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Industry Comments Show Support For MCIT Proposed Rule – With Reservations

AdvaMed, MDMA strongly back the Medicare coverage proposal, but want agency to back off codifying a definition for 'reasonable and necessary'

by Sue Darcey

Industry groups were cool to parts of the CMS's proposed Medicare Coverage of Innovative Technology (MCIT) rule dealing with commercial insurance coverage, as well as definitions used in the proposal.

While comments from AdvaMed and the Medical Device Manufacturers Association expressed strong support for a proposal from the Centers for Medicare and Medicaid Services that would allow up to four years of Medicare coverage of Food and Drug Administration-defined breakthrough devices, both groups said commercial insurance coverage decisions should not be used as a template.

Further, both AdvaMed and MDMA want the agency to either back away from defining what should be considered reasonable and necessary for Medicare's population of 65-year-olds and older – a provision included in the Medicare Coverage of Innovative Technology (MCIT) rulemaking – or to be more transparent with stakeholders about what it has in mind for the definition.

In *AdvaMed's comments*, the association said if the CMS wants to move ahead anyway on a definition of "reasonable and necessary," it should initiate a more extensive dialogue with stakeholders on the topic, using an open and transparent process. Regulating the definition has the potential of taking away some of the current flexibility the CMS has to interpret whether an item is reasonable and necessary, AdvaMed's Chandra Branham explained to *Medtech Insight* in an online interview.

> *"Commercial insurance coverage decisions lack transparency and processes for stakeholder engagement and are not appropriate for inclusion" [in a reasonable and necessary definition]. – Don May*

"We wouldn't want a strict regulatory definition to somehow restrict or limit access," said Branham, who is AdvaMed's VP, payment and health care delivery policy.

The trade group also wrote that it opposes the CMS's inclusion of an analysis of commercial insurance coverage policies as part of the reasonable and necessary definition. "Commercial insurance coverage decisions lack transparency and processes for stakeholder engagement and are not appropriate for inclusion" in the definition, wrote AdvaMed's Don May, executive VP, payment and health care delivery policy.

MCIT Should Include Diagnostic Devices, Too

AdvaMed asked for the CMS to clarify the draft coverage program's application to diagnostics, as CMS requested comment on that area, in particular. The trade group wrote that the CMS should be clear in its final rule that FDA-approved breakthrough diagnostic technologies are also eligible for the pathway.

Branham told *MTI* that new diagnostics – as well as traditional devices – sometimes are not covered by Medicare and other payers. Also, for some diagnostic companies, winning coverage by the CMS is less difficult "than seeing an appropriate payment amount for a new test," she commented.

MDMA Emphasizes Importance Of Multiple Pathways To Coverage

MDMA also praised the CMS for getting out the MCIT proposal in its *comments*. The group said that by providing multiple pathways to evaluate and provide coverage for medtech products, including national coverage determinations, local coverage determinations, claim-by-claim adjudication by Medicare Administrative Contractors, and the FDA-CMS parallel reviews – plus MCIT – the CMS has fostered a great deal of flexibility for device manufacturers.

However, the association commented that it wants the CMS to increase its focus on ensuring transparency in the coverage process. This includes answering clinical questions relevant to the Medicare population, MDMA wrote. The group agreed with the CMS that manufacturers should not be obligated by the agency to conduct clinical studies throughout the MCIT coverage period.

But a commercial insurance group, America's Health Insurance Plans (AHIP), said in its

comments that CMS should only accept those FDA-designated breakthrough devices that have been through clinical trials for the MCIT pathway. (Also see "*Attorneys, Insurers Disagree With Manufacturers On Need For Clinical Evidence For MCIT Coverage*" - Medtech Insight, 12 Nov, 2020.)

“We ask CMS to provide clear information to manufacturers utilizing the MCIT pathway about the clinical questions relevant to the Medicare population that the agency believes are unresolved by FDA market authorization and the evidence needed to support permanent coverage,” commented Mark Leahey, MDMA president and CEO.

MDMA, like AdvaMed, also stated that it supports inclusion of diagnostic and physiological monitoring products for the MCIT pathway.. CMS had requested comment on if the MCIT program “should also include “diagnostics, drugs and/biologics that utilize breakthrough or expedited approaches at FDA.”

“All product types regulated by FDA’s Center for Devices … should be able to use the MCIT pathway,” the group wrote.