

- Emma is an 11-year-old girl brought to clinic by her mother for a routine well-child visit before starting middle school. She is healthy, active in soccer, and has no significant past medical history
- During visit, her mother mentions that Emma's older brother was diagnosed with T1D at age 13 after presenting to ED in DKA
- Emma currently feels well and denies any symptoms

Case Breakout Discussion…

- Break into small groups at your table (2-3).
- Answer the initial case questions in iPADs in small groups
- Answer the open-ended case questions as a table

34

Case 1 | Continuation

11-year-old girl presenting for a routine well-child visit before starting middle school

Family history of T1D (older brother)

Currently feels well and denies any symptoms of diabetes.

Should she be tested for type 1 diabetes now?

Swipe A Card

YES | NO

35

Case 1 | Continuation

How would you test Emma for diabetes?

Swipe A Card

Fasting Glucose | HbA1c | Islet Autoantibodies

36

Case Continuation – Initial T1D Screening

Emma undergoes screening through a T1D screening program

Autoantibody results: GAD-65 (+), IA-2 (+), Insulin (-), ZnT8 (-)

Glycemic parameters: Fasting glucose = 92 mg/dL, HbA1c = 5.3%.

What is the most likely interpretation of Emma's results?

Swipe A Card

- *No evidence of T1D*
- ***Stage 1 T1D***
- *Stage 2 T1D*
- *Stage 3 T1D*

37

Case Continuation – 6 months later

Emma undergoes repeat testing

- 2-hr OGTT = 145 mg/dL, HbA1c 5.8%
- She remains asymptomatic

Open Discussion

- How would you counsel her family about the meaning of these results?
- How should the management evolve now based on these results?

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Follow-Up and Monitoring After T1D Screening

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How to Interpret T1D Screening Results

0 autoantibodies

- Lower risk for developing T1D
- Rescreening may be considered in individuals with family history of T1D or in children <15 years of age

1 autoantibody

After **confirming** a single autoantibody:

- Higher risk for developing T1D than those with no autoantibodies
- Glucose and HbA1c along with symptom evaluation
- Referral to specialist for monitoring

≥2 autoantibodies

After **confirming** multiple autoantibodies:

- Already in early-stage T1D
- Glucose and HbA1c along with symptom evaluation
- Referral to specialist for monitoring and possible disease-modifying therapy (e.g. teplizumab), or clinical trials

DMT = disease-modifying therapy.

ADA Professional Practice Committee. *Diabetes Care*. 2026;49(suppl 1):S27-S49. Simmons KMW, et al. *Diabetes Technol Ther*. 2023;25:790-799.

40

Monitoring Individuals With Confirmed IAb+

Screening

1 IAb+

Blood samples to take	Age	Frequency
▪ Antibodies ▪ HbA1C ▪ Random glycemia	≤3 years	▪ Every 6 months for 3 years ▪ Every 12 months for another 3 years ▪ If no progression, stop
	>3 years	▪ Every 12 months for 3 years ▪ If no progression, stop
	Adults	▪ Every 3 years if no other risk factors ▪ Every 12 months if additional risk factors (eg, first-degree relative with T1D, IFG or IGT, history of stress hyperglycemia)

≥2 IAb+ → **Staging OGTT***

Stage	Blood samples to take	Age	Frequency
Stage 1	▪ HbA1C ▪ Random glycemia ▪ CGM (if available)	<3 years	▪ Every 3 months
		3–9 years	▪ Every 6 months
		≥9 years	▪ Every 12 months
		Adults	▪ HbA1C every 12 months as part of primary care; if normal for 5 years, can monitor every 2 years. If HbA1C increases ≥10% from baseline, perform OGTT to assess T1D stage
Stage 2	▪ HbA1C ▪ Random glycemia ▪ CGM (if available)	<18 years	▪ Every 3 months
		Adults	▪ Every 6 months

*HbA1C, capillary/venous glucose, and CGM may be alternatives when OGTT is not feasible.

Modified from Phillip M, et al. *Diabetes Care*. 2024;47:1276-1298 and Haller MJ, et al. *Horm Res Paediatr*. 2024:1-17.

41

Patient Perspective and Panel Discussion: Follow-Up After Screening Results

Marissa and Claire

T1D Caregiver and Patient

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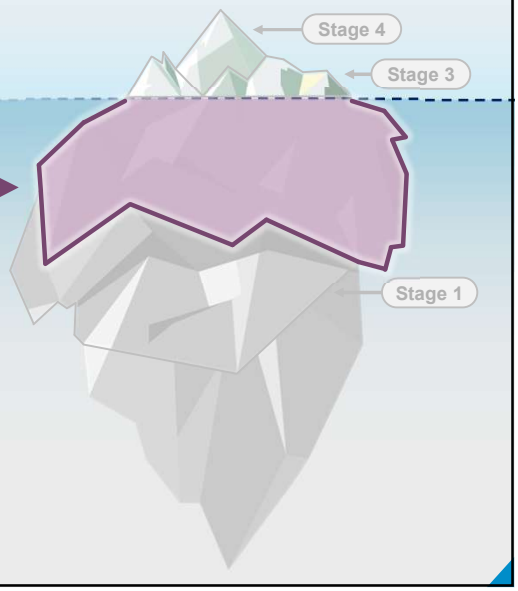
Delaying Progression to Stage 3 T1D: Review of Data & Rationale

44

Now there's something you can do to delay onset of symptoms and afford patients and family more time...

Stage 2
Dysglycemia
≥2 autoantibodies

Teplizumab is FDA approved to delay progression to stage 3 in patients ≥1year of age with stage 2 T1D



45

The Stages of T1D Inform Our Therapy Approach

Time

β-cell replacement, or better management tools

Stage 4
(Long Standing T1D)

Preserve remaining β-cells

Stage 3
Clinical diagnosis & symptoms

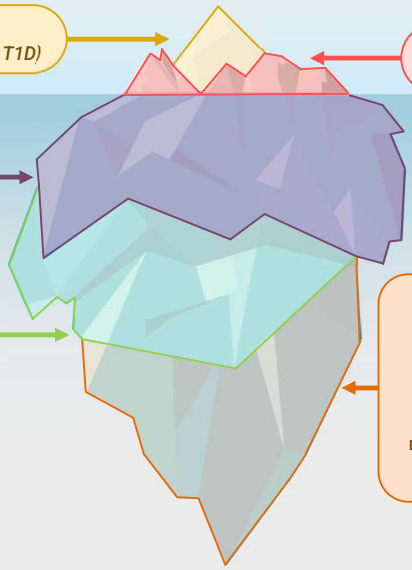
Teplizumab approved to preserve beta cell function in patients 8-17years with newly-diagnosed stage 3 T1D.

Prevent progression to stage 3

Teplizumab approved to delay progression to stage 3 in patients with stage 2 T1D:

Stage 2
Presymptomatic
Abnormal blood sugar
≥ 2 autoantibodies

Stage 1
Presymptomatic
Normal blood sugar
≥ 2 autoantibodies
START OF T1D



Immune response
Immune response Development of single autoantibody

Immune activation
Immune activation β-cells are attacked

Genetic Risk
Starting point If you have a relative with T1D: 15x greater risk of developing T1D

Primary Prevention

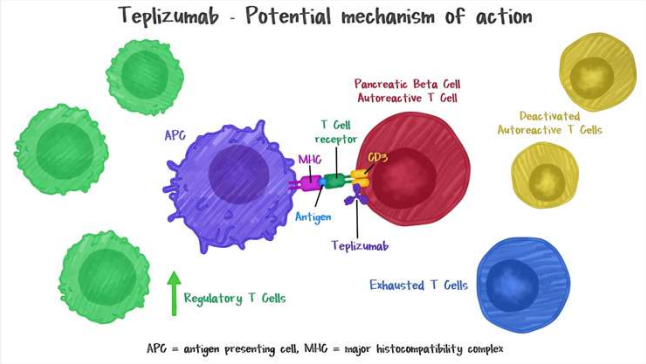
T1D = type 1 diabetes.
Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623.

46

Teplizumab: Mechanism & Overview

Humanized anti-CD3 monoclonal antibody that binds to the T-cell receptor-CD3 complex, inhibiting immune attack on β cells

- Autoreactive CD8+ T-effector cells become "exhausted" (disabled)
- Teplizumab is immunomodulatory and not immunosuppressive

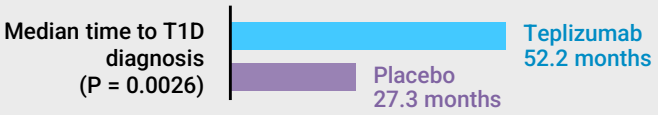


Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021;13:eabc8980. Thakkar S, et al. *touchREV Endocrinol*. 2023;19:22-30. Ramos EL, et al. *N Engl J Med*. 2023;389(23):2151-2161

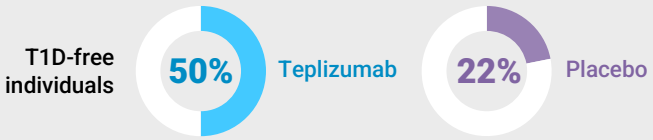
47

Efficacy & Safety of Teplizumab for Delaying T1D Progression – The TN-10 Study

Teplizumab **delayed progression to stage 3 T1D** by over 2 years in patients with stage 2 T1D, compared with placebo*



More individuals **treated with teplizumab remained diabetes free** compared with placebo



*Delay in progression was longer in certain individuals and individual results may vary.

Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021;13:eabc8980.

48

Teplizumab Treatment for Stage 2 T1D in Real-World Practice

A real-world evaluation of metabolic and immunological outcomes

Teplizumab treatment In real-world practice

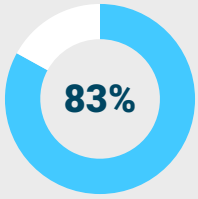
	Teplizumab treated (n = 30)	Untreated (n = 10)
Oral glucose tolerance test	Improved within the first year after teplizumab treatment	
Continuous glucose monitoring	Time above 7.8 mmol/l (140 mg/dl) reduced	
T-cell receptor sequences	Preproinsulin T-cell receptor sequences were reduced after teplizumab treatment and correlated with C-peptide levels	

Karakus KE, et al. *Diabetologia*. 2026 (https://doi.org/10.1007/s00125-025-06646-6). Accessed 2/4/2026.

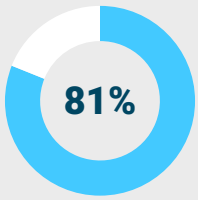
49

Survey of patients & caregivers about experience with teplizumab

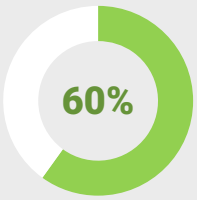
Most people (39 out of 47) agreed they were glad they (or the child they care for) received teplizumab.



Most people (38 out of 47) agreed they would recommend teplizumab to others who may be in a similar situation.



Most people (28 out of 47) believed that managing stage 3 T1D would be easier because of treatment with teplizumab.



O'Donnell HK et al. *Diabetes Obes Metab*. 2025;2495-2506.

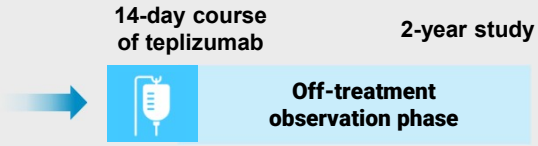
50

PETITE-T1D Study Results

Safety and pharmacokinetics of teplizumab in children <8 years of age with stage 2 type 1 diabetes

Methods

23 children with an average age of 4.8 years who met criteria for stage 2



Interim analysis findings

- Adverse events were consistent with previous studies
- No new safety risks were identified
- Probability of not progressing to stage 3 T1D was 89.6%

Teplizumab was safe and well-tolerated in children <8 years of age.

PETITE-T1D = Teplizumab in Pediatric Stage 2 Type 1 Diabetes; T1D = type 1 diabetes.

NCT05757713 (https://clinicaltrials.gov/study/NCT05757713). Accessed 2/4/2026. Gitelman SE, et al. *Diabetologia.* 2026;69(2):330-342.

51

Safety Considerations with Teplizumab

The most common adverse events with teplizumab†

- Rash
- Transient Lymphopenia and leukopenia
- Headache
- GI Side Effects (e.g diarrhea and vomiting)

Increased risk of viral reactivation and infection, particularly in immunocompromised individuals

- EBV or CMV reactivation or infection

- Cytokine release syndrome (~5% of teplizumab-treated patients)

†Not a full list of adverse events; most common adverse events were usually transient.

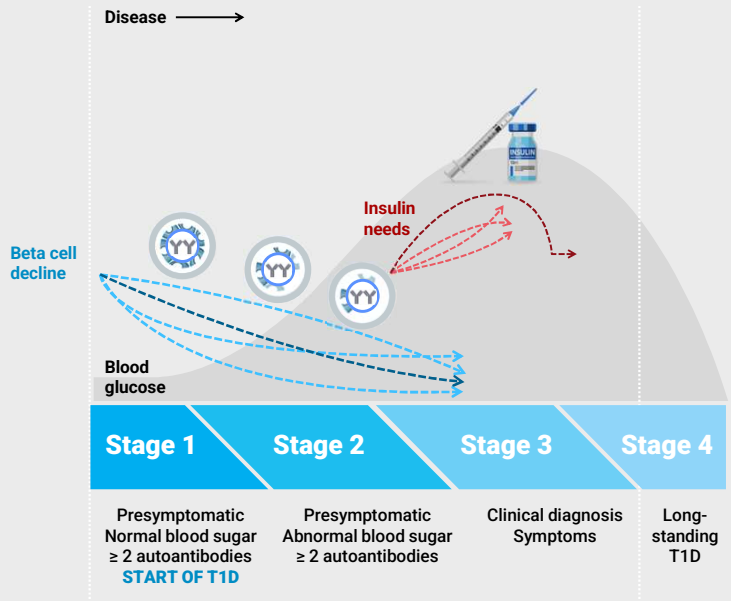
Gitelman SE, et al. *Diabetologia.* 2026;69(2):330-342. Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021;13:eabc8980. Teplizumab Prescribing Information.

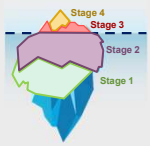
52

The Future is Now:
The Importance of Beta Cell Preservation in New-Onset (Stage 3) T1D

53

T1D Progression Occurs in Stages

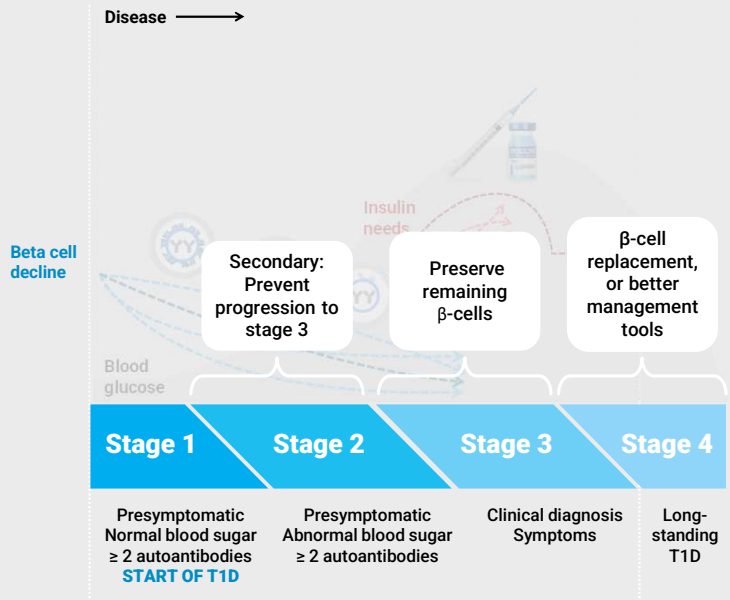


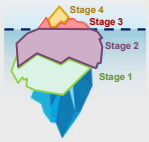


Adapted from Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Haller MJ, et al. *Horm Res Paediatr*. 2024;97(6):529-545.

54

T1D Progression Occurs in Stages





Adapted from Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Haller MJ, et al. *Horm Res Paediatr*. 2024;97(6):529-545.

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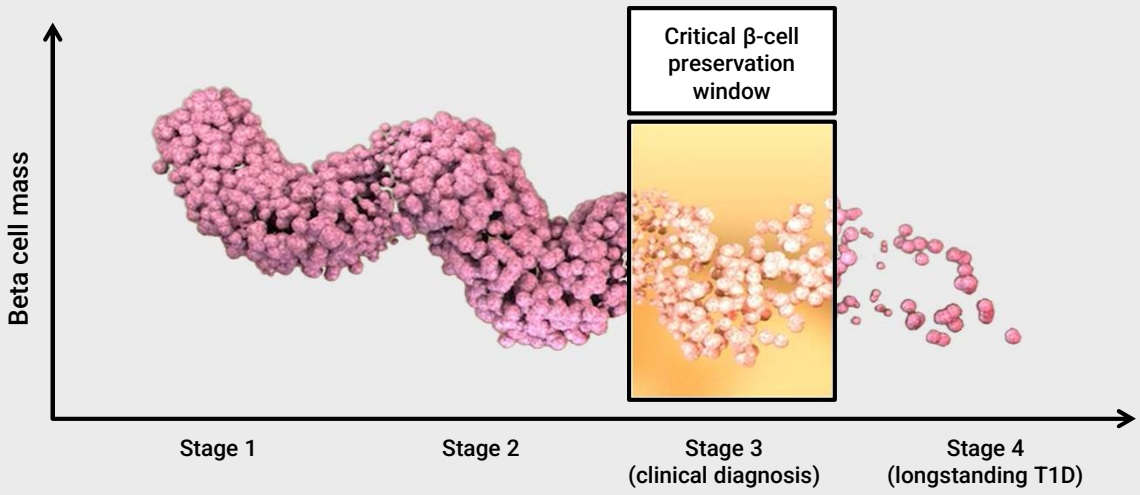
The Critical Window of Beta Cell Preservation

At clinical diagnosis many patients retain measurable β-cell function*



*as measured by C-peptide

Atkinson MA, Mirmira RG. *Cell Metab*. 2023;35(9):1500-1518. Galderisi A. *Pediatr Endocrinol Diabetes Metab*. 2023;29:1-3. Linsley PS, et al. *Diabetes*. 2021;70:831-841.

56

Implications of Higher Baseline Beta Cell Function at Diagnosis

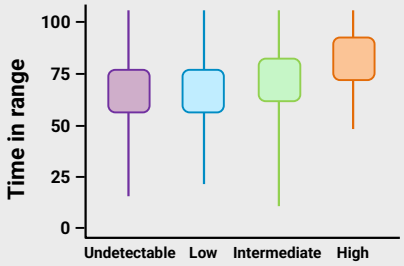
- C-peptide as a prognostic marker and beta cell preservation as a clinical goal
- Potential for lower insulin requirements
- Expanded window of intervention for disease-modifying therapies

Evans-Molina, et al. *Diabetes Care*. 2025;48(10):1651-1667.

57

Improved Glycemic Parameters with Preserved Beta Cell Function

Increased time in range



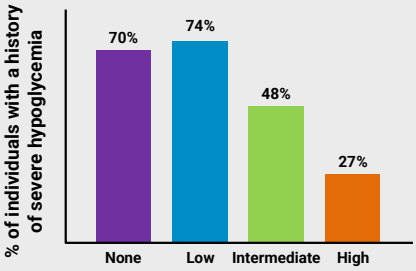
Baseline beta cell function
(as measured by C-peptide)

Lower Hemoglobin (Hb) A1C

A1C

Beta cells

Reduced episodes of severe hypoglycemia



Baseline beta cell function
(as measured by C-peptide)

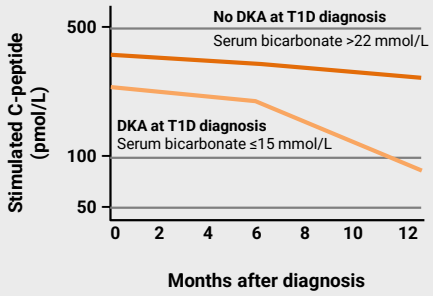
**as compared to individuals with low or undetectable c-peptide*

Fuhri Snethlage CM, et al. *Diabetes Care*. 2024;47:1114-1121. Lachin JM, et al. *Diabetes*. 2014;63(2):739-748. Taylor P, et al. *Lancet Diabetes Endocrinol*. 2023;11:915-925. Gubitosi-Klug RA, et al. *J Clin Invest*. 2021;131(3):e143011.

58

Lower Risk of Complications With Preserved Beta Cell Function

Lower incidence of DKA



Lower risk of nephropathy

= 39%

RISK REDUCTION

Lower risk of retinopathy

= 45%

RISK REDUCTION

**as compared to individuals with low or undetectable c-peptide*

DKA = diabetic ketoacidosis.

Mortensen HB, et al. *Pediatr Diabetes*. 2010;11:218-226. Harsunen M, et al. *Lancet Diabetes Endocrinol*. 2023;11:465-473. Jeyam A, et al. *Diabetes Care*. 2023;44:390-398.

59

C-Peptide as a Marker of Beta Cell Function: Potential Utility and Challenges

Clinical utility of C-peptide measurement

- Supports diabetes classification and diagnosis
- Helps guide therapy selection
- Correlates with diabetes type, duration, and age at diagnosis
- Lower levels associated with increased microvascular risk and complications
- May help predict disease progression and morbidity
- Important endpoint in trials for disease-modifying therapy in new-onset T1D

Limitations

- Urine testing unreliable in chronic kidney disease
- Potential cross-reactivity with proinsulin
- Anti-insulin antibodies may falsely elevate values
- Lack of standardized collection and processing methods
- Correct timing of first C-peptide measurement and of subsequent retesting are still arbitrary
- Suggested cutoffs are arbitrary

Galderisi A. *Pediatr Endocrinol Diabetes Metab*. 2023;29:1-3. Leighton E, et al. *Diabetes Ther*. 2017;8:475-487. Maddaloni E, et al. *Diabetes Obes Metab*. 2022;24:1912-1926. Schleicher E, et al. *J Diabetes Sci Technol*. 2025: 19322968251362848.

60

Interpretation of C-Peptide

In the context of diagnosis and classification of diabetes

Fasting	Healthy adults	Type 1 diabetes	Type 2 diabetes
C-peptide	0.5–2.0 ng/mL (0.17–0.66 nmol/L)	0.3–0.6 ng/mL (0.1–0.2 nmol/L) or undetectable	Normal or elevated
Stimulated (GST/MMT/OGT)			
C-peptide	Peaks: 2–6 ng/mL (0.66–2.0 nmol/L)	<0.6 ng/mL (or undetectable)	Blunted peak but still often >1.5 ng/mL
Reference Range: Insulin: 2–20 µU/mL (14–140 pmol/L); C-peptide: 0.5–2.0 ng/mL (0.17–0.66 nmol/L).			

From the ADA Standards of Care:

- A random sample (with concurrent glucose) within 5 h of eating can replace a formal C-peptide stimulation test in the context of classification
- Random sample must be drawn within 5 hours of eating, paired with a concurrent glucose. Do not test within 2 weeks of a hyperglycemic emergency.

Vinay ES et al. Clin Med Insights Endocrinol Diabetes. 2026 19:11795514251397811. ADA. *Diabetes Care*. 2026;49(suppl 1):S27-S49.

61

Rationale for Disease-Modifying Therapies (DMTs) in New-Onset (stage 3) T1D

- Despite advances in screening and detection of presymptomatic T1D, **nearly 500,000 individuals worldwide continue to be newly diagnosed with stage 3 T1D each year**
- All these individuals lack an approved treatment option other than insulin replacement
- DMTs can potentially help maintain endogenous insulin secretion, reduce the need for exogenous insulin, and prolong the honeymoon period
- Early identification by screening for T1D in individuals with family history or otherwise known genetic risk supports beta cell preservation and defines a critical window for evaluation of progression to stage 3 T1D

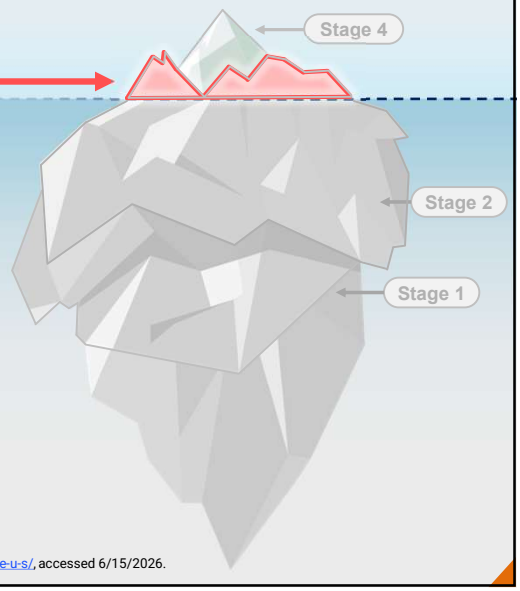
Evans-Molina C, Oram RA. *Diabetes*. 2024;73(6):8340836. ADA. *Diabetes Care*. 2026;49(suppl 1):S27-S49.

62

For the first time, individuals with newly-diagnosed (stage 3) T1D have a therapy besides insulin that addresses the root cause of the disease.

Stage 3
Clinical Diagnosis
Symptoms

Teplizumab is FDA approved to delay the decline in endogenous insulin production in patients 8-17 years of age with recently diagnosed (within the last 8 weeks) stage 3 T1D.



Adapted from Breakthrough T1D, available at https://www.breakthrought1d.org/news-and-updates/tzield-approved-for-stage-3-t1d-in-the-u-s/, accessed 6/15/2026.

63

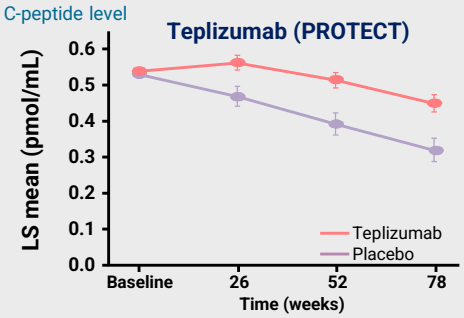
PROTECT Study and Per-Protocol Analysis: Teplizumab in New-Onset (stage 3) T1D

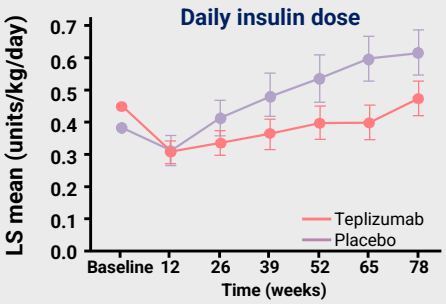
Primary endpoint

- Higher levels of stimulated C-peptide vs placebo
- Greater proportion maintained clinically meaningful C-peptide ≥0.2 pmol/mL

Key clinical secondary endpoints*

- Lower daily insulin requirements with teplizumab (0.46 vs 0.59 units/kg/day), observed after Week 12 and sustained through follow-up
- Higher % time in range (TIR)
- No difference in HbA1C
- Severe hypoglycemia (13.4% in teplizumab; 16.2% in placebo)
- Safety - AEs mostly related to administration and were mild to moderate





***Secondary endpoints were exploratory and not statistically significant.** AEs = adverse events; LS = least-squares.
Ramos EL, et al. *N Engl J Med*. 2023;389(23):2151-2161. Herold KC, et al. *Diabetes*. 2024;73(suppl 1):70-OR.

64

Several DMTs With Different Targets Have Been Studied in New-Onset T1D

ATG = anti-thymocyte globulin;

G-CSF = granulocyte-colony stimulating factor;

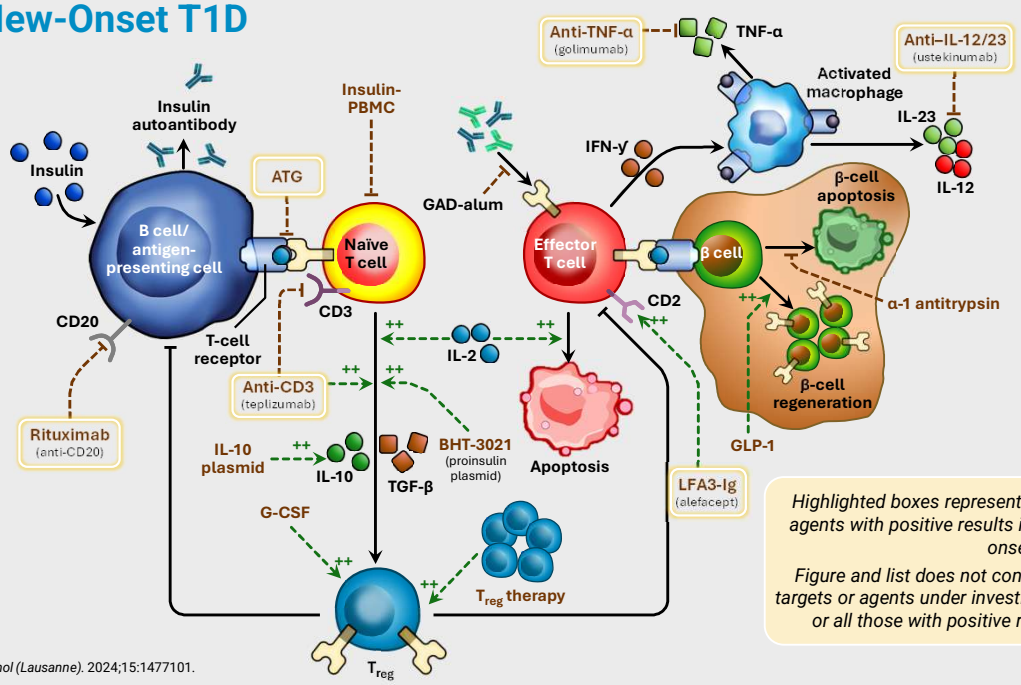
GLP = glucagon-like peptide;

IFN = interferon;

IL = interleukin;

TGF = tumor growth factor;

TNF = tumor necrosis factor.



Highlighted boxes represent select agents with positive results in new-onset T1D.

Figure and list does not contain all targets or agents under investigation or all those with positive results.

O'Donovan AJ, et al. *Front Endocrinol (Lausanne)*. 2024;15:1477101.

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Key Ongoing Trials With DMTs in New-Onset T1D

Agent	Trial name	Trial identifier*
Teplizumab	βETA PRESERVE	NCT07088068
Baricitinib	BARICADE-PRESERVE	NCT07222332
Antithymocyte globulin (ATG)	ATG with or without verapamil	NCT06455319
Difluoromethylornithine (DFMO)	TADPOL	NCT05594563
ATG with subsequent adalimumab or verapamil	WAVE T1D	NCT07061574
Frexalimab	FABULINUS	NCT06111586

These studies need to be done while patients still have enough beta cells to persevere, typically soon after a stage 3 diagnosis.

So talk about research to your patients with new-onset stage 3 T1D early in the initial education process!

*ClinicalTrials.gov.

Adapted from Breakthrough T1D (https://www.breakthrought1d.org/clinical-trials/). Accessed 4/6/2026.

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Considerations for the use of teplizumab in clinical practice

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Clinical Implications of Teplizumab for Primary Care

Screening becomes paramount to identify individuals at stage 2, as well as appropriate monitoring and staging

In primary care, consider referring appropriate patients (with stage 2 or new-onset stage 3 T1D) for treatment to endocrinology or specialty care

Clinical Implications of Teplizumab for Endocrinology / Diabetology

Identify appropriate patients (with stage 2 or newly-diagnosed stage 3 T1D) and:

- Decide on practice capacity to administer teplizumab infusions OR
- Refer to a Center of Excellence, specialized center, and/or local infusion center that has experience with teplizumab infusions

Patients need to be educated and monitored for potential adverse events

Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021:13(583):eabc8980. Mehta S, et al. *Horm Res Paediatr.* 2024: 597-608.

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Teplizumab Eligibility

Patients with Stage 2 T1D

Aged ≥1 year with stage 2 T1D confirmed by

- ≥2 T1D relevant islet autoantibodies (GAD65, IA-2, IAA, ZnT8, ICA)
- Dysglycemia using an oral glucose tolerance test (OGTT), or alternative method if appropriate or if OGTT is not available

Patients with Stage 3 T1D

Aged 8-17 years with recently-diagnosed stage 3 T1D

- Diagnosed within the last 8 weeks
- At least 1 positive islet autoantibody
- Peak C-peptide of ≥0.2 pmol/mL on a mixed-meal tolerance test (MMTT), or alternative method for measuring peak C-peptide ≥0.2 pmol/mL if if MMTT is not available

- Ensure that the clinical history of the patient does not suggest insulin resistance due to obesity, T2D, or dysglycemia due to other forms of diabetes
- Limited evidence of efficacy & safety in patients ≥45 years of age with stage 2 T1D
- Not effective as a disease-modifying therapy in non-autoimmune dysglycemic conditions.

- All age-appropriate vaccinations were administered prior to starting teplizumab
- Screenings for active CMV, EBV infection, hepatitis, HIV, and tuberculosis are negative
- Discussed potential risks and benefits and potential AEs with patient and family

ICD-10 diagnostic codes specific to early stage T1D

- E10.A0 = T1D, presymptomatic, unspecified
- E10.A1 = T1D, presymptomatic, stage 1
- E10.A2 = T1D, presymptomatic, stage 2

ICA = islet cell antibody; ICD-10 = *International Classification of Diseases, Tenth Revision*.

Adapted from Mehta S, et al. *Horm Res Paediatr.* 2024:1-12 and Teplizumab (Tzield®) prescribing information (PI) 2026 (https://products.sanofi.us/tzield/tzield.pdf). Accessed 6/15/2026.

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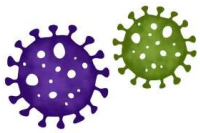
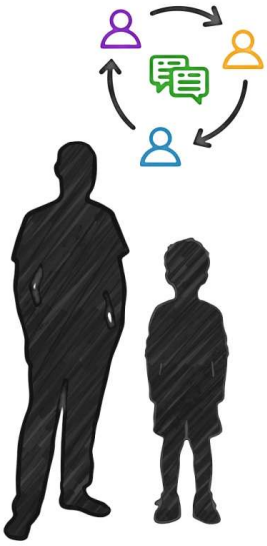
Pre-Infusion Considerations

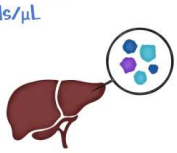
Ensure all appropriate vaccines have been administered
- Live-attenuated vaccines at least 8 weeks prior
- Inactivated or mRNA vaccines at least 2 weeks prior



Screenings for active CMV, EBV infection, hepatitis, HIV, & tuberculosis are negative



Initial bloodwork for complete blood count
- Hemoglobin >10 g/dL
- Platelets >150,000 platelets/µL
- Lymphocyte count >1000 lymphocytes/µL
- Absolute neutrophil count >1500 neutrophils/µL



Liver enzymes tests
- ALT or AST <2x the ULN & bilirubin <1.5x ULN

CMV = cytomegalovirus; EBV = Epstein-Barr virus; HIV = human immunodeficiency virus

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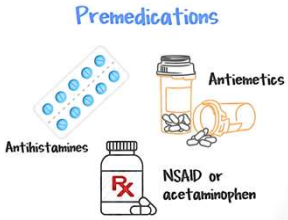
Dosing Schedule For Patients with Stage 2 T1D

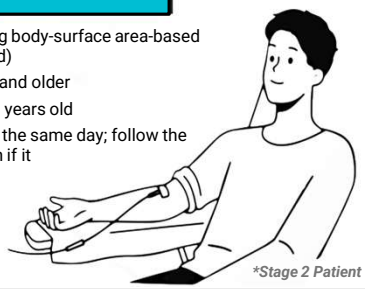
Single Treatment Course (14 days)

Premedications – typically during first 5 days when risk of AEs is higher



SUN	MON	TUE	WED	THU	FRI	SAT
		Day 1 65 mcg/m²	Day 2 125 mcg/m²	Day 3 250 mcg/m²	Day 4 500 mcg/m²	Day 5–14 1030 mcg/m²
6	7	8	9	10	11	12
Day 5 – 14 1030 mcg/m²						
13	14	15				

- Intravenous (IV) infusion using body-surface area-based dosing (PICC line may be used)
- ≥30 minutes for ages 8 years and older
- ≥2 hours for ages 1 year to <8 years old
- Do not administer 2 doses on the same day; follow the protocol for a missed infusion if it



For additional information—including treatment monitoring, drug withholding criteria, or follow up post treatment —refer to the 2024 PES guidance statement on teplizumab treatment

*Stage 2 Patient

Adapted from Mehta S, et al. *Horm Res Paediatr.* 2024:1-12. and Teplizumab (Tzield®) prescribing information (PI) 2026 (https://products.sanofi.us/tzield/tzield.pdf). Accessed 6/15/2026.

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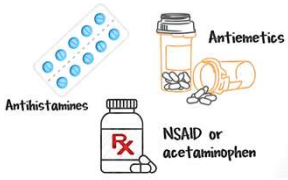
Dosing Schedule For Patients with Stage 3 T1D

Two Treatment Courses (12 days each)

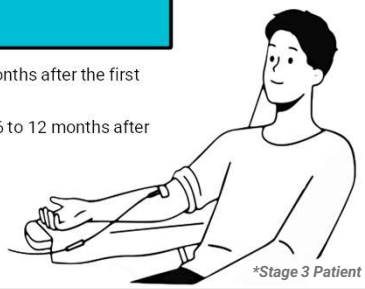
Premedications – typically during first 5 days when risk of AEs is higher



SUN	MON	TUE	WED	THU	FRI	SAT
		Day 1 106 mcg/m²	Day 2 425 mcg/m²	Day 3–12 850 mcg/m²		
6	7	8	9	10	11	12
Day 3–12 850 mcg/m²						

Second treatment Course: Administer the second 12-day treatment course 6 months after the first treatment course.

If the second course is delayed, administer the second treatment course within 6 to 12 months after the first treatment course.



For additional information—including treatment monitoring, drug withholding criteria, or follow up post treatment —refer to the 2024 PES guidance statement on teplizumab treatment

*Stage 3 Patient

Adapted from Mehta S, et al. *Horm Res Paediatr.* 2024:1-12. and Teplizumab (Tzield®) prescribing information (PI) 2026 (https://products.sanofi.us/tzield/tzield.pdf). Accessed 6/15/2026.

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Polling Question

What are your biggest barriers in applying disease modifying therapy for T1D? *Select all that apply.*

- **A** Identifying eligible patients
- **B** Lack of available infusion programs
- **C** Uncertainty about safety profile
- **D** Insurance & access
- **E** Nursing support
- **F** Weekend availability

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Considerations for Infusion Setting With Teplizumab

Infusion setting*	Pros	Cons
Doctor's office	Supervised by provider	Limited scheduling flexibility, limited personal attention in a busy clinic setting
Infusion centers	Specialized staff and equipment, experience with immunotherapy infusions	Possible travel required
At home with nurse	Convenience	Lack of immediate medical assistance, especially during the first 5 days when cytokine release syndrome is common

**For insurance purposes, infusion setting must be determined prior to starting therapy. In-home infusions for a pediatric population should be ideally avoided and limited to adult patients. Infusions for pediatric patients are recommended to be done in a controlled clinical setting with nurses who are trained in PALS.*

- This can vary based on resources and experience of the team
- Careful balance of accessibility to medication and optimizing patient care and monitoring

Type 1 Diabetes TrialNet Centers of Excellence Locations
https://www.trialnet.org/locations

National Infusion Center Association – Infusion Center Locator (can sort by medication type, including teplizumab)
https://locator.infusioncenter.org/

DETECT-T1D Infusion Portal
https://infusion.detect-t1d.com/

PALS = Pediatric Advanced Life Support.

Mehta S, et al. *Horm Res Paediatr.* 2024:1-12.

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Patient Perspective and Panel Discussion: Treatment With Disease Modifying Therapies for T1D

Marissa and Claire

T1D Caregiver and Patient

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Case #2 and Group Breakout Discussion

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Case 2 | Introduction: James

- 34-year-old elementary school teacher
- Mother was diagnosed with T1D in her 40s (initially diagnosed as T2D). After her diagnosis was clarified, James enrolled in TrialNet 2 years ago
- **Initial screening results (from 2 years ago):** GAD-65 (+), IA-2, IAA & ZnT8 (-).
- **BMI:** 24 kg/m2. Exam otherwise unremarkable

Case Breakout Discussion…

- Break into small groups at your table (2-3).
- Answer the initial case questions in iPADs in small groups
- Answer the open-ended case questions as a table

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Case Continuation

Repeat screening: GAD-65 & ZnT8 positive (2 autoantibodies).

Current labs: Fasting glucose 91 mg/dL, A1C = 5.3%, OGTT 2-hr = 123 mg/dL

Symptoms: None

What best describes James' status?

Swipe A Card

Pre-T1D	***Stage 1 T1D***
Stage 2 T1D	*Stage 3 T1D*

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Case Continuation

Repeat screening: GAD-65 & ZnT8 positive (2 autoantibodies).

Current labs: Fasting glucose 91 mg/dL, A1C = 5.3%, OGTT 2-hr = 123 mg/dL

Symptoms: None

What would your treatment recommendation be now?

Swipe A Card

- *Start basal insulin to preserve beta cell function*
- *Structured monitoring for signs and symptoms of diabetes*
- *Refer for teplizumab now*

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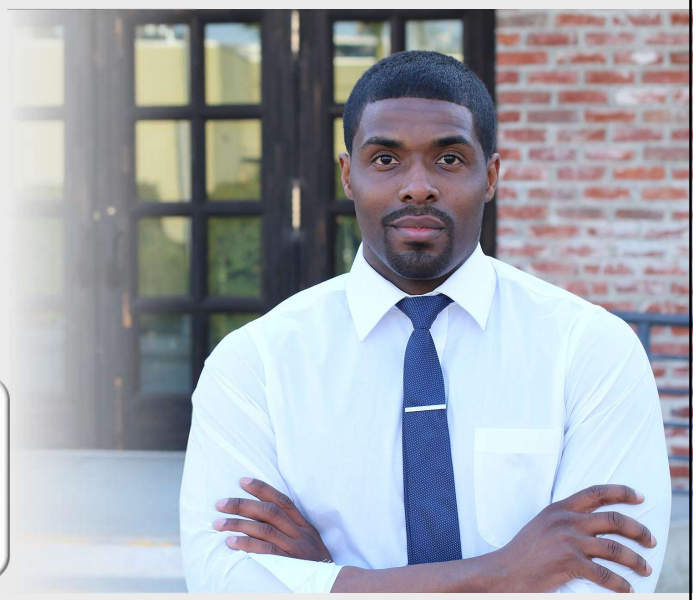
Case Continuation – 1 year follow-up

Repeat antibodies confirm GAD65 and ZnT8A.

Current labs: Fasting glucose 108 mg/dL; HbA1C 5.9%; 2-hr OGTT 174 mg/dL

Symptoms: increased fatigue but no other symptoms reported



What best describes James' status now?

Swipe A Card

- *Stage 1 T1D*
- *Stage 2 T1D*
- *Stage 3 T1D*
- *Stage 4 T1D*

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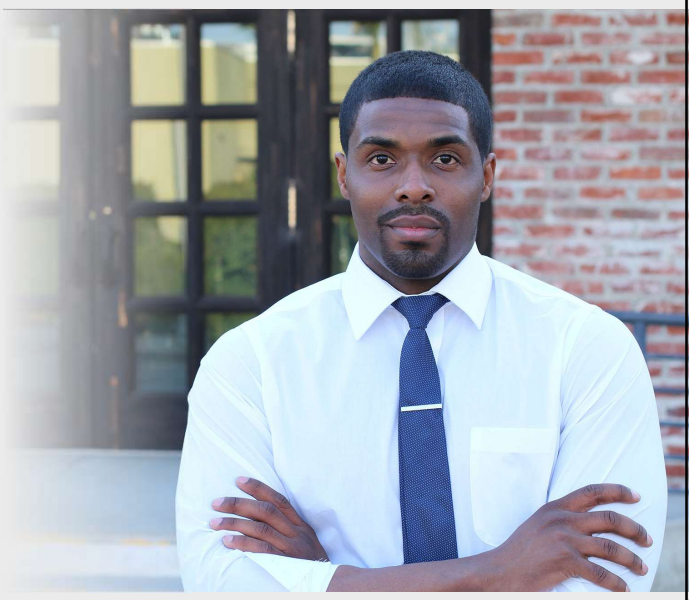
Case Continuation – 1 year follow-up

Repeat antibodies confirm GAD65 and ZnT8A.

Current labs: Fasting glucose 108 mg/dL; HbA1C 5.9%; 2-hr OGTT 174 mg/dL

Symptoms: increased fatigue but no other symptoms reported



Open Discussion

- How would you counsel James about the meaning of these results?
- How should the management evolve now based on these results?

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Conclusions

- Screening for early stage T1D should be done in those who are at increased risk (family history of T1D, personal or family history of other autoimmune conditions, elevated genetic risk scores if tested) or desire testing
- Positive T1D antibody testing should have follow up testing to confirm diagnosis or monitor for stage progression
- Teplizumab is FDA approved to delay the progression from Stage 2 to Stage 3 T1D in those 1 year and older, and in patients 8-17 years with newly-diagnosed stage 3 T1D
- Screening in primary care is critical to identifying those in early stage T1D
- Identifying individuals and families at risk for type 1 diabetes and progression to stage 3 will require a concerted effort of all members of the health care team.
- Individuals with a family history of type 1 diabetes and/or personal/family history for any autoimmune disorders are high priority for screening.
- The goal is not only delaying progression to stage 3, but to preserve as much pancreatic beta cell function as possible.
- We have treatments that are available today and many on the horizon – but their effectiveness will depend on their implementation at optimal timing/stages.

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Local Resources

Name	***Contact***
VCH Diabetes Clinic	Call: 615-322-7842 (322-SUGA)
Vanderbilt TrialNet	Visit: https://www.trialnet.org/locations/vanderbilt-university-medical-center
Dr. Daniel Moore	Email: Daniel.moore@vumc.org

Slide courtesy of Dr. Daniel Moore

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Q & A

Thank you!

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DETECT 1D

RECEIVE CME/CNE CREDIT

Pre-Test

Post-Test

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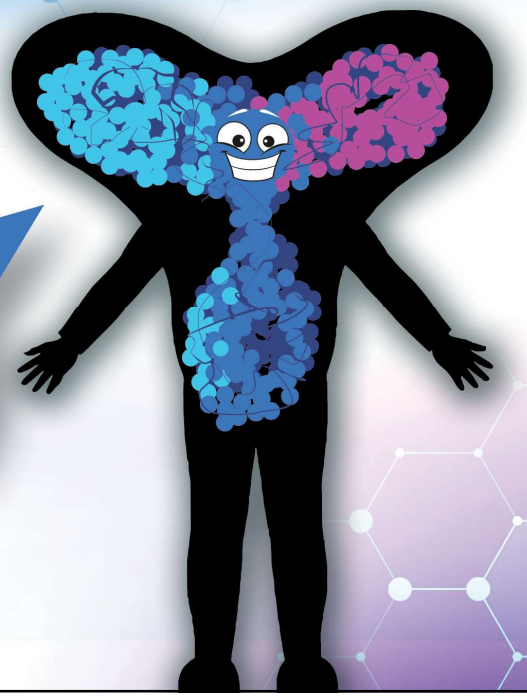
DETECT 1D

Please visit

the DETECT T1D Website!

https://detect-t1d.com/



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DETECT 1D

WE INVITE YOUR FEEDBACK ON TODAY'S SUMMIT

Scan the QR code for registration details.
Interviews to take place in 8-12 weeks.

- 30-minute Virtual Interview
- $250 USD Honorarium

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Toolkit

Guidelines and Practice Parameters

Resource	Address
American Diabetes Association Professional Practice Committee for Diabetes. 2. Diagnosis and classification of diabetes: standards of care in diabetes—2026. *Diabetes Care.* 2026;49 (suppl 1): S27–S49.	https://diabetesjournals.org/care/article/49/Supplement_1/S27/163926/2-Diagnosis-and-Classification-of-Diabetes
American Diabetes Association Professional Practice Committee. 3. Prevention or delay of diabetes and associated comorbidities: Standards of care in diabetes—2026. *Diabetes Care*. 2026;48(suppl 1):S50-S58.	https://diabetesjournals.org/care/article/49/Supplement_1/S50/163924/3-Prevention-or-Delay-of-Diabetes-and-Associated
Besser REJ, Bell KJ, Couper JJ, et al. ISPAD Clinical Practice Consensus Guidelines 2022: Stages of type 1 diabetes in children and adolescents. *Pediatr Diabetes*. 2022;23:1175-1187.	https://onlinelibrary.wiley.com/doi/10.1111/pedi.13410
Haller MJ, Bell KJ, Besser RE, et al. ISPAD Clinical Practice Consensus Guidelines 2024: Screening, staging, and strategies to preserve beta cell function in children and adolescents with type 1 diabetes. *Horm Res Paediatr*. 2024;97:529-545.	https://karger.com/hrp/article/doi/10.1159/000543035/917924/ISPAD-Clinical-Practice-Consensus-Guidelines-2024
Mehta S, Ryabets-Lienhard A, Patel N, et al. Pediatric Endocrine Society statement on considerations for the use of teplizumab in clinical practice. *Horm Res Paediatr*. 2024;Apr 30:1-12.	https://karger.com/hrp/article/doi/10.1159/000538775/906682/Pediatric-Endocrine-Society-Statement-on
Philip M, Achenbach P, Addala A, et al. Consensus guidance for monitoring individuals with islet autoantibody-positive pre-stage 3 type 1 diabetes. *Diabetes Care*. 2024;47:1276-1298.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dci24-0042

References/Reading List

Resource	Address
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Bogun MM, Bundy BN, Goland RS, Greenbaum CJ. C-peptide levels in subjects followed longitudinally before and after type 1 diabetes diagnosis in TrialNet. *Diabetes Care*. 2020;43:1836-1842.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc19-2288
Calhoun P, Spanbauer C, Steck AK, et al. Continuous glucose monitor metrics from five studies identify participants at risk for type 1 diabetes development. *Diabetologia.* 2025;68:930–939.	https://link.springer.com/article/10.1007/s00125-025-06362-1#citeas

Resource	Address
Carmella Evans-Molina, Richard A. Oram. A Golden hour and golden opportunity for β-cell preservation. *Diabetes* 20 May 2024; 73 (6): 834–836.	https://diabetesjournals.org/diabetes/article/73/6/834/154586/A-Golden-Hour-and-Golden-Opportunity-for-Cell
Demeterco-Berggren, C, Jacobsen, L, Rioles, N, et al. Beta-cell preservation throughout the stages of type 1 diabetes white paper. *T1D Exchange*. 2026.	https://journals.sagepub.com/doi/10.1177/29986702261435426
Felton JL, Tuttle A, Sims EK. Teplizumab-mzwv: perspective on clinical practice use at a single institution. SMART-MD *J Precision Med*. 2025;2:e149-e157.	https://smart-md.org/index.php/jpm/article/view/20
Fuhri Snethlage CM, et al. Residual β-cell function is associated with longer time in range in individuals with type 1 diabetes. *Diabetes Care.* 2024;47:1114-1121.	https://diabetesjournals.org/care/article/47/7/1114/153454/Residual-Cell-Function-Is-Associated-With-Longer
Fyvie MJ, Gillespie KM. The importance of biomarker development for monitoring type 1 diabetes progression rate and therapeutic responsiveness. *Front Immunol*. 2023;14:1158278.	https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2023.1158278/full
Galderisi A, Sims EK, Evans-Molina C, et al. Trajectory of beta cell function and insulin clearance in stage 2 type 1 diabetes: Natural history and response to teplizumab. *Diabetologia*. 2025;68:646-661.	https://link.springer.com/article/10.1007/s00125-024-06323-0#citeas
Galderisi A, Carr ALJ, Martino M, et al. Quantifying beta cell function in the preclinical stages of type 1 diabetes. *Diabetologia*. 2023;66:2189-2199.	https://link.springer.com/article/10.1007/s00125-023-06011-5
Gitelman, S.E., Simmons, K., Sherr, J.L. et al. Safety and pharmacokinetics of teplizumab in children less than 8 years of age with stage 2 type 1 diabetes. *Diabetologia* 69, 330–342 (2026).	https://link.springer.com/article/10.1007/s00125-025-06586-1
Greenbaum CJ, Nepom GT, Wood-Heickman LK, et al. Evolving concepts in pathophysiology, screening, and prevention of type 1 diabetes: Report of diabetes mellitus interagency coordinating committee workshop. *Diabetes*. 2024;73:1780-1790.	https://diabetesjournals.org/diabetes/article-lookup/doi/10.2337/dbi24-0020
Harsunen M, Haukka J, Harjutsalo V et al. Residual insulin secretion in individuals with type 1 diabetes in Finland: longitudinal and cross-sectional analyses. *The Lancet Diabetes & Endocrinology*, 2023; 11, 465-473	https://www.thelancet.com/journals/landia/article/PIIS2213-8587(23)00123-7/abstract
Herold KC, Bundy BN, Long SA, et al. An anti-CD3 antibody, teplizumab, in relatives at risk for type 1 diabetes. *N Engl J Med*. 2019;381:603-613.	https://www.nejm.org/doi/10.1056/NEJMoa1902226
Herold KC, Gitelman SE, Gottlieb PA, Knecht LA, Raymond R, Ramos EL. Teplizumab: A disease-modifying therapy for type 1 diabetes that preserves β-Cell function. *Diabetes Care*. 2023;46:1848-1856.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc23-0675

Resource	Address
Holt RIG, DeVries JH, Hess-Fischl A, et al. The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2021;44:2589-2625.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dci21-0043
Hood KK, Twigg AR, Gitelman SE. How to communicate with individuals and caregivers at the time of presymptomatic type 1 diabetes diagnosis. *Postgrad Med.* 2026;138:125-129.	https://www.tandfonline.com/doi/full/10.1080/00325481.2026.2635182#d1e194
Insel RA, Dunne JL, Atkinson MA, et al. Staging presymptomatic type 1 diabetes: A scientific statement of JDRF, the Endocrine Society, and the American Diabetes Association. *Diabetes Care*. 2015;38:1964-1974.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc15-1419
Jacobsen LM, Schatz D. Immunotherapy-based strategies for the treatment of type 1 diabetes. *Horm Res Paediatr*. 2024;1-10.	https://karger.com/hrp/article/doi/10.1159/000542002/914841/Immunotherapy-Based-Strategies-for-Treatment-of
Jeyam A, et al. Clinical impact of residual C-peptide secretion in type 1 diabetes on glycemia and microvascular complications. *Diabetes Care*. 2021; 44 (2): 390–398.	https://diabetesjournals.org/care/article-abstract/44/2/390/35493/Clinical-Impact-of-Residual-C-Peptide-Secretion-in?redirectedFrom=fulltext
Karakus, K.E., Chesshir, L., Walker, S. et al. Teplizumab treatment for stage 2 type 1 diabetes: a real-world evaluation of metabolic and immunological outcomes. *Diabetologia* 69, 1164–1175 (2026).	https://link.springer.com/article/10.1007/s00125-025-06646-6#citeas
Katsarou A, Gudbjörnsdottir S, Rawshani A, et al. Type 1 diabetes mellitus. *Nat Rev Dis Primers*. 2017;3:17016.	https://www.nature.com/articles/nrdp201716
Leichter SB, Felton JL, Rasmussen CG, et al. Establishing screening programs for presymptomatic type 1 diabetes: practical guidance for diabetes care providers *J Clin Endocrinol Metab.* 2025;2:dgaf194.	https://academic.oup.com/jcem/advance-article/doi/10.1210/clinem/dgaf194/8103687
Leighton E, Sainsbury CA, Jones GC. A practical review of c-peptide testing in diabetes. *Diabetes Ther* 8, 475–487 (2017)	https://link.springer.com/article/10.1007/s13300-017-0265-4#citeas
Leslie RD, Evans-Molina C, Freund-Brown J, et al. Adult-onset type 1 diabetes: Current understanding and challenges. *Diabetes Care*. 2021;44:2449-2456.	https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc21-0770
Linsley PS, et al. Uncovering Pathways to personalized therapies in type 1 diabetes. *Diabetes* 1 April 2021; 70 (4): 831–841.	https://diabetesjournals.org/diabetes/article/70/4/831/39363/Uncovering-Pathways-to-Personalized-Therapies-in
Maddaloni E, Bolli GB, Frier BM, et al. C-peptide determination in the diagnosis of type of diabetes and its management: A clinical perspective. *Diabetes, Obesity & Metabolism.* 2022 Oct;24(10):1912-1926.	https://europepmc.org/article/PMC/PMC9543865

Resource	Address
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University of Colorado – Barbara Davis Center for Diabetes. Screen TO Prevent Type 1 Diabetes – stopT1D.	https://www.stopt1dprogram.org/