



Submitted Electronically to: [www.regulations.gov](http://www.regulations.gov)

October 14, 2021

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Ave., S.W.  
Washington, D.C. 20201

**Re: Comments on CMS-3372-P2, “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of Reasonable and Necessary” (86 Fed. Reg. 51326, September 15, 2021)**

Dear Administrator Brooks-LaSure:

#### 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-P2). 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 Repeal of Medicare Coverage of Innovative Technology (MCIT) Proposal

CMS proposes to repeal its previously proposed 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 have provided national Medicare coverage on the date of FDA market authorization for “breakthrough” devices, continuing for up to 4 years. AAHomecare continues to support the goal of ensuring that Medicare beneficiaries are able to access new medical device technologies.

In this proposed rule, CMS explains its reasons for its repeal of the MCIT proposal. CMS believes “that the finalized MCIT/ R&N rule is not in the best interest of Medicare beneficiaries because the rule may

provide coverage without adequate evidence that the breakthrough device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose.”<sup>1</sup> CMS also points out the fact that only devices that meet very specific and limited FDA criteria for “breakthrough” devices would have access to expedited coverage. That coverage may occur at the expense of devices that do not meet those stringent criteria, providing disincentives for manufacturers to invest in research and development for devices that do not meet the FDA’s stringent “breakthrough” device criteria.

CMS’ MCIT proposal has illuminated the deficiencies in CMS’ current processes for determining coding, coverage and payment of medical device technologies, including new DMEPOS items. With respect to DMEPOS items, the current HCPCS code, coverage and payment process can take years before a technology is practically available to Medicare patients. Recognizing how multifaceted the coding, coverage, and payment processes are, we urge CMS to develop better processes for all new medical devices to be accessible to beneficiaries. The Medicare program has an obligation to better ensure that its 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 facilities. Some of these technologies were previously only available in acute care settings. We therefore support CMS’ belief that “a more flexible coverage pathway that leverages existing statutory authorities may be better able to provide faster coverage of new technologies to Medicare beneficiaries while prioritizing patient health and outcomes,”<sup>2</sup> and urge CMS to develop and implement revised coding, coverage and payment determination processes to ensure that beneficiaries can access all new medical device technologies more expeditiously.

For DMEPOS items, the only available payment methodology is through CMS’ increasingly outdated and insufficient gap-fill process.<sup>3</sup> The gap-fill method has been consistently 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 new technology, CMS must replace the current gap-fill payment methodology for all DMEPOS items, to assure appropriate access.

In previous rulemaking on this issue, AAHomecare had provided comments supporting the ability for Medicare beneficiaries to access more new technology, particularly those used in the home. As CMS considers potential coverage pathways for new and innovative technology, we urge CMS to consider including digital therapeutics, which do not currently have a benefit category. We would be happy to provide more extensive comments on this issue in future rulemakings.

#### Comments on Proposed 42 C.F.R. § 405.201 “Reasonable and Necessary” Definition

AAHomecare had previously supported the Agency’s proposal to codify the current Program Integrity Manual definition of “reasonable and necessary,” with some modifications. Specifically, CMS had proposed 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

---

<sup>1</sup> 86 *Fed. Reg.* at 51327

<sup>2</sup> *Id.* at 51330.

<sup>3</sup> 42 C.F.R. §414.238

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 had proposed that the Agency cover items and services that are covered by commercial plans. However, CMS had also clarified that the Agency would not cover items and services that were covered under commercial plans if there were evidence that individuals covered under the commercial plans were clinically different from Medicare beneficiaries.

AAHomecare continues to support Medicare program’s reliance upon coverage information from commercial plans, but if CMS does, it must be completely transparent about the details of that coverage information. Therefore, AAHomecare would support the addition of the commercial plan coverage language, as long as the Agency is transparent about the evidence it used to determine that individuals covered under commercial plans were 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.<sup>4</sup> 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.

---

<sup>4</sup> See Medicare National Coverage Determination for MAE, [280.3](#).

AAHomecare would also like to take this opportunity to recommend updating the definition of ‘durable medical equipment’ in the SSA to remove references to outdated technology. The use of equipment such as iron lungs have been obsolete for many years and are not generally prescribed by physicians or offered by suppliers.

Conclusion

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

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberley S. Brummett". The signature is fluid and cursive, with the first name being the most prominent.

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