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Representatives Press CMS On Coverage Of Innovative Devices

by Elizabeth Orr

Medicare coverage of innovative and life-saving devices, drugs and diagnostics were the focus of a 19 September Congressional hearing during which representatives pressed for swifter and more predictable paths to reimbursement.

The US Congress appears ready to act on Medicare coverage of innovative devices as the issue took center stage at a 19 September hearing of the House of Representatives' Energy and Commerce Committee Health Subcommittee.

The hearing was organized as a follow-up to a July hearing on how Medicare coverage pathways affect patient access to health care. But while the July hearing focused on identifying the issues, this one centered on potential legislative solutions. About two dozen proposed bills were up for discussion. (Also see "*Medtech Experts Endorse TCET In Health Subcommittee Hearing*" - Medtech Insight, 21 Jul, 2023.)

"In July, we heard from a panel of experts about the importance of updating the Medicare program to meet the needs of a growing senior population," said panel chair Rep. Brett Guthrie, R-KY. "Now we're taking the next step to examine specific solutions, which seek to turn the principles and ideas from members, previous expert witnesses, and wide-ranging stakeholder input into legislation to support millions of seniors across the country."

As examples, Guthrie cited the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, which would allow for Medicare coverage and payment for multi-cancer early detection screening tests that had been cleared by the US Food and Drug Administration, and the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, which would provide Medicare coverage of breakthrough devices for four years while the Centers for Medicare and Medicaid Services (CMS) works to make a permanent coverage determination.

The Ensuring Patient Access bill would codify proposals such as CMS' Transitional Coverage of Emerging Technologies (TCET). The first attempt, Medicare Coverage for Innovative Technologies, was proposed in 2020 but yanked in 2021 amidst budget and political concerns. (Also see "*It's Official: CMS Repeals MCIT Rule, Leaves Door Open For Alternatives*" - Medtech Insight, 12 Nov, 2021.)

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The subcommittee chair noted that proposals that would guarantee reimbursement for breakthrough products have strong bipartisan support.

"These products, many of which are FDA approved but have yet to receive CMS coverage, could transform lives and make daily activities more manageable for seniors who may currently be bedridden, or one device or technology away from being able to finally manage cardiovascular disease," he said.

Other proposed legislation would require CMS to set a more consistent process for National Coverage Determinations; establish a new payment structure for nuclear diagnostics; and provide Medicare coverage for prescription digital therapeutics. A memo listing all potential legislation is *here*.

However, there may be political trouble on the horizon. Energy & Commerce Committee Ranking Member Frank Pallone, D-NJ, expressed concern that some of the proposals would "bypass [Medicare] pathways to give handouts to Big Pharma and medical device companies." Pallone also questioned how the new coverage could be financed without raising Medicare premiums for seniors, a move Democrats have opposed.

CMS Official In the Hot Seat

The hearing featured two witnesses: Dora Hughes, who is CMS' acting chief medical officer, and Government Accountability Office health care director John Dicken. Most of the representatives' questions went to Hughes, who was asked to account for perceived flaws in Medicare coverage policy.

For example, Guthrie asked about why CMS' TCET proposal would prioritize devices seen as having the potential to help the most patients and would be limited to five products per year. (Also see "*Expanding Device Eligibility And Other Suggestions For CMS's TCET Pathway*" - Medtech Insight, 31 Aug, 2023.)

"How can you ensure smaller manufacturers – who as I've found are often developing the most novel technologies – can gain access to the program, because the greatest benefit of the program would accrue to these companies with less resources available to navigate the reimbursement process?," he asked.

In response, Hughes said that smaller manufacturers who were not selected for TCET could still receive Medicare coverage, either through Local Coverage Determinations (LCDs) or through individual coverage on a case-by-case basis. Most coverage decisions are handled at that level, she said.

However, trade group the Medical Device Manufacturers Association (MDMA) has called the utility of that approach into question. "Engaging with multiple MACs on either claim-by-claim adjudication or LCD development is time-consuming and requires significant resources that small medical device companies (the source of most new device innovations) often do not have. This is especially true in the case of denials that must be appealed, often repeatedly for the same device," MDMA president Mark Leahey wrote in *comments to CMS* on TCET.

During yesterday's hearing, Hughes further noted that only about eight potentially Medicare-eligible breakthrough devices receive FDA clearance each year, with other devices emerging from the agency's breakthrough pathway being either aimed at non-Medicare patients or part of a benefit category Medicare doesn't pay for, such as software. Of those, she believes CMS has the resources to cover five, which she said would be twice the current average.

"Certainly at CMS we share your enthusiasm for some of these newer technologies that are coming through, for those technologies that meet our statutory standard of being medically reasonable and necessary for our Medicare beneficiaries," she said. "We are able to provide coverage at the local level and claim-by-claim basis on a pathway that is, in many cases, faster."

Coverage for prescription digital therapeutics (PDTs) was another hot topic for the subcommittee members. Rep. Bill Johnson, R-Ohio, asked Hughes what CMS was doing to ensure people in underserved areas had access to PDTs, and how the agency approached coverage and reimbursement for PDTs and similar innovative products.

"According to the National Alliance on Mental Illness, 22.8% of US adults, that's about 57.8 million people, experienced some form of mental illness in 2021," he said. "There are several prescription digital therapies cleared by FDA, and still others in clinical trials, to treat major

depressive disorder, PTSD, panic attack disorder and other mental health illnesses. These treatments could help us close the coverage gap, reach underserved communities like the one I represent in rural Ohio and improve health outcomes for millions of Americans."

Hughes said that CMS "has prioritized behavioral health" and hoped to work with Congress to expand PDT access.

Reimbursement has been a persistent concern for PDT developers. Pioneering firm Pear Therapeutics got FDA approval for apps to treat migraine, depression, substance use disorder and other conditions, but filed for bankruptcy last April due in part to ongoing reimbursement challenges. (Also see "*'It's Not Going To Happen Overnight': Payors On Pear Fallout And Digital Therapeutic Coverage Prospects*" - Medtech Insight, 23 Jun, 2023.)

Industry Reacts

Trade group AdvaMed applauded ongoing Congressional focus on the issue.

"One of AdvaMed's top priorities is ensuring patients have access to the best care available, including new breakthrough technologies," said AdvaMed president and CEO Scott Whitaker. "Without Medicare coverage for these devices and treatments, beneficiaries are missing out on the latest innovation that could extend, improve, and even save their lives. AdvaMed thanks the Energy and Commerce Committee for highlighting this important legislation, and we applaud the bipartisan work being done in Congress to support patients. We look forward to continue working with lawmakers on both sides of the aisle to move this bill forward."