Rule speeds approvals for 'breakthrough' devices, other commercially covered services

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A new final rule will allow items and services to gain approval for Medicare reimbursement more quickly than in the past, particularly medical devices that clear a specific FDA hurdle. But the devil is in the details, and the rule's finer points will be ironed out in sub-regulatory guidance.

Under the rule — "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary,'" published Jan. 14, 2021 — CMS will make an important change in its "reasonable and necessary" standard for determining whether to cover an item or service for Medicare.

Currently, if an item or service is "safe and effective" and "not experimental or investigational," but is not otherwise judged to meet CMS' criteria for "appropriate for Medicare patients," CMS will usually decline to cover it.
But CMS now says it can judge appropriateness by "commercial market analysis" to determine whether an item or service is reimbursable. In other words, the agency can base coverage of a device on whether most other payers are paying for it, "except where evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals," the rule says.

Outside of the new designation status, the Medicare approval process would operate as usual: Medicare administrative contractors (MAC) "should continue to adjudicate individual claims to ensure that they are reasonable and necessary, in the absence" of a national coverage determination (NCD), the rule says.

For example, in the case of treatments for rare diseases, "application of appropriateness for a small population may be best addressed as a claim-by-claim decision that takes into consideration the individual patient's clinical situation." Also, local coverage determinations (LCD) will still define coverage in a MAC's jurisdiction.

Until it kicks in, stick to current regs

Note that the commercial analysis won't immediately take effect. "Not later than 12 months after the effective date of this rule" — the effective date being March 15, 2021 — CMS says it will publish "draft methodology by which commercial insurer's policies are determined to be relevant based on the measurement of majority of covered lives."
Also, the agency says that it still has "to define which types of commercial insurers (based on majority of covered lives) are relevant" to this analysis, according to the final rule.

"Given that CMS has yet to issue sub-regulatory guidance on how it will determine what commercial insurers to consider for national and local coverage determinations, and that consideration of what is 'reasonable and necessary' will still be granted on a case-by-case basis, practices can anticipate LCDs and NCDs operating as standard for the near future," says Alison Manson, vice president of government relations and advocacy at nonprofit advocacy group ZERO — The End of Prostate Cancer.

Enter the 'breakthrough' adoption

The rule also creates a new pathway for medical device approval for "breakthrough devices," or what the agency is calling "Medicare Coverage of Innovative Technology (MCIT)." These are devices identified by the FDA Breakthrough Devices Program, which reviews and approves applications on devices that offer "more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."

If approved, these devices get special consideration and feedback from FDA in its approval process.

Under MCIT, as soon as the FDA gives a device market approval under the breakthrough devices designation, Medicare will reimburse for it for a four-year period, after which the agency will review data and consider it for reauthorization. Note that devices can only gain immediate approval if they are not otherwise excluded from coverage by statute — for example, if the device is non-durable.

Alan J. Sedley, senior counsel with the Nelson Hardiman firm in Los Angeles, notes that "breakthrough" technology was originally "the primary focal point" of the rule, as suggested by then-President Trump's Oct. 3, 2019, Executive Order, which called for regulations to be written so that "innovative products are brought to market faster, and so that such products, including breakthrough medical devices and advances in telehealth services and similar technologies."

The MCIT part of the rule is seen as a boon to device manufacturers and to medical organizations whose patients could benefit from new avenues of treatment.

"Having a clear path to national Medicare coverage for innovative products like KidneyIntelX provides a major catalyst to drive the robust research and clinical development programs necessary to address major unmet medical needs such as kidney disease," says Tom McLain, president of device company RenalytixAI, referring to its lead product, KidneyIntelX, an artificial intelligence-enabled diagnostic for kidney disease that won FDA Breakthrough Device status in 2019.

MCIT "may be able to sooner bring life-saving treatments to patients who rely on Medicare," Manson says, pointing to the prostate cancer therapy space as an example. "We hope to see novel PARP inhibitor treatments and diagnostic capabilities," Manson adds. "Innovative advances in prostate cancer screening could also be game-changers."

Resources

- Final rule, "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary": *www.federalregister.gov/documents/2021/01/14/2021-00707/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and*
- FDA Breakthrough Device Program: *www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program*

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