CLOSING THE COVERAGE GAP FOR EMERGING TECHNOLOGIES

CALIFORNIA LIFE SCIENCES

ENSURING CALIFORNIANS CAN ACCESS BREAKTHROUGH MEDICAL DEVICES

Congress should pass the *Ensuring Patient Access to Critical Breakthrough Products Act* (H.R.5343) so California patients can access innovative medical technologies in a timely manner.

ELIMINATING THE MEDICARE COVERAGE GAP FOR BREAKTHROUGH DEVICES

The Breakthrough Devices Program at the FDA is a voluntary program for certain medical devices that provide more effective treatment options for debilitating or life-threatening conditions and offer significant advantages over approved, existing alternatives, be in the best interest of patients, or fill a gap where no approved alternatives exist.

BREAKTHROUGH IS A SUCCESS

Nearly 130 Breakthrough Devices have received marketing authorization since the start of the program.

DELAYED COVERAGE, DELAYED ACCESS

Under current policies, it takes an average of 5 years for medical technologies to achieve nationwide coding, coverage and payment.

While the FDA has recognized the importance of prioritizing approval of breakthrough medical devices, Medicare coverage has lagged, creating a significant barrier to patient access for these essential emerging technologies. Medicare transitional coverage for breakthrough products would cut through the red tape to ensure access to safe, effective breakthrough medical technologies for every patient in need.

ONGOING REGULATORY EFFORTS FOR EXPEDITED MEDICARE COVERAGE

On August 8, 2024, CMS issued its final notice for the Transitional Coverage for Emerging Technologies (TCET) pathway, which aimed to establish a clear coverage process for these products. While a positive incremental step forward, TCET ultimately excluded diagnostics and products without benefit categories while also limiting eligibility to only five technologies a year. In April 2026, HHS announced a new Medicare coverage pathway for FDA-designated breakthrough devices called the Regulatory Alignment for Predictable and Immediate Device (RAPID) pathway, that promises to be faster and more expansive than the existing TCET pathway, which the department is planning to pause for new candidate devices. While this is a step in the right direction, Congress still needs to enact H.R.5343 to ensure consistent, long-term coverage of breakthrough technologies.

CA IS THE HOME OF MEDTECH



California is home to more medical device companies than any other U.S. state.

CONGRESSIONAL SUPPORT



The bill was amended and reported to the full chamber by the House Ways & Means Committee in the 119th Congress.

PUSHING FOR A MORE COMPREHENSIVE SOLUTION

The *Ensuring Access to Critical Breakthrough Products Act* is a bipartisan legislative solution to provide automatic coverage for FDA-approved breakthrough-designated products. The bill would ensure that all FDA-designated breakthrough technologies are covered for four years by Medicare while also creating a roadmap for additional evidence collection for CMS to make a permanent coverage decision after that period.