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Industry Praises CMS Final MCIT Reimbursement Rule; Urges Biden Team To Implement It

by Sue Darcey

The US Medicare agency issued on 12 January its final MCIT rule allowing instant reimbursement for FDA breakthrough devices – unless the incoming Biden administration blocks it.

The US Centers for Medicare and Medicaid Services on 12 January approved a final reimbursement regulation, the Medicare Coverage of Innovative Technology rule, which the medtech industry has been pushing the agency to adopt for the last several years. However, there is a worry the new rule – a product of the Trump administration – could be temporarily or permanently blocked by the incoming Biden administration.

Under the *MCIT regulation*, as soon as the Food and Drug Administration approves a new breakthrough device or diagnostic, Medicare will cover it.

"It's that simple, and it should be that simple," medtech advocacy group AdvaMed president and CEO Scott Whitaker said in a 12 January *statement*. "It means that when a device is designated by the FDA as breakthrough and is determined by the FDA to be safe and effective, Medicare patients can be first in line to get it when their doctors determine it is necessary."

Now that the rule has been issued, Whitaker urged the Biden administration to keep the rule in place, and said the trade group will work closely with the incoming presidential team on MCIT's implementation. But one concern is that the new administration could block the rule, as the Biden transition team plans to issue a memo on Inauguration Day – 20 January – that will block any new Trump administration policies from taking effect. The MCIT rule goes into force on 15 March. (Also see "*With Sun Setting On Trump Admin, HHS Finalizes Regulatory Review Rule*" - Medtech Insight, 8 Jan, 2021.)

The CMS says MCIT offers these benefits for medtech product sponsors:

- Medicare can provide national coverage simultaneously for breakthrough devices for a period of up to four years;
- The CMS will reevaluate the breakthrough device based on clinical and real-world evidence of improvement in health care outcomes in Medicare patients; and
- Manufacturers will be incentivized to develop additional evidence regarding the applicability of their products to the Medicare population.

CMS Plan To Rely On Commercial Insurers' Decisions Will Be A Downside

While most of the changes that the CMS made from the proposed version to the final version of the rule will be positives for industry; for example, the rule includes a more flexible start date for MCIT coverage, allowing manufacturers to choose when data coverage begins to align with a device's market release. But not all of the agency's refinements from draft to final document are pluses, industry advocates say. To wit: A change to allow the CMS to gather more information about using commercial insurance coverage policies to determine Medicare coverage was loudly denounced by both AdvaMed and the Medical Device Manufacturers Association (MDMA) in their comments on the regulation.

"Commercial insurance coverage decisions lack transparency and processes for stakeholder engagement," so should not be made part of a "reasonable and necessary" definition CMS put into the final rule, AdvaMed wrote in November comments on the proposed rule. (Also see "*Industry Comments Show Support For MCIT Proposed Rule – With Reservations*" - Medtech Insight, 18 Nov, 2020.)