PUBLICATION

CMS Finally Proposes a Regulatory Definition of Medically "Reasonable and Necessary"

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It has taken CMS more than 50 years, but the agency has finally proposed a regulatory definition for determining whether an item or service is "reasonable and necessary" for Medicare coverage purposes. Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 85 Fed. Reg. 54327 (Proposed Rule, September 1, 2020). This move comes in response to the President's October 3, 2019 Executive Order 13890 directing the Secretary of HHS to ensure that Medicare beneficiaries have access to new cures and technologies that improve health outcomes. While CMS simultaneously seeks to establish a Medicare coverage pathway for medical devices designated as breakthrough by the FDA in this proposed rule, the proposed regulatory definition, including a possible consideration of whether an item or service is covered in the commercial insurance market, marks some progress toward clarifying when Medicare coverage is available. Comments to the proposed rule must be received by November 2, 2020.

"Reasonable and Necessary"

CMS explains that it is proposing to establish in regulations the factors it has historically used in making "reasonable and necessary" determinations under Section 1862(a)(1)(A), with "some modification." 85 Fed. Reg. at 54329. It acknowledged that stakeholders have expressed interest in codifying this definition for many years and that the proposed definition is "familiar and functional." 85 Fed. Reg. at 54328. The factors used by CMS for this purpose are set forth in the Medicare Program Integrity Manual (MPIM) and state that:

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.

MPIM, CMS 100-08, ch. 13, § 13.5.4.

In addition to codifying the above criteria, CMS is proposing to include a separate basis under which an item or service would be "appropriate for Medicare patients" based on commercial health insurers' coverage policies (non-governmental entities that sponsor health insurance plans). And, CMS states that an "item or service deemed appropriate for Medicare coverage based on commercial coverage would be covered on that basis without also having to satisfy the bullets listed above." 85 Fed. Reg. at 54328.

By considering commercial health insurer coverage policies, CMS states that it would bring together the expertise of private payers and the Medicare program. Under this separate basis, CMS proposes that an item or service would satisfy factor (3) above if it is "covered under a plan(s) coverage policy if offered in the commercial insurance market, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant." 85 Fed. Reg. at 54332. Under this proposal, CMS would exclude Medicaid managed care, Medicare Advantage, and other government administered health care coverage programs from the types of coverage CMS would consider, as these enrollees are not in the commercial market. CMS believes this definition is a "significant step in meeting the E.O.'s directive to bring clarity to coverage standards."

CMS specifically seeks comment on a myriad of issues related to this proposed definition, which include, among others, the following:

- The sources of data that could be used to implement this policy;
- The most appropriate source(s) for these coverage policies and best way to determine which commercial plan(s) it would rely on for Medicare coverage;
- Whether beneficiaries, providers, innovators, or others wishing to gain coverage for an item or service demonstrate that the item or service is covered by at least one commercial insurance plan policy. If they can provide CMS with evidence of commercial coverage or if CMS or its MACs identify such coverage from its review of compilations of health insurance offerings or data from other sources, CMS would consider factor (3) to be satisfied;
- Whether CMS should limit its consideration of commercial plan offerings or covered lives to a subset of the commercial market in the interest of simplicity, including looking at geographic subsets, subsets based on number of enrollees, subsets based on plan type (HMO, PPO, etc.), or other subsets of plans – including utilizing a singular plan; and
- Whether CMS should adopt the most or least restrictive coverage policy since commercial plans may impose certain restrictions on an item or service (related to clinical criteria, disease stage, or number and frequency of treatment).

85 Fed. Reg. at 54332-54333.

In sum, CMS is proposing to define the term "reasonable and necessary" based on the factors currently found in the MPIM, plus an alternative basis for meeting factor (3) based on any coverage in the commercial market. As CMS states, it is soliciting comment on this proposed definition of reasonable and necessary as well as other mechanisms or definitions it could establish for the term "reasonable and necessary" and the merits and drawbacks associated with each, including the potential impact on Medicare program expenses or complexity.

Key Takeaways

To be sure, CMS did not propose this regulatory definition in a vacuum. This definition, if finalized, would be codified within 42 C.F.R. Part 405, Subpart B, which addresses "Medical Services Coverage Decisions that Relate to Health Care Technology." In this proposed rule and not discussed in detail here, CMS also seeks national Medicare coverage for breakthrough devices that are FDA market-authorized and used consistent with the FDA approved or cleared indication for use. For these devices, CMS will deem coverage under the MCIT pathway "reasonable and necessary under section 1862(a)(1)(A) of the Act because the device has met the unique criteria of the FDA Breakthrough Devices Program." 85 Fed. Reg. at 54329.

What is markedly absent from this proposed regulatory definition is an explicit requirement that this new regulatory definition be used solely for medical devices participating in the MCIT pathway and/or the FDA Breakthrough Devices Program. In fact, CMS explains:

Further, under our proposal, each MAC would be responsible for reviewing commercial offerings to inform their LCDs or claim by claim decisions, which would include individual medical necessity decisions. We may also allow the MACs to develop approaches to address any or all of the considerations outlined above, parallel to their current practice of making coverage decisions in the absence of an NCD or national policy.

85 Fed. Reg. at 54332.

While it remains to be seen whether claim adjudicators may utilize this proposed regulatory definition for other services or items outside of the FDA Breakthrough Devices Program or MCIT pathway, this could be useful for individual consideration of Medicare claims since any additional clarification to the subjective "reasonable and necessary" is helpful.

For more information, please contact any member of the Baker Donelson Reimbursement Team.