# Shifting the Paradigm

## Screening and Immunotherapy for Pre-symptomatic Type 1 Diabetes

From emergency diagnosis to early identification, monitoring, and disease modification



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# Today’s Roadmap

By the end of this session, participants will be able to move from early identification to practical clinical action.

1

### REDEFINE T1D

Explain the shift from an acute diagnosis to a staged, chronic autoimmune disease.

2

### SCREEN + STAGE

Identify who to screen, which autoantibodies to test, and how Stage 1–3 are defined.

3

### MONITOR RISK

Translate a positive screen into confirmation, metabolic surveillance, and referral.

4

### INTERVENE

Describe Stage 2 immunotherapy selection, access, infusion workflow, and safety monitoring.

5

### SUPPORT FAMILIES

Recognize psychological burden and reduce “anxiety without action.”

6

### APPLY

Use clinical scenarios to make screening, monitoring, and treatment decisions.

**Screen → Confirm → Stage → Monitor → Intervene → Support**

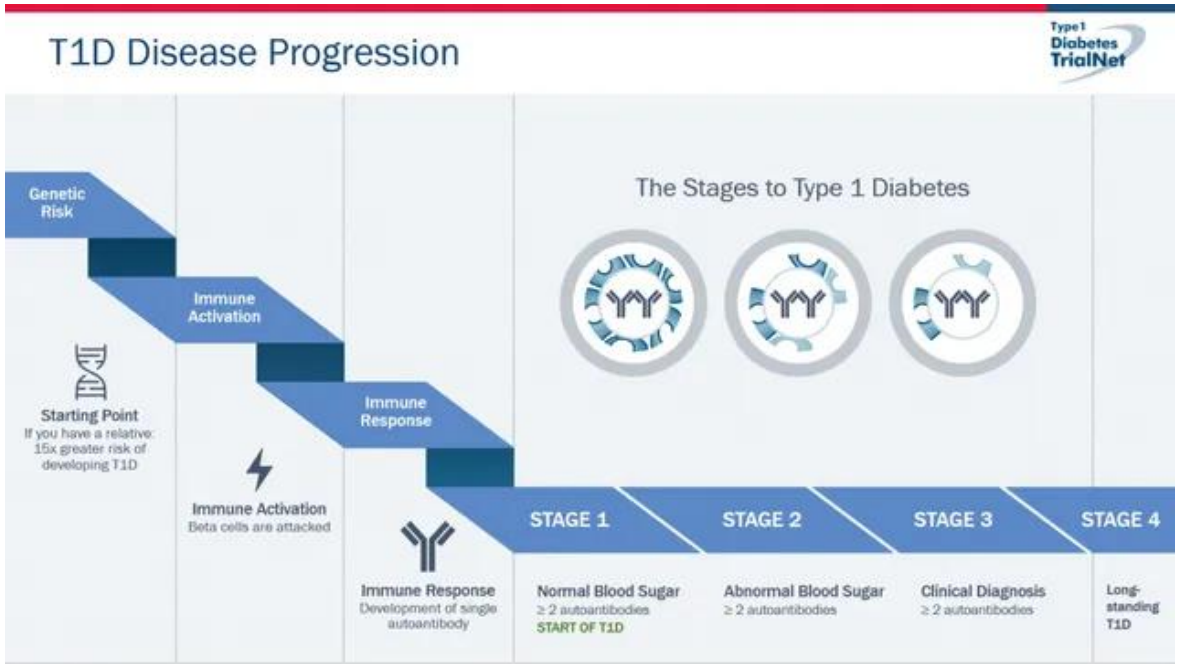
# Why this topic matters now

Type 1 diabetes can be identified months to years before symptomatic hyperglycemia.

U.S. children still commonly present in diabetic ketoacidosis (DKA) at diagnosis.

Autoantibody screening creates a “silent window” for education, surveillance, and intervention.

Teplizumab has moved disease-modifying therapy into routine clinical conversations.




Sources: CDC 2026; ADA Standards of Care 2026

# The paradigm shift: when does T1D begin?

**TRADITIONAL VIEW**
**Symptoms → hyperglycemia → diagnosis → insulin**

**CURRENT VIEW**
**Autoimmunity → Stage 1 → Stage 2 → Stage 3**

**Clinical opportunity moves upstream**

Earlier diagnosis

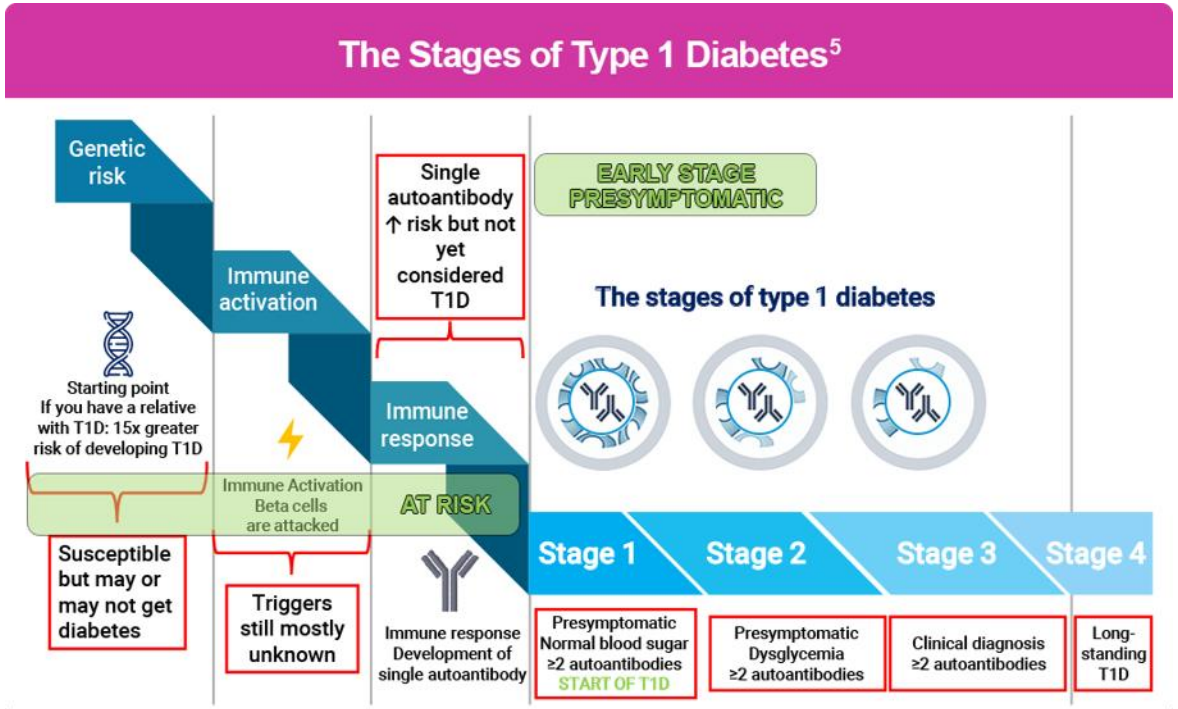
DKA prevention

Time for education

Eligibility for trials / approved therapy

# T1D is a continuum

Genetic / immune susceptibility → Islet autoimmunity → Stage 1 Normoglycemia → Stage 2 Dysglycemia → Stage 3 Clinical T1D




β-cell function declines over time; the pace is highly variable.

# Staging pre-symptomatic type 1 diabetes

ADA Standards of Care 2026

| Stage | Autoimmunity | Glycemia | Clinical state |
|---|---|---|---|
| **Stage 1** | >=2 islet autoantibodies | Normoglycemia | No symptoms |
| **Stage 2** | Usually >=2 islet autoantibodies | Dysglycemia | No symptoms |
| **Stage 3** | Autoantibodies may persist or wane | Diabetes-range hyperglycemia | Symptoms may be present |

Stage 2 examples: FPG 100–125 mg/dL; 2-h OGTT 140–199 mg/dL; A1C 5.7–6.4% or ≥10% longitudinal rise.

Source: ADA Standards of Care in Diabetes—2026, Section 2

# The four clinically useful islet autoantibodies

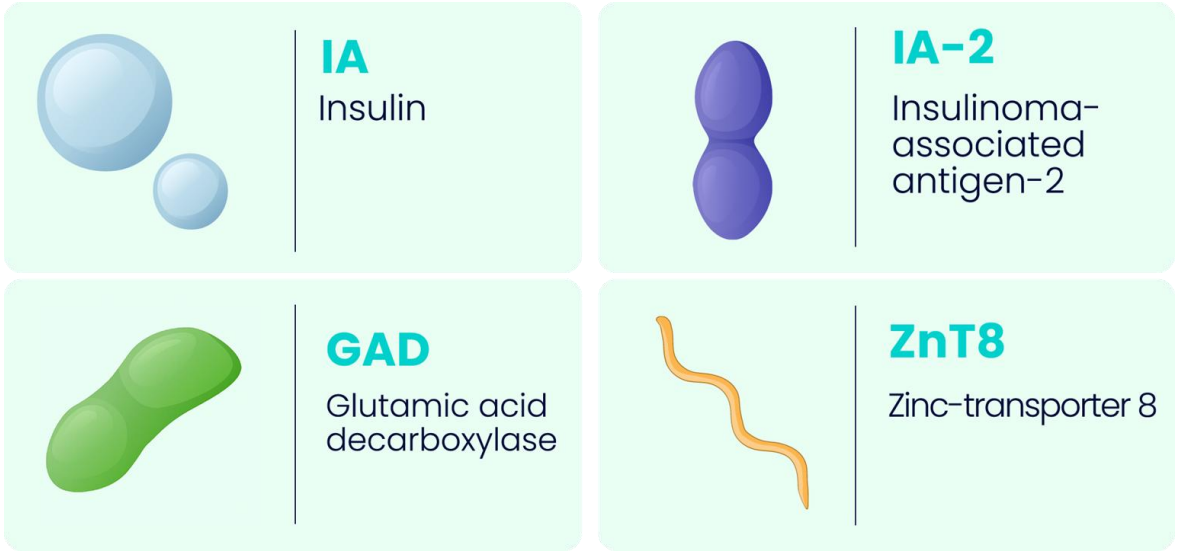
IAA / mIAA — insulin autoantibody; particularly informative in young children.

GADA — glutamic acid decarboxylase autoantibody.

IA-2A — islet antigen-2 autoantibody; single confirmed IA-2A carries higher progression risk.

ZnT8A — zinc transporter 8 autoantibody.

Positive results should be confirmed on a second sample before assigning persistent status.



# Autoantibodies convert uncertainty into quantifiable risk

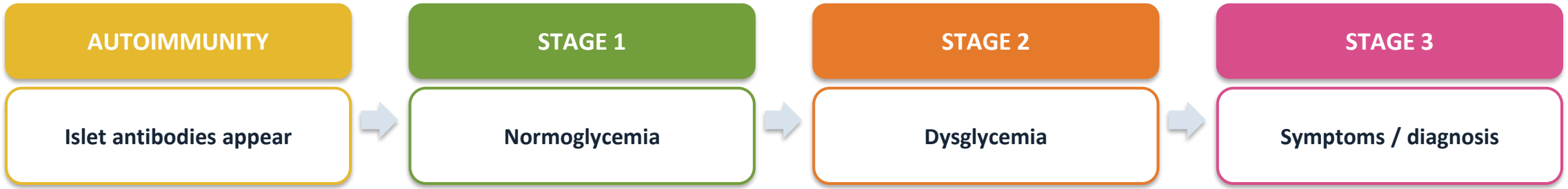
| Persistent single autoantibody | Stage 1 | Stage 2 |
| --- | --- | --- |
| ~14–15%<br>10-year pediatric risk | ~44%<br>5-year risk overall | ~60% by 2 years<br>~75% by 5 years |

Risk is modified by age at seroconversion, antibody number/type/titer, genetics, and glycemic trajectory.

Source: ADA Standards of Care in Diabetes—2026, Section 2

# Finding the “silent window”

The opportunity exists before symptoms—if we know where to look




**THE SILENT WINDOW**

1. Screen
2. Educate
3. Monitor
4. Intervene

**The goal is not simply to find antibodies—it is to create a safe pathway after the result.**

# Who should we screen today?

Start with risk—but understand who a risk-based strategy misses

## KNOWN HIGHER RISK

| | | |
|---|---|---|
| 1 | **Family history** | First-degree relative with T1D |
| 2 | **Known genetic risk** | Identified through research / risk programs |
| 3 | **Autoimmune context** | Consider the broader clinical picture |

## THE LIMITATION

**Most people who develop T1D do not have an affected relative.**

**TARGETED SCREENING** → **EMERGING POPULATION APPROACHES**

**Before ordering: know how you will confirm, stage, refer, and monitor a positive result.**

# Targeted vs population-based screening

## TARGETED / HIGH-RISK

- Higher pretest probability
- More efficient per test
- Easy entry point: family history / genetic risk
- Misses many future T1D cases

## POPULATION-BASED

- Finds children without family history
- Potential to reduce DKA broadly
- Requires scalable confirmation + monitoring
- Cost-effectiveness and implementation still evolving

# Screening strategy #1: open the conversation

A 60-second pretest conversation can prevent confusion after the result

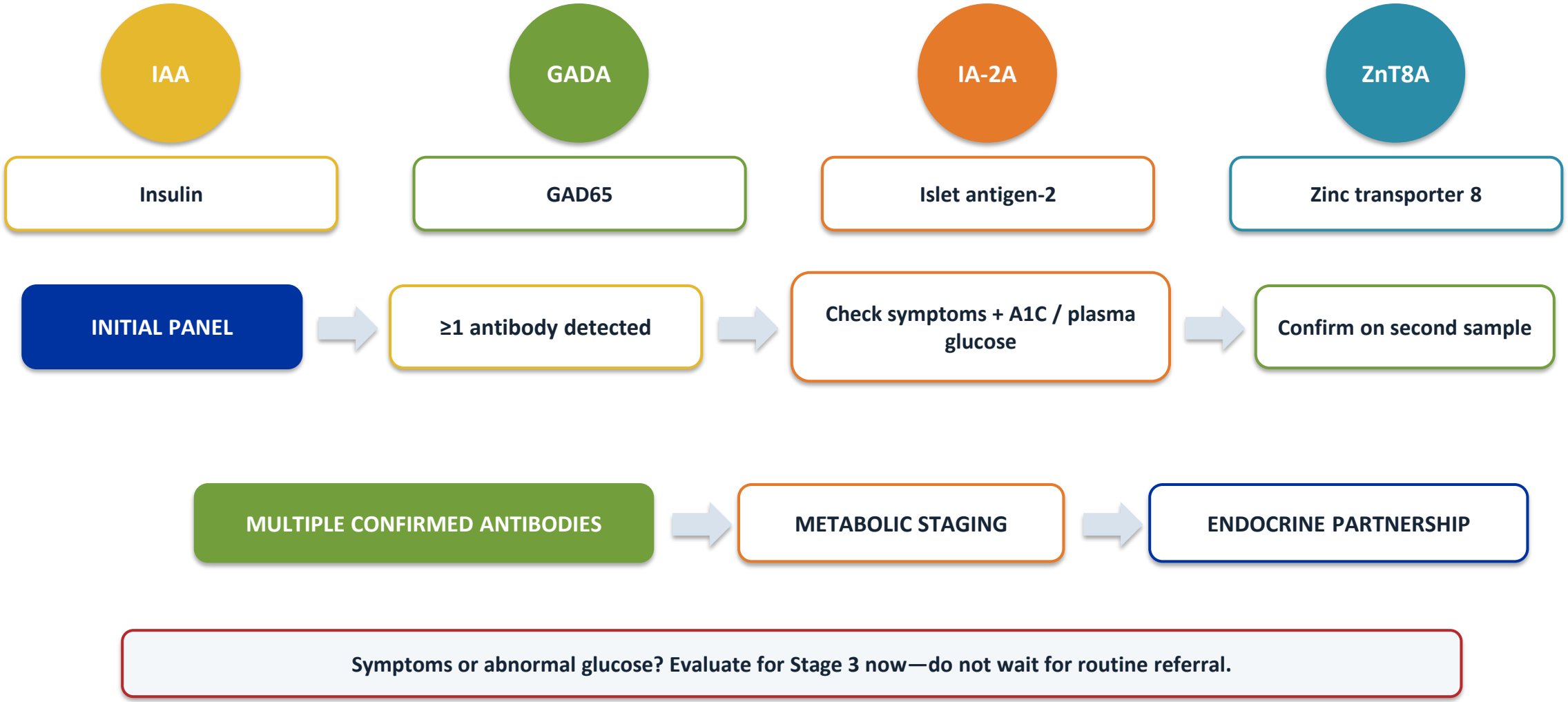
| | | |
|---|---|---|
| 1 | **NORMALIZE** | “T1D can now be detected before symptoms.” |
| 2 | **IDENTIFY RISK** | Family history • known risk • family interest |
| 3 | **EXPLAIN** | Positive ≠ symptomatic diabetes; confirmation is required |
| 4 | **PREVIEW NEXT STEPS** | Confirm → stage → monitor → refer → consider therapy |

**PRETEST SCRIPT**

“This test looks for immune markers that can appear before blood sugar becomes high. If positive, we confirm the result and decide how closely to monitor.”

# Screening strategy #2: test the right markers

Use the antibody panel to open the correct downstream pathway



# A simple way to interpret the first screen

| | | |
|---|---|---|
| **0 antibodies** | **No current evidence of islet autoimmunity** | Counsel; repeat strategy individualized |
| **1 antibody** | **At risk** | Confirm → metabolic check → age/risk-based follow-up |
| **>=2 antibodies** | **Early-stage T1D likely** | Confirm → stage → educate → refer/monitor |

# Early detection changes the diagnosis experience

**Without prospective monitoring**

**30–40% of U.S. children have DKA at first T1D diagnosis (CDC)**

**With structured high-risk monitoring**

**DKA at diagnosis can be dramatically reduced; DPT-1 monitoring reported ~4%**

**Earlier diagnosis = less physiologic crisis + more time for family preparation**

Sources: CDC 2026; ADA 2026

# Early detection changes the family experience

Move from crisis compression to planned preparation

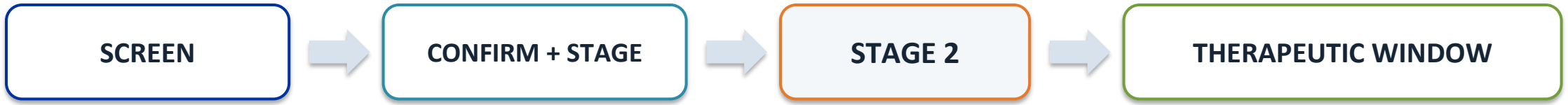
| UNEXPECTED STAGE 3 DIAGNOSIS | | PRESYMPTOMATIC IDENTIFICATION | |
|---|---|---|---|
| **Hours** | Symptoms / DKA | **Time** | Learn symptoms |
| **Same day** | Insulin + skills | **Repetition** | Practice skills |
| **Immediately** | School / caregiver plan | **Planning** | School / work / travel |
| **At once** | Fear + grief + decisions | **Support** | Process emotions + decisions |

**TRADE-OFF**

**Earlier knowledge can reduce crisis—but can also create anticipatory anxiety. Pair screening with an action plan + psychosocial support.**

# The therapeutic window is now clinically meaningful

Stage 2 changes the conversation from prediction alone to prediction + intervention




**APPROVED THERAPY**

Teplizumab can delay progression for eligible patients

**CLINICAL TRIALS**

Immune-modulating, antigen-specific, cellular, and combination approaches

**TIME HAS VALUE**

More preparation • more childhood without insulin • opportunity to preserve function

**Screening now has a potential therapeutic consequence.**

# Type 1 Diabetes Screening, Monitoring, and Staging Algorithm

From Autoimmunity to Action

**Key Goals:**
- Identify early
- Monitor appropriately
- Prevent DKA
- Open the therapeutic window

## SCREENING

**Islet autoantibodies (4 antibodies)**

- Insulin (mIAA)
- GAD65 (GADA)
- IA-2 (IA-2A)
- ZnT8 (ZnT8A)

After 1st **positive test**, repeat all **4 antibodies in 3 months** to confirm **persistence.**

## 1 ANTIBODY PRESENT

Monitor for progression with age-based frequency.

**< 3 years old**
- Recheck all antibodies every 6 months for 3 years
- If no progression, stop.

**> 3 years old**
- Recheck all antibodies every 12 months for 3 years
- If no progression, stop.

## ≥ 2 ANTIBODIES STAGING OGTT

Perform metabolic assessment:
- HbA1c
- Random glucose (or fasting)
- Oral Glucose Tolerance Test (OGTT)*

**Stage 1**
**Normoglycemia**

≥ 2 autoantibodies
Normal glucose metabolism

## STAGE 2
Dysglycemia

≥ 2 autoantibodies
Abnormal glucose metabolism
(presymptomatic)

Consider immunotherapy (e.g., teplizumab) and/or clinical trials.

## STAGE 3
Clinical T1D

≥ 2 autoantibodies
Hyperglycemia with symptoms
Requires insulin

Goal: Prevent progression to Stage 3 and reduce DKA at diagnosis.

### SCREENING FREQUENCY – 1 ANTIBODY

| Age | Screening interval (repeat all 4 antibodies) | Stop if no progression |
|---|---|---|
| < 3 years | Every 6 months for 3 years | Yes |
| > 3 years | Every 12 months for 3 years | Yes |

### MONITORING FREQUENCY – STAGE 1

| Age | Monitoring (HbA1c, random glucose ± OGTT) |
|---|---|
| < 3 years | Every 6 months × 3 years |
| 3 – 9 years | Every 6 months |
| > 9 years | Every 12 months |

### MONITORING FREQUENCY – STAGE 2

| Age | Monitoring (HbA1c, random glucose ± OGTT) |
|---|---|
| < 18 years | Every 3 months |
| ≥ 18 years | Every 6 months |

### RISK OF PROGRESSION TO STAGE 3 T1D

| Autoantibodies | 10-year risk | 15-year risk |
|---|---|---|
| 1 positive (persistent) | 14.5% | — |
| 2 positive | ~ 85% | — |
| 3 positive | ~ 92% | — |

(IA-2 = 40.5%, IAA (insulin) = 13%, GAD = 12.9% at 10 years)

### HOME GLUCOSE MONITORING (DURING ILLNESS)

Check blood glucose 3 times daily with illness

| | |
|---|---|
| **Stage 1** | • Fasting, 2 hours post-prandial OR before meals × 3 times daily<br>• Call if fasting >110 mg/dL OR 2-hour >140 mg/dL |
| **Stage 2** | • Fasting, 2 hours post-prandial OR before meals × 3 times daily<br>• Call if fasting >130 mg/dL OR 2-hour >200 mg/dL |

### ORAL GLUCOSE TOLERANCE TEST (OGTT)*

1.75 grams per kg (up to 75 grams)

| Stage | Fasting (0 min) | 1 hour | 2 hours |
|---|---|---|---|
| **Stage 1** (Normoglycemia) | < 100 mg/dL | < 155 mg/dL | < 140 mg/dL |
| **Stage 2** (Dysglycemia) | 100–125 mg/dL (impaired fasting) | 155–199 mg/dL (impaired glucose tolerance) | 140–199 mg/dL (impaired glucose tolerance) |
| **Stage 3** (T1D) | ≥ 126 mg/dL (diabetes range) | ≥ 200 mg/dL | ≥ 200 mg/dL |

*OGTT interpretation based on consensus guidelines. Values may vary by source; clinical judgment and local endocrinology consultation recommended.

# Stage 1 T1D: monitoring algorithm

Confirmed islet autoimmunity + normoglycemia → surveillance designed to detect progression before symptoms

**≥2 CONFIRMED ISLET AUTOANTIBODIES** → **Assess metabolic status**
**A1C + plasma glucose**
**± OGTT** → **NORMOGLYCEMIA**
**= STAGE 1 T1D** → **Begin structured monitoring + education**

## AGE-BASED METABOLIC SURVEILLANCE

**<3 years**
**A1C / glucose**
**~ every 3 months**

**3–9 years**
**A1C / glucose**
**~ every 6 months**

**>9 years**
**A1C / glucose**
**~ every 12 months**

**At each surveillance point:**
**Symptoms? rising A1C/glucose? abnormal home values? concerning trajectory?**

**YES → repeat/advance metabolic staging**
**Consider OGTT + endocrine review**

**Dysglycemia confirmed?**
**→ STAGE 2 pathway**

**NO → continue planned surveillance**

Individualize frequency for younger age, higher-risk antibody profile, changing glycemia, symptoms, or specialty recommendation.

# Stage 1 T1D: “At Every Visit” pathway

Monitoring is more than laboratory surveillance

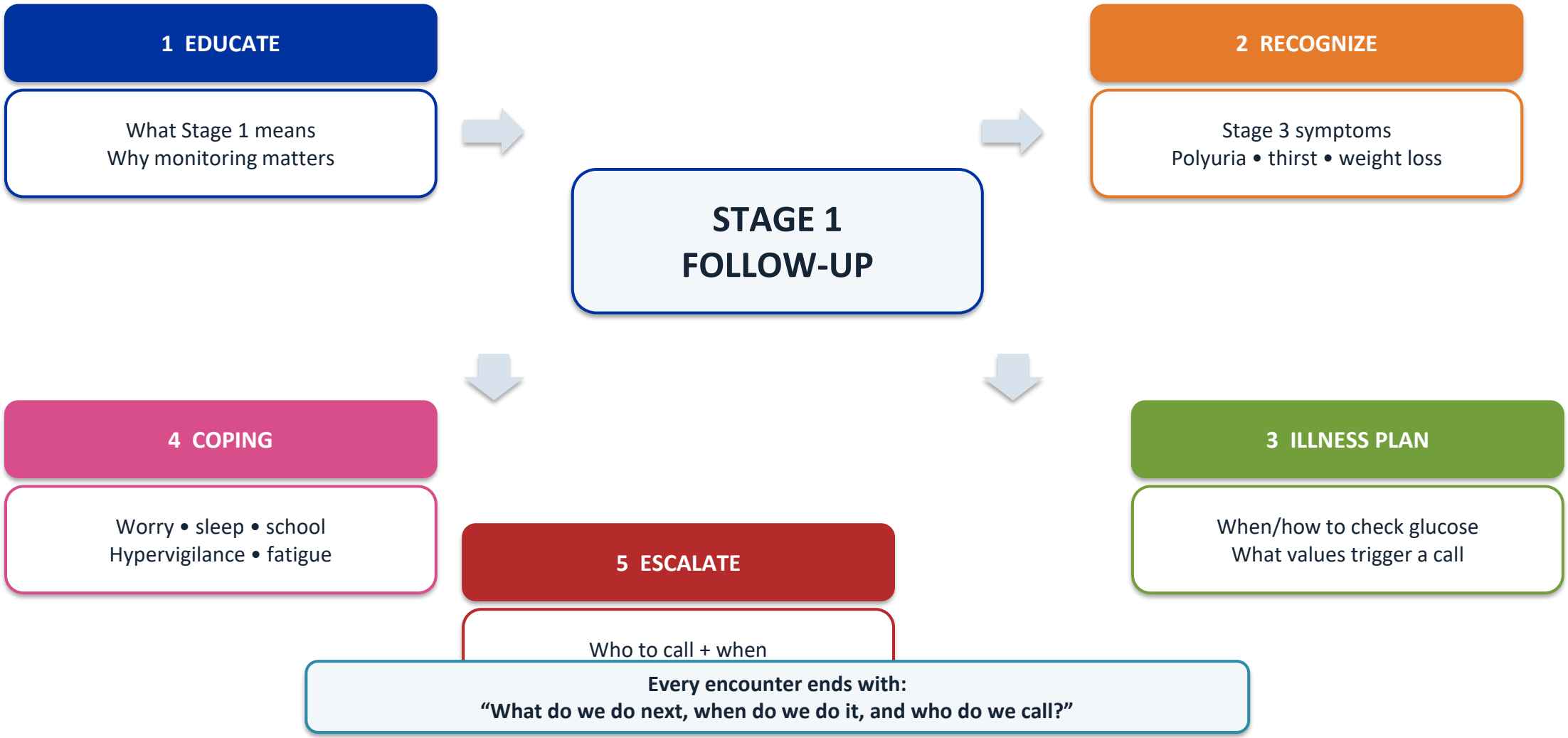
**AT EVERY VISIT / CONTACT**

| | | |
|---|---|---|
| 1 | **Family education** | Reinforce what Stage 1 means, expected uncertainty, and the purpose of monitoring. |
| 2 | **Symptoms of Stage 3** | Review polyuria, polydipsia, nocturia/enuresis, weight loss, fatigue, vomiting, and dehydration. |
| 3 | **Illness glucose plan** | During illness or concerning symptoms: check glucose as instructed; know thresholds for same-day contact. |
| 4 | **Psychosocial assessment** | Ask about worry, sleep, school impact, hypervigilance, testing fatigue, and child/family coping. |
| 5 | **When to contact endocrinology** | New symptoms, rising/abnormal glucose, meaningful A1C change, ketones, vomiting/dehydration, or family concern. |

**Every result should end with: “Here is what we do next, when we do it, and who you call.”**

# Stage 1 T1D: the “At Every Visit” safety pathway

A consistent five-part check reduces uncertainty and keeps families prepared



# Monitoring Stage 1 T1D

Match surveillance intensity to age and evidence of progression

**CONFIRMED STAGE 1**
**≥2 autoantibodies + normoglycemia**

→

**Choose monitoring cadence by age**

→

**Escalate if symptoms or glycemia changes**

| <3 YEARS | 3–9 YEARS | >9 YEARS |
|---|---|---|
| A1C / glucose about every 3 months | A1C / glucose about every 6 months | A1C / glucose about every 12 months |

| | | | |
|---|---|---|---|
| ILLNESS / SYMPTOMS | Check glucose as instructed + use rapid-access plan | CHANGING TRAJECTORY | OGTT / endocrine review |

Individualize for age, antibody profile, A1C/glucose trajectory, symptoms, and specialty recommendations.

# Monitoring Stage 2 T1D

High near-term progression risk → closer metabolic surveillance + treatment discussion

**STAGE 2**
**Autoimmunity + dysglycemia**
**No classic symptoms**

→ **MONITOR** → **ACT ON CHANGE** → **DISCUSS OPTIONS**

| A1C | OGTT | SMBG / CGM | Symptoms |
|---|---|---|---|
| ~ every 6 months<br>Trend matters | ~ annually<br>Key staging tool | When useful<br>Adds context | Every contact<br>Do not wait for labs |

**Increase intensity for younger age • worsening glycemia • symptoms • treatment planning**

**At Stage 2: discuss teplizumab eligibility + clinical trials with interested patients/families**

# Primary care and endocrinology: a shared-care model

| PRIMARY CARE | ENDOCRINOLOGY / T1D CENTER | FAMILY / PATIENT |
| --- | --- | --- |
| Identify risk | Confirm/stage | Know symptoms |
| Open screening conversation | Risk stratify | Know who to call |
| Order/route screening | Set monitoring plan | Complete monitoring |
| Recognize symptoms | Evaluate therapy/trials | Share goals & burden |
| Support adherence & coping | Coordinate Stage 3 transition | Participate in decisions |

# From screening to intervention

Immunotherapy in pre-symptomatic Type 1 diabetes

# How to frame teplizumab benefit with families

Use a shared-decision conversation—not a promise

**AVOID**

**“This prevents diabetes.”**

**USE**

**“This can delay progression to Stage 3 for some people.”**

## WHAT CAN DELAY MEAN?

| CHILDHOOD | PREPARATION | BETA-CELL FUNCTION | CHOICE |
|---|---|---|---|
| More time before insulin | Time to learn + plan | Potential preservation | Family values matter |

**Benefit is meaningful—but variable. Continue monitoring after treatment.**

# How to frame benefit with families

| | |
|---|---|
| **NOT** | “This prevents diabetes.” |
| **BETTER** | “This treatment can delay progression to Stage 3 for some people.” |
| **VALUE OF TIME** | More childhood without insulin • more preparation • more preserved beta-cell function |

# Stage 2 immunotherapy: patient-selection checklist

Before treatment, confirm both clinical eligibility and readiness

| | | | | | |
|---|---|---|---|---|---|
| ✓ | **Stage 2 confirmed** | Persistent islet autoimmunity + dysglycemia; no Stage 3 | ✓ | **Comorbidities** | Identify factors increasing treatment risk |
| ✓ | **Age / indication** | Check current FDA label | ✓ | **Logistics** | 14 consecutive treatment days are feasible |
| ✓ | **Baseline safety** | CBC • liver tests • infection assessment | ✓ | **Shared decision** | Benefit, burden, uncertainty, alternatives |
| ✓ | **Vaccines** | Review timing before treatment | ✓ | **After treatment** | Monitoring continues; progression remains possible |

**READY TO PROCEED?**

# Access: the clinical work starts before Day 1

A 14-day treatment course succeeds or fails on logistics

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| **DOCUMENT** | **AUTHORIZE** | **SITE** | **SCHEDULE** | **SUPPORT** | **READY** |
| Stage 2 criteria | Payer approval | Infusion location | 14 consecutive days | Travel • school • work | Labs + vaccines |

**COMMON BARRIERS**

- **Travel / lodging**
- **Weekend coverage**
- **School / work**
- **Infusion capacity**

**Plan barriers before Day 1—not after the first infusion.**

Patient-support resources may help with navigation; clinical decisions remain independent.

# Stage 2 teplizumab infusion: 14 consecutive days

| Day 1 | Day 2 | Day 3 | Day 4 | Days 5–14 |
|---|---|---|---|---|
| 65 mcg/m² | 125 | 250 | 500 | 1030 mcg/m² |

**IV infusion over at least 30 minutes • BSA-based dosing • no 2 doses on the same day**

Premedicate for the first 5 days with antipyretic/NSAID + antihistamine; consider antiemetic.

Source: Current TZIELD Stage 2 dosing information, accessed Oct 2026

# Before the first infusion: a pre-treatment safety check

Complete the clinical checklist before Day 1

| | | |
|---|---|---|
| ✓ | **CBC + differential** | Review counts / treatment thresholds |
| ✓ | **Liver panel** | ALT • AST • bilirubin |
| ✓ | **Infection screen** | Active serious infection? EBV/CMV per label |
| ✓ | **Vaccinations** | Confirm timing of live / inactivated / mRNA vaccines |
| ✓ | **Pregnancy / lactation** | When clinically applicable |
| ✓ | **Family action plan** | Fever • rash • respiratory symptoms • who to call |

Use current prescribing information for exact thresholds and precautions.

**GO**

Checklist complete
No unresolved safety concern

**PAUSE**

Abnormal labs / infection
/
vaccine timing issue

# What are we watching for during treatment?

| | |
|---|---|
| **Cytokine release syndrome** | Fever, nausea/vomiting, fatigue, headache, myalgia/arthralgia; often early in course |
| **Lymphopenia** | Expected/common; monitor counts and recovery; prolonged severe lymphopenia requires action |
| **Infection / viral reactivation** | Monitor during and after treatment; current label includes EBV/CMV precautions |
| **Liver injury** | Monitor ALT/AST/bilirubin; follow label stopping thresholds |
| **Hypersensitivity** | Rash, urticaria, angioedema, bronchospasm, serum-sickness-like reactions |

Source: Current TZIELD prescribing information, accessed Oct 2026

# Set expectations before the IV is placed

A clear anticipatory plan reduces anxiety and unnecessary emergency utilization

**BEFORE**

Why treat?
What benefit is realistic?
Who do we call?

**DURING**

Short-term symptoms may occur
Know expected vs urgent
14-day commitment

**AFTER**

Monitoring continues
Progression can still occur
Keep symptom plan active

**VISIBLE ACTION PLAN**

- **After-hours contact**
- **Fever / rash / respiratory symptoms**
- **Glucose / symptom thresholds**
- **When to seek urgent care**

# The psychological paradox of early detection

Screening trades an unexpected crisis for anticipatory uncertainty

| BENEFIT | BURDEN |
| --- | --- |
| ✓ Time to prepare | ! Worry / hypervigilance |
| ✓ Reduced emergency presentation | ! Guilt or altered parenting |
| ✓ Education before crisis | ! Child may feel “sick” while well |
| ✓ Potential treatment window | ! Repeated-test fatigue |

**CLINICAL RESPONSE**

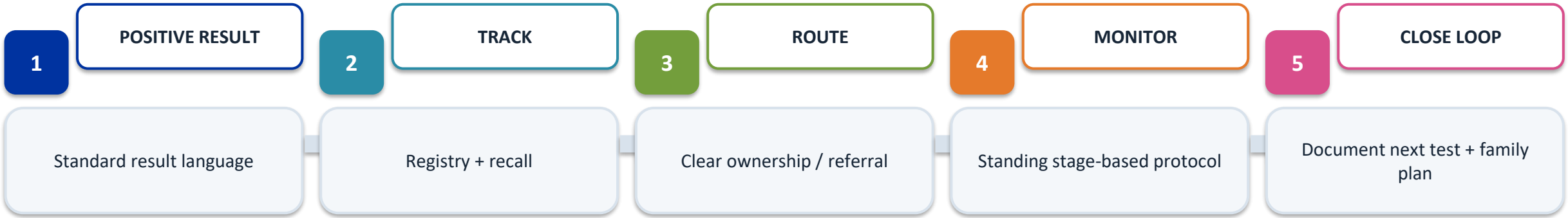
**Pair risk information with a concrete action plan + psychosocial support.**

# Avoid “anxiety without action”

1. Give a clear risk category—not vague “positive” language.
2. Pair every result with the next action and time frame.
3. Teach symptoms + exact contact/escalation instructions.
4. Limit unnecessary testing; use a planned cadence.
5. Screen for distress and normalize behavioral-health support.
6. Revisit goals and burden as risk changes.

# Prevent provider fatigue: build the system, not heroic workarounds

Screening creates longitudinal work—standardize it




**Failure points**

- Unclear ownership
- Missed recalls
- Duplicate testing
- Families unsure who to call

**Goal: one shared algorithm across primary care • endocrinology • infusion • diabetes education**

# Case 1: “Her sister has T1D—should we screen?”

**7-year-old, healthy, no symptoms.**
**Older sibling has T1D. Family asks about screening at annual visit.**

Would you offer screening?

What would you test?

What would you explain before drawing blood?

What is your plan if one antibody returns positive?

# Case 1 debrief: the primary-care opportunity

Family history creates a clear indication to offer screening.

Pretest counseling prevents the family from receiving an unexplained portal result.

A single positive antibody is not Stage 1; confirm persistence and check metabolic status.

Build the referral/monitoring plan before the result arrives.

# Case 2: two antibodies, normal glucose

**4-year-old identified through screening. GADA + IA-2A confirmed. A1C 5.3%; fasting glucose 92 mg/dL. No symptoms.**

What stage?

How do you communicate risk?

How often would you monitor?

What should the family do during illness?

When does this become urgent?

# Case 3: Stage 2 and the treatment decision

**11-year-old with multiple confirmed antibodies.**
**OGTT shows dysglycemia; no polyuria, polydipsia, or weight loss.**

What additional data confirm eligibility?

How would you describe teplizumab benefit?

What practical barriers must be solved?

What baseline safety checks are needed?

What continues after the 14-day course?

# Case 4: “I can’t keep waiting for diabetes.”

**Parent of a 6-year-old with Stage 1 T1D calls repeatedly for glucose checks. Child is well. Parent reports poor sleep and constant worry.**

What is clinically necessary today?

How do you reduce uncertainty without over-testing?

What language restores a sense of control?

When would you involve behavioral health?

# Building a screening program: minimum viable infrastructure

Eight components turn a laboratory test into a safe clinical program

**Define population**

Pretest education

**Validated testing**

Confirmation pathway

**Rapid metabolic assessment**

Positive results

**Referral ownership**

Tracking registry

**SAFE + SUSTAINABLE T1D SCREENING**

**Stage-based monitoring**

Symptoms / sick-day plan

**Therapy / trial pathway**

Stage 2 access

**Psychosocial + equity plan**

Family burden / access

**Quality metrics**

Follow-up • DKA • access

**If any one component is missing, the screening pathway can fail after the blood draw.**

# Five take-home messages

1. T1D begins before symptoms.
2. Two or more confirmed islet autoantibodies identify early-stage T1D.
3. Screening only works when confirmation, staging, monitoring, and referral are built in.
4. Stage 2 creates a therapeutic window for disease-modifying therapy.
5. Psychological safety is part of clinical safety.

# Questions & Discussion

What would it take to make presymptomatic T1D screening routine—and sustainable—in your practice?

# Clinical resources

American Diabetes Association. Standards of Care in Diabetes—2026: Diagnosis and Classification; Prevention or Delay.

Albanese-O'Neill A, et al. Consensus Guidance for Monitoring Individuals With Islet Autoantibody–Positive Pre-Stage 3 T1D. Diabetes Care. 2024;47:1276–1298.

CDC. Screening for Type 1 Diabetes. Updated April 17, 2026.

TrialNet: risk screening, monitoring, and prevention studies.

Current TZIELD (teplizumab-mzwv) Full Prescribing Information and treatment resources.

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