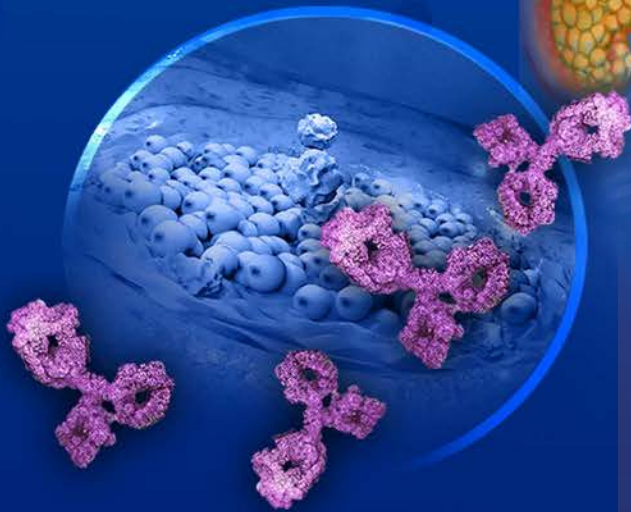
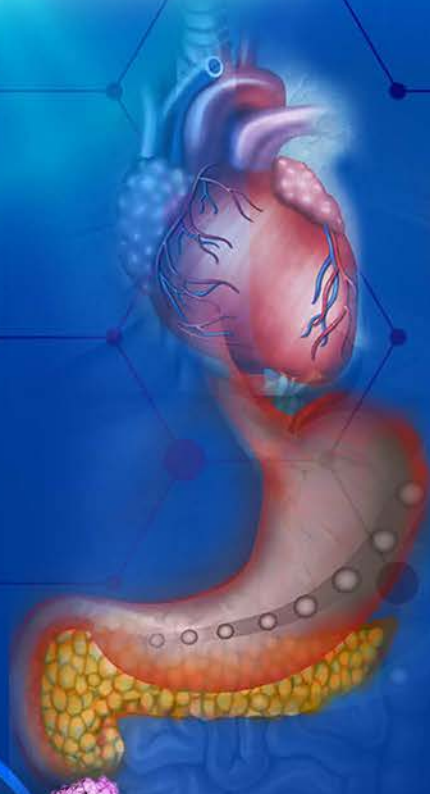
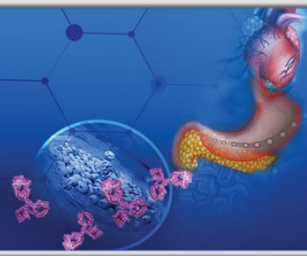


DETECT1D



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

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Vanessa Pilon and Daughter Chloe

Flower Mound, Texas

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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| | |
|--------------------------------------|---|
| Kim Pfothenauer DO, FACOFP, DABOM | Consulting Fees: Novo Nordisk Stock: ROMTech Advisory Board: Boehringer Ingelheim |
| Vanessa Pilon | Has nothing to disclose |
| Puja Singh, MD | Has nothing to disclose |
| 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



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Clinical Professor
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Vanessa Pilon and her daughter, Chloe

T1D Caregiver and Patient
Flower Mound, TX

1

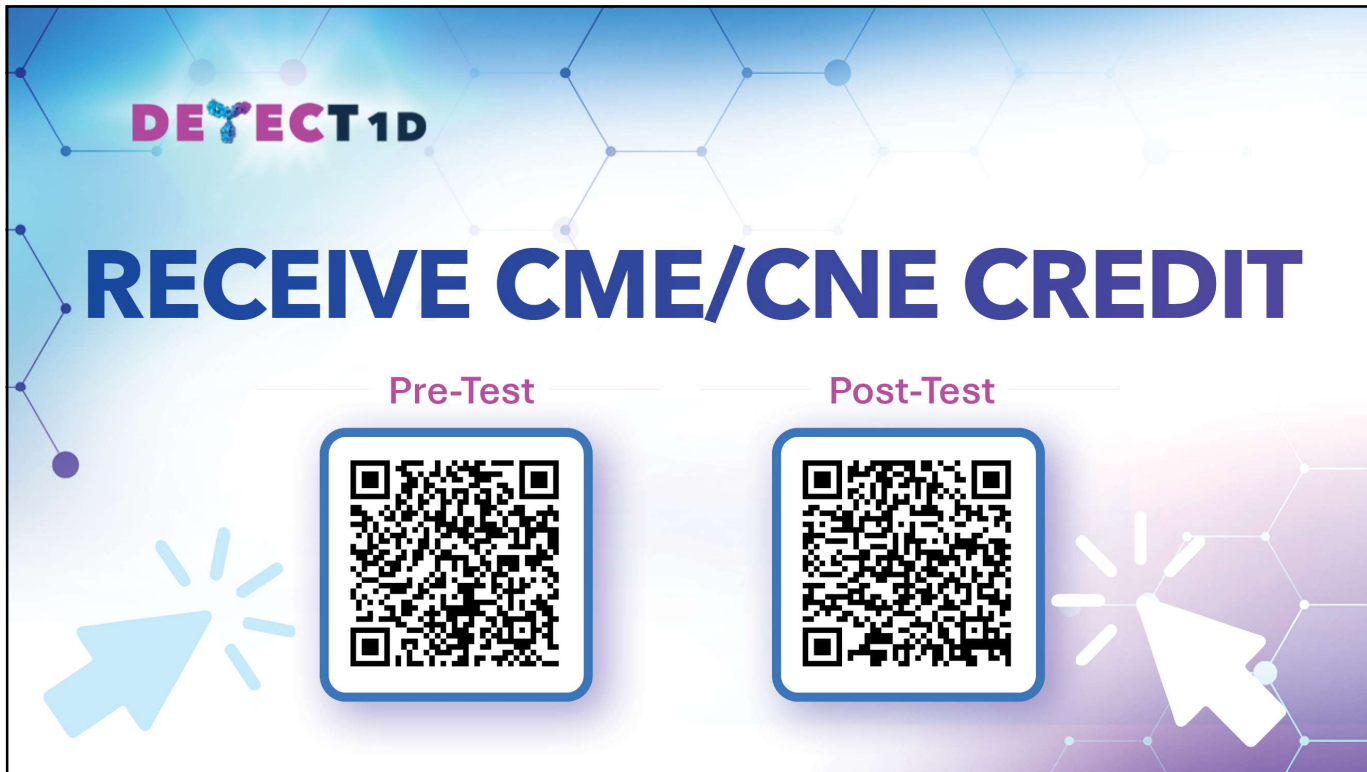
DETECT1D
INSIGHTS TO ACTION

RESOURCES → EDUCATION → ENGAGEMENT → BETTER HCP CONVERSATIONS

ONE HUB, ONE MESSAGE, GREATER IMPACT

A QR code is located in the top right corner of the banner.


2




DETECT 1D

RECEIVE CME/CNE CREDIT

Pre-Test




Post-Test



The graphic features a blue and purple background with a molecular structure pattern. It includes two QR codes, one for 'Pre-Test' and one for 'Post-Test', each with a mouse cursor icon pointing towards it. The text 'DETECT 1D' is in the top left, and 'RECEIVE CME/CNE CREDIT' is in large blue letters in the center.

3


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The slide has a light blue background with a dark blue curved footer. It contains the 'cme passport' logo in the top right, the 'Med Learning Group' logo in the bottom center, and text explaining the CME credit reporting process.

4

DETECT 1D

SWIPE OR MISS: T1D DECISIONS

Sign up

Swipe left or right to answer the case question

Live leaderboards

5

Disclosures

- **Dr. Singh** has nothing to disclose.
- **Dr. Vega** discloses that he has received consulting fees from GSK, Boehringer Ingelheim, and Exact Sciences.
- **Vanessa Pilon** has nothing to disclose.

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This activity is supported by an educational grant from Sanofi US.

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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

7

The Paradigm Shift in T1D: Screening for Presymptomatic Disease



8

The Screening Gap in T1D

Recent research shows that while clinicians 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.

10

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**



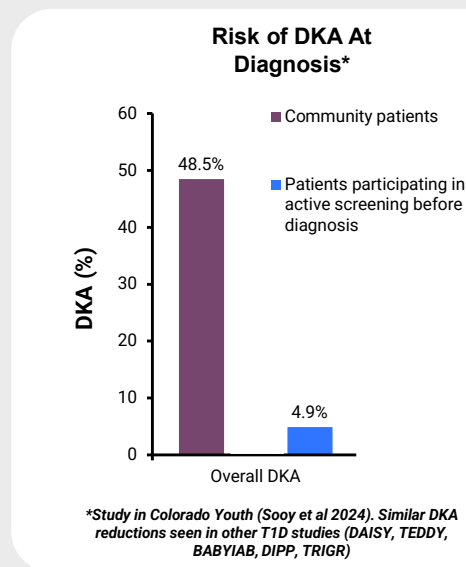
American Diabetes Association (ADA) Professional Practice Committee. *Diabetes Care*. 2026;49(suppl 1):S27-S49. Haller MJ, et al. *Horm Res Paediatr*. 2024;1-17. Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Phillip M, et al. *Diabetologia*. 2024;67:1731-1759.

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

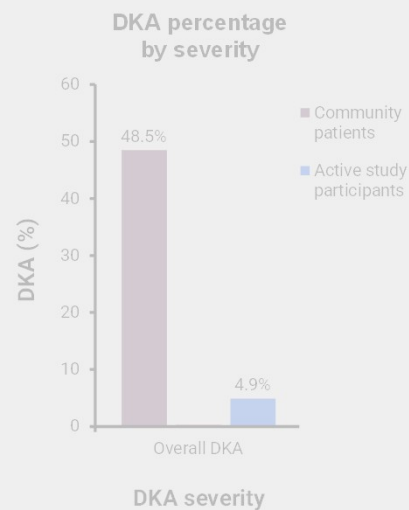


Barker JM, et al. *Diabetes Care*. 2004;27:1399-1404. Elding Larsson H, et al. *Pediatr Diabetes*. 2014;15:118-126. Winkler C, et al. *Pediatr Diabetes*. 2012;13:308-313. Hekkala AM, et al. *Pediatr Diabetes*. 2018;19:314-319. Nakhla M, et al. *JAMA Pediatr*. 2021;175:518-520. Sooy M, et al. *Diabetes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

12

Why take early T1D screening seriously?

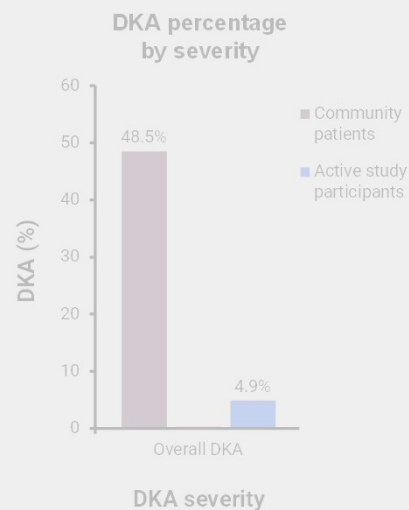
- 1 DKA prevention – asymptomatic screening and ongoing monitoring have been shown to reduce the number of patients who are first diagnosed with T1D in a state of DKA from ~49% to <5%!
 - Reduce hospitalizations
 - Improve long-term patient outcomes
- 2 Early diagnosis allows patients and family members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

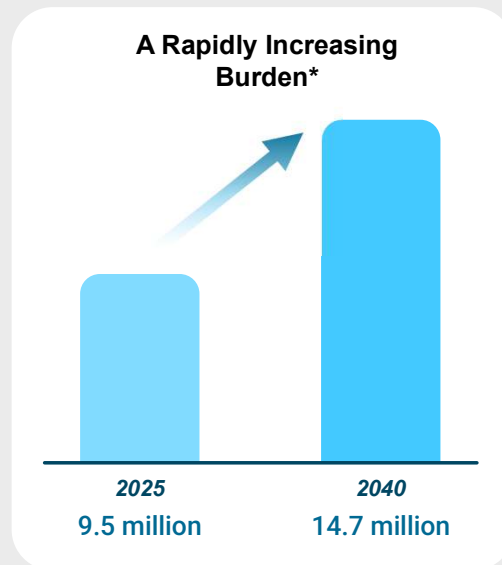
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T1D Epidemiology, Pathophysiology and Staging



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The Burden of T1D Is Growing



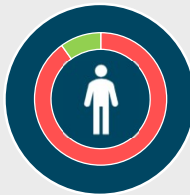
*projected increase in global prevalence
Ogle GD, et al. *Diabetes Res Clin Pract.* 2025;225:112277.

17

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

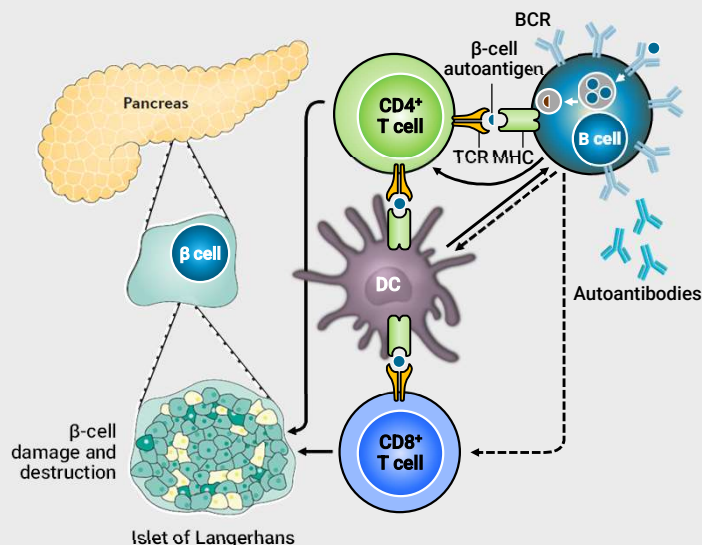


Increased risk in those with
personal or family history of
other autoimmune
conditions (e.g. celiac or
thyroid disease)

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.

18

T1D Is a Chronic Autoimmune Disease

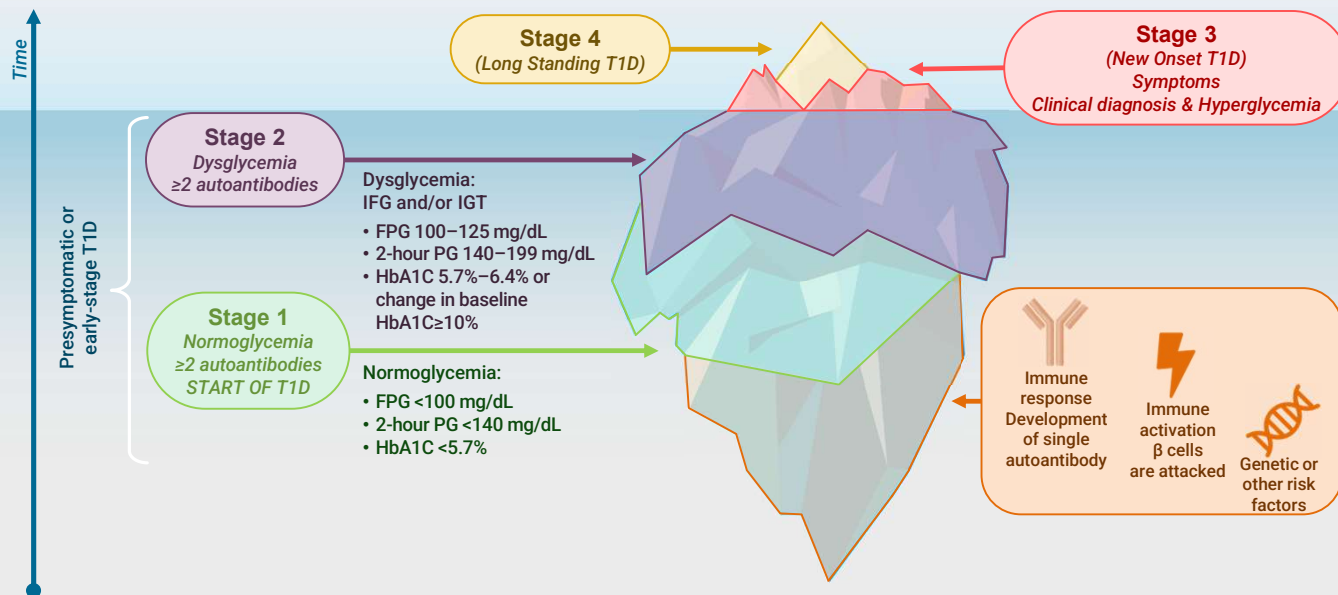


- Characterized by T-cell mediated destruction of pancreatic β -cells,
- Both genetic and environmental factors drive the immune attack of β -cells
- Autoantibodies are markers of this attack; by measuring them we can detect autoimmunity before symptoms develop

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.

19

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



Vanessa & Chloe

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:

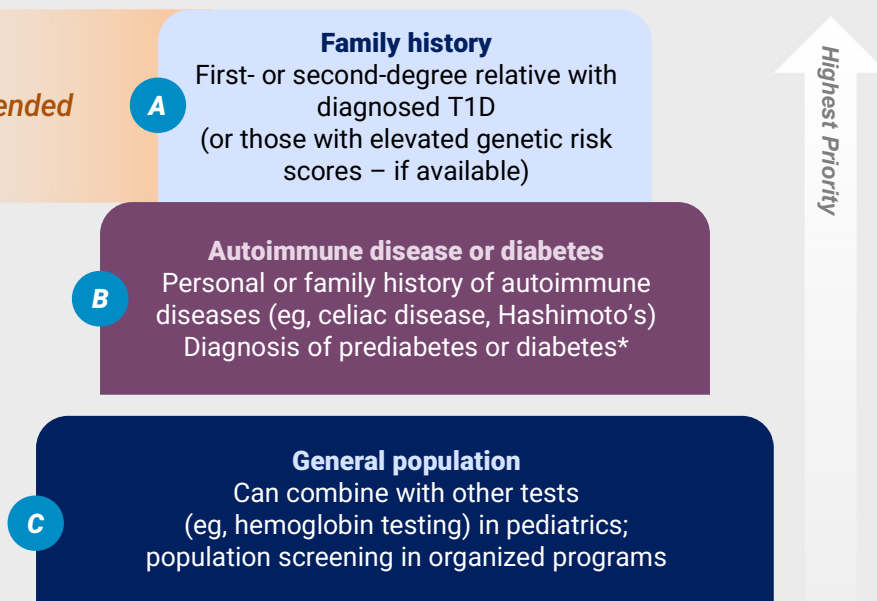
- IAA
- GAD65/GADA
- IA-2A
- ZnT8A

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

23

Who to Screen

ADA recommended



*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 AABCC 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.



Age

<35 years



Autoimmunity

Personal or family history



Body habitus

BMI <25 kg/m²



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 Presymptomatic 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.breakthrough1d.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 |

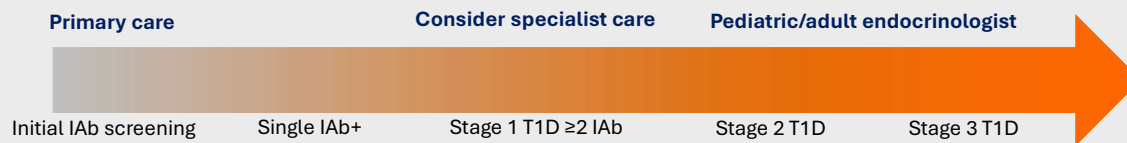
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Who Is Responsible for Presymptomatic T1D Screening and Process Considerations



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.

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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

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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

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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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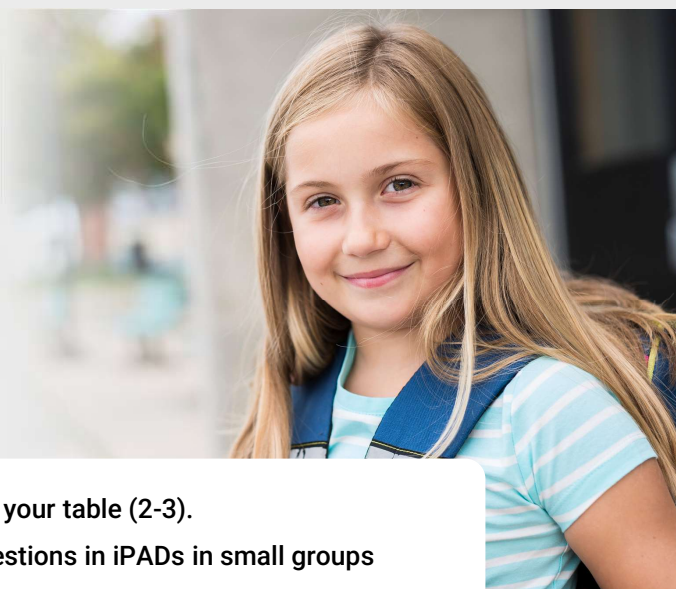
Case #1 and Group Breakout Discussion



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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

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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



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Case 1 | Continuation

How would you test Emma for diabetes?

Swipe A Card

Fasting Glucose

HbA1c

Islet Autoantibodies



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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 |



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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

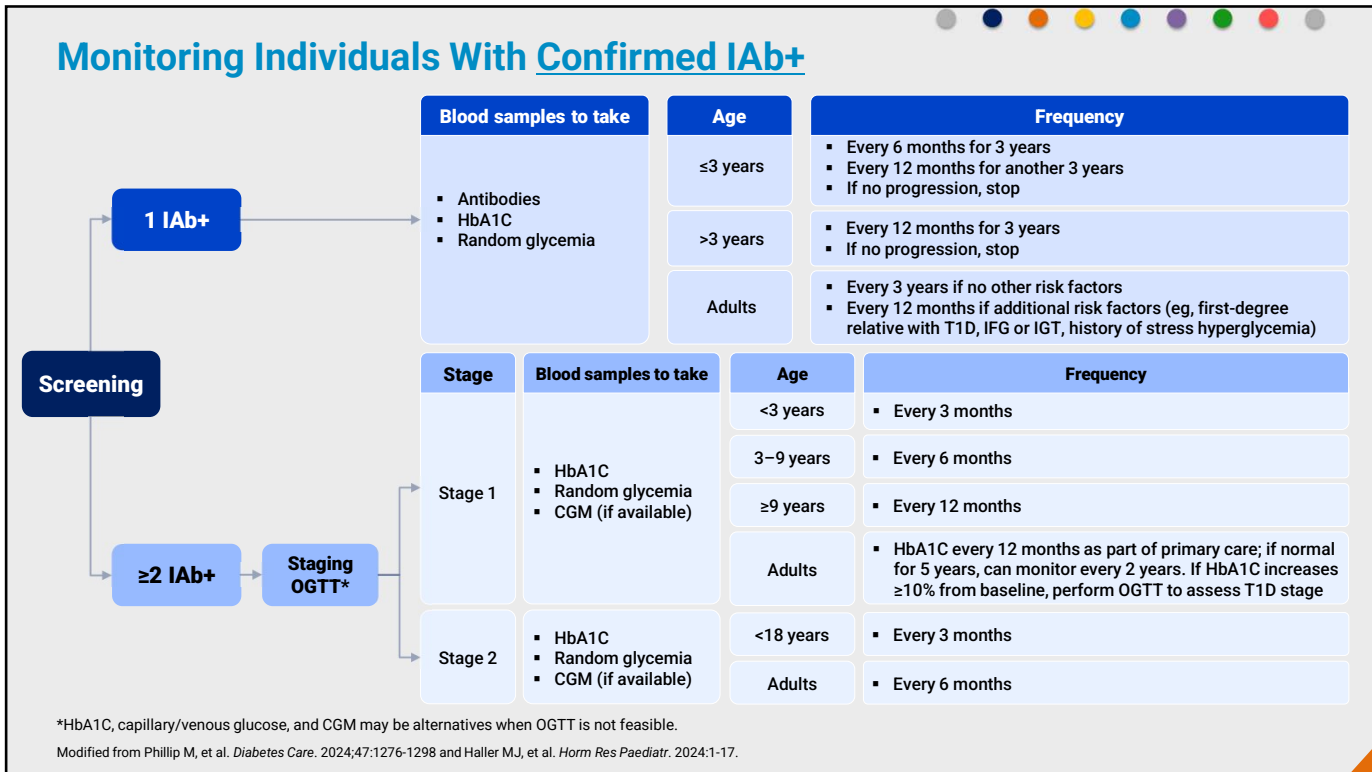


- After **confirming** multiple autoantibodies:
- Already in early-stage T1D
 - Glucose and HbA1c along with symptom evaluation
 - Referral to specialist for monitoring and possible disease-modifying therapy (e.g. teplizumab), or clinical trials

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



41

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

Vanessa & Chloe
T1D Caregiver and Patient

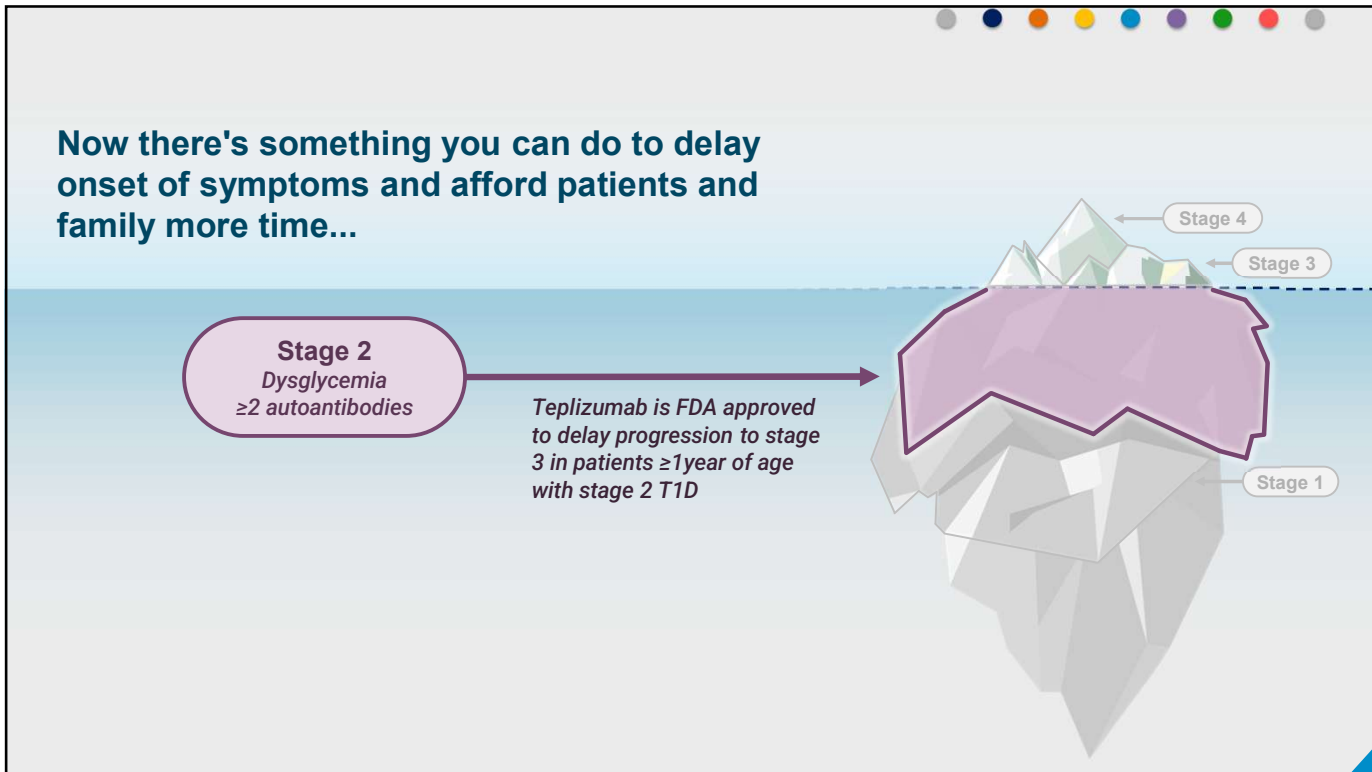
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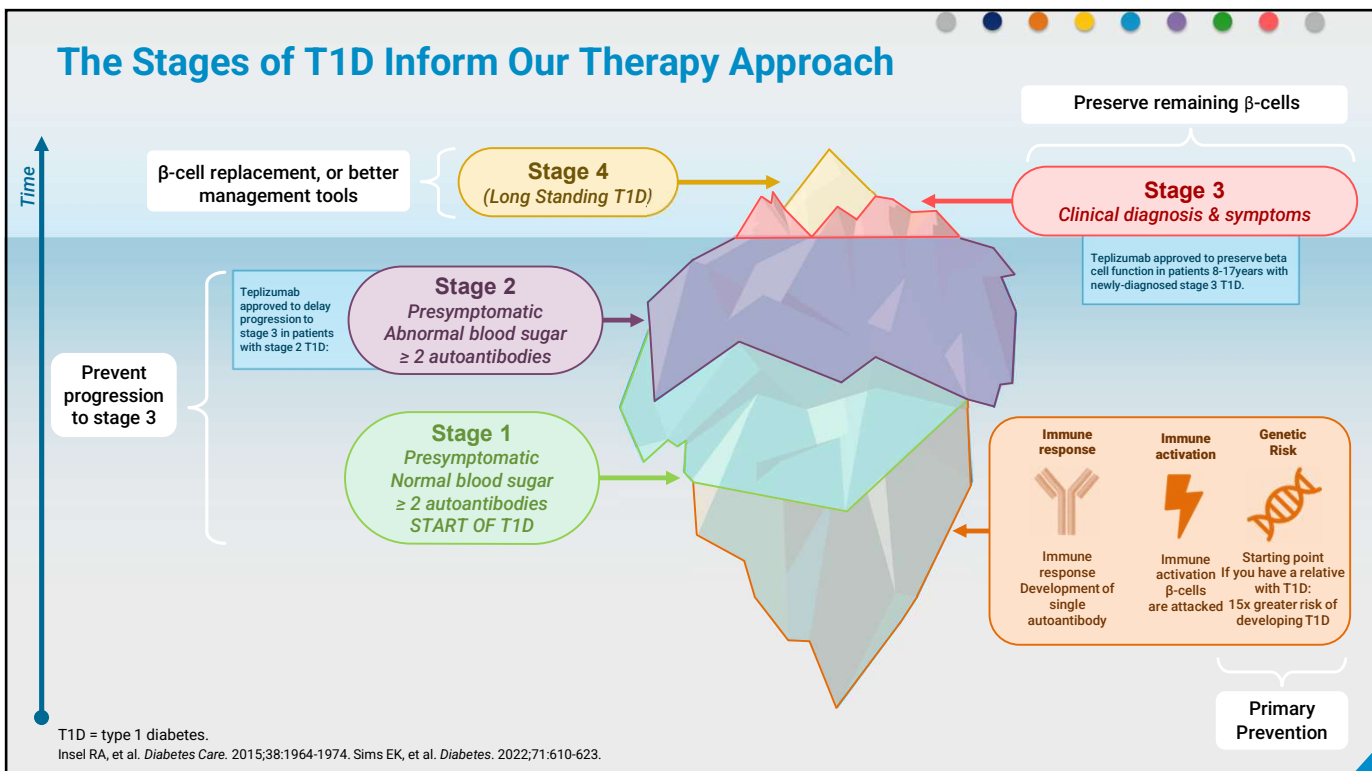
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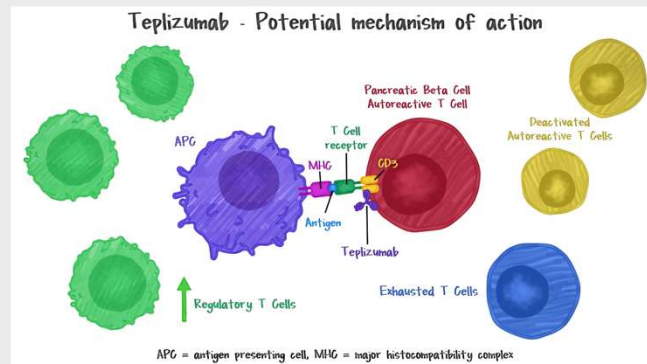


46

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



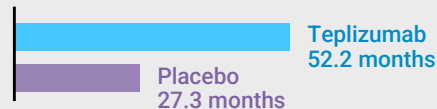
Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021;13:eabc8980. Thakkar S, et al. *touchREV Endocrinol.* 2023;19:22-30. Ramos EL, et al. *N Engl J Med.* 2023;389(23):2151-2161

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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*

Median time to T1D diagnosis
($P = 0.0026$)



More individuals treated with teplizumab remained diabetes free compared with placebo

T1D-free individuals

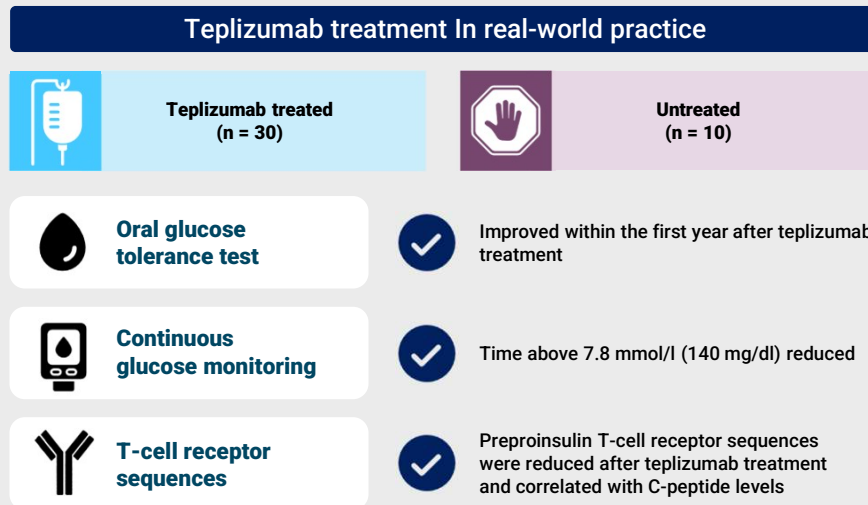


*Delay in progression was longer in certain individuals and individual results may vary.
Herold KC, et al. *N Engl J Med.* 2019;381:603-613. Sims EK, et al. *Sci Transl Med.* 2021;13:eabc8980.

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Teplizumab Treatment for Stage 2 T1D in Real-World Practice

A real-world evaluation of metabolic and immunological outcomes



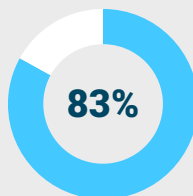
Karakus KE, et al. *Diabetologia*. 2026 (<https://doi.org/10.1007/s00125-025-06646-6>). Accessed 2/4/2026.

49

Survey of patients & caregivers about experience with teplizumab



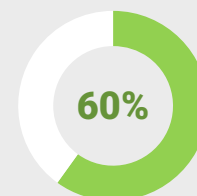
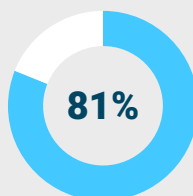
Most people (39 out of 47) agreed they were glad they (or the child they care for) received teplizumab.



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



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



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

14-day course of teplizumab

2-year study



Off-treatment observation phase

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.

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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.

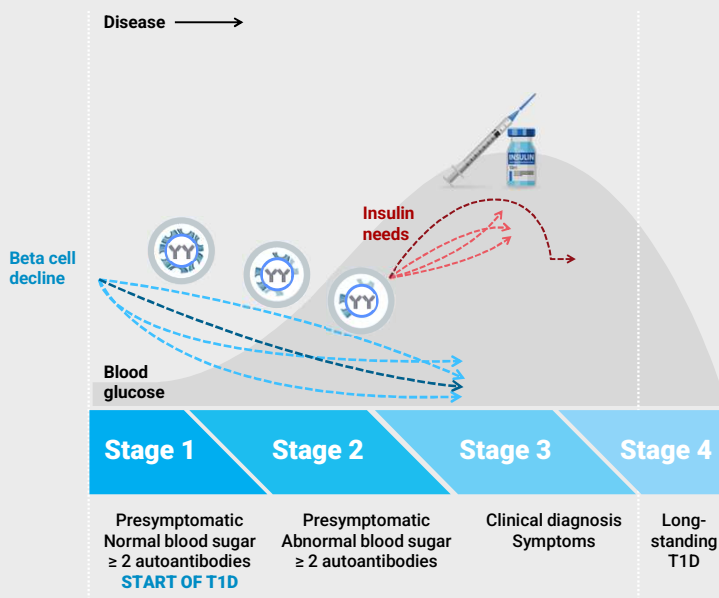
52

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



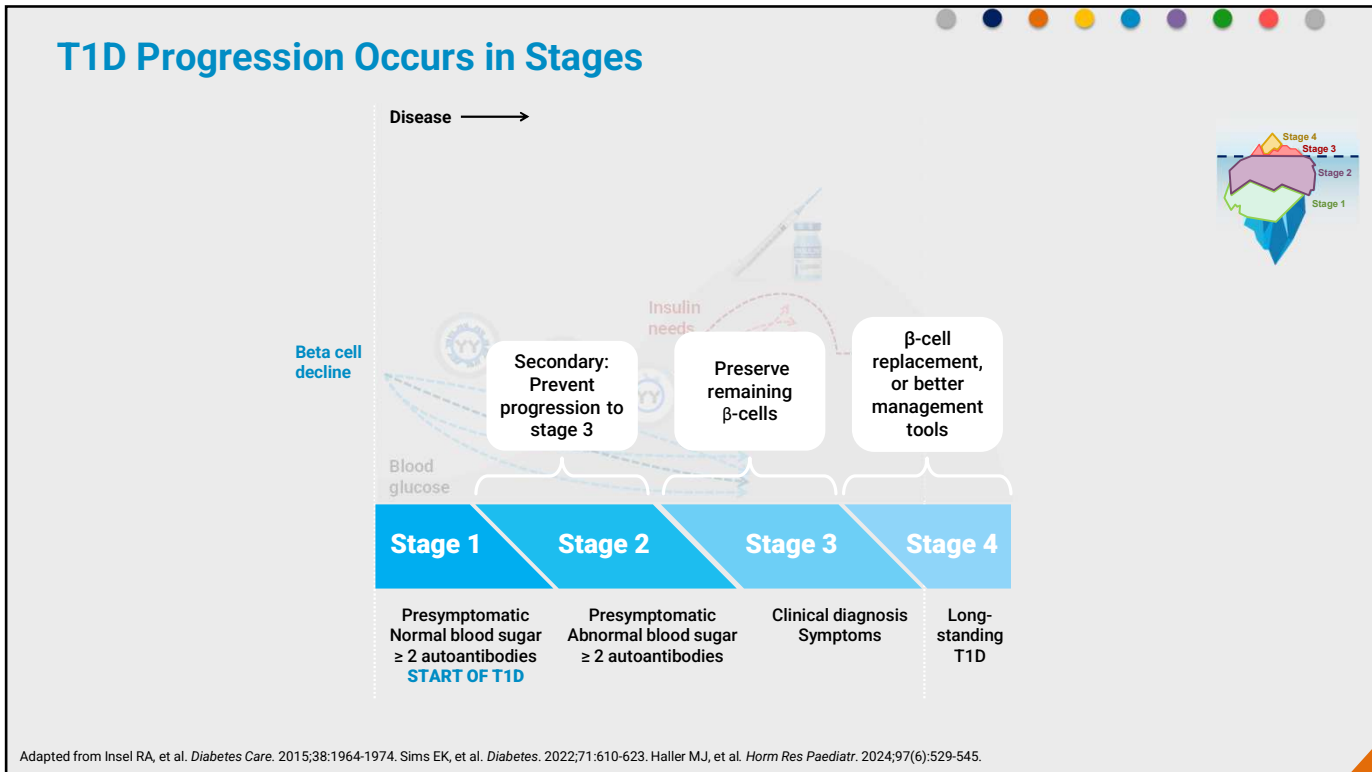
53

T1D Progression Occurs in Stages

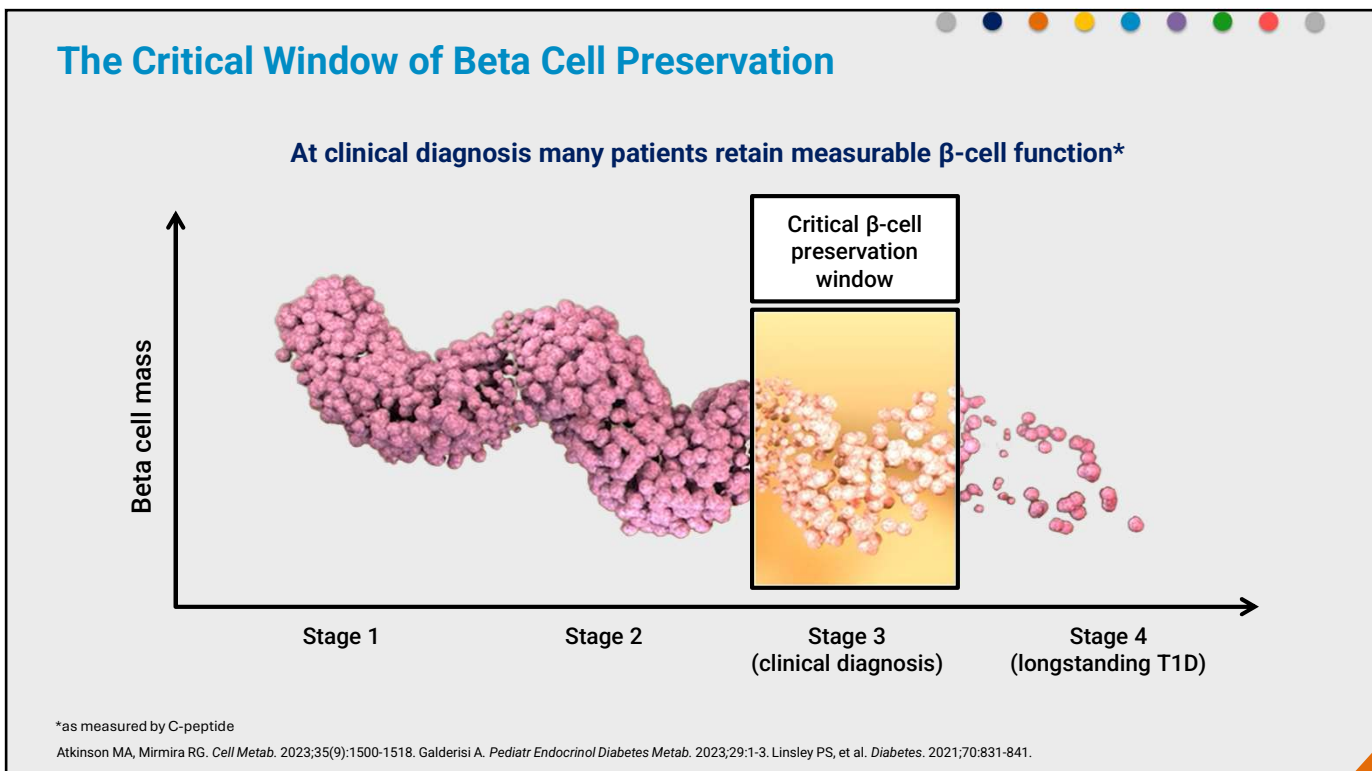


Adapted from Insel RA, et al. *Diabetes Care*. 2015;38:1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Haller MJ, et al. *Horm Res Paediatr*. 2024;97(6):529-545.

54



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56

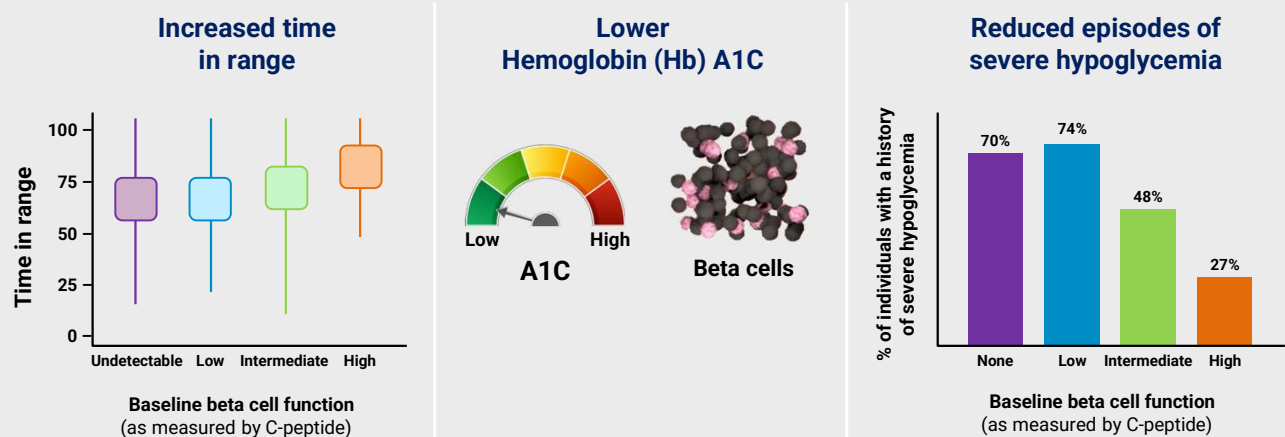
Implications of Higher Baseline Beta Cell Function at Diagnosis

- 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



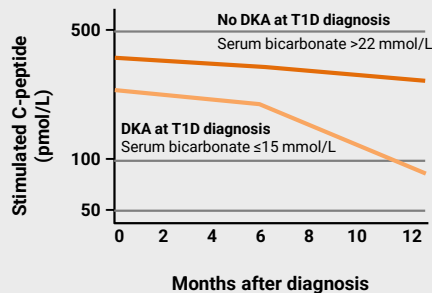
**as compared to individuals with low or undetectable c-peptide*

Fuhr S, 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.

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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.

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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 |
| <i>Stimulated (GST/MMT/OGT)</i> | | | |
| 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 $\mu\text{U/mL}$ (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

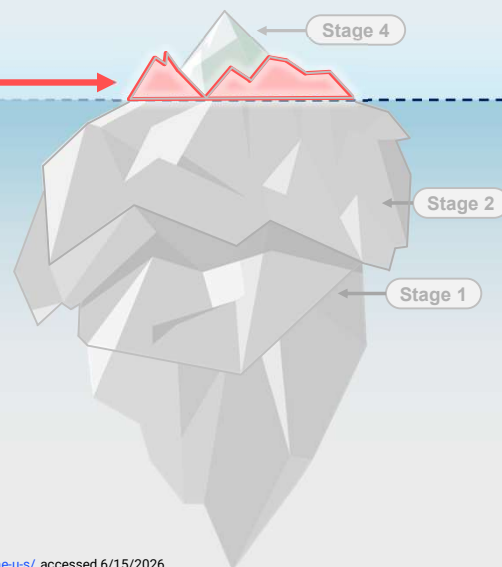
Evans-Molina C, Oram RA. Diabetes. 2024;73(6):8340836. ADA. Diabetes Care. 2026;49(suppl 1):S27-S49.

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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.breakthrough1d.org/news-and-updates/tzield-approved-for-stage-3-t1d-in-the-u-s/>, accessed 6/15/2026.

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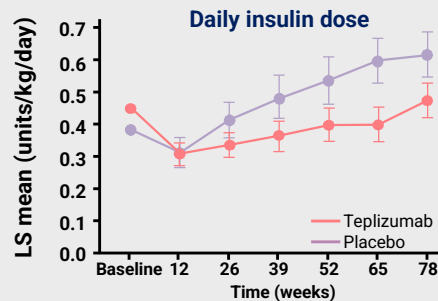
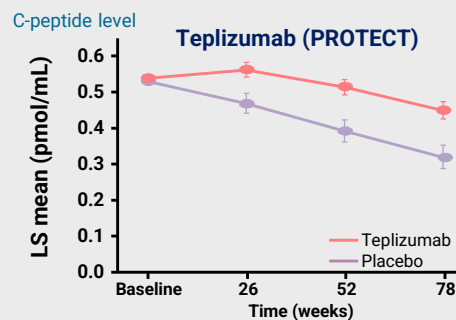
PROTECT Study and Per-Protocol Analysis: Teplizumab in New-Onset (stage 3) T1D

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

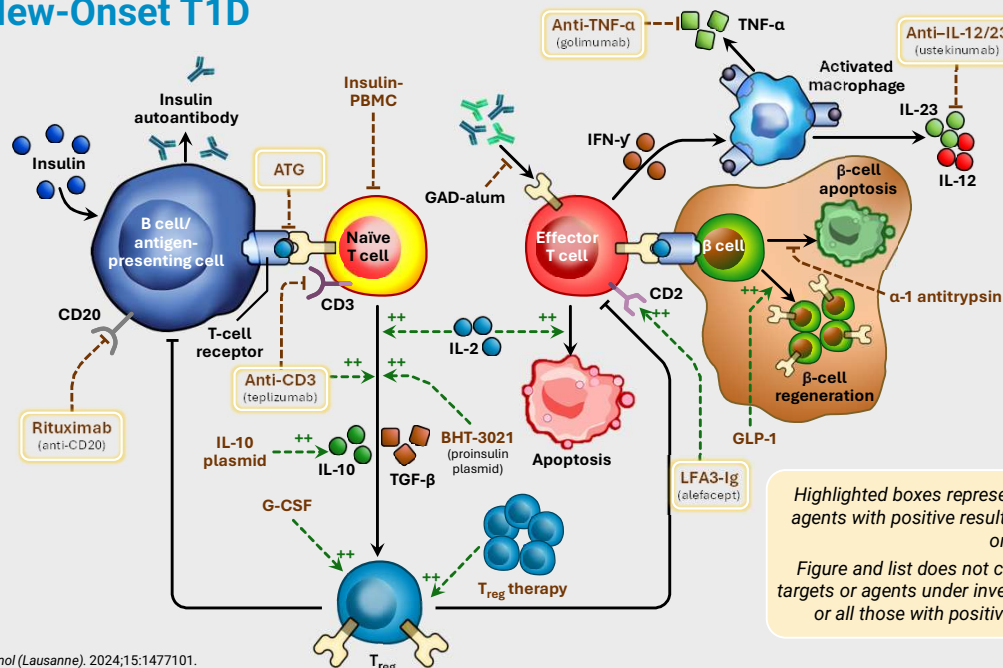


*Secondary endpoints were exploratory and not statistically significant. AEs = adverse events; LS = least-squares.
Ramos EL, et al. *N Engl J Med.* 2023;389(23):2151-2161. Herold KC, et al. *Diabetes.* 2024;73(suppl 1):70-OR.

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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.



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

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.

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Key Ongoing Trials With DMTs in New-Onset T1D

| Agent | Trial name | Trial identifier* |
|---|-------------------------------|-------------------|
| Teplizumab | β ETA 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.breakthrough1d.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 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.

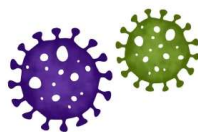
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Pre-Infusion Considerations

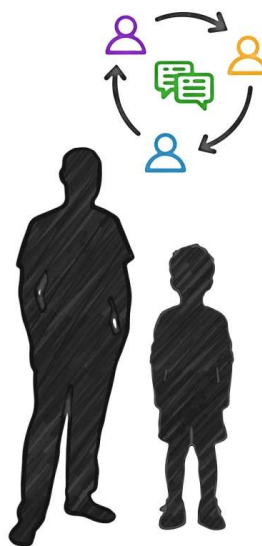


Ensure all appropriate vaccines have been administered

- 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/ μ L
- Lymphocyte count >1000 lymphocytes/ μ L
- Absolute neutrophil count >500 neutrophils/ μ L



Liver enzymes tests

- ALT or AST $<2x$ the ULN
- \dagger 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)

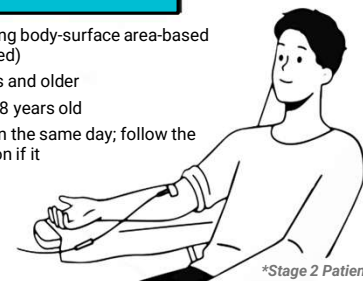
Premedications – typically during first 5 days when risk of AEs is higher

Premedications



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



*Stage 2 Patient

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

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

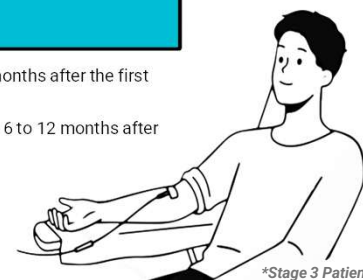
Premedications



| SUN | MON | TUE | WED | THU | FRI | SAT |
|---------------------------------|-----|---------------------------------|---------------------------------|------------------------------------|-----|-----|
| | | Day 1 106 mcg/m ² | Day 2 425 mcg/m ² | Day 3–12 850 mcg/m ² | | |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| Day 3–12 850 mcg/m ² | | | | | | |
| 12 | 13 | 14 | 15 | | | |

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.



*Stage 3 Patient

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

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



Vanessa & Chloe

T1D Caregiver and Patient

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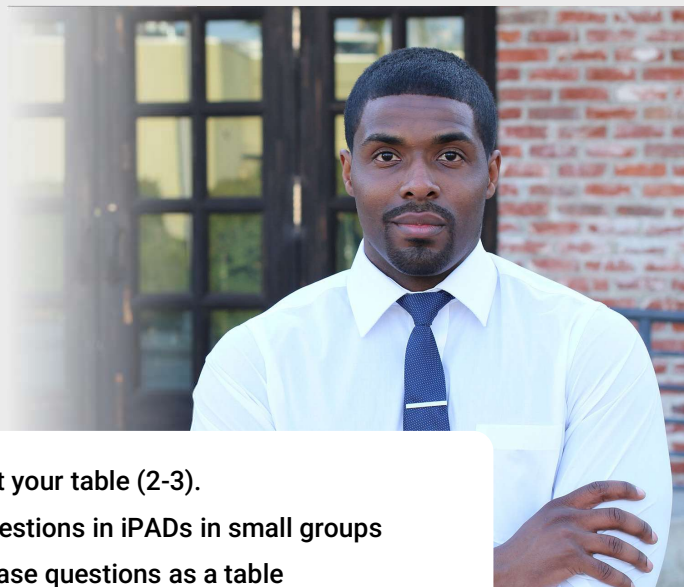
Case #2 and Group Breakout Discussion



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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

All flyers for these resources can be found in your program materials


| <i>Name</i> | <i>Contact</i> |
|---|--|
| Breakthrough T1D: San Diego and Hawaii Chapter | Visit: https://www.breakthrough1d.org/sandiegocahawaii/ |
| Breakthrough T1D Walk in San Diego | Visit: Breakthrough T1D Walk, San Diego, CA - BreakthroughT1D Walk OR Call: 619 – 961 – 7939 (Event coordinator – Samantha Kearney) |
| Rady Children’s Health | Visit: https://www.rchsd.org/programs-services/endocrinology-diabetes/t1d-screenings/ |

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Q & A


Thank you!

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RECEIVE CME/CNE CREDIT

Pre-Test




Post-Test

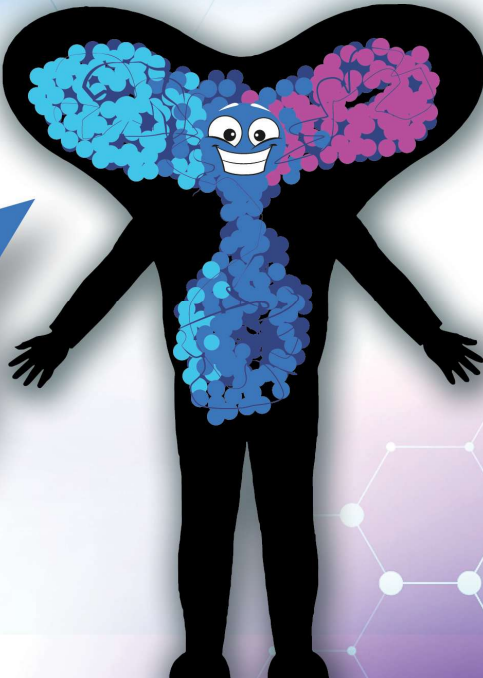



This slide features a blue and purple background with a molecular structure pattern. It includes the DETECT 1D logo at the top left. The main heading is 'RECEIVE CME/CNE CREDIT'. Below this, there are two QR codes: one labeled 'Pre-Test' and one labeled 'Post-Test'. A blue mouse cursor icon is positioned to the left of the Pre-Test QR code, and a white mouse cursor icon is to the right of the Post-Test QR code.

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Please visit
the DETECT T1D Website!
<https://detect-t1d.com/>



This slide features a blue and purple background with a molecular structure pattern. It includes the DETECT 1D logo at the top left. A large blue speech bubble contains the text 'Please visit the DETECT T1D Website!' and the URL 'https://detect-t1d.com/'. Below the speech bubble is a QR code. To the right of the speech bubble is a cartoon character with a black silhouette, a smiling face, and a brain made of blue and pink dots.

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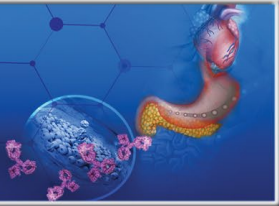
The logo for DETECT1D, featuring the word "DETECT" in pink and "1D" in blue, with a stylized blue and pink molecular structure icon.

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



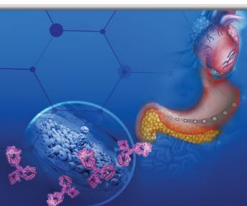
Toolkit

Guidelines and Practice Parameters

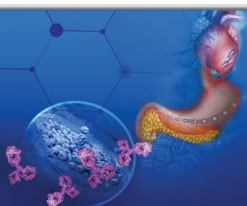
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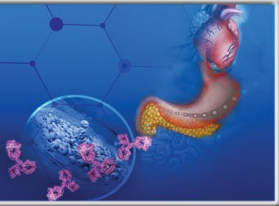
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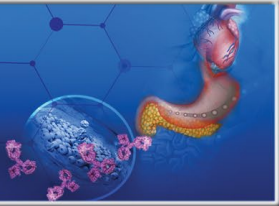
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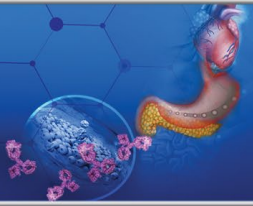
Resources and Societies

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|--|---|
| American Diabetes Association®. Summary of the American Diabetes Association® Type 1 Diabetes Screening & Awareness Roundtable. December 15, 2023. | https://diabetes.org/sites/default/files/2024-04/ADA-T1D-Screening-and-Awareness-Roundtable-Report.pdf |
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| Breakthrough T1D™. Enrolling in Clinical Trials. | https://www.breakthrough1d.org/clinical-trials/ |
| Breakthrough T1D. Type 1 Diabetes Early detection. | https://www.breakthrough1d.org/early-detection/ |
| CASCADE Research Study. Type 1 diabetes and celiac disease screening for children in the state of Washington. | https://clinicaltrials.gov/study/NCT04677699 |
| Sanford Research. PLEDGE Pediatric Screening Study. | https://research.sanfordhealth.org/fields-of-research/diabetes/pledge |
| Type 1 Diabetes TrialNet. For Healthcare Providers: TrialNet Recommendations for Clinicians. | https://www.trialnet.org/healthcare-providers |
| Type 1 Diabetes TrialNet. Resources for T1D screening & national T1D screening program. | https://www.trialnet.org/ |

The logo for DETECT1D, featuring the word "DETECT" in blue and "1D" in white, with a stylized blue and white graphic element.

Shifting the T1D Paradigm:

Early Detection, Disease Modification, and Beta Cell Preservation



University of Colorado – Barbara Davis Center for Diabetes. Ask the experts for early T1D answers and guidance.

<https://www.asktheexperts.org/>

University of Colorado – Barbara Davis Center for Diabetes. Screen TO Prevent Type 1 Diabetes – stopT1D.

<https://www.stopt1dprogram.org/>