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119TH CONGRESS
1ST SESSION

H. R. 4441

To amend title XVIII of the Social Security Act to improve Medicare beneficiary access to new medical technologies that improve health care quality and outcomes by ensuring that breakthrough devices are eligible for conditional approval under the Medicare New Technology Add-On Payment (NTAP) Program, enabling these medical breakthroughs to be provided to Medicare beneficiaries without unnecessary delay.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2025

Mr. CAREY (for himself and Mr. DAVIS of Illinois) introduced the following bill; which was 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

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A BILL

To amend title XVIII of the Social Security Act to improve Medicare beneficiary access to new medical technologies that improve health care quality and outcomes by ensuring that breakthrough devices are eligible for conditional approval under the Medicare New Technology Add-On Payment (NTAP) Program, enabling these medical breakthroughs to be provided to Medicare beneficiaries without unnecessary delay.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Access to Innovative New Technologies Act of 2025''.

SEC. 2. INCREASING ADOPTION OF AND ACCESS TO BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(x)(I) A breakthrough device that is not approved, cleared, or authorized under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act by the deadline specified in section 412.87(f)(2) of title 42, Code of Federal Regulations (or a successor regulation) may be conditionally approved for the new technology add-on payment under this subparagraph for a particular fiscal year, effective for discharges beginning in the first quarter after receiving such approval, clearance, or authorization, provided that the approval, clearance, or authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

''(II) For purposes of this clause, the term 'breakthrough device' means a medical device that—

''(aa) is designated for expedited development and priority review under section 515B of the Federal Food, Drug, and Cosmetic Act; and

''(bb) has been approved, cleared, or authorized under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act for the indication for which the designation described in item (aa) was made.

''(III) This clause shall not be considered an adjustment and shall be implemented in a budget neutral manner.''.

(b) EFFECTIVE DATE.—This section, and the amendments made by this section, shall take effect on the enactment of this Act and shall apply to a breakthrough device (as defined in section 1886(d)(5)(K)(x)(II) of the Social Security Act, as added by subsection (a)) that is approved, cleared, or authorized under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f)(2), 360e) on or after July 1, 2023.

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