Submitted Electronically to: www.regulations.gov

October 29, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on CMS-3372-P, "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of Reasonable and Necessary" (85 *Fed. Reg*. 54327, September 1, 2020

Dear Administrator Verma:

Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned Proposed Rule (CMS-3372-P). AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members provide medically necessary DMEPOS items and services to patients in their homes. Our comments focus on the proposals as it would impact DMEPOS suppliers and their provision of care to beneficiaries.

Comments on Proposed Medicare Coverage of Innovative Technology (MCIT)

CMS proposes to establish a new payment coverage pathway for innovative medical devices designated as "breakthrough" technologies by the U.S. Food and Drug Administration (FDA). The proposed Medicare Coverage of Innovative Technology (MCIT) pathway would begin national Medicare coverage on the date of FDA market authorization, continuing for up to 4 years.

The proposed rule does not include information about how Medicare would pay for devices that receive national coverage through the MCIT process. CMS does state that when manufacturers notify CMS of their intention to elect MCIT after receiving notice from the FDA of being granted the breakthrough device designation, CMS would then offer guidance to the manufacturer about the MCIT

pathway and point to resources for coding and payment, which, CMS acknowledges, "are key conversations to effectuate coverage."[1] This represents a significant departure from the current process, which can take months or years before a technology is available to Medicare patients. Recognizing how multifaceted the coding, coverage, and payment processes are, we are keen to see how this immediate coverage is implemented and the opportunities for it to be replicated so that coverage determinations can keep pace with the industry's rapid innovations. In recent years we have seen the development of a broad array of technologies designed for patients to use in their homes, outside of health care facilites. Some of these technologies were previously only available in acute care settings. If an MCIT device were a DME item, it appears the only available payment methodology would be through CMS' increasingly outdated and insufficient gap-fill process.[2] The gap-fill method has been consistenly criticized by industry stakeholders, because it results in a dramatically low payment rate, creating significant access issues for new technologies. If CMS is sincere in its effort to ensure beneficiary access to breakthrough technology, we urge CMS to develop an alternate payment system for DME innovative technology items that would assure appropriate access. CMS has in place payment methodologies for new technology used in the hospital outpatient and hospital inpatient systems.[3] Establishing a payment system for MCIT devices used outside health care facilities would be consistent with E.O. 13890 which aims to make breakthrough devices "widely available" and "appropriately reimbursed." Without appropriate payment, the expanded MCIT coverage will be meaningless.

For a device to be eligible under the proposed MCIT coverage pathway, a product must also fit within a benefit category and not be excluded by statute. We disagree that a product must be within a benefit category, and this restriction seems to be at odds with the intent to open coverage to innovative technology which, often by definition, will not fit in an established benefit category.

AAHomecare supports the ability for Medicare beneficiaries to access more innovative devices, particularly those used in the home. However, as CMS seeks comments on whether the pathway should include devices, diagnositics, or drugs authorized under expedited FDA approval pathways – we believe the Agency should strongly consider including digital therapeutics, which do not currently have a benefit category. Under FDA, digital therapeutics are commonly regulated under the Software-as-a-Medical Device (SaMD) framework. The FDA defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[4] CMS, therefore, could include it in this proposed rule that digital therapeutics and breakthrough-designated SaMD could be covered under the existing benefit category of durable medical equipment. As our nation continues to grapple with the COVID-19 pandemic, we believe these kinds of innovative home solutions will help Medicare beneficiaries access the care they deserve in a safe and effective manner.

[1] 85 *Fed. Reg*. at 54333.

[2] 42 C.F.R. §414.238

[3] In its explanation of the anticipated cost impact of this proposed rule, CMS appears to assume that many, if not all, MCIT devices would be paid for under its New Technology Add-on Payment (NTAP) system. The NTAP system is a mechanism for Medicare to recognize and pay for the costs of new medical technologies under the hospital inpatient prospective payment system. In its impact statement on small businesses, CMS states that during the first four years of the MCIT, it anticipates that approximately 14 surgical and medical instrument manufacturers will participate in the program, and that physicians and Freestanding Ambulatory Surgical and Emergency Centers will be purchasing these devices. These comments imply that CMS does not anticipate that MCIT devices will be used outside of health care institutions and physician offices. CMS does not appear to have any payment accommodation for MCIT devices used by patients outside of these types of health care facilities.

[4] https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

Comments on Proposed 42 C.F.R. § 405.201 "Reasonable and Necessary" Definition

Overall, AAHomecare supports the Agency's proposal to codify the current Program Integrity Manual definition of "reasonable and necessary," with some modifications. Specifically, CMS proposes that an item or service will meet the statutory requirement that items and services are "reasonable and necessary" if the item/service 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.

Under the third "appropriate for Medicare patients" requirement, CMS proposes that the Agency will cover items and services that are covered by commercial plans. However, CMS clarifies that the Agency will not cover items and services that are covered under commercial plans if there is evidence that individuals covered under the commercial plans are clinically different from Medicare beneficiaries.

CMS asks for comments on whether CMS should make this information public and transparent. AAHomecare supports CMS' proposal to rely upon coverage information from commercial plans, and urges CMS to be completely transparent about the details of that coverage information. Therefore, AAHomecare supports the addition of the commercial plan coverage language, as long as the Agency is transparent about the evidence it uses to determine that individuals covered under commercial plans are clinically different from Medicare beneficiaries. With respect to the medical need a beneficiary may have for DME and medical supplies, AAHomecare does not believe there would be any evidence to support a conclusion that Medicare beneficiaries are clinically different than individuals covered under commercial plans.

CMS' Restrictive "In the Home" Interpretation for DME Coverage

We believe that CMS has interpreted the phrase "in the home" beyond the original intent of Congress. Section 1816(n) of the SSA states: The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home…" This definition makes sense as the equipment must be required to meet the beneficiary's needs within their home; however, most who qualify for Medicare, Medicaid or any other insurance program are not sequestered full-time within the four walls of their home. A person's "home" and normal activities of daily living expand to the outside world. This includes every day needs such as medical visits and grocery shopping. If anything, the current COVID-19 pandemic has shown that the population that is not disabled does not want to be required to stay within their home. How could anyone expect this to be normal in the everyday life of a disabled person or anyone who qualifies for Medicare or Medicaid, even after the pandemic ends.

CMS has interpreted this "in the home" language to mean that certain items (*e.g.*, mobility assistive equipment) must be necessary to perform certain activities of daily living (*e.g.*, bathing, toileting,

feeding/eating & dressing) within the home.[5] CMS has used this language to justify restrictive coverage guidelines for mobility devices (canes, crutches, walkers, other ambulatory aids, wheelchairs, scooters and power wheelchairs). CMS' interpretation of its meaning and intent results in access issues for people with disabilities. Beneficiaries therefore have limited access to rehab and assistive technology that can enable them to independently move about the communities in which they live. We urge CMS to take this opportunity to abandon its restrictive interpretation of the "in the home" language for coverage of DME.

Conclusion

AAHomecare appreciates the opportunity to provide these comments. Please contact us with any questions, or if you would like additional information.

Sincerely,

Kimberley S. Brummett
VP, Regulatory Affairs
American Association for Homecare

[5] *See* Medicare National Coverage Determination for MAE, 280.3.