Weekly Checkup

New Solution, Same Problem

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Earlier last month, the Centers for Medicare and Medicaid Services (CMS) published its final notice on the Transitional Coverage for Emerging Technologies (TCET) Pathway. Redesigned as a scaled-back version of former President Trump's Medicare Coverage of Innovative Technologies (MCIT) final rule, the Biden Administration's TCET Pathway would allow CMS to drastically expedite the approval process of up to five Food and Drug Administration-designated (FDA) breakthrough devices each year. **While TCET is a small step in the right direction let's discuss the history behind TCET's creation to understand why this final rule will likely have only a minimal impact.**

At its root, the debate over Medicare coverage for breakthrough devices originates from a short line embedded in the program's original legislative text mandating that it only pay for items and services that are "reasonable and necessary" (R&N) for the treatment of illness and injury. In the decades following Medicare's enactment, R&N has broadly been interpreted to exclude any experimental or investigative medical services and products. As a result, **many new FDA-approved products experience long delays between their approval and Medicare coverage, with most products taking an average of five years to receive Medicare coverage following their FDA approval.**

As new products continued to face long delays due to R&N, in 2005, CMS introduced the Coverage with Evidence Development (CED) program. In its initial implementation, the CED program was designed to provide an early pathway to promising medical products and services while simultaneously allowing Medicare to further review the product's effectiveness and safety. As manufacturers quickly learned, though, the CED program proved to be costly, slow, and dated. **To date, 27 medical products and services have been subject to CED, but only four have graduated from the program to receive full coverage.** Even more dispiriting is that many of these yet-to-graduate products include readily used hospital services such as PET scans (when used in conjunction with conditions such as dementia or other neurological disorders) that have been a critical diagnostic tool

for doctors since 1977.

In response to these apparent faults in the CED program, the Trump Administration proposed the MCIT rule. This new rule was designed to provide same-day national Medicare coverage to any product or service that the FDA approved as a breakthrough device. After four years, if the product or service still proved effective, it would then graduate from MCIT to full Medicare coverage. Alongside the MCIT rule, the Trump Administration also codified a more expansive definition of R&N for any device or service covered under Medicare Part A and Part B. **Soon after President Biden took office, however, his administration quickly repealed the MCIT/R&N rule**, claiming the FDA market authorization "might not consider the difference in clinical profiles, complexities of medical conditions, or associated treatments of the diverse population of Medicare patients."

Now, three and a half years later, the Biden Administration has unveiled its solution to the R&N issue: TCET. But unlike its predecessor, TCET is not a new program; rather, it's an attempt to build on the flawed CED program. **While TCET does take some steps in the right direction** – it allows companies to coordinate with CMS prior to FDA approval as a breakthrough device and provides five-year transitional coverage for all breakthrough devices (once CMS approves a manufacturer development plan) – **it doesn't go far enough to incentivize innovation and is substantially limited by flaws in the CED program, mostly its high costs, slow approval process, and dated systems.** Furthermore, TCET also has flaws of its own. Not only has the Biden Administration limited the number of new breakthrough devices for which TCET can provide transitional coverage (only five devices every year), it has also excluded a majority of diagnostic tools from participating in the program.

Congress should consider further clarifying the statutory definition of R&N to make it more inclusive and exploring new policies that incentivize manufacturers to provide high-quality evidence when they introduce a new product.