November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3372-P
P.O. Box 8013
Baltimore, MD 21244-8013

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (Docket No. CMS-2020-0098-0002)

Heart Valve Voice US appreciates the opportunity to comment on this important proposed rule. We strongly endorse the concept of providing automatic Medicare coverage for innovative technologies upon their FDA market authorization. Patients deserve the certainty of having access to the most innovative medical technology without concerns over coverage and reimbursement. This should be a fundamental patient right and we applaud CMS for endeavoring to bring these treatments to patients 9-12 months sooner than through the current, often convoluted, National Coverage Determination process.

Heart Valve Voice US is a nonprofit patient advocacy organization that provides a united voice for people living with heart valve disease. We advocate for early detection, meaningful support, and timely access to appropriate treatment for all people affected by heart valve disease. The primary goal of this proposed rule aligns with our mission and we look forward to seeing more innovative heart valve technologies move through this pathway.

We have a major concern, however, that this primary patient benefit will not be realized. First, the proposed codification of the definition of "reasonable and necessary" is problematic in that it does not include patient preferences as a key factor, an important issue for which this proposed rule provides a venue for change. Second, while the proposed rule accelerates coverage of new technologies it does not mandate the data collection that would be necessary to fulfill the promise of the proposal. Without required data collection, via registries or other similar means, we are concerned this proposal is neither practical nor sustainable.

While there are many worthy concepts included in this proposed rule that merit further discussion, our comments will focus on the inconsistencies between the stated policy objectives

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and the lack of focus on data collection that would prevent efficient implementation of these policies.

The Definition of Reasonable and Necessary

Currently, the definition of "reasonable and necessary" in both statute and regulation is subject to interpretation concerning coverage and payment of medical services. This scenario has resulted in inconsistent or incomplete coverage of technologies across the nation rather than a more uniform interpretation that allows for predictable coverage for the benefit of patients and their families. This proposed rule would codify the current definition of "reasonable and necessary" currently utilized by Medicare administrative contractors (MACs) in making local coverage determinations:

"Under the current definition, an item or service is considered 'reasonable and necessary' 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."

Heart Valve Voice US strongly believes that any codified definition of "reasonable and necessary" include consideration of patient preferences. We are in an era of patient-focused medical product development and patient-centered research and care. The patient perspective must be incorporated into the coverage paradigm, as well. This would entail CMS establishing criteria for the consideration of patient perspectives and incorporation into coverage determinations.

For several years, the Food and Drug Administration (FDA) has undertaken numerous initiatives to incorporate the patient experience into the development and approval of novel therapies, including the Patient Science and Engagement Program at FDA's Center for Devices and Radiological Health (CDRH) and the agency's Patient Engagement Advisory Committee, among others. Further, we are aware of ongoing work being done by the Medical Device Innovation Consortium on this topic that would inform a modification of this definition to accommodate patient preferences.

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We urge CMS to closely interact with FDA regarding its history with patient engagement and look to CMS to lead in similar coordinated activities on this issue, which is in the spirit of the President's 2019 Executive Order.[1] In addition, we support this use of the Secretary's broad authority to redefine "reasonable and necessary" in a manner that makes innovative therapies potentially available to patients sooner.

We would further argue that this broad authority could also be used to compel data collection via registries, electronic health records, patient-reported outcomes, or other means to ensure consistent analysis of benefits and risks of these innovative therapies.

Finally, the proposed rule would create an alternative pathway to meeting the appropriateness criteria if the technology in question is covered by commercial insurers, unless the populations addressed by commercial coverage are clinically different than those covered under Medicare.

On its face, the proposal to default to coverage if the private market extends coverage could potentially be a means of expanding access to technologies for a larger patient population. However, this scenario is a reversal of the typical trend where commercial coverage is informed by and follows Medicare's coverage determinations, which is logical given the historical strength of Medicare's evidentiary development processes. Moreover, such a proposal could place increased emphasis on a commercial process that places greater importance on cost rather than increased health outcomes, which is an historical focus of the Medicare process and an important criteria for affected patient populations under this rule.

We note that commercial insurance coverage decisions are largely based on available data. Again, we are unclear when, where, and how this data would be collected under this proposed rule. We are concerned CMS could prioritize analyzing private market practices, which could vary from insurer to insurer, above its historical responsibilities in determining the appropriateness of an intervention through an evidence-based process. This scenario could lead to further delays for patients and uncertainty for manufacturers and providers.

In the case of heart valve technology, Heart Valve Voice US would look to CMS to act as the "market leader" because the majority of heart valve disease patients are Medicare age.

Issues Regarding Coverage Determinations and Data Collection

The proposed rule in its current form offers the ability for immediate coverage of breakthrough devices that have gained an FDA market authorization. More specifically, the proposed rule states there would be a "seamless" process for Medicare coverage of these FDA-approved technologies. The proposed rule offers several points that we would like to respond to directly.

[1] Executive Order on Protecting and Improving Medicare for Our Nation's Seniors (EO 13890). 3 Oct. 2019.

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"Traditionally, CMS relies heavily on health outcomes data to make NCDs….Even though CMS has multiple coverage pathways, at this time none are readily available to provide immediate national coverage for new breakthrough devices with a Medicare benefit category at the same time as FDA market authorization. Further, some of these new breakthrough devices are likely to have limited or developing bodies of clinical evidence because of the newness of the device; therefore, the MCIT pathway can support manufacturers that are interested in combining coverage with their own clinical study to augment clinical evidence of improved health outcomes, particularly for Medicare patients."

We are aware that FDA and CMS have engaged in a joint approval and coverage paradigm designated "Parallel Review," which was proposed in 2010 and extended permanently in 2016.[2,3] Although underutilized, this program allowed for the FDA and CMS to engage in a simultaneous review of a technology from market authorization and coverage standpoints without compromising the data collection requirements for approval under either agency's standards. While we appreciate the goal of the MCIT proposal to speed new technologies to patients, we believe that the proposal combined with some of the elements of the Parallel Review program would allow for greater access without compromising the mandatory data collection required under existing approval programs.

"We propose that the MCIT pathway would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to 4 years, unless we determine the device does not have a Medicare benefit category as determined by us as part of the MCIT pathway process."

Under this proposal, the MCIT pathway would provide a temporary coverage structure for breakthrough devices, with continuation of coverage dependent upon the organized collection of outcomes data. This would require significant alignment between CMS and FDA concerning post-approval data gathering to ensure safety and provide for the potential for comparative effectiveness research. Such data collection would benefit patient populations as well as manufacturers looking to improve upon existing technologies in a more accelerated fashion.

"The MCIT pathway is voluntary (that is, manufacturers would affirmatively opt-in), and would be initiated when a manufacturer notifies CMS of its intention to utilize the MCIT pathway …Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway. However, we seek comment as to whether CMS should require or incentivize manufacturers to provide data about outcomes or should be obligated to enter into a clinical study similar to CMS's Coverage with Evidence Development (CED) paradigm…Manufacturers are <u>encouraged</u> (emphasis added) to develop the

[2] 75 Federal Register 57045.
[3] 81 Federal Register 73114.

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clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends. This evidence is encouraged (emphasis added) not only for CMS and private commercial health insurer coverage policies but also to better inform the clinical community and the public generally about the risks and benefits of treatment."

As mentioned above, a temporary coverage structure whose permanency depends on data collection, i.e. the transfer of an MCIT breakthrough technology to the formal NCD process or some other existing payment paradigm, requires significant coordination between the agencies and the sponsor. Further, we recommend that the election of the MCIT pathway trigger mandatory data collection, and thus do not believe this data collection should be labeled a "clinical study similar to CMS CED paradigm." This mandatory data collection should be of real-world evidence through a new or existing data registry, such as the STS/ACC Transcatheter Valve Therapy (TVT) Registry (in the case of heart valve technologies), electronic health records, patient-reported outcomes, or other similar mechanisms. The aforementioned coordination between agency and manufacturer should include the transmission of predictable methods and parameters of data collection that would both inform mandatory data collection efforts for the benefit of coverage and approval while also allowing manufacturers to demonstrate the value of the device for market purposes.

"We specifically seek public comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval) or all diagnostics, drugs and/or biologics."

We could envision the MCIT pathway being made available to diagnostics, including, perhaps, innovative new imaging technologies incorporating artificial intelligence, or wearable diagnostic devices. Evidence generation would be a key component of validating these diagnostic technologies as "innovative."

"Use of the device for a condition or population that is not labeled ("off-label") will not be covered as that use would not be FDA authorized. We specifically seek comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support."

Presumably, if a device were demonstrating "off-label" benefit the manufacturer might seek a new indication from FDA and then, logically, under MCIT, the coverage would be extended to the new condition or population. Again, evidence demonstrating this benefit would need to be gathered through clinical studies or sourced from real-world data if the off-label use were broadly employed. We request clarification that a label expansion for an MCIT device would automatically receive coverage. Similarly, a follow-on device should be eligible for the

breakthrough pathway and receive the remaining portion of the initial MCIT designation for the reference technology.

In sum, MCIT could potentially accelerate access for patients to new technologies that could increase quality of life as well as overall health outcomes. However, the lack of a clear mandate for the collection of patient outcomes and safety data that would be necessary for manufacturers pursuing this pathway makes the proposal potentially unworkable. Further, the proposal as written does not adequately expand the definition of "reasonable and necessary" as it relates to patient preferences. These deficits, and other factors, could have the perverse effect of manufacturers making a business decision to choose a traditional NCD pathway rather than MCIT, thus delaying patient access to these technologies for a further 9-12 months. This would subvert the intended purpose of the MCIT pathway.

Thank you for the opportunity to comment on this important proposed rule. We look forward to working with you to further develop programs that speed new and innovative technologies to market for the benefit of patients. If you have any questions, please feel free to contact me at 202-285-5726 or john@heartvalvevoice-us.org.

Sincerely,

John Lewis
Executive Director