AAOS
American Association of Orthopaedic Surgeons

CY 2021 Medicare Coverage of Innovative Technology (MCIT) Proposed Rule

On August 31, 2020, the Centers for Medicare & Medicaid Services released a proposed rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" in response to President Trump's "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors" (EO 13890). The Executive Order specifically directs the Secretary of Health and Human Services to clarify coverage standards and make innovative medical devices widely available to Medicare patients.

Defining the term "reasonable and necessary"

CMS is proposing to codify, with some modifications, the definition of "reasonable and necessary" from the Medicare Program Integrity Manual. Specifically, an item or service would be considered "reasonable and necessary" if it is:

1) Safe and effective,
2) Not experimental or investigational,
3) And appropriate for Medicare patients, including in frequency and duration, in terms of whether it is:
    a. 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;
    b. Furnished in a setting appropriate to the patient's medical needs and condition;
    c. Ordered and furnished by qualified personnel;
    d. One that meets, but does not exceed, the patient's medical need; and
    e. At least as beneficial as an existing and available medically appropriate alternative.[1]

Alternatively, an item or service may meet the criteria under (3) if it is covered by a commercial insurance plan, except where there are clinically relevant differences between Medicare beneficiaries and commercially insured patients.

MCIT Pathway

CMS is proposing the MCIT pathway as a mechanism for providing immediate national Medicare coverage for breakthrough medical devices. The pathway applies to only those devices designated as part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and are FDA market authorized (i.e. receives Premarket Approval, 510(k) clearance, or De Novo classification). Per CMS, FDA-designated breakthrough devices generally meet the definition of "reasonable and necessary" described above.

Coverage begins on the day of FDA market authorization and would continue for up to four years, unless the device is statutorily non-covered. Devices are covered only for FDA-approved indications, thus "off-label" indications would not be covered. CMS is asking for stakeholder feedback on whether "off-label" indications should be covered and what evidence should be required to support these coverage determinations.

[1] Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 80 Fed. Reg. 54327-54339 (proposed September 1, 2020) (to be codified at 42 CFR Part 405)

After the MCIT coverage period ends, coverage of breakthrough devices can be achieved through the currently available processes: National Coverage Determination or Medicare Administrative Contractor discretion (i.e. claim-by-claim coverage decisions or Local Coverage Determination (LCD) policy). CMS is seeking comment on whether a National Coverage Analysis should be performed if an LCD does not exist for a breakthrough device six months after the MCIT coverage period ends.

The MCIT pathway would be voluntary and CMS proposes manufacturers would initiate the process by notifying CMS of the intent to utilize the pathway via email. CMS is interested in stakeholder feedback on whether an opt-out process would be less burdensome. Devices covered under the MCIT pathway would be posted on the CMS website.

CMS is also soliciting comments on whether the MCIT pathway should also apply to drugs, diagnostics, and/or biologics subject to breakthrough or expedited FDA approval mechanisms.

The proposed rule can be accessed online at https://www.federalregister.gov/d/2020-19289.
Public comments should be submitted on or before 5:00 pm EDT on November 2, 2020.