Health Industry Alert

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CMS Proposes to Streamline Medicare Coverage Process for Innovative Technology and Consider Commercial Coverage in "Reasonable and Necessary" Assessment

September 2, 2020

Key Points

- The proposed rule seeks to "demolish the existing bureaucratic barriers that have created a 'valley of death' for innovative products."
- A new Medicare Coverage of Innovative Technology (MCIT) pathway would allow automatic Medicare coverage of FDA-approved or -cleared "breakthrough" devices for four years.
- Commercial coverage of an item or service would serve as evidence of appropriateness in CMS' reasonable and necessary assessment.

Background

On August 31, 2020, the Centers for Medicare and Medicaid Services (CMS) proposed significant changes to its processes and standards for determining when an item or service is "reasonable and necessary" and therefore eligible for coverage and payment under the Medicare program.1

First, it proposes to ensure immediate access to "breakthrough" medical devices for Medicare patients once they have obtained approval or clearance from the Food and Drug Administration (FDA). This represents a sharp departure from the current process, which can take months or years before a technology is available to Medicare patients.

In addition, CMS is codifying its existing policy for determining when an item or service is reasonable and necessary, while adding a market-based twist: As an alternative to meeting standard Medicare criteria to determine whether an item or service is "appropriate," Medicare may rely on a determination from private payers to extend coverage.

Proposed Medicare Coverage of Innovative Technology (MCIT)

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The current process for securing nationwide Medicare coverage of innovative technologies is slow and can be expensive for companies that must conduct lengthy clinical and health economic studies (on top of studies that were required to secure FDA approval or clearance) to satisfy CMS' demand for Medicare-specific data. Device manufacturers and other stakeholders carry the burden of proving to CMS that the new technology is "reasonable and necessary"—a criteria for Medicare coverage found at Section 1862(a)(1)(A) of the Social Security Act. In a press release, CMS Administrator Seema Verma characterized the current process as one with too many "arcane bureaucratic requirements" that have resulted in "a 'valley of death' for innovative products," to the detriment of our nation's seniors.2

For some technologies, the proposal released on August 31 would flip the long-standing coverage paradigm on its head. Under the proposal, device manufacturers would opt-in to a new coverage pathway for medical devices designated as breakthrough by FDA—the MCIT pathway. Under this new pathway, nationwide Medicare coverage would automatically begin on the date of FDA market authorization and would continue for four years. Under MCIT, as with other coverage pathways, a product must also meet other Medicare coverage criteria—*e.g.*, it must fit within a benefit category and not be excluded by statute.3 At the end of the four-year MCIT pathway, continued Medicare coverage for the breakthrough device would be determined by a national coverage determination (which could be positive or negative), local coverage determinations or claim-by-claim adjudications.4 With the MCIT pathway, CMS aims to offer immediate, predictable Medicare coverage for breakthrough devices.

CMS has long maintained that FDA authorization does not guarantee Medicare coverage, and that the FDA's "safe and effective" standard is distinct from Medicare's "reasonable and necessary" standard. But in its proposed departure from this position, CMS explains that the unique criteria for qualification as a breakthrough device is sufficient to satisfy the elements of the "reasonable and necessary" standard.5 In this way, CMS will limit the scope and reach of the new coverage policy to a subset of medical devices. CMS, however, seeks comments on whether the MCIT pathway should include diagnostics or drugs with breakthrough designations or authorized under expedited FDA approval pathways (e.g., Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval), or all diagnostics and drugs more broadly.6

Codifying and Modifying "Reasonable and Necessary" Criteria

To date, CMS has defined an item or service as "reasonable and necessary" and therefore eligible for coverage and payment under the Medicare program if it is: (1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients. These standards do not currently exist in regulation, but are instead published in Chapter 13, Section 13.5.4 of the Medicare Program Integrity Manual.7

CMS proposes to codify these standards in regulation, a move that may be motivated in part by the recent decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).8 More importantly, CMS proposes to include an alternative to the current criteria for determining whether an item or service is "appropriate." Specifically, if an item or service fails to meet the current criteria for appropriateness, CMS proposes that it may nonetheless be covered by Medicare if it is covered under a commercial insurance plan coverage policy, unless CMS identifies "clinically relevant" differences between Medicare beneficiaries and the commercially insured population.9

CMS' consideration of private payer expertise in making coverage decisions is encouraged by Executive Order 13890, which directs CMS to make technologies "widely available, consistent with the principles of patient safety, market-based policies and value for patients."10The proposed policy, if finalized, has the potential to expand the universe of Medicare-covered items and services. However, obtaining commercial coverage presents its own challenges, especially given that many payers look to Medicare first to conduct an initial assessment for coverage and reimbursement. Additionally, the magnitude of the impact will depend on some key implementation details that CMS has yet to determine, such as:

- What sources of data could be used to implement this policy and whether such information should be made public.
- Whether Medicare should only cover an item or service if it is covered for a certain percentage of plans on the market or specific populations.
- Whether CMS should mirror coverage restrictions on an item or service (*e.g.*, related to clinical criteria, disease stage or number and frequency of treatment).
- The role that Medicare Administrative Contractors (MACs) should play in this process.
- Whether to grandfather existing CMS coverage policies.

CMS seeks comment on how it should address these key questions. The comment deadline is November 2, 2020.

1 CMS, Medicare Program; MCIT and Definition of "Reasonable and Necessary," Proposed Rule, 85 Fed. Reg. 54,327 (Sept. 1, 2020), https://www.govinfo.gov/content/pkg/FR-2020-09-01/pdf/2020-19289.pdf.

2 CMS, Press Release, CMS Acts to Spur Innovation for America's Seniors, https://www.cms.gov/newsroom/press-releases/cms-acts-spur-innovation-americas-seniors (Aug. 31, 2020).

3 *Id.* at 54,334.

4 *Id.* at 54,330–31.

5 *Id.* at 54,333. A breakthrough device is by definition one that provides "for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" and "represents a breakthrough technology; no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or device availability is in the best interest of patients." According to CMS, these criteria make breakthrough-designated devices unique among all other medical devices. *Id.* at 54,329–30.

6 *Id.* at 54,331.

7 CMS, Medicare Program Integrity Manual (Pub. 100-08), ch. 13 § 13.5.4, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

8 In *Allina*, the Supreme Court held that Section 1871 of the Social Security Act forecloses CMS' reliance on sub-regulatory "interpretive rules," and that the agency must go through notice-and-comment rulemaking each time it establishes or changes a "substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Title XVIII]." *Azar v. Allina Health Servs*., 139 S. Ct. 1804, 1817 (2019); 42 U.S.C. § 1395hh(a)(2). Since the Supreme Court's decision, the agency has been engaging in "post-*Allina* clean-up," codifying certain guidance in regulation.

985 Fed. Reg. at 54,332.

10 Executive Order 13890, Executive Order on Protecting and Improving Medicare for Our Nation's Seniors (Oct. 3, 2019), https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/.