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<http://www.regulations.gov>

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-3372-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: [CMS-3372-P] Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

Dear Administrator Verma:

The American Geriatrics Society (“AGS”) greatly appreciates the opportunity to comment on the Medicare Program; Medicare Coverage of Innovative Technology (“MCIT”) and Definition of “Reasonable and Necessary” (CMS-3372-P).¹ The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners (“NPPs”) who are devoted to improving the health, independence, and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy.

The AGS applauds the engagement by the Centers for Medicare & Medicaid Services (“CMS”) with stakeholders on expanding Medicare coverage for faster access to innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA) under the MCIT pathway. In addition to the MCIT proposal, CMS also proposes to define the term “reasonable and necessary” and to allow coverage of items based on commercial health insurance coverage. Medicare coverage based on commercial coverage would not be allowed if evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals. We are concerned this proposal could discourage manufacturers from enrolling Medicare-age beneficiaries in clinical trials.

The AGS believes that high-quality and person-centered care requires inclusive clinical trials, especially of older adults, to ensure the safety and effectiveness of drugs and other interventions for the patients who will be the ultimate recipients of the therapies. We are concerned that the proposal to allow Medicare coverage based on commercial coverage could significantly affect the population enrollment

¹ 85 Fed. Reg. 54327 (Sep. 1, 2020).

of future studies. Manufacturers may choose not to enroll older individuals in clinical trials to avoid demonstrating a clinically relevant difference between commercial and Medicare populations and thus shut off this potential route to Medicare coverage.

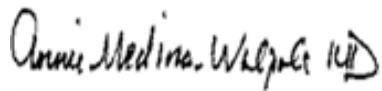
Currently, older adults, especially those with poor health, functional limitations, and multiple chronic conditions, are frequently excluded from randomized clinical trials; however, these are the individuals who disproportionately suffer from many target conditions, generate a large share of healthcare costs, and who are most vulnerable to the adverse effects of medications and device-based treatments. Despite these clinical realities, providers and older adults often have little guidance on comparative effectiveness of treatments. We believe that study populations should mirror the demographic prevalence of the conditions in the community—which translates into enrolling more, and more representative, older adults into trials. The AGS has participated in efforts by the National Institutes of Health (NIH) to improve inclusion in clinical research across the lifespan and has provided recommendations of specific strategies and requirements we believe will ensure all ages are included in clinical trials. The Inclusion Across the Lifespan policy was quickly adopted by the NIH (a copy of the AGS Report on Engagement Related to the NIH Inclusion Across the Lifespan Policy which includes a summary of the policy and NIH's implementation of the policy change is attached).

The AGS urges CMS to avoid creating a disincentive to get more and better data about how clinical therapies work or do not work for Medicare beneficiaries and to assure that older adults have access to evidence-based care and interventions. We recommend that CMS not finalize the proposal related to commercial coverage until it has provided additional guidance on how it would implement the provision, including how it would avoid creating a disincentive to enroll Medicare beneficiaries in relevant clinical trials, and offer an additional opportunity for public comment on those steps.

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Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Anna Kim, akim@americangeriatrics.org.

Sincerely,



Annette Medina-Walpole, MD, AGSF
President



Nancy E. Lundebjerg, MPA
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