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What's New In MedTech

TCET Improvements, FDA's TAP Enrolls 10 Devices, Breakthrough Updates

Relevant Companies

Our Take & Next Up

We believe MedTech friendly policies in play move the innovation ball forward, with a more positive TCET rule (CMS coverage of BT devices) likely to be finalized this year, a new TAP program that provides early-and-often FDA and payer engagement for greater predictability. This week, the House unveiled a bolus of innovation friendly bills that provide clarity & predictability on the NCD and LCD processes. Many of the bills, discussed below, are bipartisan and have minimal budgetary impact, therefore could pass in 2023-24. However, we do not think a MCIT-type bill, which would allow for 4 years of automatic CMS coverage for Breakthrough designated medical devices, is likely to pass with the rest. Breakthrough designation FDA rules were also updated this month, and we note ~5 devices of 300-500 that receive BT designation each year end up being FDA approved.

Key Points

A finalized TCET guidance is expected to be released with an allowance of (1) 5+ BT devices and (2) diagnostic test inclusion. Recall that the transitional coverage for emerging technologies (TCET) proposal this summer fell extremely short of the Medicare Coverage of Innovating Technologies (MCIT), a Trump-era automatic Medicare coverage for breakthrough medical devices. We previewed this likelihood ahead of rule release in June, and we viewed the rule as doing only a little around the edges.

We may see additional clarity from CMS on follow-on devices as well as coding/billing in final TCET rules 4Q23. Written comments were due August 28. Advamed recommended that CMS eliminate the 5 product cap and expand the number of qualifying technologies to include in vitro diagnostic tests (IVD) with breakthrough designation, AI, virtual and other digital

technologies. MDMA asked for a separate pathway from CED called “TCET-Temporary Limited Context” that allows a temporary TCET coverage for devices that are “reasonable and necessary” but have limited data.

Other asks for TCET are reasonable. Stakeholders want clarity on coding and billing and note that there are other coverage designations (e.g., New Technology Add-on Payments (NTAP)) that impact billing. Recommendations include potentially assigning a specific code for TCET products and “system readiness meeting” opportunities for collaboration between agencies and manufacturers.

A MCIT-type bill, which allows for 4 years of automatic CMS coverage for breakthrough devices, was discussed this week, but we believe it is unlikely to pass. Following MCIT withdrawal, there was confusion as to whether devices that would have qualified for MCIT would qualify for TCET as CMS provided guidance to products that are 12 months from approval. Legislation that mirrors MCIT was introduced, and in a House Energy & Commerce hearing on innovation this week, Reps considered the *Ensuring Patient Access to Critical Breakthrough Products Act*, a bipartisan bill, that requires Medicare to temporarily cover all FDA approved, breakthrough medical devices for four years, starting on the day of approval. The bill allows lookback coverage of devices that have been FDA approved since 2019.

The TAP program, a new pilot funded by MDUFA, has enrolled about ten (10) CV devices. Earlier this week, the FDA participated in Medical Device Innovation Consortium meetings and highlighted their Total Product Life Cycle Advisory Program (TAP) pilot. The pilot offers a limited number of devices with earlier and more frequent interactions with CDRH to help overcome regulatory review uncertainty, along with payer engagement.10 cardiovascular devices have been enrolled so far. Eligible devices must have been granted breakthrough designation and have not yet initiated a pivotal study. It is set to run from FY 2023-2027 and the program has only reviewed cardiovascular devices in FY23. Starting October 1st, the pilot will expand to neurological and physical medicine devices.

With little fanfare, FDA also updated its Breakthrough Device final guidance on September 14 with no major changes. The updated guidance defines the FDA's interpretation of "more effective" as encompassing all the information about the device, including the risks and benefits of using the device compared to the standard of care and clinically meaningful impact. The FDA noted that pathway is available for nonaddictive medical products for addiction or pain and for devices that address equity and accessibility. FDA also further clarified that they will not disclose a Breakthrough designation if a device receives marketing authorization for an indication other than the indication covered by its designation.

While 300-500 medical devices each year receive Breakthrough designation, only about 5 end up being FDA-approved. We believe this is the reason that the TCET rule, discussed above, includes a coverage pathway for 5 devices per year. Again, we think that the ceiling will be raised to be 5 and more in future years, given resource constraints.

Fostering innovation and increasing predictability is a common bipartisan legislative theme when it comes to MedTech, a positive for industry. Many bills were introduced this week and have limited budgetary impact but could appear as riders in future packages. The House E&C committee held a hearing on a number of bills that are would enhance clarity around national and local coverage determinations for Medicare. The *National Coverage Determination Transparency Act* would require CMS to determine if NCD applications are complete within 30 days of receipt clarifies that the timeline for an NCD starts. The *Timely Access to Coverage Decisions Act* would require Medicare Administrative Contractors (MACs) to make an LCD within 9 months, and the *Coverage Determination Clarity Act* would require CMS to annually review each LCD to determine if it denies or limits coverage beyond that provided by NCD.

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