SMART Systems Review

Teplizumab-mzwv: Perspective on Clinical Practice & Use at a Single Institution

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Abstract: Type 1 diabetes (T1D) is an autoimmune disease characterized by destruction of insulin-producing beta cells in the pancreas. Early intervention with teplizumab-mzwv (brand name Tzield) can be considered to delay the need for insulin therapy for patients with Stage 2 T1D ≥8 years of age. Eligibility requires the presence of at least two islet autoantibodies in addition to evidence of dysglycemia, but without meeting Stage 3 T1D glycemic criteria. Clinical practice and experience with this treatment is expanding; however, approval, access, administration, and subsequent monitoring practices remain variable in general practice. Here we present a brief discussion regarding our experience with teplizumab-mzwv at the Riley Hospital for Children at Indiana University Health.

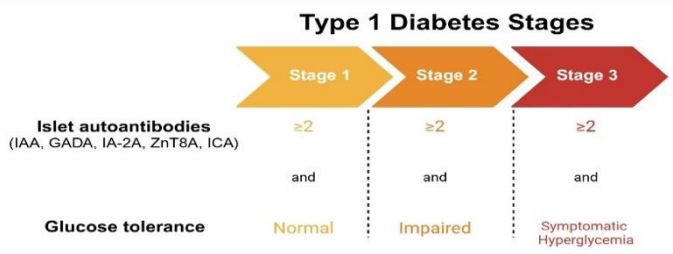
Outline:

1. Background and Consensus Statements

There is broad international consensus that T1D develops over time and progresses through presymptomatic stages of disease and that early-stage T1D can be detected before the need for insulin therapy by screening for the presence of multiple islet autoantibodies (Figure 1).[1] Detection of T1D during its presymptomatic stages allows not only for education and monitoring to prevent diabetic ketoacidosis, but also for early intervention with disease modifying therapies to preserve beta cell function and delay clinical progression.[2,3]

Teplizumab-mzwv is a monoclonal antibody that binds CD3 on T cells, modulating the immune response in T1D to reduce beta cell destruction and preserve beta cell function.[4] The TN-10 prevention trial demonstrated that teplizumab-mzwv could delay onset of Stage 3 T1D by 32.5 months in individuals with Stage 2 disease, leading to its FDA approval in November 2022 for ages 8 years and older.[5-7] The first therapeutic

Figure 1. Type 1 Diabetes Stages



Created in BioRender. Felton, J. (2025) https://BioRender.com/u53g426 CC-BY 4.0. The start of early-stage type 1 diabetes is defined by the presence of multiple islet autoantibodies, typically the biochemical autoantibodies to insulin (IAA), glutamic acid decarboxylase 65 (GADA), islet antigen-2 (IA-2A), zinc transporter 8 (ZnT8A), with some institutions also testing for islet cell antibodies (ICA) via indirect immunofluorescence. T1D Stages are further stratified based on glucose levels as shown. Refer to Table 1 for criteria for impaired glucose tolerance.

Abbreviations used in this paper: T1D, type 1 diabetes; IAA, insulin autoantibody; GADA, glutamic acid decarboxylase 65 antibody; IA-2A, islet antigen -2 antibody; ZnT8A, zinc transporter 8 antibody; ICA, islet cell antibody; OGTT, oral glucose tolerance test; CBC, complete blood count; LFT, liver function test; IV, intravenous; PICC, peripherally inserted central catheter; CGM, continuous glucose monitor.

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agent of its kind approved for delaying progression of early-stage T1D, teplizumab-mzwv is administered by intravenous (IV) infusion, daily for total of 14 days, starting with a 5-day dose escalation period.[7,8]

At the time of teplizumab-mzwv's FDA approval, individuals with presymptomatic T1D were typically identified and received therapies through clinical trials; therefore, standard operating procedures for screening, monitoring and intervention had not been developed within most clinical systems. While approaches and access to T1D autoantibody screening continue to differ depending on locally available resources, consensus guidance for staging and monitoring of individuals with positive autoantibodies has recently been published.[9,10] This guidance emphasizes the need for referral of individuals with early-stage T1D to care providers comfortable with monitoring and capacity to discuss available possibilities for intervention with disease-modifying therapies, either through trials or clinically available options. In April 2024, the Pediatric Endocrine Society published a statement on the use of teplizumab-mzwv in clinical practice.[8] This includes detailed recommendations from pre-treatment evaluation and administration through subsequent post-infusion monitoring.

Due to the novelty of teplizumab-mzwv and its specific indication, the nature by which it is administered, and the variability in local resources, its practical use and administration varies broadly across academic and non-academic clinical practices. Here, we share our single institution experience regarding the clinical use of teplizumab-mzwv.

2. How We Do It

Screening and monitoring of Early Stage T1D

Currently, consistent with American Diabetes Association guidance on T1D autoantibody screening[3], we have focused screening efforts on offering T1D autoantibody screening for family members of patients with T1D in our diabetes clinics. We start by recommending free T1D autoantibody testing via the research-based TrialNet or ASK programs. For those who decline antibody testing via these two programs, we also offer Enable Bioscience bloodspot testing kits with requisition forms that can be filled out by the provider who is recommending the testing (available at https://www.enablebiosciences.com). The testing can be completed in-office or at home. Clinical autoantibody testing via lab requisition at local commercial labs (e.g. Quest, LabCorp) is another option. In most cases, family members will not also be established patients, and so a letter is provided to the family to provide to their health care provider with instructions for ordering the T1D autoantibodies OR instructing health care providers to place a referral to our Early-Stage T1D Clinic if additional education and counseling regarding screening results is desired.

Table 1.

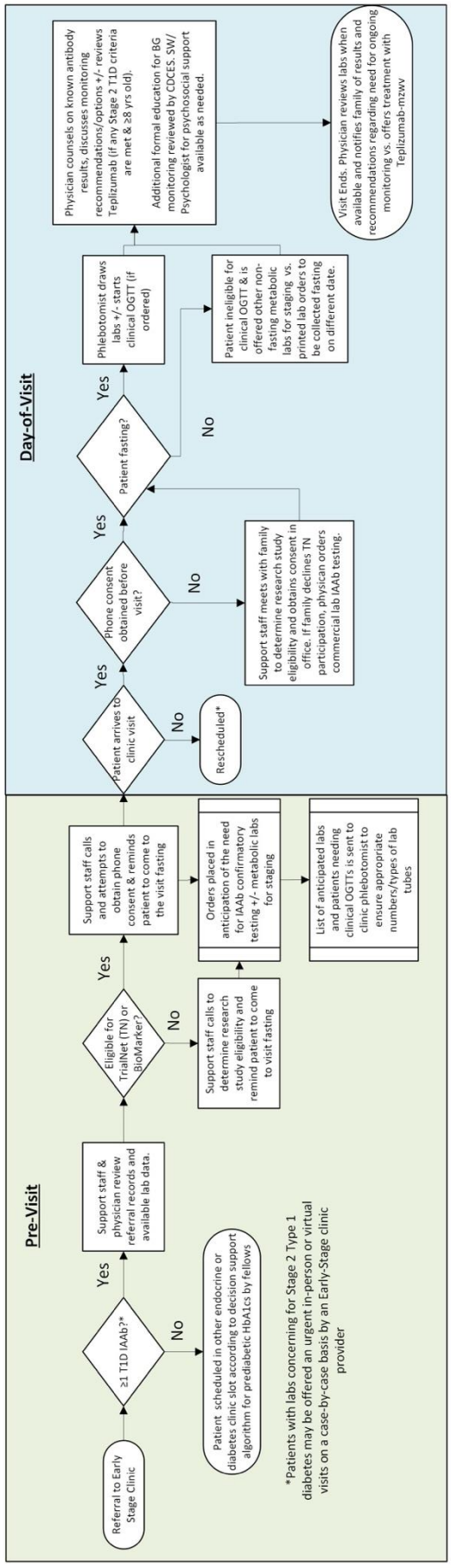
Criteria for Dysglycemia or Impaired Glucose Tolerance:
Fasting plasma glucose: 100-125 mg/dL (5.6-6.9 mmol/L)
120 min OGTT: 140-199 mg/dL (7.8-11 mmol/L)
OGTT values ≥200 mg/dL (≥ 11.1 mmol/L) at 30, 60, and/or 90 min
HbA_{1c}: 5.7-6.4% (39-47 mmol/mol)
Longitudinal ≥10% increase in HbA_{1c}

Adapted from Consensus Guidance for Monitoring Individuals with Islet Autoantibody-Positive Pre-Stage 3 Type 1 Diabetes.[9] Patients are required to meet two of the above OR meet the same single criterion at two separate time points within 12 months. Note, while CGM criterion have been proposed (values >140 mg/dL or > 7.8mmol/L for 10% of time over 10 days of continuous CGM wear AND confirmed by at least one other non-CGM dysglycemia criteria), consensus regarding CGM metrics defining dysglycemia and Stage 3 T1D have not been reached.

As the largest pediatric academic tertiary care center in Indiana, the pediatric endocrinology division at Riley receives referrals from a broad catchment area within and outside of Indiana. For individuals without diabetes requesting counseling on T1D screening or those identified as autoantibody positive, we offer an Early-Stage Type 1 Diabetes Clinic located at our Indianapolis diabetes clinic location. This clinic was established in November 2022 and currently offers 8-12, 1 hour in-person slots once a month. Direct referrals to Early-Stage Clinic currently originate primarily from referring endocrinologists, both within our division but also from outside groups without providers with experience in early-stage T1D monitoring and treatment. However, we also receive referrals from primary health care providers who have initiated autoantibody screening independently. Other referrals for prediabetic A1cs are assessed and triaged by our endocrinology fellows (Figure 2) to determine if these patients meet other criteria that would warrant initial evaluation in Early-Stage Clinic vs. a different diabetes-specific clinic, or a first available endocrinology visit slot.

In Figure 2, the pre-visit protocol for patients scheduled in Early-Stage clinic is described. A support staff member and the staff physician meet 2 weeks ahead of the visits to discuss known information about the patient and plans for T1D autoantibody confirmatory screening and metabolic staging anticipated during the visit so that orders can be placed ahead of the visits. We currently utilize a coordinator from our clinical research program, but this role could also be performed by a trained medical assistant or educator. The support staff member attempts to call the family within one week prior to their scheduled appointment date. If they answer, families are evaluated for eligibility

Figure 2. Riley Early-Stage Clinic Process Map



A flow diagram depicting the clinical workflow of the Riley Early-Stage Clinic from pre-clinic procedure through the day-of the patient visit. Abbreviations: BG, blood glucose; CDCES, Certified diabetes education specialist; HbA1c or A1c, Hemoglobin A1c; IAAb, islet autoantibodies; OGTT, oral glucose tolerance test; SW, social worker.

for T1D autoantibody screening through TrialNet and are asked to come to the clinic visit fasting.

During the clinic, a dedicated phlebotomist assists with obtaining fasting metabolic labs and confirmatory T1D autoantibodies (either via research or for commercial lab evaluation), hemoglobin A1c, and when appropriate, a 2-hour oral glucose tolerance test (OGTT). Family is counseled regarding their known autoantibody results and educated by the physician about signs and symptoms of Stage 3 T1D and diabetic ketoacidosis. Training and recommendations for blood glucose monitoring are provided as indicated with a Certified Diabetes Care and Education Specialist. A social worker is available as needed and we anticipate in the near future having a clinical psychologist available to support patients and families that may experience distress related to their autoantibody results. Follow-up monitoring for autoantibody positive individuals is offered as recommended by consensus guidance[9], or when appropriate, through TrialNet. A combined monitoring approach (between TrialNet and Early-Stage Clinic) may be deemed necessary for some patients, as TrialNet protocols do not always match consensus guidance recommendations.

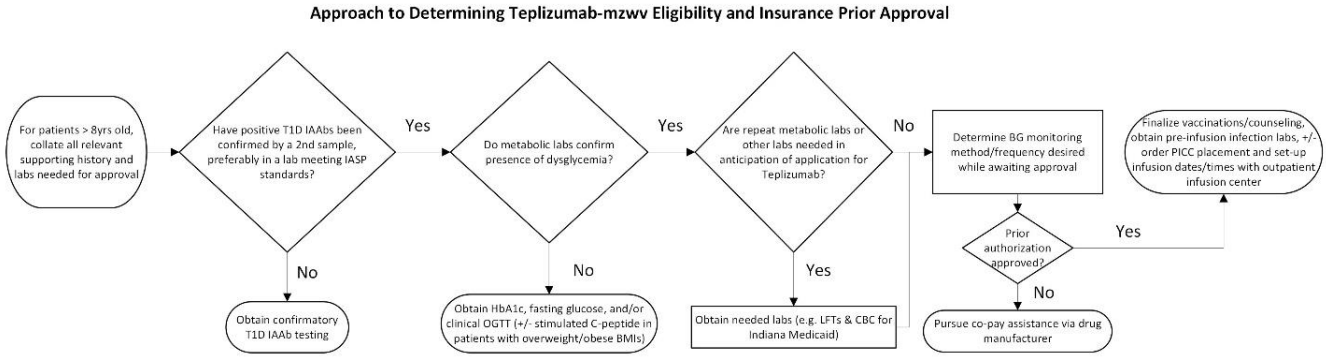
For patients eligible and interested in participation in research, our research staff discuss available clinical trials and the option of monitoring via T1D TrialNet. For multiple autoantibody positive patients who meet criteria for dysglycemia (stage 2 T1D) who are ≥ 8 years, the clinician discusses the option of treatment with teplizumab-mzwv. Discussion points around the consideration for treatment with teplizumab-mzwv are outlined in Table 2.

3. Teplizumab-mzwv Approval and Administration

Prior Authorization

After the decision to treat with teplizumab-mzwv is made, the next step is seeking insurance approval. This requires a prior authorization for which we outlined our general approach in Figure 3. Approval historically has taken several weeks and is highly variable depending on the insurance provider. In our center, where all 14 days of the infusion are given in an outpatient infusion center, the infusion center pharmacy must submit the prior authorization. Information provided to the pharmacy in name, date of birth, most recent body surface area (for an estimated dose calculation), and evidence of meeting diagnostic criteria. order to submit the prior authorization includes patient Note, that not all insurance companies require an OGTT for approval; therefore, if the patient has not had an OGTT but meets other criteria for dysglycemia, we recommend using this information alone for submission. We have also had success in obtaining approval with labs done in conjunction with research protocols, such as

Figure 3. Approach to Determining Teplizumab-mzwv Eligibility and Insurance Prior Approval.



Flow diagram depicting our approach to teplizumab-mzwv eligibility and initial navigation for insurance prior authorization. Abbreviations: BG, blood glucose; BMI, body mass index; CBC, complete blood count; HbA1c or A1c, Hemoglobin A1c; IAAb, islet autoantibodies; ISAP, Islet Autoantibody Standardization Program; LFTs, liver function tests; OGTT, oral glucose tolerance test; PICC, peripherally inserted central catheter.

TrialNet screening. We work closely with our Sanofi representatives to assist with preemptively evaluating for other labs that historically have been needed by specific insurance providers for approval to decrease need for repeated lab draws and time to approval. Lastly, our Early-Stage Clinic visits are intentionally scheduled in the morning so that we can obtain clinical OGTTs during the visit for both staging, and if needed, for insurance approval.

In our experience, both public and private insurance providers have covered the cost of the drug in addition to the care required for giving the infusion itself, and families have not required additional financial assistance. Patient-assistance programs from the drug manufacturer are available. However, it's important to note that this financial assistance currently only covers the cost of the drug itself, not the additional care required for its administration (such as infusion center visits or intravenous access placement). Additionally, this assistance is only currently available to individuals with private insurance. Therefore, we encourage direct discussion of self-pay patients meeting treatment criteria for teplizumab-mzwv with a Sanofi representative, as alternative coverage options may be available on a case-by-case basis

Pre-infusion anticipatory guidance: Vaccines

In our center, we use the time between submitting the prior authorization and receiving insurance approval to ensure that all pre-infusion anticipatory guidance has been reviewed. This includes verification that the patient is up to date on all immunizations and plans for future vaccines have been reviewed: inactivated or mRNA vaccinations are not recommended within two weeks prior to teplizumab-mzwv infusion, during treatment, or 6 weeks after completion of treatment; live-attenuated vaccinations are not recommended within 8 weeks prior to teplizumab-mzwv infusion, during treatment, or up to 52 weeks after treatment. In addition to this discussion, patients receive documentation of these recommendations and pertinent dates based on when they received the infusion.

Pre-infusion: Access

It is important to confirm and discuss the plan for intravenous (IV) access during the infusion. For pediatric patients, daily IV placement for 14 days is not ideal. Instead, we opt for PICC line placement on the morning of the first infusion day. In our experience with pediatric patients, access during the infusion is often a primary concern for families. On the first day of the infusion, the patient arrives early for PICC placement by interventional radiology. An updated body surface area and day 1 infusion labs are obtained when the IV is placed for PICC placement to ensure time for labs to result and the correct dose to be prepared by pharmacy. After recovery from sedation, patients move to the outpatient infusion center to start their infusion.

Pre-infusion: Symptom management at home

During this time, families are also counseled on what to expect regarding possible symptoms at home and plans for at home management. We discuss that in <10% of cases, individuals experience mild flu-like symptoms after the infusion, often starting with the first several days and gradually improving over the next several days. Plans for premedication and hydration during the infusion are discussed (see below) which often mitigate these symptoms, but if they occur, they can be treated using ibuprofen and diphenhydramine (over the counter) for joint/muscle aches, rash, and ondansetron for nausea and vomiting. A prescription for ondansetron is sent to the patient's pharmacy, and a document that includes the appropriate doses and timing of these agents is given for reference at home. We ask that families pick these medications up and have them available at home on the first day of the infusion.

Table 2. Discussion points for consideration of teplizumab infusion.

Discussion Point	Benefits	Risks
Delays the need for insulin	• Can delay onset of Stage 3 T1D by median of 2 years.	• None directly related to delay, but long-term effects are still being studied. • A subset of individuals may continue to progress despite treatment (non-responders).
Pre-infusion screening	• Offers an opportunity to ensure patients are adequately protected during mild immunosuppressive phase. • Chance to update vaccinations. • Screen for active viral infections and risk of re-activation of dormant viral infections.	• Requires time to update vaccinations, obtain lab results and analysis of results if abnormal. • Some labs may be dependent upon insurance requirements leading to delays in approval. • Risk of progression to Stage 3 T1D while waiting.
Immune system impact & potential side-effects or infusion-reactions	• Slows down immune system's attack on insulin-producing beta cells. • Infusion-related side-effects are generally easily managed with prn medications (e.g. Acetaminophen, diphenhydramine, ondansetron). • Patients are monitored closely by infusion-center staff and the physician for developing side-effects. • Rate of infusion may be altered as needed to alleviate some symptoms.	• Does not stop eventual progression to Stage 3 T1D. • May cause a transient decrease in white blood cell counts. • Common side-effects include: Rash, mild hypotension, headache, nausea and vomiting, muscle/joint aches (flu-like symptoms) • Less common side-effects may include cytokine release syndrome & risk of anaphylaxis, usually occurring within the first 5 days of infusion.
Quality of Life	• Provides additional time without the need for insulin therapy with close post-infusion monitoring to avoid presentation in DKA. • Allows more time for education and reinforcement of diabetes management concepts prior to initiation of insulin.	• The upfront frequency/duration, need for long-term IV access, and location/access to infusion center can be stressful.
Eligibility	• Age ≥ 8 years old with Stage 2 T1D	• Currently ineligible for treatment if <8 years old. • Not suitable for everyone; requires screening and medical consultation.

If possible, we avoid using acetaminophen given its potential for hepatotoxic effects in concert with possible elevations in liver transaminases with teplizumab-mzwv.

Pre-infusion: Labs

Upon insurance approval, an infusion date is scheduled after consultation with the infusion center nursing staff. In our center (and in many across the country), the outpatient infusion center is not open on the weekends, so patients receive the infusion in a separate area of the hospital that is staffed by infusion center nurses. Once the infusion start date is scheduled, pre-infusion labs are obtained and the PICC placement order (if needed) is made with the specific request to coordinate placement on the morning of the first day of the infusion. Because many of the pre-infusion labs are infection labs, it is important to obtain them as close as possible to the start of the infusion. We obtain pre-infusion labs approximately 10 days prior to the infusion to ensure adequate time for send out labs to result. The list of pre-infusion labs sent by our center (Table 3) was developed from both the experience of our clinical trial team who en

Table 3. List of Pre-infusion labs.

Pre-infusion labs	
General	Complete blood count (CBC) with differential
	Complete metabolic panel (CMP)
	Liver function testing (if needed by Medicaid)
	INR (if needed for PICC placement)
Infection Labs	CMV serologies and viral load (PCR)
	EBV serologies and viral load (PCR)
	Hepatitis B serologies
	Hepatitis C serologies
	HIV serologies
	QuantiferonGold (TB)
	COVID viral load (PCR)

Infection labs are collected at least 10 days prior to Day 1 of infusion. General labs are collected on Day 1 of infusion, unless specifically required before this during the prior authorization period

rolled and treated patients in TrialNet's prevention trial for teplizumab-mzwv, in addition to the package insert.

Pre-infusion: Logistics

Another practical consideration is where the family will stay if they do not live near the infusion center. Due to the large catchment area we serve, about half of our families who have received teplizumab-mzwv to date lived too far away to commute to the infusion center every day. In these cases, we have been able to provide lodging, free of charge, in our hospital's Ronald McDonald House. Availability is not always guaranteed. Therefore, with assistance from our diabetes clinic social worker, we have also developed a list of local financial assistance grants that families are eligible to apply for and a list of hotels near the infusion center that offer discounted rates for patients and families.

Infusion administration

After establishing intravenous access and obtaining/reviewing Day 1 infusion labs, the initial teplizumab-mzwv infusion is started. Teplizumab-mzwv dosing increases gradually on days 1-5, and in our experience, adverse events most commonly occur during this dose escalation period. For this reason, we start infusions on Mondays so that we will have reached the highest dose before the weekend infusion when there are less support staff readily available to respond to adverse reactions. During the infusion, CBC and LFTs are checked serially. Our infusion and lab schedules are provided in Table 4. For more convenient timing, beginning on day 2, the infusion start time is adjusted by up to 2 hours daily until the infusion start time is 8am. Close coordination with the pharmacy is necessary, as

Table 4. Daily Infusion Checklist

Infusion Day:	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Physical Exam	√	√	√	√	√				√					√
Vital Signs	√	√	√	√	√	√	√	√	√	√	√	√	√	√
CBC/differential	√		√		√			√						√
AST/ALT/direct bilirubin	√		√		√			√						√
Urine pregnancy test (in females of reproductive age)	√													
Premedication with ibuprofen and diphenhydramine 30 minutes before infusion	√	√	√	√	√	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)
Normal saline bolus 30 minutes before infusion	√	√	√	√	√	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)
Run infusion over 60 minutes	√	√	√	√	√	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)	(√)
Infusion dose (mcg/kg/m²)	65	125	250	500	1030	1030	1030	1030	1030	1030	1030	1030	1030	1030
60 minute post-infusion monitoring	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Frequency recommendations based on normal or expected results, with more frequent treatment or monitoring as indicated for abnormal findings or the presence of clinical symptoms. (√) denotes consider but not required.

teplizumab-mzwv must be administered within 2 hours of preparation, and the infusion must be completed within 4 hours of preparation.

Teplizumab-mzwv can be associated with cytokine release syndrome, which presents as flu-like illness with fever, nausea, joint aches.[5] This was a significant issue in the early clinical trials but was alleviated immensely in the teplizumab-mzwv prevention trial due to strict adherence to premedication with ibuprofen and diphenhydramine to prevent these symptoms. In our center, premedications are given 30 minutes prior to the infusion starting. We give a daily normal saline bolus (20cc/kg, max bolus) during the entire dose escalation period. We also give the infusion over one hour during the dose escalation period, rather than 30 minutes. After that, many patients choose to continue the premedication, bolus and one hour infusion for the duration of the infusion period, but this is something that can be discussed with the family (Table 4). Since the FDA approval of teplizumab-mzwv, we have not had issues with severe symptoms associated with cytokine release syndrome, and the additional time spent in the infusion center culminates to be about an extra 60 minutes. While it has not been studied, we suspect that the increased hydration, premedication, and slower infusion rates have been helpful in preventing side effects and cytokine release syndrome in our patients. To date, we have not had to stop an infusion administered as part of clinical care due to adverse events.

In addition to orders for teplizumab-mzwv, fluids, and premedications, the infusion center will likely also need orders to ensure that all agents to treat adverse events are on hand. In our center, these include things like agents to treat acute anaphylaxis or severe hypersensitivity reactions (i.e. antipyretics, diphenhydramine, ondansetron, normal saline, epinephrine). Responses to mild and severe hypersensitivity reactions, as well as vital sign and monitoring frequency and call parameters are included in our order set. We recommend working with your infusion center to determine local requirements. In many cases, existing order sets for other infusions can be repurposed or revised for teplizumab-mzwv. After the infusion, all patients are observed for 60 minutes prior to leaving the infusion center.

Managing adverse events

Management of adverse reactions will be specific to the scenario and patient. We follow the guidance published in the Pediatric Endocrine Society Statement for holding and discontinuing teplizumab-mzwv, which was derived from a combination of information from the package insert in addition to the clinical trial experience from multiple centers.[8] Lab abnormalities we have encountered most have been hyperglycemia and the expected decrease in the absolute lymphocyte count. For hyperglycemia, in cases of sustained glucose values > 300mg/dl, we have initiated a very small dose of short acting correction insulin to be used when needed. In all cases, the hyperglycemia has resolved after the infusion and insulin was not continued. In cases where hyperglycemia is intermittent and asymptomatic, we have actively observed without the initiation of insulin. Lymphopenia typically reaches its nadir on days 4-5 and in many cases, has normalized by the end of the infusion.

Follow-up

After treatment is completed, we recommend follow-up lab evaluation with a complete blood count and repeat cytomegalovirus and Epstein Barr virus labs in 2 weeks. During the 2 weeks following the infusion, we also encourage blood glucose monitoring, either using a continuous glucose monitor (CGM) for a 10-14 day window or using a home glucometer. If using a home glucometer, we ask that patients test 2 fasting and two 2-hour post-prandial glucoses per week. We also schedule a follow-up clinical OGTT 6 months after the infusion (or sooner at three months if there are any concerns for progression).

Insulin initiation

Although teplizumab-mzwv delays onset of stage 3 T1D, when treated individuals do progress, they follow a physiologically similar pattern to untreated individuals. Postprandial glucoses are typically the first to become abnormal. Starting insulin can be individualized for the patient's needs. We have typically started by first giving correction insulin at mealtimes as needed. In some cases, only 2-3 injections are needed per day, and so this is a reasonable approach. In cases where there is not a clear pattern of abnormal glucose values or glucoses are universally elevated; we start both basal and bolus insulin but at a significantly reduced total daily dose (usually 0.2-0.3u/kg/day) and adjust from there.

4. Other Considerations and Emerging Challenges

While it is well accepted that a new diagnosis of stage 3 T1D requires immediate and prompt attention, a diagnosis of stage 2 T1D has not classically been considered urgent. Now that there is a therapy available with an FDA indication for stage 2 T1D (but cannot be given after progression to stage 3), we propose that a stage 2 T1D diagnosis be considered with urgency as well. We have had several patients who presented with stage 2 disease but rapidly progressed to stage 3 prior to initiation of teplizumab-mzwv. Because rates of progression are highly variable, and because insurance approval can often take weeks, we are currently considering ways we can accommodate stage 2 patients on an

urgent basis in our clinics through the use of virtual visits and expanding our team of providers who are comfortable with teplizumab-mzwv counseling.

We recognize that the above processes and protocols described are specific to our geographic location and resource capabilities at Indiana University Indianapolis. As such, our protocol will need to be adapted to local needs and capabilities of other healthcare systems. For example, other institutions have protocols allowing for infusions given, in-part or entirely in the home setting by home-infusion nursing teams. Skilled staffing with experience in infusion reactions and the capability for a rapid formal evaluation of side effects will be critical to safe home administration of this agent, particularly during the first 5 days of the dose escalation. While home infusions may decrease the travel burden on patients and their families, the capacity to address and treat adverse events, and provider familiarity and experience with the infusion, are imperative and should be prioritized in developing protocols.

As it becomes increasingly common to identify individuals with stage 1 and stage 2 T1D, we are also reconsidering our approach to new onset education. Patients who have received teplizumab-mzwv, and many patients who have been screened but choose to not pursue therapy, have already received important components of diabetes education at the time of their stage 3 diagnosis. Development of a tailored education and insulin initiation plan in order to promote a smooth transition into stage 3 disease has become an important logistical consideration for our center. Because the reality is that most patients who receive teplizumab-mzwv currently will eventually progress, it may also be beneficial to have discussions about who and where they plan to establish care with when insulin is inevitably needed.

5. Conclusions

With the expansion of T1D treatment to include immune modulation, paradigms and approaches to the care and management of these patients will need to continue to expand and evolve as well. Administration of intravenous teplizumab-mzwv infusions can be implemented within a pediatric endocrine practice at a tertiary referral center in an outpatient setting. Addressing current challenges including early identification of individuals with early-stage T1D, rapid paths to teplizumab-mzwv insurance approval, increased outpatient pediatric infusion sites, and increased training of providers to safely administer immunotherapies will allow for increased access to this and other disease-modifying medications in individuals with early-stage T1D.

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Further Reading

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Mehta S, Ryabets-Lienhard A, Patel N, et al. Pediatric Endocrine Society statement on considerations for use of teplizumab-mzwv (Tzield) in clinical practice. *Horm Res Paediatr*. 2024 Apr 30:1-12. DOI: 10.1159/000538775.

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