AMA
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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the *Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"* proposed rule. The AMA strongly supports the Centers for Medicare & Medicaid Services (CMS) policies that establish a clear and predictable pathway to payment for innovative technologies that are supported by high quality, clinically validated data that help advance the quadruple aim of enhancing the patient experience of care and outcomes, improving population health, reducing overall costs for the health care system while increasing value, and supporting the professional satisfaction of physicians and the health care team. However, this proposal does raise some concerns and questions that we strongly urge CMS to address prior to finalization.

Medicare Coverage of Innovative Technology Pathway

The U.S. Food and Drug Administration's (FDA) Breakthrough Device program is designed to allow for speedy market access for devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions where no approved or cleared alternatives exist and the breakthrough technology offers significant advantages over available alternatives.[1] Upon receiving a breakthrough designation, the FDA provides interactive advice during the early development stages of the device and prioritizes review when a full application is submitted to the Agency. In addition, a breakthrough device application may be granted without a pre-approval inspection of quality controls if the device is granted market authorization under a premarket approval (PMA). The PMA approval or 510(k) notification for a breakthrough device may be predicated on novel study designs and be approved or granted clearance based on less evidence than would typically be required because of the potentially impactful benefits of the technology. In those cases, the FDA will require additional post-marketing studies to confirm the safety and efficacy of the device.[2]

CMS' proposed MCIT pathway would accelerate coverage of breakthrough devices by providing a voluntary pathway for device manufacturers to utilize to gain immediate coverage of a breakthrough

[1] Section 515B(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
[2] FDA, "Breakthrough Devices Program: Guidance for Industry," https://www.fda.gov/media/108135/download (Dec 18, 2018).

device upon the date of market authorization for up to four years, unless the device does not have a Medicare benefit category as determined by CMS. Upon the completion of the four-year period, coverage of breakthrough devices would be subject to National Coverage Determinations (NCD) affirmative coverage, which may include facility or patient criteria, NCD non coverage or Medicare Administrative Contractor (MAC) discretion.[3]

In the proposed rule, CMS states that "[m]anufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway," but seeks comment as to whether manufacturers should be required or otherwise incentivized "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." **AMA recommends that CMS and/or FDA mandate post-marketing study plans for manufacturers that intend to avail themselves of any expedited pathways to coverage and payment**. As proposed, it could be argued that manufacturers availing themselves of the MCIT coverage pathway do not have a significant incentive to continue to collect outcomes data after receiving both FDA market authorization and Medicare coverage. Given that approval or clearance under a breakthrough designation may require comparatively less safety and efficacy data than clearance or approval under traditional FDA review pathways, it is critical that robust post-marketing surveillance plans be in place to ensure that new technologies continue to be safe for patient use and that patient outcomes are acceptable. CMS could validate manufacturer progress in conducting and completing post-market studies on a regular pre-specified basis. This would create an additional incentive, along with any FDA requirements, to ensure that post-marketing studies are conducted and completed, including follow-up studies focused on the clinical benefit of MCIT products in the Medicare population and validating long term patient safety.

Because the breakthrough pathway explicitly contemplates the potential to grant market access for devices that may still require additional post-market studies, there is an acute need to ensure that such studies are conducted and completed, particularly where the devices will be granted coverage by CMS immediately upon approval rather than after a comprehensive review of clinical benefit under an NCD or LCD determination. Moreover, depending on the device in question and the studies that were conducted to support market authorization, there may not be robust safety and efficacy data on older patients that make up the Medicare population. By conditioning MCIT coverage on post marketing studies, CMS could help ensure that robust data are collected on the safety and efficacy of breakthrough devices in the Medicare population.

These studies would also underpin future coverage decisions when a breakthrough device completes the MCIT coverage period. Without such a requirement, the MCIT pathway may incentivize companies to seek a breakthrough designation, and, upon market authorization, receive coverage for the duration of the MCIT program only to sunset the breakthrough-designated device after the MCIT coverage period has run out. Requiring additional post-marketing studies would help ensure that devices in the MCIT program continue to be covered by Medicare only where enough evidence is developed to justify coverage and ensure that no safety concerns manifest after the product is in wide commercial use.

[3] 85 FR 54327-54339, 54331 (Sept. 1, 2020).

Additional Transparency and Inclusion of Stakeholder Input into the Coverage Process

The AMA is extremely concerned that this pathway, as proposed, does not appear to contemplate inclusion of stakeholder perspectives other than industry. Traditional Medicare coverage pathways have provided interested parties with the opportunity to review and comment on coverage determinations. With the MCIT proposal contemplating immediate coverage of emerging technologies that have received FDA market authorization, it appears that there will no longer be opportunities for consideration of the important perspectives of physicians, patients, and other stakeholders prior to granting national coverage for new technologies. This is especially concerning considering that these new technologies with breakthrough designations may be coming to market with relatively less robust outcomes data. At no point in the contemplated process is there any opportunity for interested stakeholders to raise concerns about safety, efficacy, or appropriateness for use in Medicare patients. **It is imperative that CMS considers input from physicians, patients, and other stakeholders prior to providing coverage for innovative technologies.**

For almost a decade, the AMA has maintained a written policy supporting the development of model legislation and regulations that require commercial insurers, state Medicaid agencies, and other payers to utilize "transparent and accountable processes" for developing and implementing coverage decisions and policies. We have long advocated for specialty and service organization involvement to advocate for private insurance plans and benefit management companies to utilize transparent clinical protocols as well as formal processes, just as Medicare national and local coverage determinations (LCD) are publicly available. We therefore caution against shifting the process from being transparent and accountable, as it is through the NCD and LCD processes, to one that lacks transparency and removes opportunity for input from physicians, patients, and other key stakeholders.

The AMA has advocated for private insurance plans and benefit management companies to provide insureds and participating providers with revised, written updates no less than 90 days prior to the said changes going into effect. Similarly, the AMA would expect at least 90-day notice to Medicare beneficiaries and providers before a change in coverage is made, particularly for a new, innovative technology. It may not be well known what clinical benefit the new, innovative technology will achieve and any associated risks, especially for the Medicare population, so CMS should make sure its process and its documentation can justify its actions to Medicare beneficiaries.

Additionally, CMS and/or FDA should disclose breakthrough designations as they are made to clarify which devices may be eligible for this pathway if they receive approval through the breakthrough program which would stakeholders with additional transparency into a process which, as proposed, offers little. Currently, the FDA does not disclose devices which have requested and received breakthrough designation under the Food, Drug, and Cosmetic Act. Instead, the Agency relies on companies to disclose this information as they see fit.

Coding and Valuation Under the MCIT Pathway

The AMA is also concerned that this proposal leaves a number of unanswered questions regarding how actions such as coding and valuation of technologies eligible for the MCIT pathway would be handled should the new pathway be finalized. **We urge CMS to work with stakeholders to provide additional clarity around coding and valuation under the proposed MCIT pathway.** As you are aware, the AMA maintains two robust, well-defined processes for coding and valuation. Importantly, these processes

are stakeholder-driven. **We strongly urge CMS to consider how best to involve both the Current Procedural Terminology® (CPT®) Editorial Panel and AMA/Specialty Society Relative Value Scale Update Committee (RUC) processes into this new coverage pathway**.

The CPT Editorial Panel is tasked with ensuring that CPT codes remain up to date and reflect the latest medical care provided to patients. In order to do this, the panel maintains an open process, convening meetings many times per year to solicit the direct input of practicing physicians, medical device manufacturers, developers of the latest diagnostic tests and advisors from over 100 societies representing physicians and other qualified health care professionals. The Editorial Panel itself is comprised of seventeen members, eleven of whom are nominated by national medical specialty and qualified healthcare professional societies, with additional representatives appointed from major health insurers and the American Hospital Association. Additionally, CMS provides input to the work of the Editorial Panel through the appointment of individuals who participate in a non-voting capacity. We urge CMS to work with the CPT Editorial Panel to explore ways in which the panel process can be incorporated into the proposed MCIT pathway to ensure an appropriate, consistent, stakeholder-driven coding process is in place for new and innovative technologies.

CMS should continue to review recommendations from the AMA/Specialty Society RVS Update Committee (RUC) for physician work, clinical labor, medical supplies and equipment related to any new, innovative technology. The RUC can provide a valuable basis and expertise to understand the resource costs related to new technologies, collecting information and data from physicians and other qualified health care professionals who trained in and have experience performing these new technology services. Currently, the RUC tracks utilization growth in services that reflect new technology. After a technology is diffused, the RUC reviews new survey data from national medical specialty societies to review information on services that are now in more widespread use. The RUC has submitted recommendations on more than 50 such services to CMS in recent years.

Cost Considerations for Innovative Technologies

It is not clear how CMS will factor in the costs for the new, innovative technologies—new technologies often carry high initial costs. As cited in a Medicare Payment Advisory Commission (MedPAC) report (emphasis added):

> The market dynamics for medical devices can vary greatly depending on the device. Markets for conventional devices such as surgical gloves and other routine surgical supplies are more competitive; companies compete heavily on price and often need high sales volumes to be profitable. *In contrast, markets for advanced products like implantable medical devices involve opaque pricing, are harder to enter, and are less competitive, which allows device companies to charge higher prices and earn substantial profits. Large medical device companies are consistently profitable and typically have profit margins of 20 percent to 30 percent.*[4]

Whereas Medicare pays providers when they use devices for Medicare beneficiaries, and bundles the average cost of medical devices in hospital settings, CMS should propose and seek stakeholder

[4] MedPAC Report to the Congress: Medicare and the Health Care Delivery System, June 2017, available at http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0 (last accessed October 14, 2020).

input about how the integration of new, innovative technologies will factor into important metrics that impact physicians such as the Medicare Quality Payment Program (QPP) and the Medicare Physician Fee Schedule (PFS). CMS should ensure that changes to coverage and payment for innovative technologies do not unfairly penalize QPP participants. Physician payment levels are often subject to budget neutrality adjustments, so it is important to understand in advance how cost will factor into the inclusion of a new, innovative technology. This consideration is especially important in instances where physicians are not incentivized to use lower cost devices.

Proposed Changes to the Definition of "Reasonable and Necessary"

The AMA supports CMS' proposal to codify the definition of "reasonable and necessary" as noted in the Medicare Program Integrity Manual, including the five points to define criteria appropriate. **While the AMA supports CMS policies that establish a clear and predictable pathway to payment for items or services supported by high quality, clinically validated data that helps advance the quadruple aim of enhancing the patient experience of care and outcomes, improving population health, reducing overall costs for the health care system while increasing value and supporting the professional satisfaction of physicians and the health care team, the AMA cautions against CMS' proposed approach to automatically transfer the coverage policy of commercial insurance companies to Medicare beneficiaries for these new products.** The routine assignment of Medicare coverage based on commercial coverage usurps the processes in place for coverage determinations without accountability and attention to appropriate safeguards, and relegates the important decision-making process for items and services to external organizations that have different motivations and considerations as compared to the public, government-sponsored Medicare program. The weight that would be accorded to a single health plan or to a large health plan by using its commercial coverage policy would distort the coverage determination process under Medicare, and fails to protect the safety and quality for Medicare beneficiaries. The AMA includes several proposals and considerations below for ensuring a transparent and expedited coverage process for innovative medical devices.

CMS has the authority to determine what services and technologies are "reasonable and necessary" under section 1862(a)(1)(A), although the definition of the phrase has been left to sub-regulatory guidance and judicial interpretation.[5] In the Medicare Program Integrity Manual (PIM) section 13.5.4–Reasonable and Necessary Provisions in Local Coverage Determinations (LCDs), "reasonable and necessary" is determined by the MAC Contractors by meeting three criteria: (1) safe and effective; (2) non experimental or investigational; and (3) appropriate,[6] including the duration and frequency that is considered appropriate for the item or service. To determine whether the item or service is appropriate, the PIM includes five points, all of which appear required to be met. The five points include:

1. 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;
2. Furnished in a setting appropriate to the patient's medical needs and condition;
3. Ordered and furnished by qualified personnel;

[5] *See* Heckler v. Ringer, 466 U.S. 602 (1984). In Heckler v. Ringer, the primary question was whether there was exhaustion of administrative remedies for a claim that arose under the Medicare Act. The US Supreme Court also found clear authority of the HHS Secretary to determine whether a particular item or service is "reasonable and necessary."

[6] In the proposed rule, CMS lists the third criteria as "appropriate for Medicare patients" however in the PIM, the specific reference to Medicare patients is not included.

4. One that meets, but does not exceed, the patient's medical need; and
5. At least as beneficial as an existing and available medically appropriate alternative.

The AMA supports the codification of the existing guidance to define "reasonable and necessary." This includes the five points used to determine whether the service is appropriate as noted above. The language included in the PIM has been used to clarify to the "reasonable and necessary" phrase, so it is logical that it would be incorporated as it has been applied into the statute. As it reads now, the LCD applies to individual patients, not to the entire Medicare population. Indeed, each LCD and its applicability must be evaluated in comparison to a specific patient's health and needs.

CMS now proposes an alternative to the five points to determine appropriateness where an item or service is already covered by the commercial insurance market. The alternate pathway for an item or service to meet the appropriate criteria would be based on whether there is commercial acceptance and coverage already in place. If indeed there is commercial coverage policy that covers the item or service, this would satisfy the appropriateness criteria. This alternate pathway would satisfy the appropriateness criteria unless there is existing evidence that delineates "that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant." CMS proposes to exclude Medicaid managed care, Medicare Advantage, and other government-administered health care coverage programs in its consideration of the appropriateness criteria under this alternate pathway.

The AMA has a number of concerns with the CMS proposal to rely on the commercial coverage policies to set Medicare coverage in determining which services are appropriate for the Medicare population. Whereas commercial health insurers decide to offer coverage for an item or service based on a number of factors, and many are beholden to meeting investor and shareholder expectations, the Medicare coverage has been independent, transparent, and open to public comment. Commercial health insurers may elect to issue a coverage policy in response to a mandate or a recommendation, to avoid litigation, or to diversify its offering as compared to a competing insurer. Commercial insurers for self-insured companies bend to the preferences and the requirements of the company that funds the care, supporting what the company deems credible and declining to cover items and services deemed too expensive, too risky, or not worth the cost as compared to the benefit. Indeed, commercial insurer coverage policy determinations are not a clear-cut way to determine Medicare coverage policy.

The determination to cover (or not cover) an item or service does not illustrate a standard beyond that particular commercial health insurance company, or even beyond a particular commercial health plan. There may be a single commercial insurer that decides to cover an item or service in an effort to portray the organization as a beacon of innovation or very generous in its offerings. At the same time, a commercial insurer may decline to cover that same service due to a lack of clinical evidence, the cost of services, the inability to establish an adequate network to provide the item or service, or a host of other reasons. The reliance on the commercial insurer determination for the appropriateness of an item or service for Medicare beneficiaries does not answer the necessary questions that should be asked before making a determination in the Medicare program. The focus should remain on what is most suitable and safest for Medicare beneficiaries based on Medicare's determination. Medicare should not be a follower of the unexplained determination of a commercial health plan that is beholden to shareholders, to executive management, or to unknown interests.

CMS should seek comments on the most appropriate sources for its coverage policies for new items or services. Large, national insurers may be slow to adopt an item or service. Perhaps a small, local or

regional health insurer is more apt to meet the specific needs of its commercial enrollees and elects to include an item or service as a covered benefit. It is not possible to say how different plans of varying size and scope make their determinations to set a reference standard for accepting their determinations for the Medicare population. Still, input from stakeholders including the health insurance industry and the physician associations should be received before implementing this proposed policy. It should not, however, replace the process of evaluating new items or services by CMS on its own merits.

It is worth emphasizing that CMS is proposing to rely on the determination of "at least one commercial insurance plan policy" from "beneficiaries, providers, innovators, or others wishing to gain coverage" of an item or service under its proposal. Indeed, the standard need not be what at least one commercial insurance plan decides to cover–it should be what is most salient and beneficial to the positive health outcomes of the beneficiary as determined by the physician-led team and relevant evidence. Commercial health insurers have come under scrutiny as they are not publicly accountable, their data are proprietary, and their payment policies designed to keep their organizations profitable are clandestine.

As is the case, manufacturers may petition a health plan for coverage of an item or service. The pathway to coverage may not be known within or beyond the health plan to extrapolate this coverage to the Medicare population may be problematic. There are previous instances of services that were covered commercially and sought for Medicare coverage, yet held different results for the Medicare population. The undisclosed and unvalidated process used to arrive at a health plan's coverage decision is not trustworthy enough to duplicate the same coverage to the entire Medicare program. Especially as Medicare seeks to control costs, ensure quality and safety and to promote equity, a different approach is warranted than the one proposed.

CMS has proposed limiting its consideration of commercial plan offerings or covered lives based on geography, plan type, or other factors. It is not plausible to limit the proposed process to a commercial insurer based on these factors—the coverage decisions by other insurers (such as Medicare Advantage) should be similarly considered for the services provided to those members. To rely only on the national or larger commercial insurers would place too much control on this process to a subset of payers, and would allow them to dictate what is (and is not) covered under Medicare. The exclusion of Medicare Advantage and Medicaid managed care while mentioned in the proposed rule for not being a part of the commercial market creates yet another artificial distinction. Valuable data may be obtained from both the Medicaid managed care and the Medicare Advantage programs in the use of a particular technology, or for the treatment and progression of a condition. Medicaid managed care also coordinates the care of its members, and faces questions about coverage, efficacy, appropriateness and safety. The Medicare Advantage program may provide important lessons on a condition that is particularly relevant for the Medicare beneficiary demographic. To discount these important programs from the proposed analysis is another artificial distinction that again concentrates too much power in the hands of a few commercial insurers and discounts the valid experience in coverage of items and services to be gained from those other non-commercial programs.

CMS seeks comments on how potential unreasonable or unnecessarily utilization may be curtailed, either by adopting restrictive coverage policies or by harmonizing similar coverage policies across the majority of offerings of commercial plans. The AMA believes that when MACs propose new or revised LCDs, Contractors must: (1) ensure the Carrier Advisory Committee meeting minutes are recorded and posted to the Contractor's website and (2) disclose the rationale for the LCD, including the evidence that forms the basis of the approval. The AMA has supported a new LCD reconsideration process that would allow

an independent review of a MAC's payment policies by a third party, inclusive of appropriate medical and specialty expertise. The AMA holds that MACs should be prohibited from adopting another MAC's LCD without first undertaking a full and independent review of the underlying science and necessity of such LCD in their own jurisdiction. The AMA opposes CMS making its reasonable and necessary determination on the basis of a commercial payer's coverage, and also opposes CMS adopting the other payer's coverage policies for a specific technology.

In lieu of relying on coverage determinations and policies of commercial health plans to determine what is "reasonable and necessary" for purposes of coverage in the Medicare populations, the AMA suggests CMS consider alternative pathways that serve to both expedite determinations where necessary but also retain a strong level of control within CMS. For example, when considering an item or service that is covered by a commercial insurer, it could be proactively identified as having potential application among Medicare beneficiaries, and the manufacturer could be asked to produce any information on whether specific research has been conducted on the relevant populations. This evaluation between CMS and the area Clinical Medical Directors (CMDs) at MACs could be conducted in an expedited timeframe to hasten the determination. The MACs can confer with the medical directors at the health plans in its jurisdiction to provide input, if necessary, for their determination regarding a new item or service. The MAC should develop an approved process to review the new item or service but should not completely relinquish this responsibility to a commercial health plan.

If ample evidence does not yet exist for a product to warrant a national coverage decision, it could be listed for potential experimental use for a period of time for MAC consideration until more information relevant to the Medicare population is gathered. Alternatively, the MAC and CMS could ask for the item or service to be submitted for consideration after additional clinical data has been compiled. If evidence does support the item or service for Medicare coverage, the plurality determination from the MACs and CMS should be sufficient to authorize its coverage. Ultimately, the MACs and CMS should retain the opportunity to extend Medicare coverage to an item or service and should not concede this responsibility strictly to a commercial insurer.

As discussed during the above comments regarding the MCIT coverage pathway, inclusion of stakeholder input is critical across the coverage determination process. Stakeholders including physicians, specialty societies, patient advocacy groups and others should have the opportunity to weigh in on whether a proposed innovative technology should receive Medicare coverage. Similarly, while it is plausible to consider that a new item or service would be met with support, it should be the standard process that for the public, government program there is transparency, input, and involvement. Any process employed by CMS, by the MACs, or by another body that might make these determinations should include perspectives from interested stakeholders.

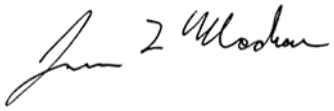
Additionally, while reasonable and necessary determinations should not rely solely on commercial health insurer coverage, their coverage of an item or service by Medicaid managed care or Medicare Advantage may provide valuable insight on the success and the failures, and should be used in the consideration by CMS and the MACs. CMS can review the clinical data and the coverage decisions of health plans and use this information to make its own determinations. If the experience of health plans is used, this information should be made public, including any adverse occurrences, reasons for coverage and reasons for denial. Contraindications are also very important for CMS to understand, as it may be the case that Medicare beneficiaries with a comorbidity or a particular condition are not well-suited for an item or service. The

information provided for CMS' consideration from health insurers must be transparent and withstand public scrutiny.

The AMA remains steadfastly supportive of clear, predictable, least burdensome pathways to coverage for innovative technologies. However, we must ensure that the technologies we provide to our nations' Medicare beneficiaries are safe, effective, high quality, and meet the goals of the quadruple aim. **We therefore strongly recommend CMS consider additional modifications and improvements to the proposed MCIT pathway and reconsider the proposed changes to the definition of "reasonable and necessary" to meet these shared goals.**

Please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org to discuss these recommendations further. The AMA looks forward to continuing to work with you to bring emerging technologies to the market.

Sincerely,



James L. Madara, MD