

October 30, 2020

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Re: File code CMS-3372-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary'" in the *Federal Register*, vol. 85, no. 170, pp. 54327–54339 (September 1, 2020). We appreciate your staff's ongoing efforts to administer coverage policies for items and services covered under Original Medicare, particularly considering the competing demands on the agency.

Our comments address the following provisions in the proposed rule:

- Modifying and codifying the definition of "reasonable and necessary" that Medicare uses to make coverage determinations.
- A new national coverage pathway—the Medicare Coverage of Innovative Technology (MCIT) pathway—that would provide national coverage for new breakthrough devices concurrent with market authorization from the Food and Drug Administration (FDA).

**Modifying and codifying the definition of "reasonable and necessary" that Medicare uses to make coverage determinations**

Section 1862(a)(1)(A) of the Social Security Act requires that Part A and Part B of Original Medicare cover items and services (herein referred to as *services*) that are included in a Medicare benefit category, are not statutorily excluded, and are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Neither the statute nor regulations explain how "reasonable and necessary" is to be applied in making coverage determinations. In this rule, CMS proposes to codify the current definition of reasonable and necessary, published in Medicare's Program Integrity Manual (section 13.5.4), that Medicare's administrative contractors (MACs) use to make local coverage determinations. Medicare's Program Integrity Manual considers an item or service reasonable and necessary if it is:

- safe and effective;
- not experimental or investigational; and
- 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 definition of reasonable and necessary that MACs currently use, CMS proposes to include an alternative way to meet the third criterion based on commercial health insurers’ coverage policies.<sup>1</sup> Under CMS’s proposal, a service that meets the first two coverage criteria (that is, a service that is safe and effective and not experimental or investigational) but does not meet the third criterion (that it be appropriate for Medicare patients) could gain Medicare coverage if it “is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.”<sup>2</sup> CMS would adopt the least restrictive commercial coverage policy for the service amongst the coverage policies that are considered.

It is unclear whether the agency’s proposal to define reasonable and necessary would apply only to devices or to all Original Medicare services. The regulation that CMS proposes to modify—Chapter 42, Part 405.21, Subpart B—applies to devices that qualify for investigational device exemptions. However, other parts of the proposed rule (including the background section that refers to section 1862(a)(1)(A) of the Social Security Act) might suggest that CMS is considering applying this commercial-based definition of reasonable and necessary more broadly to all services in Original Medicare. CMS did not provide an economic impact of the proposal on Medicare spending.

#### *Comment*

As set forth below, out of concern that the proposed rule could increase the provision of low-value care, undermine Medicare’s evidentiary standard, diminish the transparency and rigor of the coverage determination process, and adversely alter the relationship between manufacturers and

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<sup>1</sup> According to CMS, commercial health insurers include non-governmental entities that sponsor health insurance plans but exclude Medicaid managed care, Medicare Advantage, and other government-administered healthcare coverage programs.

<sup>2</sup> Centers for Medicare & Medicaid Services. 2021. Medicare program; Medicare Coverage of Innovative Technology (MCIT) and definition of “reasonable and necessary.” *Federal Register* 85, no. 170: 54327–54339.

commercial payers, the Commission strongly believes that CMS should not adopt a commercial insurance standard to determine coverage of services under Original Medicare.

- Relying on commercial coverage policies could result in coverage of services that do not improve the health outcomes of Medicare patients. CMS has stated in its national coverage determinations (NCDs) and guidance documents on developing NCDs that an improved health outcome is one of several considerations in determining whether a service is reasonable and necessary.<sup>3,4</sup> Further, in statements to the medical community, agency officials have articulated this consideration in determining whether a service is reasonable and necessary: “adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population.”<sup>5,6</sup> But commercial insurance coverage policies are not designed to evaluate the appropriateness of a service for the Medicare population. The Commission strongly urges CMS to codify in regulation a definition of reasonable and necessary that explicitly ensures a service’s efficacy for the Medicare population. The criteria of such a definition should first and foremost verify that the service in question has adequate evidence to demonstrate that it improves health outcomes for the Medicare population.
- The proposal circumvents Medicare’s coverage determination processes and could undermine Medicare’s evidentiary standard. Over time, both the national and local coverage determination processes have been formalized and strengthened to be more analytical, evidence-based, and transparent. For example, according to researchers, NCDs issued between 1999 and 2013 increasingly cited as evidence limitations a lack of relevant outcomes and a lack of applicability of study results to the Medicare population.<sup>7</sup>

When CMS assesses the clinical evidence of a service in making a coverage determination, the agency takes into account: (1) the quality of the individual studies, (2) the relevance of findings from individual studies to the Medicare population, and (3) overarching conclusions that can be drawn from the body of the evidence about the direction and magnitude of the risks and benefits of the service under investigation.<sup>8</sup> CMS is required to use a formal and transparent process to make coverage determinations, with reliance on a review of the best available medical and scientific evidence about the effectiveness of the service under consideration. By contrast, the processes that commercial payers used to develop their coverage policies, including evidentiary standards, are unknown and outside

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<sup>3</sup> Centers for Medicare & Medicaid Services. 2016. Guidance for public, industry, and CMS staff. National coverage determinations with data collection as a condition of coverage: coverage with evidence development. July 12.

<sup>4</sup> Centers for Medicare & Medicaid Services. 2020. Decision memo for next generation sequencing (NGS) for Medicare beneficiaries with advanced cancer (CAG-00450R). <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296>.

<sup>5</sup> Jacques, L. 2012. WSMOS 2012. Presentation at Washington State Medical Oncology Society. <http://www.wsmos.org/events/view/13>

<sup>6</sup> Syrek Jensen, T. 2014. CMS coverage perspective. Diagnostic tests. Medical Device Innovation Consortium. [https://mdic.org/wp-content/uploads/2014/06/Role-of-Regulatory-Science-MDIC-in-Molecular-Diagnostics\\_A-CMS-Perspective.pdf](https://mdic.org/wp-content/uploads/2014/06/Role-of-Regulatory-Science-MDIC-in-Molecular-Diagnostics_A-CMS-Perspective.pdf).

<sup>7</sup> Chambers, J. 2016. Changing face of Medicare’s national coverage determinations for technology. *International Journal of Technology Assessment in Health Care* 31, no. 5: 1–8.

<sup>8</sup> Centers for Medicare & Medicaid Services 2016.

the purview of the Medicare program. Indeed, CMS’s proposal has the potential to cover the off-label use of a service if it is covered in the commercial coverage market. We recognize that CMS faces the challenging task of striking an appropriate balance between beneficiaries (who with their health care providers may seek access to new services) and taxpayers (who bear some of the financial burden of paying for covered services). However, the agency should strive for a process that, in covering innovative, new services, does not abandon evidentiary requirements that ensure that such innovations do indeed improve beneficiaries’ outcomes.

- The determination of whether a service is “appropriate” for Medicare patients should rest with CMS, not commercial payers, because commercial payers’ coverage policies may not explicitly consider whether a service under question is appropriate for Medicare patients. The program’s coverage determinations should rely on a service’s ability to specifically address the needs (diagnosis and treatment) of Medicare patients. Furthermore, to ensure the appropriateness of a service for Medicare patients, the program’s coverage determination process is designed to be transparent, systematic, evidence-based, and to permit opportunities for public comment. We are concerned that CMS’s proposal to use commercial coverage policies would diminish the transparency and rigor of Medicare’s coverage process. In the most extreme case, coverage of a service by only a single commercial payer could trigger coverage for the entire Medicare population, with little if any transparent and publicly available evidence of its appropriateness for Medicare beneficiaries.<sup>9</sup>
- Relying on commercial coverage policies that do not consider whether a service improves the health outcomes of Medicare patients and that lower the evidentiary standard in Original Medicare could increase the already substantial provision of low-value care—care that has little or no clinical benefit or in which the risk of harm from the service outweighs its potential benefit.<sup>10</sup> An increase in low-value care is concerning from a quality-of-care perspective in and of itself, but it could also exacerbate the fiscal challenges faced by the Medicare program. Note, too, that CMS’s proposal might also increase the provision of low-value care in Medicare Advantage (MA) plans since plans are generally required to provide the same set of benefits that are available under Original Medicare.<sup>11</sup> At a time when Original Medicare is promoting strategies to advance the adoption of value-based strategies in other parts of the program, CMS should be making a similar effort to incorporate value into the determination of whether a service is reasonable and necessary. To do so, it is important that Medicare maintain responsibility for Medicare coverage determinations rather than defer to commercial payer policies.
- The proposed rule could alter the relationship between manufacturers and commercial payers. For example, consider a service that does not meet the third coverage criterion on

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<sup>9</sup> CMS is seeking comment on whether to grant coverage if a service is covered by at least one commercial insurance plan.

<sup>10</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the healthcare delivery system*. Washington, DC: MedPAC.

<sup>11</sup> MA plans are permitted to use medical management tools not available in Original Medicare, such as requiring providers to seek prior authorization to have a service covered. Plans also have leeway in controlling utilization through beneficiary cost sharing.

appropriateness (because it is not as beneficial as an existing available medically appropriate alternative across all populations). Adoption of the proposed rule could result in a commercial payer covering certain services because of certain financial relationships with manufacturers.

**A new national coverage pathway—the Medicare Coverage of Innovative Technology (MCIT) pathway—that would provide national coverage for new breakthrough devices concurrent with market authorization from the FDA**

CMS proposes national coverage under the MCIT pathway for a device approved by the FDA’s Breakthrough Program.<sup>12</sup> Medicare coverage could begin on the same date the device receives FDA market authorization and would last for four years. CMS designed the MCIT “to ensure beneficiaries have a predictable access to new devices.” At the end of the four-year MCIT pathway, national coverage of the breakthrough device would be subject to one of these outcomes: (1) NCD of affirmative coverage, which may include facility or patient criteria; (2) NCD of non-coverage; or (3) MAC discretion through either a local coverage determination or claim-by-claim adjudication. This pathway is voluntary, meaning that manufacturers would have to opt in to the process by notifying CMS of their intent to use the MCIT pathway. The agency would publish devices that are covered under this process on its website to ensure that stakeholders are aware of what is covered through the MCIT pathway. Manufacturers of breakthrough devices would not be required to conduct clinical studies under the MCIT pathway. Use of the device for a condition or population that is off-label would not be covered (as that use would not be FDA-authorized). Any reasonable and necessary procedures to implant the breakthrough device would also be covered. Breakthrough devices that received FDA market authorization no more than two calendar years prior to the effective date of the regulation would be eligible for coverage under the pathway for claims submitted on or after the effective date of this rule.

In the rule, CMS states that this proposal was issued in response to the 2019 Executive Order “Protecting and Improving Medicare for Our Nation’s Seniors,” which directs the Secretary to propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients including by streamlining the approval, coverage, and coding process. In addition, CMS discusses concerns from stakeholders that breakthrough devices are not automatically covered nationally by Medicare once they are FDA market-authorized as a rationale for this proposal.

Based on the cost and utilization data on new devices that applied for a new technology add-on payment under the inpatient prospective payment system (IPPS) in fiscal year (FY) 2020, CMS estimates that this provision would increase Medicare spending in 2024 by between \$66 million (assuming low use and cost) and \$2.0 billion (assuming high use and cost) for devices that would not have been eligible for coverage in the absence of this proposed rule.

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<sup>12</sup> The FDA’s Breakthrough Devices Program is an expedited review process available to medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Devices subject to premarket approval applications, premarket notification or requests for De Novo classification are eligible for Breakthrough Device designation so long as they meet certain eligibility criteria.

*Comment*

The Commission recognizes the need to promote beneficiary access to new devices. However, the Commission does not support the use of the FDA's Breakthrough Device Program for qualification for Medicare coverage unless the device in question also meets the standards that Medicare uses to determine national or local coverage. The Commission maintains that the Medicare program, not the FDA, should adjudicate coverage and spending determinations based on the specific needs of the Medicare population.

CMS should not use FDA's approval processes, including the Breakthrough Program, as a proxy for Medicare's coverage process. We reiterate our comments on the IPPS proposed rule for FY 2020, the IPPS proposed rule for FY 2021, and the ESRD proposed rule for calendar year 2021; in these comment letters we said that:

- The Medicare program, not the FDA, should adjudicate coverage and spending determinations based on the specific needs of the Medicare population. CMS's evidence base for a coverage determination should rely on the device's ability to specifically address the needs (diagnosis and treatment) of Medicare beneficiaries.
- The FDA's role in the drug and device development process as a regulator is distinct and separate from the role of CMS as a payer. The FDA regulates whether a device or pharmaceutical product is "safe and effective" for its intended use by consumers. The FDA approval process may or may not include the new device's or pharmaceutical product's safety or effectiveness with regard to the Medicare population.
- Through the Breakthrough Device Program, the FDA considers whether a device is reasonably expected to provide more effective treatment or diagnosis relative to the current standard of care. The device manufacturer or sponsor could demonstrate this expectation through literature or preliminary bench, animal, or clinical data. In the proposed IPPS rule for FY 2020, CMS acknowledged that "...the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization." Therefore, participation in the Breakthrough Device Program on its own does not necessarily reflect improvements in outcomes.
- The Breakthrough Device Program is available for devices subject to review under a premarket approval application, premarket notification (510(k)) clearance, or De Novo marketing authorization. In a July 2011 report, the Institute of Medicine of the National Academies concluded that the 510(k) process "is not a determination that the cleared device is safe or effective." Further, a review of several studies that presented clinical trial evidence of certain approved devices under the FDA's Priority Review Program (also superseded by the Breakthrough Device Program) found that 4 out of 9 expert advisory panel reviews did not find the devices to be effective; indeed, as of May 23, 2018, recalls had been issued for 6 of 14 devices. The Commission remains concerned about inappropriate incentives (through increased payment) for providers to use new technology without proven safety or efficacy.

The Commission does not support using the FDA’s Breakthrough Program as a proxy for Medicare coverage determinations, but if CMS proceeds with the proposal, the agency should cover new devices under a coverage with evidence development (CED) policy. CED is an approach for Medicare to cover potentially beneficial services (including devices) that lack clear evidence showing their clinical effectiveness in specific patient populations. Under CED, beneficiaries have access to medical services while clinical evidence is being collected in prospective clinical studies and registries.

Because CED provides Medicare the opportunity to generate clinical evidence that otherwise might not have been collected, it enables the program to ultimately develop better, more evidence-based policies. CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. For example, researchers have reported that older adults are underrepresented in cancer and cardiovascular clinical trials. In addition, through CED, Medicare can collect evidence on long-term outcomes and effectiveness in different practice settings that are not always collected in clinical trials.

CMS should consider strengthening the CED process to better ensure that application of the policy results in scientifically rigorous data that can be used to formulate coverage policies. Researchers have called for CMS to take various actions to improve CED including: clarifying the standards of evidence, developing rigorous study design, improving the quality of evidence, and developing an infrastructure for more routine use of electronic health data (compiled into longitudinal clinical registries) that could support CED as well as quality measurement.<sup>13,14,15,16</sup>

The Commission appreciates the opportunity to comment on this proposed rule. We value the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues and look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC’s Executive Director at (202) 220-3700.

Sincerely,



Michael E. Chernew, Ph.D.  
Chair

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<sup>13</sup> Tunis, S. R. and S. D. Pearson. 2006. Coverage options for promising technologies: Medicare's 'coverage with evidence development'. *Health Affairs* 25, no.5: 1218–1230.

<sup>14</sup> Mohr, P.E., S. R. Tunis. 2010. Access with evidence development: The U.S. experience. *Pharmacoeconomics* 28, no. 2: 153–162.

<sup>15</sup> Tunis, S. R., R.A. Berenson, S. E. Phurrough, and P. E. Mohr. 2011. *Improving the quality and efficiency of the Medicare program through coverage policy*. Urban Institute: Washington, DC.

<sup>16</sup> Daniel, G. W., E. K. Rubens, and M. McClellan. 2013. Coverage with evidence development for Medicare beneficiaries: Challenges and next steps. *JAMA Internal Medicine* 173, no. 14: 1281–1282.