July 2, 2020

Dear National Clinical Care Commission Members:

The Diabetes Advocacy Alliance (DAA) has appreciated the opportunity to engage with the National Clinical Care Commission (the Commission) via written and oral public comment and through interactions with the Commission's Subcommittees in their data collection efforts. The DAA includes 24 organizations representing the patient, provider, and industry perspective. As the Commission enters its third year of activity and begins to shape its recommendations and report to Congress, the DAA has summarized key federal policy issues that continue to impact access to care for people with diabetes and prediabetes. These recommendations reflect consensus within the diabetes community and a commitment by diverse stakeholders to work collectively to achieve shared policy goals. We urge the Commission to consider these policy recommendations.

Via previous letters to the Commission and in-person comments at Commission meetings, the DAA has provided in-depth comments that support the following recommendations. (We have attached copies of our previous letters for your convenience and reference.) Also, since the DAA's last written communication with the Commission was in November 2019, we have added new comments related to the coronavirus and diabetes.

Coronavirus, COVID-19, and Diabetes

From the beginning of the spread of the coronavirus, public health officials have repeatedly warned that health complications of COVID-19 are more severe among people with underlying health conditions, among which diabetes, chronic kidney disease, cardiovascular disease, and obesity are prominent. New data from CDC scientists showed that people with underlying health conditions were 6 times more likely to be hospitalized than those with no such conditions (45.4% versus 7.6%) and deaths were 12 times higher (19.5% versus 1.6%).[1]

Also, analysis of COVID-19 cases by race and ethnicity showed incidence out of proportion to percent of the overall U.S. population for Hispanic (33% vs. 18%), Black (22% vs. 13%), and American Indian/Alaska Native populations (1.3% vs. 0.7%), respectively.[1] Other research says that among people with diabetes with COVID-19, it is possible that higher BMI and A1c levels are linked to worse outcomes.[2] Also, scientists and clinicians believe that disruptions caused by the pandemic, including increased stress, missed regular medical appointments and diabetes self-management education sessions, and changes to diet and physical activity routines could contribute to worse outcomes for people with diabetes, and could exacerbate health disparities.[2]

New research also suggests that COVID-19 and diabetes may be a two-way street. Not only do people with both diabetes and COVID-19 suffer disproportionately higher rates of severe outcomes, it is also possible that COVID-19 is triggering new cases of type 1 and type 2 diabetes, and among people with existing diabetes, it may be triggering severe metabolic complications, such as diabetic ketoacidosis.[3] To help assess this bi-directional hypothesis, a new global registry to track COVID-19-related diabetes, called CoviDiab, has been started by Kings College London and Monash University.

The DAA has convened a workgroup of its members to examine this new research, along with various policy and legislative proposals currently being discussed in the Administration and on Capitol Hill, in order to determine the DAA's next steps in supporting people with diabetes and prediabetes in this time of the pandemic. The DAA will share its ideas with the Commission later this year. Some of our initial ideas include maintaining CMS COVID-19 policies long term, such as reduced restrictions around telehealth, non-enforcement of clinical indications for continuous glucose monitoring (CGM) and insulin pumps, and allowing flexibility around in-person requirements for CGM and insulin pump coverage and supplies.

Reducing Health Disparities and Achieving Health Equity in Diabetes and Prediabetes Care

The COVID-19 pandemic has also reinforced the critical need to address health disparities that disproportionately affect Black, Hispanic, and tribal communities, as well as other racial, ethnic, and socioeconomic groups. There are socioeconomic, structural, societal, and environmental factors that continue to exacerbate health disparities in this country and affect the prevalence of diabetes and prediabetes among certain populations. Factors that contribute to health disparities, specifically for diabetes, but across all chronic conditions, include higher rates of food insecurity, less access to a safe place to be physically active, healthcare resource allocation, lack of access to care, the quality of available care, employment, stress, social and physical environment, income, housing insecurity, etc.

The DAA appreciates the Commission's ongoing efforts to address health disparities and recognizes the work of many federal agencies to improve health outcomes. The Commission has discussed the importance of focusing on the individual with or at risk for diabetes, but also on examining the role of the community and the healthcare system as a whole and how these factors contribute to health outcomes. The DAA believes the Commission is uniquely positioned to address health disparities among people with and at risk for diabetes. The DAA urges the Commission to develop final recommendations that support interagency collaboration to achieve health equity and reduce existing barriers and disparities to improve outcomes for all Americans.

Diabetes Prevention

The DAA commends the Commission for its focus on diabetes prevention. In previous letters the DAA has pointed out, in detail, how and why differences are problematic

between the Medicare Diabetes Prevention Program at CMS and the National Diabetes Prevention Program at CDC. In summary, the DAA recommends the following federal policy changes.

Medicare Diabetes Prevention Program Alignment with National Diabetes Prevention Program

The Commission should recommend to Congress that CMS align its Medicare Diabetes Prevention Program (Medicare DPP) with CDC's National Diabetes Prevention Program (National DPP) and with the standards in the CDC's Diabetes Prevention Recognition Program. Alignment would help reduce confusion among prevention program providers, and among health care professionals who refer individuals to these programs; increase the number of organizations able to offer the Medicare DPP due to increased/adequate reimbursement; and increase the number of Medicare beneficiaries able to access programs either in-person or virtually. Alignment is needed in these areas:

- Making virtual programs available in the Medicare DPP (as they are now in the National DPP)
- Weight loss thresholds (expressed as % of weight loss needed)
- 2 year program duration (CMS) versus 1 year (CDC)
- Reimbursement rates
- Payment adjustments for special populations
- Once per lifetime benefit
- Screening guidelines for eligibility (CMS uses WHO guidelines while CDC uses ADA cut points for defining prediabetes)
- Use of A1c test to screen for prediabetes and diabetes (CMS does not allow; CDC allows)

Medical Nutrition Therapy in Medicare for Beneficiaries with Prediabetes

Medicare covers medical nutrition therapy (MNT) for people with diabetes but does not cover this service for individuals with prediabetes, reducing the options that Medicare beneficiaries have for improving their health. MNT for individuals with prediabetes has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months.[4,5,6] Increased frequency of MNT visits correlated with greater improvements in these metrics. A review of 66 programs by the Community Preventive Services Task Force found that programs that combined diet and physical activity counseling decreased diabetes incidence, and that the most intensive programs—primarily led by registered dietitian nutritionists in those studies—were the most effective at obtaining these outcomes.[7,8] The DAA encourages the Commission to review the body of literature on the effectiveness of medical nutrition therapy for treating prediabetes.

Diabetes Self-Management Education and Support (DSMES)/Diabetes Self-Management Training (DSMT)

CMS has publicly recognized the significant underutilization of the DSMT benefit in Medicare. Although the evidence base for DSMT is very strong,[9,10,11] and even though DSMT is a covered benefit under the Medicare program, only 5% of Medicare beneficiaries with newly diagnosed diabetes participate in this evidence-based service. Thus, the DAA urges the Commission to recommend to Congress that CMS implement regulatory reforms to expand access to DSMT so older adults with diabetes can prevent costly complications. The DAA is working to implement regulatory reforms in addition to advocating for legislation to expand access to DSMT so older adults with diabetes can prevent costly complications.

The DAA has identified several CMS barriers to DSMT that we urge the Commission to address in its recommendations to Congress:

- Extend the initial 10 hours of DSMT covered by Medicare beyond the first year until fully utilized and cover additional hours based on individual need;
- Allow medical nutrition therapy (MNT) and DSMT to be provided on the same day;
- Remove patient cost-sharing;
- Broaden which providers can refer to DSMT beyond the provider managing the beneficiary's diabetes to include other providers caring for the patient;
- Clarify agency policy that hospital outpatient department-based DSMT programs can
  expand to community-based locations, including alternate non-hospital locations;
- Pilot the use of virtual DSMT programs through the Center for Medicare and Medicaid Innovation (CMMI); and
- Expand telehealth for DSMT so that all DSMT programs, eligible to Medicare Part B, are considered distant site practitioners approved to furnish telehealth services.

Diabetes Care and Technology

The DAA urges regulatory reforms that would allow CMS flexibility to cover innovative diabetes technologies and services, so that as new diabetes technologies and services are approved by the FDA, there is a coverage pathway in Medicare for them. Rapid advances in this space have outpaced Medicare's existing coverage and reimbursement guidelines resulting in overly complicated – or even a lack of – access processes for patients, health care professionals and suppliers. The DAA would like the Commission, in its report to Congress, to recommend:

- Improving CMS coverage for innovative technologies;
- Better coordination between FDA and CMS for coverage pathways for innovative technologies; and
- Reducing existing coverage barriers to diabetes technology, such as eliminating the "four times per day" testing that Medicare requires for coverage of continuous glucose monitors (CGM).

The Future of Diabetes Care

As a result of the pandemic, long-awaited changes to healthcare delivery in this country have been implemented in just a few short months. These changes, especially the expansion of telehealth, have increased access for many individuals. They also have underscored the stark disparities that exist in our current healthcare system and the need to ensure consistent access to high-quality care for people with diabetes and prediabetes. The Commission is uniquely positioned to dramatically shift current federal diabetes policy and improve access to diabetes care and services, reduce health disparities, increase adoption of and coverage for diabetes technologies, and prioritize diabetes prevention. In addition to the points made throughout this letter and in previous letters and comments, the following points represent different ways the Commission can usher in the future of diabetes care.

- Revisit innovative solutions;
- Promote use of multiple delivery modes – virtual and telehealth;
- Implement lessons learned from the COVID-19 pandemic and, as mentioned, make permanent temporary flexibilities, like expanding telehealth, non-enforcement of clinical indications for continuous glucose monitoring (CGM) and insulin pumps, and allowing flexibility around in-person requirements for CGM and insulin pump coverage and supplies.

Thank you for the opportunity to submit these comments to the Commission. As the Commission moves forward with its critically important work to improve patient care, we offer the DAA and our member organizations as resources for information and expertise. If you have any questions related to our comments or would like further information, please contact Karin Gillespie at KGIL@novonordisk.com.

Sincerely,

Academy of Nutrition and Dietetics
American Diabetes Association
American Optometric Association
American Podiatric Medical Association
Association of Diabetes Care and Education Specialists
Diabetes Patient Advocacy Coalition
Endocrine Society
Healthcare Leadership Council
National Council on Aging
National Kidney Foundation
Novo Nordisk Inc.
Omada Health
WW International, Inc.
YMCA of the USA

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