



October 15, 2021

The Honorable Chiquita Brooks-LaSure
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 Administrator Brooks-LaSure:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services’ (CMS) decision to repeal final rule on *Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary.”*

Representing more than 21,000 physicians, scientists, nurses, and other kidney health professionals, ASN 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. The rule would have granted expedited Medicare coverage for up to four years for any U.S. Food & Drug Administration (FDA)-designated breakthrough device once the device received or cleared market authorization.

More than 37,000,000 Americans have kidney disease and nearly 550,000 Americans receive dialysis treatment. As such, innovative, breakthrough devices—whether they are solely kidney-specific or not – are urgently needed for these and millions of other chronically ill patients who are Medicare beneficiaries. A real “coverage gap” exists for Americans under Medicare who often face difficulty accessing the new therapy, include denials of coverage by Medicare Administrative Contractors (MACs) and Medicare Advantage plans based on a general finding that the technology is “experimental or investigational” without any evidentiary review. This gap can result in Medicare beneficiaries who must pay the full cost out of their pocket for such new therapies.

In the announcement of this decision, CMS wrote: “It [the rule] would have guaranteed coverage of any device that received FDA breakthrough designation and market authorization without consideration as to whether the device is appropriate and provides benefits for the Medicare population. In other words, the rule did not require that the device demonstrate clinical benefits for people with Medicare—as well as concerns that the device might later be shown to pose greater risk of harm for those patients.”

Considering these concerns, ASN urges CMS to move forward on a proposed new rule with an understanding of the need to protect the Medicare program and its beneficiaries. ASN stands ready to help CMS in this regard however possible. Kidney patients and other chronically ill Americans need CMS's diligence to ensure coverage of innovative, safe devices.

ASN's members, leadership, staff, and I appreciate the opportunity to provide comments on CMS's decision. My colleagues and I would be pleased to discuss these comments with you and your team if it would be helpful.

Again, ASN thank you. ASN looks forward to working with CMS on any of the issues related to payment for innovation. 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.

Sincerely,

A handwritten signature in cursive script that reads "Susan Quaggin".

Susan E. Quaggin, MD, FASN
President

cc: David L. White