MEDICARE RIGHTS CENTER
Getting Medicare right

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November 2, 2020

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD, 21244

Re: RIN 0938-AT88 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (CMS-3372-P)

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on the Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (CMS–3372–P) proposed rule. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals.

1. **Medicare Coverage of Innovative Technology (MCIT)**

CMS proposes to provide Medicare beneficiaries with expedited access to new, innovative medical devices. We generally support increasing the access people with Medicare have to innovative health services and devices, though we caution CMS to continue to monitor and oversee research into such devices and to remove such coverage if the devices are found to cause harm or have little to no utility.

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We also urge CMS to expedite access to other devices, drugs, biologics, and diagnostics to ensure people with Medicare truly have access to innovative care. Such coverage should also be provided only under strict oversight with appropriate safety and efficacy guidelines. This should include devices that were FDA approved outside of the proposed two-year lookback window.

2. Definition of "Reasonable and Necessary"

CMS proposes to codify the existing Program Integrity Manual's definition of "reasonable and necessary" for coverage of Medicare items and services. The criteria in the proposed definition include:

1) Whether the item or service is safe and effective;
2) Whether the item or service is not experimental or investigational;
3) Whether the item or service is "appropriate for Medicare patients," including 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. Meets, but does not exceed, the patient's medical need; and
    e. At least as beneficial as an existing and available medically appropriate alternative.

We do not support this codification and encourage the agency to adopt the following revisions.

First, CMS must refine the proposed language to ensure that it does not codify ambiguity that could lead to arbitrary denials of critical medical items or services. In particular, the requirements that the item or service "meets, but does not exceed, the patient's medical need" and is "at least as beneficial as an existing" alternative are unnecessarily ambiguous and may overburden both Medicare beneficiaries and providers.

We also urge CMS to clarify that the entire Medicare population is included in any consideration for Medicare coverage. While most people with Medicare are over age 65, many are Medicare eligible due to disability or end-stage renal disease. No coverage determination, and no policy in general, can be wise if it ignores or overlooks these important populations.

CMS must also update the definitional language to include reference the maintenance or prevention of deterioration of function, as well as any functional improvement. While improving functional outcomes is ideal, it is not always achievable. For many beneficiaries—especially those with disabilities, injuries, illnesses, and chronic conditions—maintaining existing function is crucial for health outcomes and well-being. Further, the *Jimmo v. Sebelius* settlement affirms that Medicare covers care to maintain or prevent deterioration of a patient's functional status, not solely to improve functional abilities.

Finally, CMS also proposes that an item or service would be considered "appropriate for Medicare patients" if the item or service is covered by commercial insurers, unless there is evidence supporting clinically relevant distinctions between commercially insured individuals and Medicare beneficiaries. We may cautiously support a consideration of the commercial market if and only if it is used to expand coverage, rather than to restrict or deny it. Many commercial insurers may look to Medicare for a model of what should be covered. If Medicare looks to commercial insurers who are, in turn, looking to

Medicare, little progress would be made. And it is important to note that such commercial insurers may expect to keep enrollees only for a short time, prompting decisions based on profitability or short-term considerations that should not be part of Medicare policy. We also caution against including language about "clinically relevant distinctions" unless it is clear what evidence, metrics, and factors would be considered in determining what these differences might be.

Thank you again for the opportunity to provide comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

Fred Riccardi
President
Medicare Rights Center