

October 11, 2019

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Jensen:

I am writing on behalf of the American Medical Association (AMA) and our physician and medical student members to request that the Centers for Medicare & Medicaid Services (CMS) expand Medicare coverage of hemoglobin A1c (HbA1c) testing to include screening for prediabetes and abnormal glucose metabolism. Current Medicare policy allows coverage of HbA1c tests for management of diabetes, but not for screening. The AMA continues to strongly support the CMS expansion of the Medicare Diabetes Prevention Program (MDPP) model, implemented 18 months ago. An estimated 20 percent of Medicare beneficiaries currently have type 2 diabetes. Its prevalence is expected to increase over time, but effective preventive measures like the MDPP can change this forecast and improve health outcomes. The AMA is committed to preventing new cases of type 2 diabetes by addressing prediabetes and assisting physicians and clinical teams in delivering effective preventive care. A core aspect of the AMA's diabetes prevention work is to support the successful implementation of the MDPP by raising awareness of the model among physicians and facilitating screening of beneficiaries and referrals to the program.

The AMA now has five years of experience working with physician practices and health care systems to implement diabetes prevention strategies, including referrals to MDPP. Systematic screening of patients for prediabetes and abnormal glucose metabolism is an important aspect of preventing type 2 diabetes and optimizing participation in the MDPP. Robust MDPP participation is necessary for CMS to realize the cost savings that were estimated by the CMS Actuary for the expanded MDPP model.

The AMA's work with health systems has identified barriers that physicians and care teams face when they seek to follow the standards of care and clinical guidelines for screening. A major barrier is that the CMS coverage policy for HbA1c tests does not include the indication of prediabetes or abnormal glucose screening. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for at least ten years. The "International Expert Committee Report on the Role of the A1C Assay in the Diagnosis of Diabetes" states that "the A1C assay provides a reliable measure of chronic glycemia and correlates well with the risk of long-term diabetes complications."¹ Per the American Diabetes Association 2019 Standards of Care, "the A1c has several advantages compared with the [fasting plasma glucose] and [oral glucose tolerance test], including greater convenience (fasting not

¹ The International Expert Committee. International Expert Committee Report on the Role of the A1C Assay in the Diagnosis of Diabetes. *Diabetes Care*. 2009;32(7):1327-1334; DOI: 10.2337/dc09-9033.

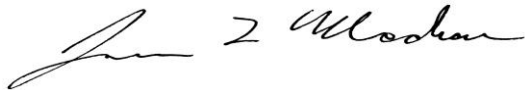
required), greater preanalytical stability, and less day-to-day perturbations during stress and illness.”² These features facilitate testing among populations that experience difficulty fasting or experience more frequent illness, which are characteristic of many people in the Medicare population. For these reasons, HbA1c is increasingly the preferred method of screening for abnormal glucose among physicians. According to a survey of primary care physicians, 60 percent preferred HbA1c as a screening test for prediabetes compared to 35 percent that preferred fasting plasma glucose.³ The lack of coverage for the screening HbA1c test disadvantages Medicare beneficiaries compared to those with commercial insurance, which typically does cover the HbA1c test for screening, and precludes patient referrals to the MDPP. According to the [Centers for Disease Control and Prevention](#), 90 percent of people with prediabetes do not know they have it. Expansion of Medicare coverage to include the HbA1c test for prediabetes screening could significantly increase Medicare patient referrals to the MDPP.

The AMA requests that CMS expand Medicare Part B coverage of HbA1c testing to include the indication of screening for prediabetes or abnormal glucose. This coverage policy would allow physicians to better adhere to the clinical recommendations issued by the United States Preventive Services Task Force and the American Diabetes Association Standards of Care, both of which recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose.^{2,4}

Medicare coverage of screening HbA1c tests is also necessary for consistency with the CMS regulations for the MDPP at § 410.79, which state that beneficiaries are MDPP-eligible if they have “received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL.” The use of HbA1c as an eligibility criterion for participation in MDPP indicates that CMS views HbA1c as an appropriate test to screen an individual for abnormal glucose, so the lack of Medicare coverage for the test is a policy contradiction that creates confusion for patients and physicians.

The AMA urges CMS to uniformly cover all three designated prediabetes screening tests. Physicians and care teams need consistent guidance to identify at-risk patients and refer them to the MDPP in order to stem the rapidly rising tide of Medicare patients with type 2 diabetes and its adverse impacts on their health care outcomes and costs. Thank you for your consideration of this recommendation. If you have any questions or require additional information, please contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD

² American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2019. *Diabetes Care*. 2019; 42(Suppl 1): S13-S28; DOI: 10.2337/dc19-S002.

³ Mehta S, Mocarski M, Wisniewski T, Gillespie K, Narayan KMV, Lang K. Primary care physicians’ utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey-linked retrospective study. *BMJ Open Diab Res Care*. 2017;5:e000406.

⁴ Siu AL. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 2015;163(11):861-8.