

## Implementing an Early T1D Clinic for Patients with Stage 1 and Stage 2 Type 1 Diabetes

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# Background

- Teplizumab-mzwv was approved for delaying onset of stage 3 type 1 diabetes in November 2022.
- We designed an early T1D clinic to identify individuals eligible for treatment per stage 2 ADA criteria and provided proper guidance around treatment options.

#### Methods

- In December 2023, we opened a weekly clinic staffed with a nurse, physician and psychologist
- Individuals with islet autoimmunity and concern for dysglycemia are offered metabolic staging, which includes a fasting glucose level, HbA1C, 2-hour OGTT, and 10-day CGM wear
- Patients are offered a health and behavior assessment to assess coping and T1D risk perception. Metabolic staging results are obtained during clinic and treatment options are discussed
- If a patient desires Teplizumab-mzwv therapy, we prescribe and initiate the prior authorization process

## Results

	HbA1 <u>c(</u> %)	Fasting Glucose (mg/dl)	OGTT 120 Glucose (mg/dl)	CGM time >140 mg/dl (%)
1	5.2	90	64	8%
2	6	76	196	63%
3	6.1	93	184	16%
4	5.4	74	154	5%
5	5	60	122	9%
6	5.6	89	98	6%
7	5.2	83	85	12%
8	5.4	97	157	5%
9	6.3	145	234	46%
10	5.7	88	136	7%
11	5.8	97	107	16%
12	5.7	90	231	18%
13	6	145	268	44%
14	5.9	110	292	28%
15	5.4	92	142	15%
16	5.7	87	216	36%
17	5.7	77	130	28%
18	6.1	149	328	33%
19	5.4	102	181	6%
20	6.4	125	245	24%
21	5.1	77	143	TBD
22	6.3	112	167	28%

#### Stage of T1D by Monitoring Tool Used in Early T1D Clinic

	Stage 1	Stage 2	Stage 3
HbA1c	9	13	0
Fasting Blood Glucose	15	4	3
2-Hour OGTT Glucose	7	8	7

Individuals in Stage 1 (n=4), CGM time ≥ 140 mg/dl (7.8 mmol/L) 6 to 12% Stage 2 (n=17), CGM time ≥ 140 mg/dl (7.8 mmol/L) 5 to 63% Stage 3 (n=1), CGM time ≥ 140 mg/dl (7.8 mmol/L) 46%

## Results

- We have completed staging in 22 patients (TABLE).
- Using ADA T1D staging criteria, 17/22 (77%) patients are stage 2, 4/22 (18%) are stage 1, and one patient was diagnosed as stage 3.
- Of those with stage 2, we have successfully infused a 14-day course of teplizumab-mzwv in 6 patients.
- One patient initially classified as stage 2 progressed to symptomatic T1D before treatment.
- Eleven stage 2 patients have been authorized for teplizumab-mzwv treatment, and five are under review for treatment by their insurance carriers.

### Conclusions

- Individuals attending Early T1D clinic tolerated complete metabolic staging per ADA guidelines.
- We have successfully treated 6 eligible patients by using ADA criteria.