



April 12, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

CMS-3372-IFC: Medicare Program: Coverage of Innovative Technology and Definition of Reasonable and Necessary; Delay of Effective Date: Public Comment Period

Dear Acting Administrator Richter:

The Heart Rhythm Society appreciates CMS' review of the plan to cover innovative technologies. **We urge CMS to implement the rule as it will offer more care options for Medicare beneficiaries.** Following are comments that we submitted on November 2, 2020. Our recommendations have not changed.

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on CMS' proposed rule titled, *Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."* HRS represents more than 7,100 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. Electrophysiology (EP) is a distinct specialty of cardiology, with eligibility for board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as in cardiology. HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards.

HRS appreciates that this rule would establish a Medicare coverage pathway for devices designated as breakthrough by the Food and Drug Administration (FDA). According to the proposed rule, the MCIT pathway would provide for immediate Medicare coverage of a device that would begin upon the date that the device receives FDA market authorization and would continue for up to four years. During the four-year period, CMS recommends that manufacturers develop additional evidence showing the applicability of their products to Medicare beneficiaries so they can apply for further coverage.

The specialty of electrophysiology is dedicated to saving and enhancing the life of its patients through advances in medical technology. Since our members are highly dependent on medical technology and other rapid innovations, we support CMS' overall effort to reduce regulatory burden and improve access to new technology for Medicare beneficiaries. Currently, once a

device obtains FDA approval, there is a delay to securing Medicare coverage for use of that device. This process is often lengthy and uncoordinated, and routinely results in coverage delays and inconsistent coverage determinations, which in the end, can delay a patient's access to life-saving therapies. If finalized, this proposal would enhance patients' access to critical devices that have been designated by the FDA as qualifying for the breakthrough devices program because it provides more effective treatment or diagnosis of a life-threatening disease or condition.

Although this rule would establish a Medicare coverage pathway for breakthrough devices, specifically, CMS also seeks comment on whether the pathway should also include diagnostics, drugs, and/or biologics. HRS supports expanding this pathway beyond devices. The EP field has rapidly evolved in terms of the new technologies and therapies used to both diagnose and treat a wide range of arrhythmias. Adopting this pathway on a broader scale will support more accurate identification and appropriate treatment of patients with heart rhythm disorders.

This rule also would establish regulatory standards to be used in making reasonable and necessary determinations for items and services that are furnished under Medicare Part A and Part B, including outside of the MCIT pathway. Traditionally, CMS and its contractors have determined whether items and services are reasonable and necessary without relying on a codified regulatory standard, but under this proposal, these standards would now be defined in regulation. The proposed standards would largely mirror existing standards included in CMS' Program Integrity Manual, including:

- Factor 1: Safe and effective;
- Factor 2: Not experimental or investigational (except for Category B Investigational Device Exemption devices); and
- Factor 3: Appropriate for Medicare beneficiaries, including the duration and frequency that is considered appropriate for the item or service.

Currently, to meet Factor 3, the item or service must meet all of the following sub-criteria:

- 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;

However, CMS proposes to add an alternative sub-criterion on which the Medicare beneficiary appropriateness criterion (factor 3) could be met based on whether the item or service is covered by at least one commercial payer, except if there is evidence that suggests there are clinically relevant differences in commercial patients and Medicare patients, in which case the current sub-criteria for determining appropriateness would apply. If the item or service is covered by multiple commercial payers, CMS proposes to adopt the least restrictive coverage

policy of all the offerings. HRS agrees with adopting the least restrictive coverage policy. In addition, we recommend that Medicare Advantage plans also be considered when reviewing commercial coverage policies. Due to the broad landscape of innovative technologies, and variations in the patient populations who would benefit from those technologies, including Medicare Advantage plans in the review may offer coverage policies that more closely reflect Medicare beneficiary demographics.

HRS generally supports CMS' proposal to offer stakeholders an additional mechanism to secure coverage, particularly for situations where Medicare coverage policies do not keep up with the commercial market. HRS thanks CMS for the opportunity to comment on these proposals. Should you have any questions, please contact Kimberley Moore, HRS's Senior Director of Health Policy and Reimbursement.

Sincerely,

A handwritten signature in black ink, appearing to read "Christine Albert", enclosed in a thin black rectangular border.

Christine M. Albert, MD, MPH, FHRS

President