Transitional Coverage for Emerging Technologies

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Medical devices – everything from pacemakers to hip implants to x-ray machines – have helped countless people live longer and healthier lives. As part of our mission to improve health outcomes and enhance health care quality, the Centers for Medicare & Medicaid Services (CMS) is committed to making sure people with Medicare have access to the newest medical technologies.

Working in close collaboration with the medical device industry, physicians and other clinicians, patient groups, and other stakeholders, CMS is excited to have recently launched a new initiative called the Transitional Coverage for Emerging Technologies (TCET) pathway that will encourage greater medical innovation while giving people with Medicare faster and more consistent access to the latest technologies.

TCET builds on the existing Medicare coverage review process to provide an efficient, predictable, and transparent coverage pathway for certain Food and Drug Administration (FDA)-designated Breakthrough Devices. These are cutting-edge technologies that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions beyond the current standard of care.

In finalizing the TCET pathway, CMS heard from and listened to people with Medicare who want access to the latest medical options, clinicians and caregivers who want the best for their patients and loved ones, and medical device manufacturers who want predictability and timeliness in CMS coverage decisions.

The new coverage pathway also places a strong emphasis on evidence development. This means that people with Medicare, their caregivers, and their doctors will have more information about Breakthrough Devices and can be empowered to make more informed and personalized health care decisions.

Finally, TCET supports innovation within the medical device industry by providing what it has long asked for: a more efficient and transparent coverage pathway, with enhanced communications between industry and CMS, clear evidence requirements, and more defined timelines for final coverage actions.

Under TCET, CMS will conduct an early evidence preview before FDA makes a final marketing decision for a designated Breakthrough Device. CMS will discuss with the manufacturer the best available coverage pathways depending on the strength of the evidence. Additionally, CMS will share information about any evidence gaps for coverage purposes and the types of study

designs that could address them. These conversations will better position manufacturers to efficiently satisfy both FDA and CMS requirements.

For devices in the TCET pathway, CMS' goal is to finalize a coverage decision within six months after FDA market authorization. The TCET pathway will also help coordinate other aspects of Medicare payment – such as benefit category determination, coding, and payment reviews – which will further expedite access to these devices for people with Medicare.

TCET is a prime example of how successful engagement with stakeholders can result in new initiatives that can benefit people with health care needs, the people who serve them, and industry innovation. CMS gathered extensive feedback from patient groups, medical professionals, device manufacturers, innovators, and other federal agencies to develop this new coverage pathway.

With the support of policymakers, the trust of people with Medicare and providers, and meaningful collaboration with manufacturers, we can improve care and quality of life for individuals with Medicare while fostering innovation.

To learn more about the TCET pathway, please visit: https://www.cms.gov/newsroom/fact-sheets/final-notice-transitional-coverage-emerging-technologies-cms-3421-fn