

117TH CONGRESS
1ST SESSION

H. R. 4043

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 22, 2021

Ms. DELBENE (for herself, Mrs. WALORSKI, Mr. CÁRDENAS, Mr. BILIRAKIS, Ms. SEWELL, and Mr. UPTON) 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

A BILL

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Ensuring Patient Ac-
5 cess to Critical Breakthrough Products Act of 2021”.

1 **SEC. 2. COVERAGE AND PAYMENT FOR BREAKTHROUGH**
2 **DEVICES UNDER THE MEDICARE PROGRAM.**

3 (a) IN GENERAL.—Part E of title XVIII of the Social
4 Security Act (42 U.S.C. 1395x et seq.) is amended by add-
5 ing at the end the following new section:

6 **“SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.**

7 “(a) BREAKTHROUGH DEVICES.—For purposes of
8 this section, the term ‘breakthrough device’ means a med-
9 ical device that is a device (as defined in section 201 of
10 the Federal Food, Drug, and Cosmetic Act) and that is—

11 “(1) provided with review priority by the Sec-
12 retary under subsection (d)(5) of section 515 of such
13 Act; and

14 “(2) approved or cleared pursuant to section
15 510(k), 513(f), or 515 of such Act for use in treat-
16 ing an indication on or after March 15, 2019.

17 Such term also includes a breakthrough device that is a
18 specified breakthrough device (as defined in subsection
19 (e)(1)(B)) approved or cleared pursuant to section 510(k),
20 513(f), or 515 of such Act for use in treating an indication
21 on or after March 15, 2019.

22 “(b) COVERAGE.—

23 “(1) TRANSITIONAL COVERAGE.—

24 “(A) IN GENERAL.—During the transi-
25 tional coverage period (as defined in subpara-
26 graph (B)) a breakthrough device shall be—

1 “(i) deemed to be reasonable and nec-
2 essary for purposes of section
3 1862(a)(1)(A);

4 “(ii) deemed to be approved for an ad-
5 ditional payment under section
6 1886(d)(5)(K) (other than with respect to
7 the cost criterion under clause (ii)(I) of
8 such section);

9 “(iii) deemed to be approved for pass-
10 through payment under section 1833(t)(6)
11 and section 1833(i) (other than with re-
12 spect to the cost criterion under section
13 1833(t)(6)(A)(iv)); and

14 “(iv) insofar as such breakthrough de-
15 vice may be furnished in a setting for
16 which payment is made under an applica-
17 ble payment system described in subpara-
18 graphs (D) through (I) of subsection
19 (c)(4), deemed eligible for an additional
20 payment or payment adjustment, as the
21 case may be, pursuant to subsection (d)(3)
22 when furnished in a setting for which pay-
23 ment is made under such an applicable
24 payment system during such transitional
25 coverage period.

1 “(B) TRANSITIONAL COVERAGE PERIOD
2 DEFINED.—As used in this section, the term
3 ‘transitional coverage period’ means, with re-
4 spect to a breakthrough device, the period
5 that—

6 “(i) begins on the date of the approval
7 under section 515 of the Federal Food,
8 Drug, and Cosmetic Act or of the clear-
9 ance under section 510(k) of such Act, as
10 applicable, of such device by the Secretary
11 for the indication described in subsection
12 (a)(1); and

13 “(ii) ends on the last day of the 4-
14 year period that begins on the date that
15 the Secretary, pursuant to subsection
16 (c)(2), updates the relevant applicable pay-
17 ment system (as defined in subsection
18 (c)(4)) to recognize the unique temporary
19 or permanent code or codes assigned under
20 subsection (c)(1) to such breakthrough de-
21 vice, except as provided in subsections
22 (d)(1)(B) and (d)(2)(B).

23 “(C) DATA USED TO MEET THE NTAP AND
24 PASS-THROUGH COST CRITERIA.—In deter-
25 mining whether a breakthrough device qualifies

1 for an additional payment under section
2 1886(d)(5)(K) or for pass-through payment
3 under section 1833(t)(6) or section 1833(i), the
4 Secretary shall use the most recently available
5 data and information on the costs of such
6 breakthrough device, which may include list
7 prices and invoice prices charged for such
8 breakthrough device.

9 “(2) PROCESS FOR REGULAR COVERAGE.—For
10 purposes of the application of section 1862(a)(1)(A)
11 to a breakthrough device furnished after the transi-
12 tional coverage period (as defined in paragraph
13 (1)(B)) for such device, the Secretary shall establish
14 a process for the coverage of such breakthrough de-
15 vices under this title after such period as follows:

16 “(A) IDENTIFICATION OF ADDITIONAL EVI-
17 DENCE.—

18 “(i) IN GENERAL.—With respect to a
19 breakthrough device, not later than 1 year
20 after the date of the approval of such de-
21 vice under section 515 of the Federal
22 Food, Drug, and Cosmetic Act or of the
23 clearance of such device under section
24 510(k) of such Act, as applicable, the Sec-
25 retary shall identify whether any additional

1 data or evidence is required with respect to
2 any indications for such device for pur-
3 poses of the application of such section
4 1862(a)(1)(A) to such device for such indi-
5 cations.

6 “(ii) NON-DUPLICATION OF DATA RE-
7 QUESTS.—In carrying out clause (i) with
8 respect to a breakthrough device, the Sec-
9 retary shall ensure that data or evidence
10 identified—

11 “(I) does not duplicate data re-
12 quired to be collected by the Food and
13 Drug Administration with respect to
14 such breakthrough device;

15 “(II) minimizes the administra-
16 tive burdens of data collection and re-
17 porting on providers of services, sup-
18 pliers, and manufacturers of break-
19 through devices; and

20 “(III) is not otherwise unneces-
21 sary or redundant.

22 “(B) PROPOSAL FOR COVERAGE AFTER
23 THE TRANSITIONAL COVERAGE PERIOD.—Not
24 later than 2 years after the date of the approval
25 or clearance of a breakthrough device by the

1 Food and Drug Administration, the Secretary
2 shall develop a proposal for coverage under this
3 title of such breakthrough device for such indi-
4 cations as the Secretary determines to be ap-
5 propriate, based on the data and evidence col-
6 lected under subparagraph (A), for such devices
7 furnished after the transitional coverage period
8 under paragraph (1) for such device. If the Sec-
9 retary does not, on a date that is before the end
10 of such two-year period, take action to modify
11 the indications for which coverage of a break-
12 through device may be provided under this title
13 after such period, for purposes of section
14 1862(a)(1)(A) coverage under this title of such
15 breakthrough device shall be made for all indi-
16 cations for which such device is approved under
17 section 515 of the Federal Food, Drug, and
18 Cosmetic Act or cleared under section 510(k) of
19 such Act.

20 “(3) RULES OF CONSTRUCTION.—Nothing in
21 this section shall be construed to—

22 “(A) affect the ability of the manufacturer
23 of a breakthrough device to seek approval for
24 pass-through payment status under section
25 1833(t)(6) or to seek approval for an additional

1 payment under section 1886(d)(5)(K) insofar
2 as such breakthrough device does not qualify
3 for transitional coverage under paragraph (1);
4 or

5 “(B) affect the application and approval
6 process for pass-through payment status under
7 section 1833(t)(6) or for an additional payment
8 under section 1886(d)(5)(K) in the case of a
9 medical device that is not approved by the Food
10 and Drug Administration as a breakthrough de-
11 vice.

12 “(c) CODING.—

13 “(1) PROMPT ASSIGNMENT.—Not later than
14 three months after the date of approval or clearance
15 of a breakthrough device by the Food and Drug Ad-
16 ministration, the Secretary shall assign a unique
17 temporary or permanent code or codes for purposes
18 of coverage and payment for such breakthrough de-
19 vice under the applicable payment systems (de-
20 scribed in paragraph (4)).

21 “(2) UPDATES.—

22 “(A) IPPS.—The Secretary shall provide
23 for semiannual updates under the applicable
24 payment system described in paragraph (4)(A)
25 (relating to the inpatient hospital prospective

1 payment system) to recognize the code or codes
2 assigned under paragraph (1).

3 “(B) OPPS.—The Secretary shall provide
4 for quarterly updates under the applicable pay-
5 ment system described in paragraph (4)(B) (re-
6 lating to the outpatient hospital prospective
7 payment system) to recognize the code or codes
8 assigned under paragraph (1).

9 “(C) OTHER PAYMENT SYSTEMS.—The
10 Secretary shall provide for semiannual or quar-
11 terly updates, as the case may be, under the ap-
12 plicable payment systems described in subpara-
13 graphs (C) through (K) of paragraph (4) to
14 recognize the code or codes assigned under
15 paragraph (1).

16 “(3) TRANSPARENCY.—The process for the as-
17 signment of a code or codes under this subsection
18 shall provide for public notice and a meaningful op-
19 portunity for public comment from affected parties.

20 “(4) APPLICABLE PAYMENT SYSTEMS DE-
21 SCRIBED.—For purposes of this subsection, the term
22 ‘applicable payment systems’ means—

23 “(A) with respect to inpatient hospital
24 services, the prospective payment system for in-

1 patient hospital services established under sec-
2 tion 1886(d);

3 “(B) with respect to outpatient hospital
4 services, the prospective payment system for
5 covered OPD services established under section
6 1833(t);

7 “(C) with respect to ambulatory surgical
8 center services, the fee schedule for such serv-
9 ices established under 1833(i);

10 “(D) with respect to physicians’ services,
11 the physician fee schedules established under
12 section 1848;

13 “(E) with respect to covered items of dura-
14 ble medical equipment, the applicable fee sched-
15 ules established under section 1834;

16 “(F) with respect to diagnostic laboratory
17 tests, the payment amounts under section
18 1834A and the fee schedules establish under
19 section 1848, as the case may be;

20 “(G) with respect to inpatient hospital
21 services furnished by rehabilitation facilities,
22 the prospective payment system established
23 under section 1886(j);

24 “(H) with respect to inpatient hospital
25 services furnished by long-term care hospitals,

1 the prospective payment system under section
2 1886(m);

3 “(I) with respect to inpatient hospital serv-
4 ices furnished by psychiatric hospitals and psy-
5 chiatric units, the prospective payment system
6 under section 1886(s);

7 “(J) with respect to home health services,
8 the prospective payment system under section
9 1895; and

10 “(K) with respect to items and services, or
11 a provider of services or supplier, not described
12 in subparagraphs (A) through (K), the payment
13 system established under this title for such
14 items and services when furnished by such pro-
15 vider of services or supplier.

16 “(d) PAYMENT.—

17 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
18 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
19 THROUGH PAYMENT.—The Secretary shall deem
20 each breakthrough device as approved for an addi-
21 tional payment under section 1886(d)(5)(K) for the
22 4-year period that begins—

23 “(A) except as provided in subparagraph
24 (B), on the date that the Secretary, pursuant to
25 subsection (c)(2)(A), updates the payment sys-

1 tem under section 1886(d) to recognize the
2 unique temporary or permanent code or codes
3 assigned under subsection (c)(1) to such break-
4 through device; or

5 “(B) in the case of a device that has not
6 received approval or clearance as a break-
7 through device by the Food and Drug Adminis-
8 tration before such payment system is updated
9 under subsection (c)(2)(A) to recognize the
10 unique temporary or permanent code or codes
11 assigned under subsection (c)(1) to such device,
12 on the date of such approval or clearance.

13 Nothing in this paragraph shall be construed to af-
14 fect the authority of the Secretary to use claims
15 data to establish new diagnosis or procedure codes
16 for breakthrough devices or to identify appropriate
17 diagnosis-related groups for the assignment of
18 breakthrough devices under annual rulemaking to
19 carry out section 1886(d)(5)(K).

20 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
21 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH
22 PAYMENT.—The Secretary shall deem each break-
23 through device as approved for pass-through pay-
24 ment under section 1833(t)(6) (including for pur-

1 poses of section 1833(i)(2)(D)) during the 4-year pe-
2 riod that begins—

3 “(A) except as provided in subparagraph
4 (B), on the date that the Secretary, pursuant to
5 subsection (c)(2)(B), updates the payment sys-
6 tem under section 1833(t) to recognize the
7 unique temporary or permanent code or codes
8 assigned under subsection (c)(1) to such break-
9 through device; or

10 “(B) in the case of a device that has not
11 received approval or clearance as a break-
12 through device by the Food and Drug Adminis-
13 tration before such payment system is updated
14 under subsection (c)(2)(B) to recognize the
15 unique temporary or permanent code or codes
16 assigned under subsection (c)(1) to such device,
17 on the date of such approval or clearance.

18 Nothing in this paragraph shall be construed to af-
19 fect the authority of the Secretary to use claims
20 data to establish new ambulatory payment classifica-
21 tion groups for breakthrough devices or to revise
22 such groups to take into account breakthrough de-
23 vices under annual rulemaking to carry out section
24 1833(t).

25 “(3) OTHER PAYMENT SYSTEMS.—

1 “(A) IN GENERAL.—In the case of break-
2 through device that is furnished and for which
3 payment may be made under the payment sys-
4 tem established under section 1834, 1834A,
5 1848, 1886(j), 1886(m), 1886(s), or 1895 or
6 any other provision of this title (other than sec-
7 tions 1833(i), 1833(t), and 1886(d)), the Sec-
8 retary shall provide for an additional payment
9 for such breakthrough device under such appli-
10 cable payment system or an adjustment to such
11 applicable payment system, as the case may be.
12 The payment basis for such additional payment
13 or adjustment, as the case may be, shall equal
14 an amount that the Secretary determines covers
15 the costs of such breakthrough device.

16 “(B) COST INFORMATION.—In determining
17 the costs of a breakthrough device for purposes
18 of determining an additional payment or pay-
19 ment adjustment under subparagraph (A), the
20 Secretary shall use the most recently available
21 data and information on the costs of such
22 breakthrough device, which may include list
23 prices and invoice prices charged for such
24 breakthrough device.

1 “(C) RULE OF CONSTRUCTION.—Nothing
2 in this paragraph shall be construed to affect
3 the authority of the Secretary to use claims
4 data to establish new or modify existing ambu-
5 latory payment classification groups, diagnosis-
6 related groups, level II HCPCS codes or such
7 other groups or codes as the Secretary may es-
8 tablish under the annual rulemaking authority
9 under the provisions referred to in subpara-
10 graph (A).

11 “(D) CLINICAL DIAGNOSTIC LABORATORY
12 TESTS.—An additional payment or payment ad-
13 justment under subparagraph (A) for a break-
14 through device under the applicable payment
15 system established in section 1834A may be in
16 the form of an increase to the amount deter-
17 mined for the breakthrough device using cross-
18 walking under section 1834A(c)(1)(A), an ex-
19 tension of the initial period of payment applica-
20 ble to advance diagnostic laboratory tests under
21 section 1834A(d)(1)(A), and in such other form
22 or manner as the Secretary determines reflects
23 the costs for such breakthrough device under
24 the relevant provisions of section 1834A.

1 “(4) PAYMENT FOR BREAKTHROUGH DEVICES
2 AFTER THE TRANSITIONAL COVERAGE PERIOD.—
3 Payment for a breakthrough device that is furnished
4 after the conclusion of the transitional coverage pe-
5 riod under subsection (b)(1) for such device shall be
6 made pursuant to the applicable payment system in-
7 volved, taking into account the additional evidence
8 and data collected under subsection (b)(2).

9 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
10 DEVICES.—

11 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
12 DEVICES.—

13 “(A) IN GENERAL.—Subject to the suc-
14 ceeding provisions of this subsection and not-
15 withstanding any other provision of law, the
16 Secretary shall provide for coverage and pay-
17 ment pursuant to this section of a specified
18 breakthrough device (as defined in subpara-
19 graph (B)).

20 “(B) SPECIFIED BREAKTHROUGH DEVICE
21 DEFINED.—In this section, the term ‘specified
22 breakthrough device’ means a breakthrough de-
23 vice with respect to which no Medicare benefit
24 category exists.

25 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (C), the provisions of subsection (b)(1)
3 (relating to the transitional coverage period and
4 payment for breakthrough devices, including the
5 use of the most recently available data and in-
6 formation on costs) shall apply to a specified
7 breakthrough device in the same manner as
8 such provisions apply to a breakthrough device.
9 The Secretary may use methodologies under ex-
10 isting payment systems established under this
11 title, may provide for appropriate adjustments
12 to such methodologies, or may establish a new
13 payment methodology under this title, to pro-
14 vide for payment for a specified breakthrough
15 device to ensure the payment basis for such
16 payment covers costs of the specified break-
17 through device are covered by such payment.

18 “(B) REPORT.—

19 “(i) IN GENERAL.—With respect to
20 each specified breakthrough device, the
21 Secretary shall submit to Congress a re-
22 port on the coverage of and payment for
23 such specified breakthrough device under
24 this section that includes the following in-
25 formation:

1 “(I) The manner in which cov-
2 erage is provided and payment is
3 made for the specified breakthrough
4 device, including how such device was
5 classified (such as an item of durable
6 medical equipment or otherwise) and
7 the payment methodology the Sec-
8 retary applied with respect to such de-
9 vice.

10 “(II) The impact of the avail-
11 ability of the specified breakthrough
12 device to Medicare beneficiaries, in-
13 cluding impacts on the quality of pa-
14 tient care, patient outcomes, and pa-
15 tient experience.

16 “(III) The impact of the avail-
17 ability of the specified breakthrough
18 device to Medicare beneficiaries on
19 program expenditures under this title.

20 “(IV) Such other information as
21 the Secretary determines to be appro-
22 priate.

23 “(ii) DEADLINE.—

24 “(I) IN GENERAL.—Except as
25 provided in subclause (II), the Sec-

1 retary shall submit a report required
2 under this subparagraph no later than
3 the end of the transitional period of
4 coverage and payment applicable to
5 such specified breakthrough device.

6 “(II) EXTENSION TO GENERATE
7 ADDITIONAL DATA.—If the Secretary
8 determines that additional data or evi-
9 dence is required to complete a report
10 required under this subparagraph
11 with respect to a specified break-
12 through device, the deadline under
13 this clause may be extended for an
14 additional two years.

15 “(C) ADDITIONAL PERIOD OF TRANSI-
16 TIONAL COVERAGE TO DEVELOP ADDITIONAL
17 DATA.—Insofar as the Secretary determines
18 that additional data or evidence is required to
19 complete a report required under subparagraph
20 (B) with respect to a specified breakthrough de-
21 vice, the transitional coverage period of cov-
22 erage and payment for such device shall be ex-
23 tended by the lesser of—

24 “(i) two years; or

1 “(ii) the amount of additional time re-
2 quired for the submission of the report
3 with respect to such device.

4 “(3) COVERAGE AND PAYMENT AFTER THE
5 TRANSITIONAL PERIOD.—The Secretary may con-
6 tinue to provide for coverage of and payment for a
7 specified breakthrough device after the end of the
8 transitional period of coverage and payment for
9 breakthrough devices through the national coverage
10 determination process if the Secretary determines
11 that the specified breakthrough device—

12 “(A) improves the quality of care and pa-
13 tient outcomes;

14 “(B) improves the delivery of care; or

15 “(C) reduces spending under this title
16 without reducing the quality of care.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) INPATIENT PROSPECTIVE PAYMENT SYS-
19 TEM.—Section 1886(d)(5)(K) of the Social Security
20 Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by
21 adding at the end the following new clause:

22 “(x) Effective for discharges occurring on
23 or after October 1, 2019, in the case of a new
24 medical service or technology that is a break-
25 through device (as defined in section

1 1899C(a)), the additional payment established
2 for such breakthrough device under this sub-
3 paragraph shall be made for the 4-year period
4 applicable to such breakthrough device under
5 section 1899C(d)(1). In determining the
6 amount of the additional payment for a break-
7 through device under this subparagraph during
8 such 4-year period, the Secretary shall apply
9 section 412.88(b) of title 42, Code of Federal
10 Regulations, as in effect on the date of the en-
11 actment of this clause, except as if the ref-
12 erence in such section to ‘65 percent’ were a
13 reference to ‘65 percent (or such greater per-
14 cent specified by the Secretary)’.”.

15 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
16 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
17 1395l(t)(6)(C)) is amended by adding at the end the
18 following new clause:

19 “(iii) SPECIAL RULE FOR BREAK-
20 THROUGH DEVICES.—Notwithstanding
21 clause (i) or (ii), or any other provision of
22 this paragraph to the contrary, in the case
23 of a breakthrough device (as defined in
24 section 1899C(a)) that is furnished on or
25 after January 1, 2020, payment under this

1 paragraph for such breakthrough device
2 shall be made for the 4-year period appli-
3 cable to such breakthrough device under
4 section 1899C(d)(2). The provisions of this
5 clause shall also apply for purposes of
6 transitional pass-through payment under
7 section 1833(i)(2)(D).”.

8 (c) EFFECTIVE DATE.—This section, and the amend-
9 ments made by this section, shall take effect on the date
10 of the enactment of this Act and, unless otherwise speci-
11 fied in this section (or in an amendment made by this sec-
12 tion), shall apply to breakthrough devices (as defined in
13 section 1899C(a) of the Social Security Act, as added by
14 subsection (a)), approved or cleared on or after July 1,
15 2019, or, in the case of a specified breakthrough device
16 (as defined in such section as so added), approved or
17 cleared on or after December 1, 2018.

○