



CMS Issues Proposed Rule for Medicare Coverage of Breakthrough Medical Devices

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The Centers for Medicare and Medicaid (CMS) released a [proposed rule](#) on September 1 which would provide Medicare beneficiaries nationwide with faster access to innovative medical devices. This rule originated from an [Executive Order](#) signed by President Trump on October 3, 2019. The Order sought to enhance Medicare coverage by making breakthrough medical devices “widely available, consistent with the principles of patient safety, market-based policies, and value for patients.” The proposed rule is another initiative of CMS to reduce or eliminate burdensome regulations that slow down the innovation process.

The new pathway created for breakthrough medical devices will be called the Medicare Coverage of Innovative Technology (MCIT). MCIT will greatly improve the existing go-to-market requirements, which typically require FDA approval prior to Medicare coverage being available. This delay has been dubbed the “valley of death” due to the significant amount of time which can occur between the two stages. Without Medicare approval, patients are required to pay out of pocket for any devices which may be beneficial to their health.

For a device to utilize this new pathway, the device must meet two criteria. First, it must provide for effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The second criterion is that the device must satisfy one of the following elements:

- It represents a breakthrough technology;
- No approved or cleared alternatives exist;
- It offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or
- Device availability is in the best interest of patients

To accelerate the pathway for coverage of new, innovative breakthrough devices to Medicare beneficiaries, CMS has also proposed a new definition for the term “reasonable and necessary.” Previously, CMS relied upon factors not established in regulations for determining whether certain coverages are “reasonable and necessary.” This new codification of the definition is in line with CMS’s [previous proposed rule](#) regarding good guidance practices.

Now, CMS is modifying factors found in the Medicare Program Integrity Manual to create a definition which will be codified by rule and provide greater clarity for stakeholders in how the Secretary of Health and Human Services will make a determination of “reasonable and necessary” devices that will be covered by Medicare. The new requirements provide that to be considered “reasonable and necessary,” the item or service must be:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate for Medicare patients, including the duration and frequency that is considered appropriate and whether it is covered by commercial insurers.

Device makers can voluntarily opt to utilize the MCIT pathway by informing CMS of their interest. The coverage approval would then begin on the date of the FDA market authorization and continue for a period of four years.

If you have questions about how the new MCIT proposed pathway may affect you or are interested in submitting comments to these proposed rules, please contact [Matthew R. Wagner](#), [Bill Williams](#), or any attorney with Frost Brown Todd’s [Insurance Regulation & Risk Management Group](#).

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