Summary: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

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Comments Due: November 2, 2020

On September 1, 2020, the Centers for Medicare & Medicaid Services (CMS) published the "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" proposed rule, detailing the establishment of a national coverage pathway for new, innovative medical devices approved by the Food and Drug Administration (FDA) to allow Medicare beneficiaries faster access to these breakthrough technologies. The MCIT pathway will apply to devices that receive market authorization by the FDA through the agency's Breakthrough Devices Program, which has been used for market authorization of digital therapeutics. The proposed rule would also codify CMS's definition of "reasonable and necessary."

Comments on this proposed rule must be submitted to CMS by November 2, 2020. You may provide feedback via email to advocacy@amcp.org on any provisions included in the proposed rule by October 16. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the proposed rule that may be of interest to AMCP members:

A. FDA Breakthrough Device Program

a. The FDA's Breakthrough Device Program provides a pathway for market authorization of new and innovative devices that meet two criteria:
   1. that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and
   2. that the device represents a breathrough technology, no approved or cleared alternatives exist, it offers significant advantage over existing approved or cleared alternatives, or device availability is in the best interest of patients.

b. The Breakthrough Device Program has been used for market authorization of digital therapeutics, serving as an important pathway for these technologies.

B. MCIT Pathway

a. CMS proposes to create the Medicare Coverage of Innovative Technology coverage pathway which would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continuing for up to 4 years (unless the device does not fit into a Medicare Part A or Part B benefit category).

1. Current Medicare coverage pathways do not necessarily provide immediate national coverage of new and innovative devices.
2. These pathways include: National Coverage Determinations (which take on average 9-12 months); Local Coverage Determinations (which apply only in the jurisdiction of the Medicare Administrative Contractors that develops the LCD); claim-by-claim adjudication; Clinical Trial Pathway; or parallel review.

b. The MCIT pathway will be voluntary for device manufacturers and CMS proposes to adopt an opt-in process through which a manufacturer will notify CMS of its intent to pursue coverage through the MCIT pathway.
    1. The agency does solicit comments on whether it should consider a opt-out process.
c. While CMS does not propose to require manufacturers to conduct additional clinical studies during the MCIT coverage period, the agency encourages manufacturers to use the MCIT period to develop the clinical evidence required to receive coverage approval through one of the other pathways after the end of the MCIT coverage period.
    1. The agency solicits comments on whether it should require manufacturers to provide data about outcomes or to enter into additional clinical studies as a condition of MCIT coverage.
d. CMS seeks comments on whether it should include additional categories in the MCIT pathway such as diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA, or all drugs and/or biologics.
e. CMS proposes that the MCIT pathway be available to devices receiving market authorization through the FDA's Breakthrough Devices Program no more than 2 calendar years prior to the finalization of this rule.
    1. The 4 year MCIT period would still apply to these devices, starting from the date of FDA market authorization.
    2. Additionally, if a manufacturer chooses not to pursue the MCIT pathway immediately after or simultaneously with FDA market authorization, the MCIT period will still begin on the date of FDA market authorization.
f. CMS proposes that MCIT coverage will not include off-label use of a device.
g. Devices covered through the MCIT pathway would be covered the same as other Medicare-covered devices, including the coverage of surgery if the device is implantable and of related care and service costs (i.e. battery or part replacements that are reasonable and necessary).

C. Defining "Reasonable and Necessary"

a. CMS proposes to codify the longstanding definition of "reasonable and necessary" that has existed in the Medicare Program Integrity Manual (PIM), with one addition.
b. Under the current definition, an item or service is considered reasonable and necessary when:
    1. It is safe and effective,
    2. Not experimental or investigational, and
    3. Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is

        - 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,
        - Furnished in a setting appropriate to the patient's medical needs and condition,
        - Ordered and furnished by qualified personnel,
        - One that meets but does exceed the patient's medical need, and
        - At least as beneficial as an existing and available medicallt appropriate alternative.
    4. In addition to these criteria, CMS proposes to include that under factor 3, an item or service can be deemed reasonable and necessary based on commercial health insurer's coverage policies (i.e. non-governmental health insurance entities).
        - CMS seeks comment on the sources of data that should be used to implement this proposal and whether the agency should limit this to only certain commercial plan types.
        - CMS clarifies that when evidence supports differences between Medicare beneficiaries and commercially insured individuals, the agency will rely on the original definition of "reasonable and necessary."
c. CMS proposes that devices receiving market approval through the FDA's Breakthrough Device Program would be deemed "reasonable and necessary" because they have met the unique breakthrough device criteria, which CMS has determined is sufficient to satisfy the "reasonable and necessary" standards, and are innovations that serve unmet needs.