Congressional Budget Office
Cost Estimate

November 18, 2024

At a Glance

H.R. 1691, Ensuring Patient Access to Critical Breakthrough Products Act of 2024

As ordered reported by the House Committee on Ways and Means on June 27, 2024

By Fiscal Year, Millions of Dollars	2025	2025-2029	2025-2034
Direct Spending (Outlays)	5	234	994
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	5	234	994
Spending Subject to Appropriation (Outlays)	0	0	not estimated

Increases *net direct spending* in any of the four consecutive 10-year periods beginning in 2035?	> $2.5 billion	Statutory pay-as-you-go procedures apply?	Yes
Increases *on-budget deficits* in any of the four consecutive 10-year periods beginning in 2035?	> $5 billion	**Mandate Effects**	
		Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

The bill would

- Require Medicare to automatically cover certain medical devices for a four-year period following approval from the Food and Drug Administration (FDA)

Estimated budgetary effects would mainly stem from

- Increases in new technology add-on payments (NTAPs) to hospitals for medical devices that would not otherwise have been covered by Medicare
- The shorter period between FDA approval of a device and NTAPs made to hospitals
- Increases in payments to Medicare Advantage plans

Areas of significant uncertainty include

- The number and cost of medical devices likely to be approved by the FDA and eligible for automatic coverage

Detailed estimate begins on the next page.

Bill Summary

H.R. 1691 would require Medicare to automatically cover devices approved under the Breakthrough Devices Program of the Food and Drug Administration (FDA). That program is directed at simplifying the approval process for devices used in the treatment of especially severe diseases and conditions. Under the bill, Medicare would be required to cover devices within four years of FDA approval.

Estimated Federal Cost

The estimated budgetary effect of H.R. 1691 is shown in Table 1. The costs of the legislation fall within budget function 570 (Medicare).

Table 1.
Estimated Budgetary Effects of H.R. 1691

	By Fiscal Year, Millions of Dollars											
	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2025-2029	2025-2034
	Increases or Decreases (-) in Direct Spending											
Estimated Budget Authority	10	10	38	84	99	118	125	144	175	191	241	994
Estimated Outlays	5	8	38	84	99	118	131	145	175	191	234	994

Basis of Estimate

For this estimate, CBO assumes that H.R. 1691 will be enacted early in fiscal year 2025.

The Medicare program does not automatically cover the use of every medical device approved by the FDA; Medicare conducts its own evaluations—reviews that can delay or prevent payments to hospitals that use the devices in treating beneficiaries. CBO expects that enacting H.R. 1691 would lead Medicare to cover more FDA-approved breakthrough devices and that the program's payments to hospitals would increase as a result. In particular, spending would rise for new technology add-on payments (NTAPs), which supplement Medicare's payments to hospitals for treatments that have been identified as novel, effective, and costly.

CBO estimates that under current law, over the 2027-2034 period, NTAPs will amount to $1.6 billion for roughly 120 breakthrough devices, at a cost of about $13 million per device. (Because devices typically can qualify for NTAPs for multiple years, the annual payment per device will be less than $13 million.)

Direct Spending

Based on analyses of the rate and timing of NTAPs for breakthrough devices, CBO expects that enacting H.R. 1691 would increase by roughly 25 percent the number of devices that

would be covered by Medicare and eligible for NTAPs. As a result, over the 2025-2034 period, fee-for-service spending would increase by about $409 million for Medicare and by $525 million for Medicare Advantage plans.

H.R. 1691 also would appropriate $10 million each year between 2025 and 2030 to cover the administrative costs of implementing the bill. Based on the cost of similar activities, CBO estimates the appropriations would cost $60 million over the 2025-2034 period.

In total, CBO estimates that enacting H.R. 1691 would increase direct spending by $994 million over the 2025-2034 period (see Table 1).

Uncertainty

CBO's estimate for H.R. 1691 is subject to considerable uncertainty. The FDA's pace of device approvals has accelerated in the recent past. According to data from the agency, more than twice as many devices were approved between 2021 and 2023 than were approved between 2018 and 2020.[1] Although this estimate is based on the number of currently approved breakthrough devices, it is difficult to predict how many FDA will approve over the next few years or what Medicare would spend on their coverage.

Pay-As-You-Go Considerations

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in Table 1.

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting H.R. 1691 would increase net direct spending by more than $2.5 billion in any of the four consecutive 10-year periods beginning in 2035.

CBO estimates that enacting H.R. 1691 would increase on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2035.

Mandates

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

1. Food and Drug Administration, "Breakthrough Devices Program" (March 2024), https://tinyurl.com/55zyyvs8.

Estimate Prepared By

Federal Costs: Sarah Sajewski

Mandates: Brandon Lever

Estimate Reviewed By

Asha Saavoss
Chief, Health Systems and Medicare Cost Estimates Unit

Kathleen FitzGerald
Chief, Public and Private Mandates Unit

Chad Chirico
Director of Budget Analysis

Estimate Approved By

Phillip L. Swagel
Director, Congressional Budget Office