TANDEM Diabetes Care

MEDCAC Meeting

Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes

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positively different

Disclosures: Laurel Messer, PhD, RN, MPH, CDCES

Laurel Messer is an employee and shareholder of Tandem Diabetes Care, Inc.

OLDER ADULTS WITH DIABETES…

Are heterogeneous:

- Life expectancy
- Baseline health/comorbidities
- Cognitive function

Require individualization

- Relaxation of glycemic targets (Int. consensus TIR of 50% target)[a]

Higher risk for hypoglycemia:[b]

- Erratic meal intake
- Progressive renal insufficiency
- Treatment with hypoglycemic agents

a i et al https://doi.org/10.2337/dci19-0028
b ADA standards of care: https://doi.org/10.2337/dc24-S013

ENDPOINT DOMAIN RATINGS

The following endpoint domains are important for clinical trials for devices for self-management of type 1 or insulin-dependent type 2 diabetes in older adults:

Surrogate Markers

Device Related Safety

The following endpoint domains **provide less clarity** and are less important for determining the safety, effectiveness, and medical necessity of newer diabetes self-management devices for older adults:

Health Outcomes

Quality of Life

PRIORITIZING SURROGATE MARKERS

+ The ideal duration of follow-up required for detection of an impact on various endpoint measures is **three months**.

Specific Endpoint	Appropriateness of each measure (using Likert Scale)	Minimally-Clinically Important Difference (MCID) Recommendation
Percentage of time in acceptable glucose range (70-180 mg/dL)	5	■ 5% change in time in range (TIR) is clinically meaningful within an individual in a trial. ■ Within-person change is important since comparator group may be in-class in the future (control group = AID)
Percentage of time in hypoglycemia (<70 mg/dL)	4	Any reduction in percentage of time in hypoglycemia is clinically meaningful given that older adults are at high risk for hypoglycemia

PRIORITIZING SURROGATE MARKERS

Specific Endpoint	Appropriateness of each measure (using Likert Scale)	Minimally-Clinically Important Difference (MCID) Recommendation
Number of hypoglycemic episodes (<70 mg/dL), especially episodes of Level 2 hypoglycemia (<54 mg/dL)	3	No MCID. • # number of events is not as important as the total duration.
Percentage of time in level 2 hypoglycemia (<54 mg/dL)	3	No MCID • Often already low at baseline
Percentage of time in hyperglycemia (>180 mg/dL)	3	MCID: 5% • Overall TIR encompasses
Impact on A1C (MCID = 0.5% change)*	2	0.3%-0.5% or more reduction in A1c is clinically meaningful, but difficult to achieve in clinical trials • A more direct measurement of glycemic control (TIR and TBR) should be prioritized.

PRIORITIZING DEVICE RELATED SAFETY

Specific Endpoint	Appropriateness of each measure (using Likert Scale)	Minimally-Clinically Important Difference (MCID) Recommendation
Device discontinuation rates	5	Less than 20% discontinuation rates
Patient preferences (comparing the device with conventional self-management) ***and adherence***	4	**Greater than 75% device use.** • Available for all systems • Directly indicate whether user willing to use
Hypoglycemia-related emergency department visits	2	Infrequent in clinical trial level data, better for real world surveillance. Any reduction is clinically meaningful.

CONCLUSION AND RECOMMENDATIONS

+ **Surrogate markers:** *Improvement in Time-in-Range 70-180 mg/dl*) within individual indicates most important metric for approval of AID systems for the older adult population.

+ **Device Related Safety:** *Device discontinuation and adherence* to device indicate tolerability and safety of device in older populations.

+ Clinical trial duration can be minimum **three months**

+ Stringent MCIDs would inappropriately deny coverage for new diabetes treatments that would be of clinical benefit to Medicare beneficiaries with diabetes.

We ask that CMS does not require long and costly trials to make decisions about the coverage of new diabetes technologies.

Thank You

Please contact Laurel Messer at lmesser@tandemdiabetes.com **with any questions.**