

**Repeal of the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"**  
**Final Rule: What Orthopaedic Surgeons Should Know**

On September 15, 2021 CMS released a proposed rule to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule, which is set to become effective on December 15, 2021. The MCIT pathway would have provided immediate Medicare coverage of newly FDA market authorized breakthrough devices for up to four years. CMS cites concerns that the MCIT policy could "provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose" as the primary reason for walking back the policy.

Highlights from the proposed rule:

- The proposed repeal would happen prior to implementation of the MCIT pathway, hence current Medicare coverage of medical devices will not be affected.
  - Repeal of the MCIT policy also does not bar future Medicare coverage of Breakthrough Devices.
- CMS is concerned that the clinical evidence used to gain Breakthrough Device designation is not applicable to the Medicare population because the MCIT pathway does not require clinical trial data on Medicare beneficiaries.
- There are also concerns that the MCIT pathway could incentivize healthcare providers to choose an MCIT-covered device instead of a device that is more beneficial to the patient due to the guarantee of coverage.
- CMS is open to addressing coverage for innovative technologies in future rulemaking and points to better utilizing existing pathways (e.g. National Coverage Determinations, Local Coverage Determinations, and claim-level adjudications) as a potential solution.
- CMS is interested in whether the previously codified definition of "reasonable and necessary" should be repealed, remain as is, or be modified to address concerns about how CMS would utilize commercial insurer coverage policies in future sub-regulatory guidance.

For more information see the [Notice of Proposed Rulemaking in the Federal Register](#).

For AAOS's comment letter on the 2020 MCIT Proposed Rule [here](#).