

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-3641
Minority (202) 225-2927

July 14, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

Providing access to innovative technologies is critical to ensuring our federal health care programs are best serving patients. Despite stating the Transitional Coverage of Emerging Technologies (TCET) rule would be proposed by April of this year, the Centers for Medicare and Medicaid Services (CMS) released the TCET proposed process nearly two months later on June 22, 2023.¹ As we review the CMS coverage policies in the rule, we urge you to encourage transparency in the agency's consideration of Medicare National Coverage Determination (NCD) requests overall.

An NCD defines the parameters of Medicare coverage for a particular item or service across the nation. The process requires a comprehensive, evidence-based review that necessarily incorporates public participation and feedback.² Today, however, there are an unknown number of review requests pending before the agency, with unknown time intervals for each review, and an unknown methodology for how these requests are prioritized. Consequently, patients are waiting for access to items and services without any visibility into the government's decision-making process or a means to anticipate when such products may be available to them, even after clearance, approval, or licensure by the Food and Drug Administration (FDA).

¹ Office of Management and Budget Unified Agenda, Fall 2022, available at

<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0938-AU86>

² Centers for Medicare & Medicare Services "Medicare Coverage Determination Process" available at

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess>

This uncertainty could prove harmful to Medicare patients. Beneficiaries may not be able to afford a product without Medicare coverage and will resort to less effective alternative treatments for their unique needs, or wait to receive necessary care until a coverage decision is granted by CMS. Some may choose to delay necessary care altogether until a coverage decision is granted by CMS. Additionally, patients outside of the Medicare program may also face barriers to getting an FDA-approved medical product their doctor may think is best while a CMS coverage decision is pending.

The uncertain timelines and opaque methodology used by CMS leave patients and medical innovators without any predictability for when products will formally be considered and what specific criteria will be used to determine whether or not innovators have submitted a “complete, formal request.”³ Ambiguity and uncertainty in the process also has the effect of deterring investment in better, innovative products.

CMS has not updated its NCD dashboard since September 16, 2020.⁴ The general public and medical innovators who have submitted applications for review have no certainty if a request is under review or on a waiting list. We are concerned that an unknown number of requests have fallen behind the statutory deadlines for review.⁵ The current status of the NCD waiting list may signify either the agency's inability to fulfill its duty of processing and informing the public about these requests or its unwillingness to carry out its statutorily assigned role. Either way, the agency should not interpret this breakdown in the application review process or failure to uphold the basic tenets of transparency and accountability as an opportunity to now begin the consideration of and acceptance of requests on its own timeline and terms.

In order to serve patients, providers, and medical innovators with greater transparency in the NCD process, please provide the following information to the Committees no later than July 28:

1. A comprehensive list of up-to-date items awaiting a formal NCD, which shall include, but not be limited to, all NCD requests which are under review, on the wait list, open, or that have been finalized within the past 12 months. Each request should include the date the request was initially made;
2. A plan for updating the NCD dashboard, which will detail how this information will be made available to the public and include specific timelines for how frequently CMS will publicly update the NCD dashboard.

³ Federal Register (78 FR 48164), Medicare Program; Revised Process for Making National Coverage Determinations, August 7, 2013, available at <https://www.federalregister.gov/documents/2013/08/07/2013-19060/medicare-program-revised-process-for-making-national-coverage-determinations>

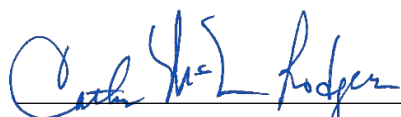
⁴ CMS National Coverage Determination Dashboard as of July 14, 2023, available at <https://www.cms.gov/files/document/ncd-wait-list.pdf>

⁵ Social Security Act, Section 1862(l), available at https://www.ssa.gov/OP_Home/ssact/title18/1862.htm and Social Security Act Section 1869 (f), available at https://www.ssa.gov/OP_Home/ssact/title18/1869.htm

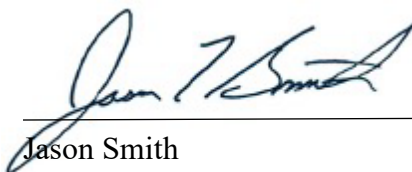
Providing basic transparency to the wait list is an important first step towards earning back the trust of patients and innovators who are disappointed in the prolonged delays of a new coverage pathway and the uncertainty about existing NCD requests. We also implore you to reconsider the unprecedented decision to restrict Medicare coverage for an entire class of Alzheimer's treatments through a blanket NCD, a decision that illustrates the fundamental problems with the vast agency discretion and political uncertainty within the review and determination process. Families struggling with Alzheimer's or other health conditions deserve a more transparent and predictable process for medical products already approved by the FDA.

We look forward to your cooperation and continued attention to these important matters that will have a meaningful impact on medical innovation and the patients who stand to benefit from it.

Sincerely,



Cathy McMorris Rodgers
Chair
House Committee on Energy and Commerce



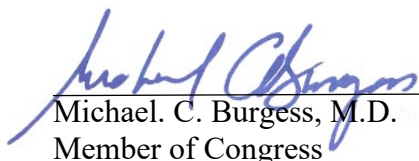
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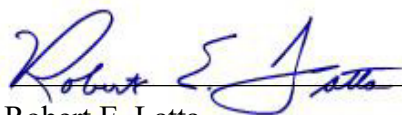
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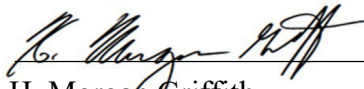
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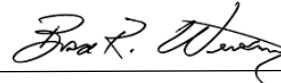
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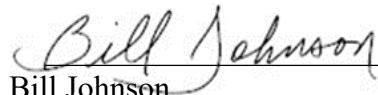
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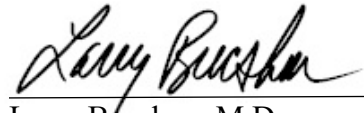
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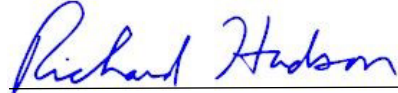
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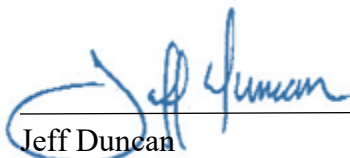
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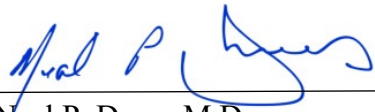
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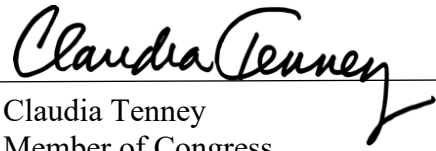
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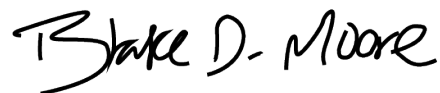
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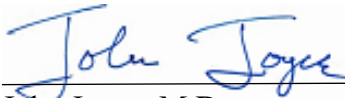
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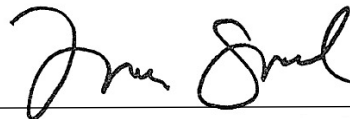
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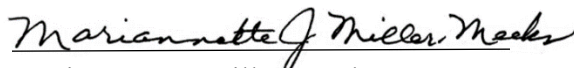
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