Dear Administrator Verma:

The American Academy of Nursing (Academy) is pleased to offer the following comments in response to the September 1, 2020 proposed rule to establish a Medicare coverage pathway to provide Medicare beneficiaries faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). The Academy serves the public and the nursing profession by advancing health policy and practice through the generation, synthesis, and dissemination of nursing knowledge. It’s more than 2,900 Fellows are nursing’s most accomplished leaders in education, management, practice, research, and policy. They have been recognized for their extraordinary contributions to the promotion of the public’s health through evidence and innovation.

The proposed rule sets to increase access for the Medicare population for early detection of health/disease deterioration which can increase quality, safety, costs, and satisfaction. This encompasses the quadruple aim as a measure of high-quality care. Additionally, the Academy recognizes and appreciates the role of a public-private partnership in clinical studies and research. However, the Academy cautions the Centers for Medicare and Medicaid Services (CMS) to consider a more holistic approach for this pathway in the final rule as it has implications on access and health equity. Our comments will focus on the following areas of the proposed rule:

- Definition of “reasonable and necessary”;
- Equitable access; and
- Qualified personnel needs to be defined.

Definition of “Reasonable and Necessary”

On page 54331, the proposed rule outlines the current definition of “reasonable and necessary” for an item or service if it is “(1) 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 not exceed, the patient’s medical need; and
• At least as beneficial as an existing and available medically appropriate alternative.

In addition to codifying the above criteria, we propose to include a separate basis under which an item or service would be appropriate under (3) above what is based on commercial health insurers’ coverage policies (that is, non-governmental entities that sponsor health insurance plans). The commercial market analysis would be initiated if an item/service fails to fulfill the existing factor (3) criteria defined appropriate for Medicare patients but fulfills “(1) safe and effective and (2) not experimental or investigational.” Criteria for the definition behind “meet but does not exceed the patient’s medical need” as well as “at least beneficial” must be clarified in the final rule. This is important as it is unclear how a breakthrough device would satisfactorily demonstrate “meets but does not exceed” and “at least as beneficial.” This clarification is especially crucial as there is usually less evidence regarding the outcomes of these breakthrough medical devices. Additionally, the Academy recommends the term “medical/healthcare value” be added as measured by quality, safety, costs, and satisfaction to the definition of “reasonable and necessary” as CMS finalizes this rule. Finally, we recommend the agency clarify how the definition of “reasonable and necessary” would be applied.

Equitable Access of Innovative Technology

The Academy has a clear and distinct focus on health equity along with the social determinants of health and uses this lens to advance health policy solutions. As you codify the definition of “reasonable and necessary” into the Program Integrity Manual definition, the Academy recommends you consider the issue of health equity. On page 54328 of the proposed rule, CMS is proposing that an “item or service would be “appropriate for Medicare patients” under [3] if it is covered in the commercial insurance market, except where evidence supports that there are clinically relevant differences between Medicare and commercially insured individuals.” The Academy is concerned as this definition is vague and subject to interpretation. This especially concerning as it does not consider the clinically relevant differences between Medicare and commercially insured individuals. Medicare is designed to absorb risk, serving individuals who have or may have costly and complex medical needs as well as the relatively healthy care needs of its beneficiaries. Commercial insurance plans on the other hand is required to protect its business interests by avoiding those most likely to use medical care. Additionally, there are many elements that are left unspecified in the proposed rule and therefore could have potential implications on health equity. For example, specific medical devices and services that might qualify for coverage under the commercial health insurance plans is unclear. This could in turn jeopardize health equity for vulnerable populations with co-morbidities and those who live in underserved populations. Additionally, Medicare beneficiaries are older adults who typically require more extensive care than beneficiaries in the commercial health care market. The Academy recommends CMS apply the commercial coverage factor to items and services currently covered by Medicare and grandfather coverage policies.

The proposed rule additionally excludes Medicaid and Medicare managed care plans and other government administered healthcare coverage programs from the commercial plans CMS would consider. The Academy recommends these managed plans be included in the final rule as excluding them would prevent the populations in these plans from access to approved innovative technology and further exacerbate health equity.
Qualified Personnel Needs to Be Defined

During review of the proposed rule, the Academy noted the term “qualified personnel” was included throughout the language in the proposed rule but this term is not defined in the rule. The Academy recommends the final rule outline what CMS considers qualified personnel as well as include Registered Nurses and Advanced Practice Registered Nurses in the agency’s definition of this term. Nurses are essential members of the health care team and have always been quick to adopt innovative solutions and technology to improve patient care and access.6, 7 It is unclear from the way the proposed rule is written if the pathway includes coverage for just the medical device or whether it includes the device and the professional services required related to the device and care of the patient. Examples of professional services could include but are not limited to professional interpretation of data from the device or any intervention by health care staff in the future. The health care team will need to monitor the data that would be generated by a medical device. The Academy encourages CMS to consider the care delivery implications created by this vague language and provide coverage for not only the device, but the patient support needed from qualified personnel such as nurses on health care delivery teams and/or care delivery models necessary to ensure high quality care for these newly approved devices.

Thank you again for the opportunity to provide our comments and recommendations for this proposed rule. Please contact the Academy’s Senior Director of Policy, Christine Murphy, at cmurphy@aannet.org if you have any questions or need additional information.

Sincerely,

Suzanne Miyamoto, PhD, RN, FAAN
Chief Executive Officer

3 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary,” 2020
4 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary,” 2020