NATIONAL HEALTH COUNCIL
Celebrating 100 Years

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November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS-3372-P: Medicare Program: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on Medicare coverage of innovative technology and the definition of reasonable and necessary.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health- related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The following is our specific response to the details of the proposed rule.

Medicare Coverage of Innovative Technology (MCIT) Pathway
We applaud CMS for creating the Medicare Coverage of Innovative Technology (MCIT) pathway to accelerate the coverage of new, innovative

breakthrough devices for Medicare beneficiaries. Patients will benefit from these breakthrough devices because the pathway promotes faster coverage and access to devices that can support their health and independence.

While we support the creation of this pathway, one area that we would like greater clarity is on coverage of devices for off-label usage. CMS proposes requiring that devices covered under this pathway must be used according to an FDA approved or cleared indication for use*,* with off-label uses not covered on a national basis**.** We are concerned that these requirements could limit access for people with chronic conditions and disabilities who often need off-label drugs and devices to manage their health conditions. While we understand CMS' intent, we encourage them to develop safeguards to ensure patients have access, with minimal barriers, to the innovative devices they and their treating practitioners deem their best option, even if not specifically indicated for their condition. CMS should clarify that coverage through the MCIT pathway or other coverage pathways should not create a presumption of non-coverage for off-label use.

To assure the MCIT pathway truly supports the needs of patients, the NHC also urges CMS to work with stakeholders to ensure the pathway does not drive unintended consequences for beneficiaries with complex care needs. One such potential unintended consequence is that implementing the MCIT pathway through regulation, rather than a National Coverage Determination (NCD), while facilitating more timely access, could preclude beneficiaries from using the reconsideration or appeals processes to establish that a particular use is reasonable and necessary for their specific condition(s). The NHC is available and willing to work with CMS to develop patient safeguards.

Defining "Reasonable and Necessary"

The NHC urges CMS to withdraw the section of the proposed rule that codifies the definition of "reasonable and necessary" and suggests working through a separate, more deliberate approach that includes patient and other stakeholder input. The codification of the Program Integrity Manual definition of "reasonable and necessary" breaks from long-standing precedent, is not applicable to the overarching aim of the proposed rule, and could potentially have significant impacts on access for patients to devices and potentially pharmaceutical products. Because it is unclear what the scope of the definition would include, particularly whether it would include both devices and pharmaceutical products, it is difficult to comment on this definition in any detail. We suggest a thoughtful and thorough process to assure the definition is meets the needs of patients.

CMS has traditionally avoided a blanket definition of "reasonable and necessary" because it is a question without a single answer. Defining it would almost certainly deter adoption of many newer technologies, denying needed care to patients with rare conditions and/or combinations of comorbidities. The concept of medical necessity has, therefore, been interpreted as a beneficiary-specific inquiry. This is precisely why 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 that is focused within the context of a specific condition and could trigger broader population-based non-coverage of emerging treatments. It may also hyper-focus 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.

The proposed rule would also add 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 patients and Medicare patients. The NHC expects that this policy refinement could have a significant impact on coverage for the items and services to which it applies. The proposal states that MACs would be responsible for reviewing commercial offerings to inform Local Coverage Decisions (LCDs) and may also be allowed to develop coverage policies that mirror coverage limitations contained in commercial policies. 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, making decisions for their commercial plans that impact their Medicare coverage requirements. If this proposal moves forward, carefully crafted guardrails are needed to prevent the opportunity to develop policies in one program that influence requirements in other programs which could lead to poorer coverage for both commercial and Medicare beneficiaries.

Conclusion

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Eleanor Perfetto, PhD, MS
Interim Chief Executive Officer and
Executive Vice President, Strategic Initiatives