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November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Proposed Rule (CMS-3372-P; RIN: 0938-AT88)

Dear Administrator Verma:

We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') proposed rule on the Medicare Coverage of Innovative Technology (MCIT) pathway and the definition of "reasonable and necessary" as applicable to items and services furnished under the Medicare program.

Prevent Blindness is the nation's leading nonprofit, voluntary organization committed to preventing blindness and preserving sight. We strive to improve our nation's vision and eye health by enhancing state and community capacities through our core competencies of early detection, improved access to eye care, patient support, care coordination, public policy, research, advocacy, public awareness, and health education. As well, protecting and expanding access to sight-saving care is our priority for patients across the age continuum.

Introduction

As part of the Administration's goal to enhance seniors' access to new cures and technologies and improve health outcomes, CMS is issuing this proposed rule in accordance with President Trump's October 2019 Executive Order 13890 (E.O. 13890) "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors." E.O. 13890 directs the Secretary of the U.S. Department of Health and Human Services to make a number of regulatory changes to ultimately encourage innovation in the Medicare program, specifically by "streamlining the approval, coverage, and coding process" for breakthrough medical devices provided they also meet principles of patient safety and value. CMS is following up on this directive by offering two main proposals: codifying the term "reasonable and necessary" and creating the Medicare Coverage of Innovative Technology (MCIT) pathway to accelerate the new coverage of new, innovative breakthrough devices for Medicare beneficiaries. Prevent Blindness submits our feedback in response to these two proposals.

Medicare Coverage of Innovative Technology (MCIT) Pathway

We applaud CMS for creating the MCIT pathway to accelerate the coverage of new and innovative breakthrough devices for Medicare beneficiaries. If implemented, the MCIT pathway would promote faster coverage of and access to devices that can support patients in their health, ability to function in their daily lives, and live independently. We agree with CMS that the existing coverage pathways are not always admissible to new technologies and can present access and coverage barriers for the patients who need them.

In addition, we agree that the proposed four-year coverage term beginning on the date of market authorization, or premarket approval, granted by the Food and Drug Administration (FDA) under the MCIT is sufficient for purposes of developing and acquiring clinical evidence and data regarding real-world use and impact to health outcomes. We note the proposed rule does not include requirements for collecting data on device efficacy, which would help ensure permanent coverage and payment for devices at the conclusion of the four-year term.

Our concern is such that the proposed FDA process to cover devices used in accordance with an FDA-approved or cleared indication of use would preclude patient access to off-label drugs and devices. Implementing this policy must include specific guardrails to ensure that patients can access the devices and drugs that best applies to their conditions as determined by the patient and his or her provider. In addition, implementing the MCIT pathway through a regulation, rather than a National Coverage Determination (NCD), creates a rigidity that precludes beneficiaries from using the reconsideration or appeals processes to establish that a particular use is reasonable and necessary for their specific condition(s). We ask that CMS work with stakeholders to mitigate unintended consequences for patients who live with complex conditions who rely on innovative devices that may not necessarily be specific to their condition but may still contribute to better outcomes.

Of particular note, we reference our recent prior advocacy to this Administration that coverage for low vision aids, devices, and assistive technologies for patients who live with low vision or a visual impairment are typically prescribed and customized to meet the specific medical and functional needs of individuals with low vision resulting from a variety of medical eye conditions. We note that CMS is limiting devices under the proposals of this rule to medical devices because the E.O. 13890 specifically names them and because “breakthrough devices” specifically face coverage and payment barriers. We also note that the rule states: “Coverage would occur unless the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute (that is, the Medicare statute does not allow coverage for the particular device).” It is our hope that, should CMS reconsider its low vision aid exclusion in the future, streamlining the coverage and payment policies for new technologies will also ensure that patients can benefit from use of novel visual assistive devices and technologies that can enhance or restore a patient’s visual function and enable them to achieve better outcomes and quality of life.

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"Reasonable and Necessary" Definition

Prevent Blindness has significant concerns with the proposed criteria to codify how "reasonable and necessary" is defined, and we urge CMS to withdraw this proposal until additional and extensive stakeholder input is requested and considered. We are uncertain as to whether this definition as codified would apply to both devices and technologies as well as drugs, treatments, and biologics and are thus unable to offer specific recommendations as to how CMS ought to move forward with this proposal.

"Reasonable and necessary," should CMS codify it to the specific criteria outlined in this rule, may consequentially pose future barriers to the adoption of new technologies, especially for patients who face rare eye diseases or unique disease comorbidities. We believe medical necessity is a definition that is beholden to the patient's condition and clinical need as determined by a physician. For this reason, CMS uses carrier medical directors and local jurisdictions, where Medicare Administrative Contractors (MACs) determine medical necessity based on whether something is "reasonable and necessary" for an individual patient. Local MACs and their decision processes were designed to account for local variability in practice standards and adoption of new technologies. The insertion of a newly codified requirement, that a therapy be "appropriate for Medicare patients" may be overly broad, as it moves the inquiry away from one focused within the context of a specific condition and could trigger broader population-based non-coverage of emerging treatments. It may also hyperfocus medical necessity on evidence supporting treatments in aging populations and ignore the disparate needs of the program's disabled population. In addition, the Proposed Rule is not clear on whether it would apply only to devices or more broadly. We are particularly concerned about broader application, as it would likely trigger access constraints and increased provider burden.

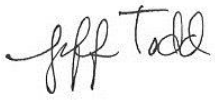
In addition, CMS proposes to include a requirement that Medicare cover technology if it is covered by one or more commercial plans, unless evidence supports that there is a difference between commercial plans and Medicare patients. Medicare has historically offered greater levels of coverage than the commercial market with fewer restrictions such as step therapy and prior authorization. If this approach is implemented, we are concerned that MAC duties would start to focus more on tracking commercial policies and incorporating their restrictions into the Medicare program than on making coverage decisions on claims-specific basis to ensure beneficiaries have access to care that it is appropriate. Additionally, we are concerned about the potential opportunity for insurers, who participate in both the commercial market and Medicare, to make decisions for their commercial plans to impact their Medicare coverage requirements. If this proposal moves forward, carefully crafted guardrails are needed to prevent the opportunity to craft policies in one program to influence requirements in other programs that could lead to poorer coverage for both commercial and Medicare beneficiaries.

Conclusion

Once again, Prevent Blindness appreciates the opportunity to submit comments on this proposed rule. We stand ready to work with CMS and the Administration to develop policies that truly lessen the

burden for patients and creates true access for those who face vision loss and eye disease. Please do not hesitate to contact Sara D. Brown, Director of Government Affairs, at (312) 363-6031 or email at sbrown@preventblindness.org if you or your staff would like to discuss these issues.

Sincerely,



Jeff Todd
President and Chief Executive Officer
Prevent Blindness