Issue Brief

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CMS Proposes Repealing Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

The Centers for Medicare and Medicaid Services (CMS) are proposing to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule, which was published on January 14, 2021, and was to be effective beginning December 15, 2021.

In an interim final rule that took effect on March 12, 2021 (hereinafter referred to as the "March 2021 IFC"), CMS delayed the MCIT/R&N final rule effective date until May 15, 2021.

The proposed 29-page rule is scheduled for publication in the September 15 ***Federal Register***. A 30-day comment period is provided.

CMS says it developed MCIT in part due to concerns that delays and uncertainty in Medicare coverage slowed innovation and impaired beneficiary access to important new technologies, specifically those designated as breakthrough devices by the Food and Drug Administration (FDA). In response to those concerns, the rule provided 4 years of expedited coverage to FDA market authorized Breakthrough Devices on the first day of FDA market authorization or a select date up to 2 years after the market authorization date as requested by the device manufacturer.

CMS now believes that the finalized MCIT/R&N rule is not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose.

Further, CMS says that in general, Medicare patients have more comorbidities and often require additional and higher acuity clinical treatments which may impact the outcomes differently than the patients generally enrolled in early clinical trials. These considerations are often not addressed in the early device development process.

While CMS is proposing to repeal the MCIT/R&N final rule, this action would not prohibit coverage of Breakthrough Devices. CMS says that in the May 2021 final rule, even without the MCIT/R&N final rule in effect, a review of claims data showed that Breakthrough Devices have received and are receiving Medicare coverage when medically necessary. Many of the eligible Breakthrough Devices are coverable and payable through existing mechanisms.

CMS states that if the MCIT/R&N final rule is repealed as proposed, the revisions to part 405 of Title 42 of the Code of Federal Regulations would not occur and the text would remain unchanged. Specifically, a definition of "reasonable and necessary" would not be included among the terms defined at 42 CFR 405.201(b) and the guidance that the rule would have required (subregulatory guidance on the topic of utilization of commercial insurer polies) would not be introduced. Additionally, Subpart F, which wholly consisted of Medicare Coverage of Innovative Technology, would not be added, and Subpart F would remain reserved for other purposes.

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