May 23, 2016

To The Institute for Clinical and Economic Review:

The Diabetes Advocacy Alliance (DAA), a coalition of 21 diverse members, appreciates the opportunity to provide comments related to the **Diabetes Prevention Programs: Effectiveness and Value** draft evidence report and draft questions for deliberation.

Overall, we support the Institute for Clinical and Economic Review's (ICER) review of diabetes prevention programs (DPPs) and its findings that DPPs are effective at preventing or delaying the onset of type 2 diabetes. We also support ICER's findings that DPPs, particularly in-person group and digital human-coached programs, are cost-effective and cost-savings over time.

The DAA provides the following suggestions for ICER to consider as it finalizes the Diabetes Prevention Program report:

Characterization of Prediabetes and Diabetes

The DAA is extremely concerned about ICER's characterization of prediabetes and diabetes and strongly urges ICER to revise this mischaracterization in the final report. Specifically, the DAA is opposed to ICER stating *"…critics of the term 'prediabetes' have raised concerns about the adverse effects of labeling patients given that prediabetes is simply a group at high risk for diabetes, which in itself is primarily a risk factor for conditions that matter to patients: strokes, heart attacks, blindness, kidney failure and death* (ES8)*."* For the nearly 30 million Americans living with diabetes, the disease is not simply a "risk factor for other conditions." Diabetes is, in fact, a serious and life-threatening condition that impacts the daily lives of people with diabetes, as well as the lives of their loved ones. Diabetes is a very complex, chronic disease that requires daily decisions about how to manage one's glucose levels. Without proper management, diabetes can lead to devastating and costly complications including, but not limited to, the conditions ICER mentions in the above statement.

In downplaying the seriousness of diabetes and the diabetes epidemic, ICER does a huge disserve to public health efforts to better prevent, manage and treat this devastating disease. In addition to the tens of millions of people who already have diabetes—and live with and manage their disease every day—there are 86 million Americans with prediabetes who are at risk for developing the disease without intervention. The diabetes epidemic, which includes diabetes and prediabetes, costs our nation $322 billion per year. In the draft report, ICER refers to critics who have raised concerns about labeling patients with prediabetes. The DAA would like to point out, as referred to in the draft report, the Center for Medicare and Medicaid Innovation (CMMI) found improved health outcomes and significant cost savings accrued when individuals with prediabetes participated in a DPP through the YMCA of the USA. It's difficult to understand what kind of "adverse effects" result from targeting individuals with prediabetes and enrolling them in DPPs when the outcomes are improved health and reduced health spending. Further, new guidelines for screening for abnormal blood glucose and type 2 diabetes released by the United States Preventive Services Task Force (USPSTF) in October 2015 found no long-term psychological harms associated with measuring blood glucose and also that the harms of lifestyle intervention (DPP) to reduce the incidence of diabetes are small to none.

Potential Budget Impact

The DAA is requesting a clarification within the "Potential Budget Impact" section of the Draft Report. (pages ES11-ES13 and Sec 6.3 in the Main Report and Appendix I). Specifically, the DAA observes that the first year cost-offset and budget impact numbers for in-person group coaching appear far greater than the other program approaches. Because digital plus human coaching is designed to be scalable and efficient, and because ICER establishes in this report that both approaches are equally clinically effective (B+), it is not intuitive that digital plus human coaching would be dramatically less cost-effective at any point in time relative group in-person coaching. Therefore, we are recommending that ICER include possible explanations and limitations for the dramatic difference in year one savings among in person group coaching. The reason this point is important is because, commercial payers, who have high turn-over among their membership and relatively short payback periods could seize upon these differences to limit their policies to in-person group coaching. The DAA – and the CDC through its Recognition Program – believe that both in-person group coaching and digital plus human coaching are viable alternatives. Furthermore, the DAA believes that the cost-effectiveness literature associated with both modalities is too nascent to clearly establish the short-term cost-effectiveness of one versus the other at this point in time.

Draft Voting Questions

The DAA recommends ICER add an additional voting question related to the cost-effectiveness of DPPs. The draft report includes an in-depth analysis and discussion of the potential budget impact of DPPs and, overall, finds evidence supporting the cost-effectiveness and cost-savings of DPPs. Because payers and employers will be interested in ICER's findings related to the impact DPPs may have on their budget and health spending, ICER should include a direct question on the cost-effectiveness of DPPs as opposed to referring to "value" in some of the draft questions which is not clearly defined. A potential draft question could be: "Given the available evidence, in-person DPP with group coaching/digital DPP with human coaching is cost-effective/cost-saving?"

Other

We'd like to clarify that Omada Health, a DAA member, has renamed its "Prevent Program" to "The Omada Program". To avoid confusion, we recommend ICER refer to it as such throughout the report.

Thank you for considering our suggestions. We look forward to the final report and June public meeting. Please feel free to contact Amy Wotring at awot@novonordisk.com with any questions.

Sincerely,

Karin Gillespie	Meghan Riley	Henry Rodriguez, MD
Novo Nordisk	American Diabetes Association	Pediatric Endocrine Society
DAA Co-chair	DAA Co-chair	DAA Co-chair