NATIONAL HEALTH COUNCIL

National Health Council
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April 16, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–1850

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

Dear Acting Administrator Richter:

The National Health Council (NHC) appreciates the opportunity to provide comments on the above-referenced Interim Final Rule (the MCIT Rule) as the Centers for Medicare & Medicaid Services (CMS) determines next steps on Medicare coverage of innovative technologies and a codified definition of "reasonable and necessary."

Created by and for patient organizations over 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.

Our comments and recommendations build upon those submitted in response to the proposed MCIT Rule (November 2, 2020 comments attached) and address the specific areas on which CMS has requested stakeholder feedback.

Medicare Coverage of Innovative Technology (MCIT) Pathway

The NHC continues to support CMS' efforts to pursue a streamlined coverage pathway for breakthrough devices and urges swift implementation.

Responses to CMS' Questions

CMS highlighted concerns expressed by stakeholders that the MCIT pathway should not be initiated until CMS establishes coverage, coding, and payment for breakthrough devices. The NHC agrees that advances in technology often present challenges for CMS with respect to determining benefit category and establishing the necessary coding and payment mechanisms to support claims payment. These concerns are independent of the MCIT pathway and have been resolved by the Agency each time innovations are introduced and incorporated into medical practice. Given that it is unlikely, if not impossible, that CMS can accurately predict breakthrough devices seeking coverage through the MCIT pathway, there is little benefit to delaying MCIT to proactively predict benefit category, coding gaps, and payment methodologies for future breakthrough devices. The NHC suggests CMS outline the MCIT process to incorporate a timeline for benefit category determinations, with payment mechanisms based on benefit category and sets of miscellaneous codes to enable claims processing until permanent coding is established.

CMS also requested feedback on whether reliance on medical device safety communications, FDA-issued warning letters, and revocation of market authorization to trigger removal of breakthrough devices from the MCIT pathway is sufficient to balance safety with access to new technologies. The NHC agrees with this approach and urges CMS to decline requiring specific evidence of benefit to the Medicare population, particularly if this definition is solely focused on the elderly population. The Medicare beneficiary population is quite diverse. Nearly one in six Medicare beneficiaries are under the age of 65 and are enrolled based on their disability status. Population-based evidence requirements tend to ignore this diversity and focus on elderly patients to the detriment of Medicare's disabled population. CMS' revision to the MCIT strikes an appropriate balance between adequately protecting patients and ensuring access to promising new technologies.

Protecting Appropriate Off-Label Usage

We remain concerned that codifying national non-coverage for off-label uses of breakthrough devices utilizing the MCIT pathway could disproportionately limit access for people with chronic diseases and disabilities who often rely on off-label uses to manage their health conditions. Absent a national coverage decision, device coverage is generally left to contractor discretion, evolving over time as providers gain experience with new technologies and identify the patients most likely to benefit from their use. Establishing blanket, codified noncoverage for these devices would deny beneficiaries all rights of appeal and require a direct challenge to the underlying regulatory language to enable access. The NHC urges CMS to retain the potential for off-label coverage of MCIT pathway devices by either (1) establishing the MCIT pathway through a National Coverage Determination (NCD) rather than regulation, or (2) explicitly provide for contractor discretion with respect to coverage of off-label uses.

Defining "Reasonable and Necessary"

The NHC appreciates CMS' acknowledgement of stakeholder concerns associated with the codification of a "reasonable and necessary" definition. Our November 2, 2020 comments urged CMS to finalize the MCIT pathway and rescind this provision, and we continue to believe that this option would best serve patients, providers, and the Medicare program.

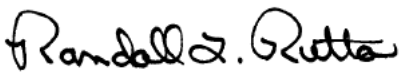
The NHC is concerned that the proposed MCIT Rule failed to give notice to the public that CMS intended to take the unprecedented step of identifying and codifying a single definition of "reasonable and necessary" that would apply beyond MCIT devices to drive coverage decisions for all items and services and apply to individual claim disposition, local coverage decisions, and NCDs. We believe that this procedural deficiency is particularly problematic in light of the far-reaching implications the definition could have on access to care for people with chronic conditions.

The "appropriate for Medicare patients" requirement in the MCIT Rule's definition of "reasonable and necessary" sets a population-level benchmark that may be appropriate within the context of national coverage but has far less relevance in determining whether a particular patient would benefit from a specific treatment or service. As previously stated, we are concerned that this population-based approach would likely largely ignore the needs of the program's non-elderly, disabled population. Also importantly, the population-level inquiry would likely drive evidence required on appeal, leaving patients unable to demonstrate that their care needs justify a particular item or service. Without properly considering these gaps, we are concerned that this new approach to defining "reasonable and necessary" will likely drive non-coverage of products and services people with chronic diseases and disabilities need to manage their conditions.

Conclusion

We appreciate the opportunity to provide additional input on these important issues. As we did in our November 2020 comments, we continue to support implementation of the MCIT pathway but have concern regarding the codification of "reasonable and necessary." 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,



Randall L. Rutta
Chief Executive Officer