

115TH CONGRESS
2D SESSION

H. R. 5997

To amend titles XVIII and XIX of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare and Medicaid programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2018

Ms. DELBENE (for herself, Mrs. WALORSKI, Ms. SEWELL of Alabama, Mr. BILIRAKIS, and Mr. CÁRDENAS) 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 titles XVIII and XIX of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare and Medicaid programs, 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 2018”.

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.—

8 “(1) IN GENERAL.—For purposes of this sec-
9 tion, the term ‘breakthrough device’ means a med-
10 ical device that is a device (as defined in section 201
11 of the Federal Food, Drug, and Cosmetic Act) and
12 that is—

13 “(A) provided with review priority by the
14 Secretary under subsection (d)(5) of section
15 515 of such Act; and

16 “(B) approved or cleared pursuant to sec-
17 tion 510(k), 513(f), or 515 of such Act for use
18 in treating an indication.

19 “(2) LIMITATION ON NUMBER OF 510(k) DE-
20 VICES.—With respect to a 5-year period, in no case
21 may more than five medical devices described in
22 paragraph (1) that are classified under section
23 510(k) of the Federal Food, Drug, and Cosmetic
24 Act be covered and paid for under this title by rea-
25 son of this section during each such 5-year period.

26 “(b) COVERAGE.—

1 “(1) TRANSITIONAL COVERAGE.—

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

5 “(i) deemed to be reasonable and nec-
6 essary for purposes of section
7 1862(a)(1)(A);

8 “(ii) deemed to be approved for an ad-
9 ditional payment under section
10 1886(d)(5)(K);

11 “(iii) deemed to be approved for pass-
12 through payment under section 1833(t)(6)
13 and section 1833(i); 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 pursuant to subsection (d)(3)
21 when furnished in a setting for which pay-
22 ment is made under such an applicable
23 payment system during such transitional
24 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 subpara-
12 graph (A)(ii) or (B) of subsection (a)(1),
13 respectively; and

14 “(ii) ends on the last day of the 3-
15 year period that begins on the date that
16 the Secretary, pursuant to subsection
17 (c)(2), updates the relevant applicable pay-
18 ment system (as defined in subsection
19 (c)(4)) to recognize the unique temporary
20 or permanent code or codes assigned under
21 subsection (c)(1) to such breakthrough de-
22 vice, except as provided in subsections
23 (d)(1)(B) and (d)(2)(B).

24 “(2) PROCESS FOR REGULAR COVERAGE.—For
25 purposes of the application of section 1862(a)(1)(A)

1 to a breakthrough device furnished after the transi-
2 tional coverage period (as defined in paragraph
3 (1)(B)) for such device, the Secretary, acting
4 through the Council for Technology and Innovation
5 (established under section 1868(b)) in conjunction
6 with the Coverage and Analysis Group of the Cen-
7 ters for Medicare & Medicaid Services, shall estab-
8 lish a process for the coverage of such breakthrough
9 devices under this title after such period as follows:

10 “(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—

11 DENCE.—

12 “(i) IN GENERAL.—With respect to a
13 breakthrough device, not later than 1 year
14 after the date of the approval of such de-
15 vice under section 515 of the Federal
16 Food, Drug, and Cosmetic Act or of the
17 clearance of such device under section
18 510(k) of such Act, as applicable, the Sec-
19 retary shall identify whether any additional
20 data or evidence is required with respect to
21 any indications for such device for pur-
22 poses of the application of such section
23 1862(a)(1)(A) to such device for such indi-
24 cations.

1 “(ii) NON-DUPLICATION OF DATA RE-
2 QUESTS.—In carrying out clause (i) with
3 respect to a breakthrough device, the Sec-
4 retary shall ensure that data or evidence
5 identified—

6 “(I) does not duplicate data re-
7 quired to be collected by the Food and
8 Drug Administration with respect to
9 such breakthrough device;

10 “(II) minimizes the administra-
11 tive burdens of data collection and re-
12 porting on providers of services, sup-
13 pliers, and manufacturers of break-
14 through devices; and

15 “(III) is not otherwise unneces-
16 sary or redundant.

17 “(B) PROPOSAL FOR COVERAGE AFTER
18 THE TRANSITIONAL COVERAGE PERIOD.—Not
19 later than 2 years after the date of the approval
20 or clearance of a breakthrough device by the
21 Food and Drug Administration, the Secretary
22 shall develop a proposal for coverage under this
23 title of such breakthrough device for such indi-
24 cations as the Secretary determines to be ap-
25 propriate, based on the data and evidence col-

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

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

17 “(A) affect the ability of the manufacturer
18 of a breakthrough device to seek approval for
19 pass-through payment status under section
20 1833(t)(6) or to seek approval for an additional
21 payment under section 1886(d)(5)(K) insofar
22 as such breakthrough device does not qualify
23 for transitional coverage under paragraph (1);
24 or

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

8 “(c) CODING.—

9 “(1) PROMPT ASSIGNMENT.—Not later than
10 three months after the date of approval or clearance
11 of a breakthrough device by the Food and Drug Ad-
12 ministration, subject to subparagraph (B), the Sec-
13 retary shall assign a unique temporary or permanent
14 code or codes for purposes of coverage and payment
15 for such breakthrough device under the applicable
16 payment systems (described in paragraph (4)).

17 “(2) UPDATES.—

18 “(A) IPPS.—The Secretary shall provide
19 for semiannual updates under the applicable
20 payment system described in paragraph (4)(A)
21 (relating to the inpatient hospital prospective
22 payment system) to recognize the code or codes
23 assigned under paragraph (1).

24 “(B) OPPI.—The Secretary shall provide
25 for quarterly updates under the applicable pay-

1 ment system described in paragraph (4)(B) (re-
2 lating to the outpatient hospital prospective
3 payment system) to recognize the code or codes
4 assigned under paragraph (1).

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

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

12 “(A) with respect to inpatient hospital
13 services, the prospective payment system for in-
14 patient hospital services established under sec-
15 tion 1886(d);

16 “(B) with respect to outpatient hospital
17 services, the prospective payment system for
18 covered OPD services established under section
19 1833(t);

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

23 “(D) with respect to physicians’ services,
24 the physician fee schedules established under
25 section 1848;

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

4 “(F) with respect to diagnostic laboratory
5 tests, the fee schedule established under section
6 1834(h), the payment amounts under section
7 1834A, and the fee schedules establish under
8 section 1848, as the case may be;

9 “(G) with respect to inpatient hospital
10 services furnished by rehabilitation facilities,
11 the prospective payment system established
12 under section 1886(j);

13 “(H) with respect to inpatient hospital
14 services furnished by long-term care hospitals,
15 the prospective payment system under section
16 1886(m); and

17 “(I) with respect to inpatient hospital serv-
18 ices furnished by psychiatric hospitals and psy-
19 chiatric units, the prospective payment system
20 under section 1886(s).

21 “(d) PAYMENT.—

22 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
23 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
24 THROUGH PAYMENT.—The Secretary shall deem
25 each breakthrough device as approved for an addi-

1 tional payment under section 1886(d)(5)(K) for the
2 3-year period that begins—

3 “(A) except as provided in subparagraph
4 (B), on the date that the Secretary, pursuant to
5 subsection (c)(2)(A), updates the payment sys-
6 tem under section 1886(d) 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)(A) 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 diagnosis or procedure codes
21 for breakthrough devices or to identify appropriate
22 diagnosis-related groups for the assignment of
23 breakthrough devices under annual rulemaking to
24 carry out section 1886(d)(5)(K).

1 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
2 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH
3 PAYMENT.—The Secretary shall deem each break-
4 through device as approved for pass-through pay-
5 ment under section 1833(t)(6) (including for pur-
6 poses of section 1833(i)(2)(D)) during the 3-year pe-
7 riod that begins—

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

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

23 Nothing in this paragraph shall be construed to af-
24 fect the authority of the Secretary to use claims
25 data to establish new ambulatory payment classifica-

1 tion groups for breakthrough devices or to revise
2 such groups to take into account breakthrough de-
3 vices under annual rulemaking to carry out section
4 1833(t).

5 “(3) OTHER PAYMENT SYSTEMS.—

6 “(A) IN GENERAL.—In the case of break-
7 through device that is furnished and for which
8 payment may be made under the payment sys-
9 tem established under section 1819(a), 1834,
10 1834A, 1848, 1886(j), 1886(m), 1886(s), or
11 1895 or any other relevant provision of this
12 title (other than sections 1833(i), 1833(t), and
13 1886(d)), the Secretary shall provide for an ad-
14 ditional payment for such breakthrough device
15 under such payment system in an amount equal
16 to 80 percent of the costs of such breakthrough
17 device.

18 “(B) RULE OF CONSTRUCTION.—Nothing
19 in this paragraph shall be construed to affect
20 the authority of the Secretary to use claims
21 data to establish new or modify existing ambu-
22 latory payment classification groups, diagnosis-
23 related groups, level II HCPCS codes or such
24 other groups or codes as the Secretary may es-
25 tablish under the annual rulemaking authority

1 under the provisions referred to in subpara-
2 graph (A).

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

11 “(e) TREATMENT OF BREAKTHROUGH DEVICES
12 UNDER ALTERNATIVE PAYMENT MODELS.—

13 “(1) ALTERNATIVE PAYMENT MODEL DE-
14 FINED.—In this subsection, the term ‘alternative
15 payment model’ means, with respect to items and
16 services for which payment is made under the appli-
17 cable payment systems under this title, payment ini-
18 tiatives designed to improve the quality, efficiency,
19 and overall value of health care furnished to individ-
20 uals entitled to benefits under part A or enrolled
21 under part B through financial incentives to pro-
22 viders of services and suppliers for meeting or ex-
23 ceeding certain quality or performance measures or
24 through financial penalties on providers that fail to

1 achieve specified goals or cost savings, or both. Such
2 term includes—

3 “(A) the Medicare shared savings program
4 under established section 1899;

5 “(B) shared savings programs tested by
6 the Center for Medicare and Medicaid Innova-
7 tion under section 1115A;

8 “(C) the National Pilot Program on Pay-
9 ment Bundling under section 1866D;

10 “(D) bundled payment programs tested by
11 the Center for Medicare and Medicaid Innova-
12 tion under section 1115A; and

13 “(E) any other similar program conducted
14 under this title or under applicable authorities
15 under title XI.

16 “(2) EXCLUSION OF ADDITIONAL COSTS OF
17 BREAKTHROUGH DEVICES.—Insofar as the amount
18 of payment for a breakthrough device exceeds the
19 amount of payment that the item or service would
20 otherwise receive under an alternative payment
21 model for which shared savings or shared losses are
22 calculated, the Secretary shall exclude from the cal-
23 culation of such shared savings or losses under such
24 program for such period the amount by which the
25 payment for the breakthrough device involved ex-

ceeds the payment amount for such other item or service that would have been made but for the use of the breakthrough device.

“(3) ADJUSTMENT TO QUALITY PROCESS MEASURES FOR BREAKTHROUGH DEVICES.—

“(A) IN GENERAL.—In the case that the furnishing by a provider of services or supplier participating in an alternative payment model of a breakthrough device to an individual entitled to benefits under part A or enrolled under part B and participating in such program would result in such provider or supplier, with respect to the condition and episode of care for which such device is furnished, receiving a poor or failing score for a quality measure under such program that measures whether such provider or supplier gave the treatment known to give the best results for most patients with a particular condition (commonly known as a ‘clinical process of care’ measure), the Secretary shall exclude such quality measure from any determination of whether such provider or supplier met applicable quality performance thresholds under such program with respect to such condition and episode of care of such individual.

1 “(B) INAPPLICABILITY TO CLINICAL OUT-
2 COMES MEASURES.—Nothing in subparagraph
3 (A) may be construed to allow for the exclusion,
4 with respect to a breakthrough device furnished
5 to an individual by a provider or supplier under
6 an alternative payment model, of any quality
7 measure designed to reflect the results of care
8 furnished to such individual by such provider or
9 supplier (commonly known as a ‘clinical out-
10 come’ measure) from a determination described
11 in such subparagraph.”.

12 (b) STUDY ON LIMIT OF 510(k) BREAKTHROUGH
13 DEVICES.—

14 (1) STUDY.—The Secretary of Health and
15 Human Services shall conduct a study on the effect
16 of the limit (under section 1899C(a)(2) of the Social
17 Security Act, as added by subsection (a)) on the
18 number of devices cleared under section 510(k) of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 360(k)) that are breakthrough devices for
21 purposes of such section 1899C.

22 (2) MATTERS EXAMINED.—In conducting the
23 study described in paragraph (1), the Secretary
24 shall—

1 (A) determine the number of medical de-
2 vices cleared under such section 510(k) during
3 the 5-year period beginning on the date of the
4 enactment of this Act;

5 (B) determine the number of such devices
6 that were not breakthrough devices for pur-
7 poses of such section 1899C by reason of the
8 limitation under subsection (a)(2) of such sec-
9 tion; and

10 (C) examine the impact of such limitation
11 on access to such devices for individuals entitled
12 to benefits under part A or enrolled in part B
13 of title XVIII of the Social Security Act (42
14 U.S.C. 1395 et seq.).

15 (3) REPORT.—Not later than 6 years after the
16 date of the enactment of this Act, the Secretary
17 shall submit to Congress a report on the study con-
18 ducted under this subsection and shall include such
19 recommendations for legislative or administrative
20 changes as the Secretary determines to be appro-
21 priate.

22 (c) MODIFICATIONS TO THE COUNCIL FOR TECH-
23 NOLOGY AND INNOVATION.—

24 (1) EXPANSION OF DUTIES.—Paragraph (3) of
25 section 1868(b) of the Social Security Act (42

1 U.S.C. 1395ee(b)) is amended by adding at the end
 2 the following: “The Council shall also coordinate ac-
 3 tivities of the Secretary for the implementation of
 4 section 1899C (relating to breakthrough devices), es-
 5 pecially with respect to timely coverage, coding, evi-
 6 dence-gathering, and payment for such devices.”.

7 (2) REORGANIZATION WITHIN THE CMMI.—
 8 Such section is further amended—

9 (A) in paragraph (1), by striking “within
 10 the Centers” and all that follows through the
 11 end and inserting “within the Center for Medi-
 12 care and Medicaid Innovation established under
 13 section 1115A (in this subsection referred to as
 14 ‘CMMI’).”; and

15 (B) in paragraph (4), by striking “the Ad-
 16 ministrator of CMS” and inserting “the Direc-
 17 tor of the CMMI”.

18 (d) IMPROVEMENTS TO NTAP PAYMENT ADJUST-
 19 MENT UNDER THE INPATIENT PROSPECTIVE PAYMENT
 20 SYSTEM.—

21 (1) PAYMENT FOR COSTS OF NEW TECH-
 22 NOLOGIES.—With respect to hospital discharges for
 23 which payment is made under section 1886(d) of the
 24 Social Security Act (42 U.S.C. 1395ww(d)) occur-
 25 ring on or after October 1, 2016, in calculating the

1 amount of the additional payment for a new medical
2 service or technology under paragraph (5)(K) of
3 such section with respect to such a discharge, the
4 Secretary of Health and Human Services shall apply
5 section 412.88 of title 42, Code of Federal Regula-
6 tions, as if the reference to “50 percent” each place
7 it appears in such section were a reference to “80
8 percent”.

9 (2) CLARIFICATION REGARDING PAYMENTS FOR
10 NEW TECHNOLOGIES.—

11 (A) IPPS NEW TECHNOLOGY PAYMENT.—

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

15 “(x) During the period with respect to
16 which a new medical service or technology
17 is eligible for an additional payment under
18 this subsection by reason of this subpara-
19 graph, any local coverage determination
20 (as defined in section 1869(f)(2)(B)) that
21 would affect the coverage of, or the addi-
22 tional payment under this subsection for,
23 such new medical service or technology
24 shall have no force or effect in law or regu-
25 lation.”.

1 (B) CONFORMING AMENDMENT FOR OPPS
2 PASS-THROUGH PAYMENT.—Section 1833(t)(6)
3 of the Social Security Act (42 U.S.C.
4 1395l(t)(6)) is amended by adding at the end
5 the following new subparagraph:

6 “(G) PROHIBITION ON USE OF LOCAL COV-
7 ERAGE DETERMINATIONS TO AFFECT COV-
8 ERAGE OF AND PAYMENT FOR PASS-THROUGH
9 DEVICES.—During the period with respect to
10 which a drug, biological, or medical device is eli-
11 gible for an additional payment under this
12 paragraph, any local coverage determination (as
13 defined in section 1869(f)(2)(B)) that would af-
14 fect the coverage of, or the additional payment
15 under this paragraph for, such drug, biological,
16 or medical device shall have no force or effect
17 in law or regulation.”.

18 (C) EFFECTIVE DATE.—This paragraph,
19 and the amendments made by this paragraph,
20 shall apply with respect to items and services
21 furnished on or after the date of the enactment
22 of this Act, including any such item or service
23 that is eligible on such date for an additional
24 payment under section 1833(t)(6) of the Social
25 Security Act (42 U.S.C. 1395l(t)(6)) or under

1 section 1886(d) of such Act (42 U.S.C.
 2 1395ww(d)) by reason of paragraph (5)(K) of
 3 such section, or that would have been so eligible
 4 on such date but for a local coverage deter-
 5 mination that limits or denies coverage of and
 6 such additional payment for the item or service.

7 (3) REVISION TO THE COST THRESHOLD.—

8 (A) IN GENERAL.—Section
 9 1886(d)(5)(K)(ii)(I) of the Social Security Act
 10 (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended
 11 by striking “75 percent” each place it appears
 12 and inserting “50 percent”.

13 (B) EFFECTIVE DATE.—The amendment
 14 made by subparagraph (A) shall take effect on
 15 the date of the enactment of this Act.

16 (4) USE OF BEST AVAILABLE COST DATA FOR
 17 MS-DRG CLASSIFICATION.—

18 (A) IN GENERAL.—Section 1886(d)(5)(K)
 19 of the Social Security Act (42 U.S.C.
 20 1395ww(d)(5)(K)), as amended by paragraph
 21 (2)(A), is further amended by adding at the end
 22 the following new clause:

23 “(xi) In carrying out the requirement
 24 under clause (ii)(IV) for classification of a
 25 new medical service or technology to a new

1 or existing diagnosis-related group after
 2 the close of the period under clause (ii)(II),
 3 the Secretary shall use the most recently
 4 available data and information on the costs
 5 of such service or technology in making
 6 such a classification for the service or tech-
 7 nology, including data and information
 8 from surveys of providers of services and
 9 suppliers conducted by the Secretary, pri-
 10 vate payers, health plans, physician spe-
 11 cialty societies, or manufacturers as well as
 12 commercial price data and data from man-
 13 ufacturer invoices.”.

14 (B) EFFECTIVE DATE.—The amendment
 15 made by subparagraph (A) shall take effect on
 16 the date of the enactment of this Act.

17 (5) CRITERIA APPLIED IN MAKING SUBSTAN-
 18 TIAL IMPROVEMENT DETERMINATIONS.—

19 (A) IN GENERAL.—Section 1886(d)(5)(K)
 20 of the Social Security Act (42 U.S.C.
 21 1395ww(d)(5)(K)), as amended by paragraphs
 22 (2)(A) and (4)(A), is further amended by add-
 23 ing at the end the following new clause:

24 “(xii)(I) In making a determination
 25 under this subparagraph whether a new

1 medical service or technology represents an
2 advance in medical technology that sub-
3 stantially improves the diagnosis or treat-
4 ment of Medicare beneficiaries relative to a
5 medical service or technology that was pre-
6 viously available, the Secretary shall also
7 consider whether such new medical service
8 or technology meets one or more of the fol-
9 lowing criteria:

10 “(aa) The use of the new medical
11 service or technology can result in a
12 reduction of the length of a hospital
13 stay.

14 “(bb) The use of the new medical
15 service or technology can improve pa-
16 tient quality of life.

17 “(cc) The use of the new medical
18 service or technology can create long-
19 term clinical efficiencies in treatment.

20 “(dd) The use of the new medical
21 service or technology can address pa-
22 tient-centered objectives (as defined
23 by the Secretary).

24 “(ee) The use of the new medical
25 service or technology decreases the

1 number of hospitalizations or physi-
2 cian visits.

3 “(ff) The use of the new medical
4 service or technology reduces recovery
5 time compared to the technologies
6 previously used.

7 “(gg) The use of the new medical
8 service or technology reduces device-
9 related complications.

10 “(hh) The use of the new medical
11 service or technology can result in de-
12 creased rate of subsequent diagnostic
13 or therapeutic interventions (such as
14 due to the reduced rate of recurrence
15 of the disease process).

16 “(ii) The use of the new medical
17 service or technology can result in
18 more rapid beneficial resolution of the
19 disease process treatment.

20 “(jj) The use of the new medical
21 service or technology can result in de-
22 creased pain, bleeding, or other quan-
23 tifiable symptom.

24 “(kk) The use of the new medical
25 service or technology can meet such

1 other criteria as the Secretary may
2 specify.

3 “(II) In considering whether a new
4 medical service or technology potentially
5 meets the criteria under subclause (I), the
6 Secretary shall consider the following
7 forms of evidence:

8 “(aa) Evidence described in well-
9 documented case histories, including
10 registry data.

11 “(bb) Studies published in peer-
12 reviewed journals.

13 “(cc) Data collected in countries
14 other than the United States so long
15 as such data otherwise meet the cri-
16 teria specified in this clause.”.

17 (B) EFFECTIVE DATE.—The amendment
18 made by subparagraph (A) shall take effect on
19 the date of the enactment of this Act.

20 (6) REVISION TO THE NEWNESS CRITERION.—

21 (A) IN GENERAL.—Section
22 1886(d)(5)(K)(vi) of the Social Security Act
23 (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—
24 (i) by inserting “(I)” after “(vi)”; and

1 (ii) by adding at the end the following
2 new subclauses:

3 “(II) Under the criteria estab-
4 lished under this clause with respect
5 to the determination of whether a
6 medical service or technology is con-
7 sidered new for purposes of this sub-
8 paragraph and subparagraph (L), the
9 Secretary shall include devices that in-
10 volve a significant technological
11 change that do not raise different
12 questions of safety and effectiveness
13 (in a comparison to the predicate de-
14 vice) and result in enhanced clinical
15 advantages or reduced cost, even
16 though they use the same or similar
17 mechanism of action or are assigned
18 to the same diagnosis-related group.

19 “(III) Under the criteria estab-
20 lished under this clause with respect
21 to the determination of whether a
22 medical service or technology is con-
23 sidered new for purposes of this sub-
24 paragraph and subparagraph (L), the
25 Secretary shall not disqualify a new

1 medical service or technology as not
 2 meeting the newness criterion solely
 3 on the basis of a finding of a de mini-
 4 mis number of claims for such med-
 5 ical service or technology in Medicare
 6 claims data. For purposes of this sub-
 7 clause, the term ‘de minimis’ means,
 8 with respect to claims, an amount
 9 that is fewer than 50.”.

10 (B) EFFECTIVE DATE.—The amendment
 11 made by subparagraph (A) shall take effect on
 12 the date of the enactment of this Act.

13 (7) REVISION TO THE COMMENCEMENT OF THE
 14 PERIOD FOR COLLECTION OF COST DATA FOR NEW
 15 TECHNOLOGIES.—

16 (A) IN GENERAL.—Section
 17 1886(d)(5)(K)(ii)(II) of the Social Security Act
 18 (42 U.S.C. 1395ww(d)(5)(K)(ii)(II)) is amend-
 19 ed by inserting “the later of the date that is the
 20 date of the clearance or approval by the Com-
 21 missioner of Food and Drugs of the service or
 22 technology or” after “beginning on”.

23 (B) EFFECTIVE DATE.—The amendment
 24 made by subparagraph (A) shall take effect on
 25 the date of the enactment of this Act, and shall

1 apply with respect to hospital discharges for in-
2 patient hospital services for which payment is
3 made under section 1886(d) of the Social Secu-
4 rity Act (42 U.S.C. 1395ww) occurring on or
5 after October 1, 2016.

6 (8) PERMITTING APPEALS OF NTAP DETER-
7 MINATIONS.—

8 (A) IN GENERAL.—Section 1886(d)(5)(K)
9 of the Social Security Act (42 U.S.C.
10 1395ww(d)(5)(K)), as amended by paragraphs
11 (2)(A), (4)(A), and (5)(A), is further amended
12 by adding at the end the following new clause:

13 “(xiii)(I) An individual or entity that
14 submits an application for additional pay-
15 ment under this subparagraph for a new
16 technology shall be entitled to administra-
17 tive review of an adverse determination by
18 the Secretary with respect to such applica-
19 tion.

20 “(II) The Secretary shall establish a
21 process for administrative review for pur-
22 poses of subclause (I). Under such process,
23 administrative review shall be conducted by
24 an official of the Department of Health
25 and Human Services (other than an offi-

1 cial of the Centers for Medicare & Med-
 2 icaid Services). Under such process, the
 3 Department official involved shall complete
 4 administrative review within 90 days of re-
 5 ceipt of a request for such review.

6 “(III) In the case of an application
 7 for additional payment under this subpara-
 8 graph for a new technology that is ap-
 9 proved under administrative review, the
 10 Secretary shall provide for such additional
 11 payment for such new technology during
 12 the period that—

13 “(aa) begins on the date that is
 14 the first day of the first calendar
 15 quarter that begins after the date of
 16 the completion of such administrative
 17 review; and

18 “(bb) ends on the date that is
 19 not less than 2 years and not more
 20 than 3 years after the date referred to
 21 in item (aa).”.

22 (B) CONFORMING AMENDMENT.—Section
 23 1886(d)(7)(B) of such Act (42 U.S.C.
 24 1395ww(d)(7)(B)) is amended by inserting “but
 25 not including a denial by the Secretary of an

1 application for additional payment under para-
2 graph (5)(K) with respect to a discharge occur-
3 ring on or after the date of the date of the en-
4 actment of the Ensuring Patient Access to Crit-
5 ical Breakthrough Products Act of 2018” after
6 “paragraph (4)(D)”.

7 (C) EFFECTIVE DATE.—The amendments
8 made by this paragraph shall take effect on the
9 date of the enactment of this Act, and shall
10 apply with respect to hospital discharges for in-
11 patient hospital services for which payment is
12 made under section 1886(d) of the Social Secu-
13 rity Act (42 U.S.C. 1395ww) occurring on or
14 after October 1, 2016.

15 (e) CONFORMING AMENDMENTS.—

16 (1) INPATIENT PROSPECTIVE PAYMENT SYS-
17 TEM.—Section 1886(d)(5)(K)(i) of the Social Secu-
18 rity Act (42 U.S.C. 1395ww(d)(5)(K)(i)) is amended
19 by adding at the end the following new sentence:
20 “Effective for discharges occurring on or after Octo-
21 ber 1, 2016, in the case of a new medical service or
22 technology that is a breakthrough device (as defined
23 in section 1899C(a)) payment for such breakthrough
24 device shall be made for the 3-year period applicable

1 to such breakthrough device under section
2 1899C(d)(1).”.

3 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
4 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
5 1395l(t)(6)(C)) is amended by adding at the end the
6 following new clause:

7 “(iii) SPECIAL RULE FOR BREAK-
8 THROUGH DEVICES.—Notwithstanding
9 clause (i) or (ii), or any other provision of
10 this paragraph to the contrary, in the case
11 of a breakthrough device (as defined in
12 section 1899C(a)) that is furnished on or
13 after January 1, 2019, payment under this
14 paragraph for such breakthrough device
15 shall be made for the 3-year period appli-
16 cable to such breakthrough device under
17 section 1899C(d)(2). The provisions of this
18 clause shall also apply for purposes of
19 transitional pass-through payment under
20 section 1833(i)(2)(D).”.

21 (f) EFFECTIVE DATE.—This section and the amend-
22 ments made by this section shall take effect on the date
23 of the enactment of this Act and, unless otherwise speci-
24 fied in this section (or in an amendment made by this sec-
25 tion), shall apply to breakthrough devices (as defined in

- 1 section 1899C(a), as added by subsection (a)) approved
- 2 on or after January 1, 2019.

