

## S 3914

Ensuring Patient Access to Critical Breakthrough Products Act of 2020

**Congress:** 116 (2019–2021, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jun 8, 2020

**Current Status:** Read twice and referred to the Committee on Finance.

**Latest Action:** Read twice and referred to the Committee on Finance. (Jun 8, 2020)

**Official Text:** <https://www.congress.gov/bill/116th-congress/senate-bill/3914>

### Sponsor

**Name:** Sen. McSally, Martha [R-AZ]

**Party:** Republican • **State:** AZ • **Chamber:** Senate

### Cosponsors

*No cosponsors are listed for this bill.*

### Committee Activity

Committee	Chamber	Activity	Date
Finance Committee	Senate	Referred To	Jun 8, 2020

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

Bill	Relationship	Last Action
116 HR 5333	Related bill	<b>Dec 9, 2019:</b> Referred to the Subcommittee on Health.

## **Ensuring Patient Access to Critical Breakthrough Products Act of 2020**

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**

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- **Jun 8, 2020:** Introduced in Senate
- **Jun 8, 2020:** Read twice and referred to the Committee on Finance.

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