HR 5333

Ensuring Patient Access to Critical Breakthrough Products Act of 2019

Congress: 116 (2019–2021, Ended)
Chamber: House
Policy Area: Health
Introduced: Dec 6, 2019
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Dec 9, 2019)
Official Text: https://www.congress.gov/bill/116th-congress/house-bill/5333

Sponsor

Name: Rep. DelBene, Suzan K. [D-WA-1]
Party: Democratic • **State:** WA • **Chamber:** House

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Dec 6, 2019
Rep. Cárdenas, Tony [D-CA-29]	D · CA		Dec 6, 2019
Rep. Marshall, Roger [R-KS-1]	R · KS		Dec 6, 2019
Rep. Sewell, Terri A. [D-AL-7]	D · AL		Dec 6, 2019
Rep. Walorski, Jackie [R-IN-2]	R · IN		Dec 6, 2019
Rep. Kim, Andy [D-NJ-3]	D · NJ		Jul 9, 2020
Rep. Perry, Scott [R-PA-10]	R · PA		Jul 9, 2020
Rep. Van Drew, Jefferson [R-NJ-2]	R · NJ		Jul 9, 2020

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 9, 2019
Ways and Means Committee	House	Referred To	Dec 6, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 S 3914	Related bill	**Jun 8, 2020:** Read twice and referred to the Committee on Finance.

Summary (as of Dec 6, 2019)

Ensuring Patient Access to Critical Breakthrough Products Act of 2019

This bill provides for Medicare coverage of medical devices that are approved under the Food and Drug Administration (FDA) Breakthrough Devices Program. (Under the program, manufacturers work with the FDA to expedite the review and approval of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions.)

The bill allows designated medical breakthrough devices to be temporarily covered under Medicare during a three-year transitional period. The Centers for Medicare & Medicaid Services (CMS) must assign payment codes for such devices within three months of FDA approval. The CMS must also establish a process to allow for continued coverage after the transitional period has expired, taking into account any additional evidence or data the CMS deems necessary.

The CMS must also provide for temporary and, where appropriate, permanent Medicare coverage of breakthrough devices for which there is no existing benefit category (i.e., classification).

Actions Timeline

- **Dec 9, 2019:** Referred to the Subcommittee on Health.
- **Dec 6, 2019:** Introduced in House
- **Dec 6, 2019:** Referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.