

September 13, 2023

ICD-10 Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Committee Members,

Thank you for your consideration of the need for new ICD-10 codes to align with the clinical consensus regarding the early stages of type 1 diabetes. We appreciate the opportunity to provide comments.

The undersigned organizations represent the roughly 1.4 million people living with type 1 diabetes in the United States. As you may know, type 1 diabetes (T1D) is an autoimmune disease in which insulin-producing beta cells in the pancreas are mistakenly destroyed by the body's immune system. T1D can be diagnosed early in life but also in adulthood. Its causes are not fully known, although a combination of genetic and environmental factors are suspected. There is currently no available cure. People with T1D are dependent on injected or pumped insulin to survive.

In 2015 JDRE, the American Diabetes Association, and the Endocrine Society published a scientific statement outlining a classification staging system for the early, or pre-symptomatic, stages of T1D.ⁱ Upon confirmation of two or more T1D autoantibodies that identify someone with nearly 100% likelihood of developing T1D, the following stages chart the progression to eventual clinical diagnosis:

Stage 1: Positive for two or more T1D autoantibodies. Normal blood sugar. No symptoms.

Stage 2: Positive for two or more T1D autoantibodies. Abnormal blood sugar. Rare to have symptoms.

Stage 3: Positive for two or more T1D autoantibodies. Abnormal blood sugar. Usually symptoms such as excessive thirst, fatigue, weight loss, and frequent urination.ⁱⁱ

It is upon progression to Stage 3 where someone typically becomes dependent on insulin to stay alive. We cannot say exactly when someone will become insulin dependent, nor can we predict the speed at which each person will progress through these stages. However, we do know that the risk of developing T1D at some point in their life for those with two or more persistent autoantibodies nears 100%.^{iii,iv}

As a result of nearly 30 years of dedicated research, we know that early detection and identification of T1D risk, coupled with follow-on monitoring by providers, allows people to avoid the life-threatening condition diabetic ketoacidosis (DKA) and the long-term consequences of this event that some experience. Studies have also shown that early detection of T1D via screening and monitoring results in better lifetime glycemic control and better health for the person with T1D. We also know that reducing and avoiding DKA at diagnosis in children is associated with better HbA1c outcomes, reduces the need for hospital stays, and improves glucose control as well as cognitive function.^v

Importantly, early detection provides an opportunity for education and preparation that reduces anxiety and stress. Given the prevalence of children diagnosed with T1D, advanced awareness and education can prove critical to a parent's ability to help their child manage their diabetes.

The expanding knowledge base regarding early detection of T1D and the availability of the first ever disease-modifying therapy that delays the onset of T1D, Tzield, is changing T1D clinical practice, which we believe requires new CPT codes to accommodate the evolving nature of care.

As highlighted by Dr. Frohnert during the Sept. 13th meeting, ICD-10-CM currently has one code for “prediabetes” (R73.03) regardless of etiology. In practice, this is used nearly exclusively for individuals at risk of developing type 2 diabetes (T2D). The immunopathology of T1D is distinct and there are also differences in typical progression of glycemic abnormalities, monitoring and intervention strategies, and eventual treatment. This is reflected in distinct ADA definitions for dysglycemia in stage 2 T1D vs. “prediabetes.”^{vi} Confusion between T1D and T2D can lead to inappropriate management, particularly in the youngest children who are at highest risk of adverse outcomes. An additional code, “raised antibody titer” (R76.0), may apply, but gives providers no indication that a patient is developing T1D. Codifying the distinction between early-stage T1D and pre-T2D, as well as incorporating early T1D diagnoses into problem lists will facilitate recognition of the potential risks at the time of clinical care and can help underline the differences to appropriately manage these two disease states.

As screening for T1D risk becomes more common, recognizing early-stage T1D patients who present for care will be ever more important to prevent poor outcomes and appropriately manage the care of someone who is at risk of developing T1D. We strongly encourage the committee to adopt the recommendations outlined by Dr. Frohnert to create codes reflecting the 3 stages of T1D.

Thank you again for your consideration of this important topic and for the opportunity to provide written comment. We stand ready to assist in any way we can. If you have any questions, please contact Aaron Turner-Phifer (aturner-phifer@jdrf.org) with JDRF.

Sincerely,

American Association of Clinical Endocrinology
American Diabetes Association
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Endocrine Society
JDRF

ⁱ Insel, R. A., Dunne, J. L., Atkinson, M. A., Chiang, J. L., Dabelea, D., Gottlieb, P. A., Greenbaum, C. J., Herold, K. C., Krischer, J. P., Lernmark, K., Ratner, R. E., Rewers, M. J., Schatz, D. A., Skyler, J. S., Sosenko, J. M., & Ziegler, A. G. (2015). Staging Presymptomatic Type 1 Diabetes: A Scientific Statement of JDRF, the Endocrine Society, and the American Diabetes Association. *Diabetes Care*, 38(10), 1964–1974. <https://doi.org/10.2337/dc15-1419>

ⁱⁱ Ibid.

ⁱⁱⁱ Ibid.

^{iv} Ziegler, A. G., Rewers, M., Simell, O., Simell, T., Lempainen, J., Steck, A., Winkler, C., Ilonen, J., Veijola, R., Knip, M., Bonifacio, E., & Eisenbarth, G. S. (2013). Seroconversion to Multiple Islet Autoantibodies and Risk of Progression to Diabetes in Children. *JAMA*, 309(23), 2473. <https://doi.org/10.1001/jama.2013.6285>

^v Elsamahy, M., Elhenawy, Y., & Altayeb, N. (2017). Long-term prognosis of type 1 diabetes in relation to the clinical characteristics at the onset of diabetes. *Egyptian Pediatric Association Gazette*, 65(3), 90–94. <https://doi.org/10.1016/j.epag.2017.04.004>

^{vi} Besser, R. E. J. *et al.* ISPAD Clinical Practice Consensus Guidelines 2022: Stages of type 1 diabetes in children and adolescents. *Pediatr. Diabetes* 23, 1175–1187 (2022).