

# **CMS Proposes Changes to Medicare's Coverage Determination Criteria and Expedites Approval of Breakthrough Devices**

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The Centers for Medicare and Medicaid Services recently issued a [proposed rule](#) that would grant Medicare coverage to breakthrough medical devices immediately upon FDA approval. The rule also proposes to codify a new definition of “reasonable and necessary” for Medicare national coverage determinations that takes into account commercial insurance coverage of items and services. It is unclear how broadly this new “reasonable and necessary” definition will apply if the proposed rule is finalized.

## **New Devices Face a Lag in Medicare Coverage**

Newly approved medical devices currently undergo a lengthy process to obtain Medicare coverage after FDA approval. CMS [describes](#) the gap between FDA approval and Medicare coverage as a “valley of death” for innovative products designed for Medicare beneficiaries. Hyperbole aside, the lag between approval and coverage can delay seniors' access to innovative products. It also requires device manufacturers to expend additional time and resources after FDA approval to begin generating Medicare revenue, which may dissuade some investment in innovative products.

CMS purports to address two barriers to Medicare coverage through the proposed rule. First, CMS notes that new products can face a “chicken and egg” scenario when seeking coverage. Medicare coverage determinations require device manufacturers to demonstrate the relevance and medical benefits of the device to individuals eligible for Medicare. Obtaining that evidence may be a challenge: new devices will not be widely available to Medicare enrollees when coverage is sought because the devices are not covered by Medicare at that time. Second, initial coverage determinations are often made at the local level by one of sixteen Medicare Administrative Contractors (MACs). Each MAC's local coverage determination (LCD) applies only within its jurisdiction. National coverage determinations (NCDs), by contrast, apply nationwide. The LCD system creates a patchwork of Medicare coverage for new devices. CMS suggests patchwork coverage may dissuade investment and leaves some seniors without access to novel devices that could improve their health.

## **The MCIT Pathway Eliminates the Medicare Coverage Lag for Breakthrough**

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## Devices

CMS proposes to create the Medicare Coverage of Innovative Technologies (MCIT) Pathway to address both of the above barriers. The MCIT Pathway would grant immediate, national-level coverage for devices designated as “breakthrough devices” by the FDA. FDA’s Breakthrough Devices Program is a product of the 21st Century Cures Act. The program is intended to expedite the development, review, and approval of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or debilitating conditions.

Under the MCIT Pathway, Breakthrough Devices would automatically be considered “reasonable and necessary” by Medicare and thus meet the standard for Medicare coverage. MCIT Pathway coverage will be effective immediately upon FDA approval and would last four years. In CMS’s view, these four years of Medicare coverage permit manufacturers to conduct clinical studies in support of an eventual NCD, while simultaneously obtaining Medicare reimbursement to fund those efforts. Thus, the MCIT Pathway would eliminate the Medicare coverage gap and avoid inconsistent LCD coverage determinations for Breakthrough Devices.

CMS is expressly seeking comment on whether the MCIT pathway should also include diagnostics, drugs, and/or biologics that utilize other breakthrough or expedited approaches at FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval). CMS is also seeking comment on whether the MCIT pathway should be expanded to all diagnostics, drugs, and/or biologics.

### **The Proposed Codifies a New Definition of “Reasonable and Necessary”**

The proposed rule would codify a new definition of “reasonable and necessary” if finalized. By statute, Medicare may cover items and services if they are “reasonable and necessary,” as that term is defined by HHS. HHS currently defines “reasonable and necessary” in [guidance to MACs regarding their LCD criteria](#). Items and services are “reasonable and necessary” under the proposed rule when they are:

1. Safe and effective;
2. Except as set forth in § 411.15(o)) of this chapter, not experimental or investigational; and
3. Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it
  1. Meets all of the following criteria:
    1. Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
    2. Furnished in a setting appropriate to the patient’s medical needs and condition;
    3. Ordered and furnished by qualified personnel;
    4. One that meets, but does not exceed, the patient’s medical need; and

5. At least as beneficial as an existing and available medically appropriate alternative; or
2. Is covered by commercial insurers, unless evidence supports that differences between Medicare.

This proposed definition is identical to the agency's LCD guidance to MACs, with the new addition of an alternate avenue for Medicare coverage based on commercial insurer coverage in (3)(ii).

## Open Questions

The proposed rule opens several questions. First, it is not clear what role commercial coverage and commercial insurance policies will play in CMS's "reasonable and necessary" determinations going forward. CMS states that "the commercial market analysis would be initiated if an item/service fails to fulfill the existing factor (3) criteria defining appropriate for Medicare patients ...," and that the agency "will bring together the expertise of private payers and CMS." But the proposed rule does not indicate the weight CMS will place on commercial coverage, or how the agency will handle coverage differences among commercial insurers.

Second, it is unclear to what set of items and services the proposed "reasonable and necessary" criteria apply. CMS's [Fact Sheet](#) published along with the proposed rule states, "this proposed definition would apply all Medicare items and services ... ." But the text of the proposed rule indicates otherwise. The proposed rule adds "reasonable and necessary" to the definitions listed at [42 CFR § 405.201\(b\)](#). This subsection is specific to Medicare coverage of devices with an investigational device exemption from FDA. As such, terms defined here are not broadly applicable to all "Medicare items and services," as CMS suggests. CMS has not clarified this discrepancy.

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