



October 15, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3372-P2  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
*Submitted electronically at: <http://www.regulations.gov>*

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" [CMS-3372-P2]

Dear Administrator Brooks-LaSure:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,800 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. SIR appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) CY 2022 Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Proposed Rule.

**Proposed:** CMS released the proposed MCIT rule to establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as a breakthrough by the Food and Drug Administration (FDA). The MCIT pathway would begin national Medicare coverage on FDA market authorization and continue for four years. This ruling has undergone several iterations since it was initially proposed on August 30, 2020, and the final rule was published in the Federal Register on January 14, 2021. On January 20, 2021, the memorandum "Regulatory Freeze Pending Review" delayed the final rule for 60 days from publication with a 30-day comment period open to stakeholders to comment on the appropriateness of the ruling and whether it should be revised or rescinded. CMS determined that further delay of the ruling was appropriate and supported by stakeholders. CMS indicated this delay would allow time to review and consider the issues explicitly raised related to Medicare patient protections and evidence criteria. The Interim Final Rule, which took effect on March 12, 2021, delayed the implementation until May 15, 2021. Based on comments received in the March 2021 comment period, CMS released a proposed repeal of MCIT/R&N on September 14, 2021. Within this proposed rule, CMS expanded on the definition for "Reasonable and Necessary." Due to the timeline, a 30-day comment window was opened to ensure stakeholder feedback could be reviewed and appropriately considered before the deadline for implementation of this ruling, previously set for December 15, 2021.

**Impact:** SIR appreciates CMS' delay in implementing this rule and extending the comment period for specialty societies and other stakeholders. However, the proposal's current form defeats its original purpose of improving the health of Medicare beneficiaries by reducing the time between the receipt of FDA marketing authorization and the completion of the Medicare coverage, coding, and payment changes.

**SIR's recommendation:** CMS must move forward quickly to develop, propose and finalize a new rule to create an expedited coverage pathway for innovative new technologies to improve care for Medicare beneficiaries. CMS should also immediately address issues specifically related to coding and payment for the applicable devices.

**Proposed:** CMS expressed concerns on whether the approved Breakthrough Devices have enough support and evidence to be reasonable and necessary for treating Medicare beneficiaries for specific diseases and conditions. The Medicare Administrative Contractor (MAC) can currently deny claims for a device if deemed harmful to Medicare beneficiaries. However, with the current proposal, CMS is concerned that MAC's will no longer have the ability to address MCIT/R&N coverage determination on a case-by-case basis. CMS is also concerned that the Medicare population is not required by the Federal Drug Administration (FDA) to be part of or included in the clinical studies for market authorization of the Breakthrough Devices. This could lead to coverage of devices without evidence demonstrating any benefit or reasonable outcome for Medicare beneficiaries.

**Impact:** MCIT/R&N only addresses or eliminates issues with coverage but does not outline how coding and payment would be established. This proposed ruling will compound the existing coverage gap for Medicare beneficiaries. The available pathways for defining Medicare coverage policy—the national coverage determination (NCD) process, the issuance of local coverage determinations (LCDs) by Medicare Administrative Contractors (MACs), and claim-by-claim adjudication by MACs—have proven insufficient to address those adverse impacts, as have other initiatives such as FDA-CMS parallel review. In addition, such restrictions will make it more difficult for device innovators to navigate the Medicare coverage process and ascertain the evidence that will be required to achieve coverage. The adverse impacts of all these issues include further delays and uncertainty for both beneficiaries and investments in new medical innovations.

**SIR's recommendation:** SIR appreciates that CMS has indicated that the proposed repeal of this rulemaking does not remove the possibility of future rulemaking related to access to innovative and beneficial technologies. Therefore, SIR agrees with the CMS proposal to repeal the MCIT/R&N ruling slated to take effect on December 15, 2021. However, CMS must involve specialty societies in the necessary review and consideration of other potential solutions ensuring the inclusion of and appropriate access to care for Medicare beneficiaries. In addition, CMS must engage with specialty societies to provide recommendations on the valuation for the devices/related physician services within the MCIT pathway. This guidance by the specialty societies will provide CMS with additional support to understanding the new technologies and the populations they are designed to serve.

**SIR's additional comments:** At this time, the operational concerns which have yet to be addressed will create more confusion and stress for stakeholders as they attempt payment for Breakthrough Device services. Additionally, SIR has concerns with the lack of evidence to support efficacy for the Breakthrough Devices in the Medicare population covered by this ruling. Therefore, as expressed in our previous comment letter, to the initial proposed rule released on August 30, 2020:

- SIR opposes coverage policies from insurers operating in the commercial market as a determinative basis for Medicare coverage. CMS must establish less restrictive coverage policies and conduct post utilization review to determine if actual utilization matched CMS' projected utilization numbers and create a consistent MCIT coverage within the MAC jurisdictions
- SIR urges CMS to require manufacturers to conduct and publish clinical studies during the MCIT coverage period of their device.

Once again, SIR appreciates the opportunity to provide meaningful feedback to the MCIT proposed rule. If you have any questions, please feel free to reach out to SIR's Senior Director, Clinical and Practice Affairs, Miata Koroma Ekanem, at [mkoroma@sirweb.org](mailto:mkoroma@sirweb.org) or (703) 460-5599.

Sincerely,

A handwritten signature in black ink, appearing to read 'Matthew S Johnson', with a stylized flourish at the end.

Matthew S Johnson, MD, FSIR  
SIR President

Cc: Keith M Hume  
SIR Executive Director