American Diabetes Association®
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April 16, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

Submitted via www.regulations.gov

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period; Interim final rule; request for comments (IFC)
File code: CMS-3372-IFC

Dear Acting Administrator Richter:

The American Diabetes Association (ADA) is pleased to submit comments on the interim final rule on Medicare Coverage of Innovative Technology (MCIT), and urges the Centers for Medicare & Medicaid (CMS) to move forward with implementing the final rule, which will have a significant impact on people with living with diabetes, without further delay

About ADA

The ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 122 million individuals living with diabetes and prediabetes, and has more than 500,000 general members, 15,000 health professional members, and more than one million volunteers. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes[1] and publishes the most influential professional journals concerning diabetes research and treatment.[2]

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1 (January 2021).
[2] The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).

ADA Urges CMS to Implement MCIT Without Further Delay

The ADA was pleased to see that CMS published the MCIT Final Rule in the January 14, 2021 Federal Register, under which FDA-designated breakthrough technologies would be covered by Medicare once they are approved by the FDA, subject to their applying to participate in the MCIT program. The promise that these life-changing technologies would be reaching the hands of Medicare beneficiaries with diabetes more quickly was welcome information.

While we understand the necessity of reviewing the complete regulatory landscape, we urge you to continue to move forward and make MCIT final without additional delay, so individuals with diabetes awaiting new disease management technologies are not further impacted. Additionally, we believe that the agency's existing divisions will be able to address the additional operational questions around coding and payment through existing rulemaking and sub-regulatory guidance.

The MCIT Program Is of Great Importance to Medicare Beneficiaries with Diabetes

We acknowledge the troubling trend of the time delay between when a device is approved by the FDA and the period of time it takes to receive Medicare coverage; and note that the ADA broadly supports measures that will expand access to technology for beneficiaries with diabetes, whether this refers to technologies on the market today or in the future. We respectfully urge that CMS take extra care to avoid making choices that would limit access for people with diabetes, especially once it has already been rigorously tested and proven safe and effective.

Under MCIT, once the FDA approves a breakthrough technology as safe and effective, Medicare can quickly cover it – sometimes immediately after. That means Medicare patients can be some of the first people in line to get these vital technologies. Under current regulations, individuals with diabetes are often left waiting. FDA approval does not guarantee patients and providers immediate access to breakthrough devices; and obtaining Medicare coverage for new devices that could benefit Medicare-eligible seniors can take several years. Medicare-eligible seniors with conditions like diabetes could benefit from these new technologies if they were available more quickly.

We would be remiss if we did not acknowledge the rapid pace of development in diabetes technology. The ADA's *Standards of Medical Care in Diabetes – 2021 (Standards of Care)* states that new approaches and tools are available each year. It is at times hard for research to keep up with these advances because by the time a study is completed, newer versions of the devices are already on the market.[3] However, these technologies and devices are only effective for individuals with diabetes, if they actually make it into their hands.

[3] American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1, S93-94 (January 2021).

Lack of Access to Breakthrough Devices and Health Equity

In 2020, the ADA launched its HealthEquityNow initiative,[4] bringing attention to systemic barriers to healthcare faced by America's under-served communities. People with diabetes, a disproportionate number of whom are socioeconomically disadvantaged, are faced with barriers that include uneven access to diabetes management devices and other breakthrough technologies like insulin pump therapies and artificial pancreases. These FDA-approved technologies have been demonstrated to improve glucose control, which is known to reduce the long-term complications of diabetes, kidney failure, blindness, and amputations. The lack of access to these devices is a reality that brings with it the prospect of less-well-managed diabetes for those whose resources are most modest. This in turn raises serious risks of adverse health outcomes or even premature death for these individuals in our community.

One third (33%) of Medicare beneficiaries had diabetes in 2016, up from 18% in 2000; and the rate of diabetes is higher among certain groups, including more than 40% of black and Hispanic beneficiaries.[5] Many such beneficiaries, especially those in lower income brackets have no ability to access diabetes management technologies unless they are covered by Medicare. The MCIT program provides a crucial pathway for large numbers of Medicare beneficiaries living with diabetes to achieve more positive health outcomes, along with cost-savings.

Failure to implement MCIT could further compromise access to breakthrough devices by Medicare beneficiaries who lack supplemental insurance coverage, those who are dually eligible for Medicare and Medicaid, and traditionally suffer from diminished access to advanced technologies to treat their diabetes.

Conclusion

The American Diabetes Association appreciates the opportunity to submit our perspectives to CMS on MCIT.

As the agency continues to make decisions about moving forward with this rule, please do consider the individuals who are most impacted by this technology coverage pathway. On behalf of the community of 34 million Americans with diabetes, we value CMS' efforts to expand access to FDA-approved breakthrough technologies, especially those that help beneficiaries with diabetes live more fulfilled lives. We urge CMS to implement MCIT without delay, so Medicare beneficiaries may have quicker access to important next generation devices that will enhance their lives.

Should you have any questions or seek additional information regarding these comments, you may reach me at: lfriedman@diabetes.org.

[4] See https://www.diabetes.org/healthequitynow
[5] https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/

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Sincerely,

Laura Peck Friedman

Laura Friedman
Vice President, Federal Payment Policy