AAHOMECARE
American Association for Homecare

Final Rule Summary

MEMORANDUM

Date: January 15, 2020

Subject: Medicare Coverage of Innovative Technology and the Definition of "Reasonable and Necessary" (CMS-3372-F)

On January 14, CMS published the final rule to the August 30, 2020 proposed rule titled: Medicare Coverage of Innovative Technology and the Definition of "Reasonable and Necessary". The rule finalizes a new coverage program called "Medicare Coverage of Innovative Technology" (MCIT) which would streamline ""FDA-designated breakthrough medical devices" to get Medicare coverage up to four years. The final rule also codifies the "reasonable and necessary" definition with some modifications. The creation of MCIT comes after President Trump's Executive Order from late 2019 that directed HHS Secretary to streamline approval and coverage for medical innovation.

This final rule is effective March 15, 2021.

Medicare Coverage of Innovative Technology (MCIT)

MCIT is a pathway for FDA approved devices to receive up to four years of national coverage under Medicare. Including a breakthrough device into MCIT is voluntary. To include a breakthrough device into MCIT, the manufacturer of the breakthrough device will need to notify CMS shortly after the breakthrough device designation from the FDA. The final rule states that the notice should be sent to CMS within two weeks of the designation, but there are no penalties for notifying CMS after the two weeks. CMS' Coverage and Analysis Group will be establishing an email inbox for communication on participating in MCIT. CMS will be using the existing coverage implementation process to offer immediate coverage for items included in MCIT.

MCIT does not include drugs or biologics. "Breakthrough device" will be defined as, "as a medical device that receives such designation by the FDA (section 515B(d)(1)) of the FD&C Act (21 U.S.C. 360e3(d)(1))." Breakthrough devices that received FDA market authorization no more than 2 calendar years before the effective date of the final rule will qualify for MCIT. However, claims for the eligible devices with dates of service before the effective date will not be covered under MCIT. For eligible devices that received market authorization prior to the effective date will have the 4-year period start on the date authorization was approved.

"Reasonable and Necessary" Definition

CMS finalized the established Program Integrity Manual definition of "reasonable and necessary" that an item or service will meet the "reasonable and necessary" requirement if it is:

1. *safe and effective;*
2. *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 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.

For devices that do not meet the appropriateness criteria (3rd bullet), CMS will review commercial payer coverage to determine coverage. CMS will determine coverage based on whether the majority of commercial plans cover the device/service. To determine the methodology to conduct this review, CMS will issue a sub-regulatory guidance no later than March 2022 (12-months after the effective date of this final rule) to establish a methodology for this review. This would be an opportunity for stakeholders to provide feedback to CMS on the methodology.