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Voluntary TCET Pathway: Extension of CED

No Automatic CMS Coverage for MedTech, Diagnostic Tests Excluded

Relevant Companies



Today, the Center for Medicare & Medicaid Services released their procedural notice for transitional coverage for emerging technologies (TCET) pathway which provides CMS coverage for new medical technologies. Link [Here](#).

»» Our Take & Next Up

This is less positive for large companies and better for smaller device companies, but unhelpful for digital therapeutics that may not easily fit into a benefit category. The proposal is in line with our preview: a voluntary, CED-type process by CMS for Breakthrough-only devices (not diagnostic tests). This is not economically significant and a far cry from 'automatic coverage' supported by AdvaMed and other companies over the last 3-4 years. Stakeholders (manufacturers, trade associations like AdvaMed) have 60 days to comment on the notice. A final notice will be released after the comment period. CMS is also seeking public comment on whether similar devices to the Breakthrough Device should be addressed under a separate NCD or should be subject to the same coverage conditions.

»» Key Points

The proposal is formatted as a procedural notice rather than rulemaking and is not economically significant. TCET will leverage the existing National Coverage Determination (NCD) pathway (specifically the Coverage with Evidence Development mechanism) to provide coverage for emerging technologies. CMS expects most TCET NCDs to result in CEDs ...

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