PUBLICATION

CMS Finalizes Regulatory Definition of Medically "Reasonable and Necessary"

February 11, 2021

On January 14, 2021, CMS finalized 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," 86 Fed. Reg. 2987 (Final Rule, January 14, 2021). In response to President Trump's October 3, 2019 Executive Order 13890 directing the Secretary of HHS to clarify the application of coverage standards, CMS explained that codifying "reasonable and necessary" will "provide greater certainty to stakeholders seeking coverage for innovative items and services and to ensure that this substantive legal standard is codified." The effective date of the final rule is listed as March 15, 2021.

"Reasonable and Necessary"
In September 2020, CMS proposed codifying the longstanding Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, ch. 13, § 13.5.4 definition of "reasonable and necessary" into its regulations at 42 C.F.R. § 405.201(b), with modification. However, the finalized definition departs from the both the proposed version and the MPIM language in a few ways, but specifically in section (b)(iii)(F):

(b) * * * *Reasonable and necessary* means that an item or service is considered –

Safe and effective;

Except as set forth in § 411.15(o) of this chapter, not experimental and investigational; and

Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it meets the following criteria:

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;

Meets, but does not exceed, the patient's medical need; and

Is at least as beneficial as an existing and available medically appropriate alternative; or

Not later than March 15, 2022, CMS will issue draft subregulatory guidance on the methodology of which commercial insurers are relevant based on the measurement of majority of covered lives. For national and local coverage determinations, which have insufficient evidence to meet paragraphs (b)(3)(i) through (v) of this section, CMS will consider coverage to the extent the items or services are covered by a majority of commercial insurers. As part of CMS' consideration, CMS will include in the national or local coverage determination its reasoning for its decision if coverage is different than the majority of commercial insurers.

86 Fed. Reg. at 3009.

Commercial Insurance Policies

CMS' proposed modification in September 2020 to the MPIM definition was that an item or service would satisfy factor (b)(iii) if it is covered under a commercial health insurer's plan, unless evidence supported that differences between Medicare beneficiaries and commercially insured individuals were clinically relevant. However, CMS decided *not* to finalize this modification to allow commercial insurers to be the sole determinant of factor (b)(iii). Instead, CMS finalized the above-quoted language in (b)(iii)(F) and committed to publishing subregulatory guidance within 12 months to propose a draft methodology to determine the relevancy of commercial insurance policies to ensure there is adequate public input on the process.

As part of its reasoning for this choice, CMS noted that it has relied on commercial insurance policies in the past as part of the National Coverage Determination (NCD) development process. The agency explained that if Medicare coverage is different from the majority of commercial insurance policies, then it would include in the NCD or local coverage determination (LCD) its reasoning for different coverage. Therefore, CMS stated that it will, no later than March 15, 2022, publish the draft methodology for public comment by which commercial insurance policies are determined to be relevant based on "the measurement of majority of covered lives."

Applicability to All Medicare-Covered Services and Items under Part A and B

This final rule was published in connection with the rule for Medicare coverage of devices that receive Breakthrough Device designation by the FDA under the Medicare coverage of innovative technology (MCIT) program. CMS was clear, however, in the preamble discussion of the final rule that the regulatory definition of "reasonable and necessary" will apply to *all* items and services Medicare covers under Part A and Part B. CMS states that this includes, but may not be limited to, drugs, devices and biologics, and that Medicare Advantage plans are required to offer coverage of these items and services on terms at least as permissive as those adopted by fee-for-service Medicare under this policy.

CMS did not use this opportunity to otherwise expand coverage and expressly declined to extend coverage to prevention and screening services or items. Further, CMS did not clarify the existing definitions of "safe and effective" or "at least as beneficial," instead referring back to "long-standing" definitions of these terms and refusing to update or otherwise modify these terms. Finally, CMS specifically states that the Medicare Administrative Contractors (MACs) will continue to adjudicate individual claims to ensure that they are reasonable and necessary and that the MACs will continue to have the flexibility to decide the best approach to coverage on a local level.

Key Takeaways

While this new regulatory definition perhaps provides some additional clarity to the subjective term of "reasonable and necessary," it is not entirely clear how 42 C.F.R. § 405.201(b)(iii)(F) will impact medical necessity determinations until after promulgation of the draft subregulatory guidance regarding the relevant commercial insurance policies promised by March 15, 2022. CMS itself acknowledges that the regulatory

impact of defining "reasonable and necessary" in regulations is difficult "without knowing the . . . criteria that CMS will use for determining which commercial insurers will be considered." 86 Fed. Reg. at 3005-6.

Further, this final rule may be subject to review pursuant to the new administration's January 20, 2021 Regulatory Freeze Pending Review Memorandum, which could postpone the effective date beyond March 15, 2021. For now, however, CMS is poised to have a regulatory definition of "reasonable and necessary" for the first time in more than 50 years.

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