April 16, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary;" Delay of Effective Date; Public Comment Period; Interim final rule; request for comments (IFC)

Dear Acting Administrator Richter:

The American Society of Nephrology (ASN) thanks you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Interim Final Rule (IFR) delaying the effective date and requesting comments on the recent final rule on *Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."* ASN, representing more than 21,000 physicians, scientists, nurses, and other kidney health professionals, has long advocated for streamlined approaches to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for beneficiaries who suffer from kidney diseases – especially kidney failure. While ASN's comments have most recently dealt with the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) in the End-Stage Renal Disease (ESRD) bundle, ASN believes the same principles apply to the MCIT program and urge CMS to implement the program on May 15, 2021 as scheduled.

With 37,000,000 Americans with kidney disease and 550,000 receiving dialysis treatment, innovative, breakthrough devices – whether they are solely kidney-specific or not – are urgently needed for these and millions of other chronically ill patients in the Medicare system. The IFR is crucial to ensuring patient access to breakthrough devices determined to be safe and effective by the Food and Drug Administration (FDA) and equally critical to promoting the development of Real-World Evidence (RWE). The MCIT pathway helps address access barriers arising from the existence of a "coverage gap" between FDA approval and CMS or Medicare Administrative Contractor (MAC) coverage of breakthrough devices. This gap can delay access to innovative and well-reviewed technologies by patients who may greatly benefit from their use and whose health might deteriorate otherwise.

CMS wrote:

The MCIT pathway would address uncertainty in Medicare coverage for newly FDA market-authorized breakthrough devices. While the rule would eliminate coverage uncertainty early after FDA market authorization and automates coverage "so that

innovative products are brought to market faster," the rule did not directly address operational issues, such as how the agency would establish coding and payment levels for particular devices, which are both central to prompt market access.[i]

CMS appears to be both making a case for the MCIT pathway and identifying necessary next steps – not reasons for delay. ASN concurs with this approach of identifying next steps and moving forwards with MCIT. Therefore, while the IFR is implemented, ASN encourages CMS to provide additional guidance to address any operational difficulties surrounding coding, payment, and benefit category determination. These efforts could be guided by the new Technology, Coding, and Payment Group CMS established in late 2020. This new group incorporates a pilot project under which knowledgeable CMS staff could address the coverage, coding, and payment issues to assist with the objective of delivering critical new technologies to Medicare patients safely and expeditiously.

Apart from the new MCIT pathway, the IFR also codifies long-standing sub-regulatory guidance as to when items and services that are not covered during the 4-year MCIT approval period will be deemed eligible for Medicare coverage. One of the Medicare coverage limitations imposed under Section 1862(a) of the Social Security Act (the "Act") is that items and services may not be covered if they are not "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.[ii] While there was disagreement among some healthcare groups regarding the "reasonable and necessary" language in relation to commercial insurers, CMS clarified that it will promulgate sub-regulatory guidance within the next 12 months that details how coverage of an item or service by commercial insurers may influence Medicare coverage determinations. CMS also clarified that Breakthrough Devices are considered "reasonable and necessary" during the four-year period of MCIT eligibility by virtue of meeting the unique criteria of FDA Breakthrough Devices Program.[iii]

By providing more predictability across the four-year MCIT window, the policy meets a major gap in the existing process of bringing innovative new products to market to address unmet patient needs. Because four-year window is just that—a window—there is ample time to utilize RWE to ensure products that qualify for FDA Breakthrough status are appropriately and safely meeting the needs of CMS beneficiaries. ASN believes CMS should finalize the IFR and proceed with sub-regulatory guidance consecutively.

ASN encourages CMS to leverage existing approaches in developing guidance to implement the benefit category, coding, and payment processes as it implements MCIT, as proposed, moving forward.

As was acknowledged in prior comments and by CMS, MCIT - like all other facets of CMS payment - does not take into account cost effectiveness. Should CMS wish to incorporate cost-effectiveness, the methodology to do so would need to be developed in

a highly transparent manner that engages stakeholders as well as prioritizes patient input and preferences.

Kidney patients and other chronically ill Americans need CMS' diligence to ensure coverage of innovative devices supports the intent of FDA's breakthrough status in a timely fashion and allows the collection of RWE to be gathered as long as both CMS and FDA deem the device safe.

Again, ASN stands ready to work with CMS on any of the issues raised in this comment letter. Thank you for the opportunity to provide comments on this IFR. ASN would be pleased to discuss these comments with CMS if it would be helpful. To discuss ASN's feedback regarding the IFR, please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org or (202) 640-4635.

Thank you for your consideration.

Sincerely,

Susan E. Quaggin, MD, FASN
President

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[i] https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf
[ii] 42 U.S.C. § 1395u(a)(1)(A)
[iii] 86 Fed. Reg. 2987, 2997 (Jan. 14, 2021)