HEALTH CARE POLICY AND LAW

A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value

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Therapeutic advances enable new treatments and cures for disease. The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring access to emerging technologies that benefit Medicare beneficiaries. For individuals covered by Medicare Part A or Part B, Congress has charged CMS with determining whether items and services are reasonable and necessary to diagnose or treat an illness or injury, or “to improve the functioning of a malformed body member.” The US Food and Drug Administration (FDA) determines that the item or service (eg, drug, biologic, medical device) is safe and effective for the intended population.

In January 2021, a federal regulation known as “The Medicare Coverage of Innovative Technology and Definition of ‘Reasonable and Necessary’” final rule was published. The rule would have automatically provided 4 years of Medicare coverage, regardless of where in the US a beneficiary lived, for newly approved medical devices. The goal was to accelerate the availability of medical devices approved through the FDA breakthrough pathway for innovative technologies.

Physicians and others who commented on this CMS rule raised concerns that the policy did not have sufficient patient protections and that there was frequently a lack of evidence of clinical benefit for the newly approved medical devices in the Medicare population. There were several reasons for these concerns. First, accelerated approval of a medical device by the FDA is often based on short studies that rely on intermediate outcomes. In contrast, when making coverage decisions, CMS generally relies on the demonstration of improved clinical outcomes. Second, manufacturers seeking FDA approval of a device or other therapeutic often design studies that exclude many patients with comorbidities. In many cases, this population of patients is not representative of the Medicare population. For coverage decisions, CMS specifically requires evidence of benefit in the Medicare population, which is often older, has more complex medical needs, and is inadequately represented in clinical studies used to obtain FDA market authorization. For these reasons, in November 2021, CMS rescinded “The Medicare Coverage of Innovative Technology and Definition of ‘Reasonable and Necessary’” final rule.

In 2022, CMS and the FDA reiterated an “unwavering commitment” to continue collaborating to ensure effective treatments are made available to Medicare beneficiaries, regardless of where they live, recognizing that the work of both agencies is critical. One example is the parallel review program, in which both agencies collaboratively engage with manufacturers regarding evidence development for FDA premarket review decisions and the reasonable and necessary coverage criteria of CMS. Early feedback can assist manufacturers in designing pivotal trials and collect evidence that can answer evidentiary questions from both agencies. If there are insufficient data that are relevant to the statutory requirements of CMS, it is difficult for the agency to make a favorable evidence-based decision regarding whether a drug, device, or other medical product meets the legal criteria to be reasonable and necessary. The CMS is also considering releasing a series of “Medicare Evidence Development and Coverage Advisories” that would provide more guidance to manufacturers about the clinical outcomes the agency will be looking for when reviewing studies, as well as the clinical differences that will be considered meaningful.

The CMS remains committed to establishing an expedited Medicare coverage pathway that achieves timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence, including criteria to ensure that qualified physicians and hospitals are delivering the care. In the coming months, the agency is preparing to move forward with a new proposed rule that would create an accelerated coverage pathway. This pathway will build on prior initiatives, including coverage with evidence development. Coverage with evidence development allows Medicare to cover technologies, including medical devices, on the condition that the product is used in clinical studies approved by the agency. Also, the collection of additional clinical data has been used to expand the indications of a novel technology beyond the initial population for which it was approved. In September 2022, to better inform the coverage with evidence development process, the Agency for Healthcare Research and Quality released a draft report on “The Analysis of Requirements for Coverage with Evidence Development (CED).” The Agency for Healthcare Research and Quality report will be discussed at the December 7, 2022, meeting of the Medicare Evidence Development & Coverage Advisory Committee.

The CMS rule that is being developed will meet the following principles:

1. Manufacturers may enter the process on a voluntary basis. This process will be limited to medical devices that fall within the Medicare statute and are relevant to the Medicare population.

2. The CMS may conduct an early evidence review (before the device secures FDA marketing authorization) and discuss with the manufacturer the best
Medicare coverage pathway, depending on the strength of the evidence collected.

3. At the manufacturer’s request, CMS may initiate the coverage review process before FDA market authorization, which could require developing an additional evidence development plan and confirming that there are appropriate safeguards and protections for Medicare beneficiaries.

4. If CMS determines that further evidence development is the best coverage pathway, the agency would explore how to reduce the burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements.

The CMS believes that a rule guided by these principles would strike a balance between promoting access to emerging medical technologies and maintaining the protections and rigorous evidence standards that are essential to the welfare of Medicare beneficiaries. The CMS is also considering whether the proposed rule would establish a clear timeline for decisions requiring coverage with evidence development. In promoting and then reviewing the evidence needed to make a determination that a medical device is reasonable and necessary, CMS will consider whether a device is associated with an overall improvement in health (benefits exceed any harms) in the Medicare population or a subset of individuals. The agency will also consider whether the evidence generated will help guide patients and clinicians in deciding whether to use new or emerging technologies.

In continuing to develop the rule, CMS will work closely with patient groups, medical professionals and societies, medical device manufacturers, other federal agencies (including the FDA), and others involved in developing innovative medical devices. The CMS will rely on feedback to define emerging technologies and evidence standards, maintain the quality of care, and protect Medicare beneficiaries. The CMS looks forward to further engagement to ensure that the Medicare program provides expeditious and evidence-based coverage of medical devices.

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REFERENCES