

116TH CONGRESS  
2D SESSION

# S. 3914

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

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IN THE SENATE OF THE UNITED STATES

JUNE 8, 2020

Ms. MCSALLY introduced the following bill; which was read twice and referred to the Committee on Finance

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## 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 2020”.

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

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

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

2 “(a) BREAKTHROUGH DEVICES.—

3 “(1) IN GENERAL.—For purposes of this sec-  
4 tion, the term ‘breakthrough device’ means a med-  
5 ical device that is a device (as defined in section 201  
6 of the Federal Food, Drug, and Cosmetic Act) and  
7 that is—

8 “(A) provided with review priority by the  
9 Secretary under subsection (d)(5) of section  
10 515 of such Act; and

11 “(B) approved or cleared pursuant to sec-  
12 tion 510(k), 513(f), or 515 of such Act for use  
13 in treating an indication on or after July 1,  
14 2019.

15 Such term also includes a breakthrough device that  
16 is a specified breakthrough device (as defined in sub-  
17 section (e)(1)(B)) approved or cleared pursuant to  
18 section 510(k), 513(f), or 515 of such Act for use  
19 in treating an indication on or after December 1,  
20 2018.

21 “(2) LIMITATION ON NUMBER OF 510(k) DE-  
22 VICES.—With respect to a 5-year period, in no case  
23 may more than five medical devices described in  
24 paragraph (1) that are classified under section  
25 510(k) of the Federal Food, Drug, and Cosmetic

1 Act be covered and paid for under this title by rea-  
2 son of this section during each such 5-year period.

3 “(b) COVERAGE.—

4 “(1) TRANSITIONAL COVERAGE.—

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

8 “(i) deemed to be reasonable and nec-  
9 essary for purposes of section  
10 1862(a)(1)(A);

11 “(ii) deemed to be a medical or other  
12 health service for purposes of section  
13 1861(s);

14 “(iii) deemed to be approved for an  
15 additional payment under section  
16 1886(d)(5)(K) (other than with respect to  
17 the cost criterion under clause (ii)(I) of  
18 such section);

19 “(iv) deemed to be approved for pass-  
20 through payment under section 1833(t)(6)  
21 and section 1833(i) (other than with re-  
22 spect to the cost criterion under section  
23 1833(t)(6)(A)(iv)); and

24 “(v) insofar as such breakthrough de-  
25 vice may be furnished in a setting for

1           which payment is made under an applica-  
2           ble payment system described in subpara-  
3           graphs (D) through (L) of subsection  
4           (c)(4), deemed eligible for an additional  
5           payment or payment adjustment, as the  
6           case may be, pursuant to subsection (d)(3)  
7           when furnished in a setting for which pay-  
8           ment is made under such an applicable  
9           payment system during such transitional  
10          coverage period.

11           “(B) TRANSITIONAL COVERAGE PERIOD  
12          DEFINED.—As used in this section, the term  
13          ‘transitional coverage period’ means, with re-  
14          spect to a breakthrough device, the period  
15          that—

16               “(i) begins on the date of the approval  
17               under section 515 of the Federal Food,  
18               Drug, and Cosmetic Act or of the clear-  
19               ance under section 510(k) of such Act, as  
20               applicable, of such device by the Secretary  
21               for the indication described in subsection  
22               (a)(1); and

23               “(ii) ends on the last day of the 3-  
24               year period that begins on the date that  
25               the Secretary, pursuant to subsection

1 (c)(2), updates the relevant applicable pay-  
2 ment system (as defined in subsection  
3 (c)(4)) to recognize the unique temporary  
4 or permanent code or codes assigned under  
5 subsection (c)(1) to such breakthrough de-  
6 vice, except as provided in subsections  
7 (d)(1)(B) and (d)(2)(B).

8 “(C) DATA USED TO MEET THE NTAP AND  
9 PASS-THROUGH COST CRITERIA.—In deter-  
10 mining whether a breakthrough device qualifies  
11 for an additional payment under section  
12 1886(d)(5)(K) or for pass-through payment  
13 under section 1833(t)(6) or section 1833(i), the  
14 Secretary shall use the most recently available  
15 data and information on the costs of such  
16 breakthrough device, which may include list  
17 prices and invoice prices charged for such  
18 breakthrough device.

19 “(2) PROCESS FOR REGULAR COVERAGE.—For  
20 purposes of the application of section 1862(a)(1)(A)  
21 to a breakthrough device furnished after the transi-  
22 tional coverage period (as defined in paragraph  
23 (1)(B)) for such device, the Secretary shall establish  
24 a process for the coverage of such breakthrough de-  
25 vices under this title after such period as follows:

1                   “(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—  
2

3                   “(i) IN GENERAL.—With respect to a  
4                   breakthrough device, not later than 1 year  
5                   after the date of the approval of such de-  
6                   vice under section 515 of the Federal  
7                   Food, Drug, and Cosmetic Act or of the  
8                   clearance of such device under section  
9                   510(k) of such Act, as applicable, the Sec-  
10                  retary shall identify whether any additional  
11                  data or evidence is required with respect to  
12                  any indications for such device for pur-  
13                  poses of the application of such section  
14                  1862(a)(1)(A) to such device for such indi-  
15                  cations.

16                  “(ii) NON-DUPLICATION OF DATA RE-  
17                  QUESTS.—In carrying out clause (i) with  
18                  respect to a breakthrough device, the Sec-  
19                  retary shall ensure that data or evidence  
20                  identified—

21                                 “(I) does not duplicate data re-  
22                                 quired to be collected by the Food and  
23                                 Drug Administration with respect to  
24                                 such breakthrough device;

1                   “(II) minimizes the administra-  
2                   tive burdens of data collection and re-  
3                   porting on providers of services, sup-  
4                   pliers, and manufacturers of break-  
5                   through devices; and

6                   “(III) is not otherwise unneces-  
7                   sary or redundant.

8                   “(B) PROPOSAL FOR COVERAGE AFTER  
9                   THE TRANSITIONAL COVERAGE PERIOD.—Not  
10                  later than 2 years after the date of the approval  
11                  or clearance of a breakthrough device by the  
12                  Food and Drug Administration, the Secretary  
13                  shall develop a proposal for coverage under this  
14                  title of such breakthrough device for such indi-  
15                  cations as the Secretary determines to be ap-  
16                  propriate, based on the data and evidence col-  
17                  lected under subparagraph (A), for such devices  
18                  furnished after the transitional coverage period  
19                  under paragraph (1) for such device. If the Sec-  
20                  retary does not, on a date that is before the end  
21                  of such 2-year period, take action to modify the  
22                  indications for which coverage of a break-  
23                  through device may be provided under this title  
24                  after such period, for purposes of section  
25                  1862(a)(1)(A) coverage under this title of such

1 breakthrough device shall be made for all indi-  
2 cations for which such device is approved under  
3 section 515 of the Federal Food, Drug, and  
4 Cosmetic Act or cleared under section 510(k) of  
5 such Act.

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

8 “(A) affect the ability of the manufacturer  
9 of a breakthrough device to seek approval for  
10 pass-through payment status under section  
11 1833(t)(6) or to seek approval for an additional  
12 payment under section 1886(d)(5)(K) insofar  
13 as such breakthrough device does not qualify  
14 for transitional coverage under paragraph (1);  
15 or

16 “(B) affect the application and approval  
17 process for pass-through payment status under  
18 section 1833(t)(6) or for an additional payment  
19 under section 1886(d)(5)(K) in the case of a  
20 medical device that is not approved by the Food  
21 and Drug Administration as a breakthrough de-  
22 vice.

23 “(c) CODING.—

24 “(1) PROMPT ASSIGNMENT.—Not later than  
25 three months after the date of approval or clearance



1 of a breakthrough device by the Food and Drug Ad-  
2 ministration, subject to subsection (b)(1)(B), the  
3 Secretary shall assign a unique temporary or perma-  
4 nent code or codes for purposes of coverage and pay-  
5 ment for such breakthrough device under the appli-  
6 cable payment systems (described in paragraph (4)).

7 “(2) UPDATES.—

8 “(A) IPPS.—The Secretary shall provide  
9 for semiannual updates under the applicable  
10 payment system described in paragraph (4)(A)  
11 (relating to the inpatient hospital prospective  
12 payment system) to recognize the code or codes  
13 assigned under paragraph (1).

14 “(B) OPPI.—The Secretary shall provide  
15 for quarterly updates under the applicable pay-  
16 ment system described in paragraph (4)(B) (re-  
17 lating to the outpatient hospital prospective  
18 payment system) to recognize the code or codes  
19 assigned under paragraph (1).

20 “(C) OTHER PAYMENT SYSTEMS.—The  
21 Secretary shall provide for semiannual or quar-  
22 terly updates, as the case may be, under the ap-  
23 plicable payment systems described in subpara-  
24 graphs (C) through (L) of paragraph (4) to rec-

1           ognize the code or codes assigned under para-  
2           graph (1).

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

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

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

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

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

21                   “(D) with respect to physicians’ services,  
22                   the physician fee schedules established under  
23                   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 payment amounts under section  
6           1834A and the fee schedules establish under  
7           section 1848, as the case may be;

8           “(G) with respect to renal dialysis services  
9           furnished by a provider of services or a renal  
10          dialysis facility, the single payment system es-  
11          tablished under section 1881(b)(14);

12          “(H) with respect to inpatient hospital  
13          services furnished by rehabilitation facilities,  
14          the prospective payment system established  
15          under section 1886(j);

16          “(I) with respect to inpatient hospital serv-  
17          ices furnished by long-term care hospitals, the  
18          prospective payment system under section  
19          1886(m);

20          “(J) with respect to inpatient hospital  
21          services furnished by psychiatric hospitals and  
22          psychiatric units, the prospective payment sys-  
23          tem under section 1886(s);

1           “(K) with respect to home health services,  
2           the prospective payment system under section  
3           1895; and

4           “(L) with respect to items and services, or  
5           a provider of services or supplier, not described  
6           in subparagraphs (A) through (K), the payment  
7           system established under this title for such  
8           items and services when furnished by such pro-  
9           vider of services or supplier.

10          “(d) PAYMENT.—

11           “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-  
12          MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-  
13          THROUGH PAYMENT.—The Secretary shall deem  
14          each breakthrough device as approved for an addi-  
15          tional payment under section 1886(d)(5)(K) for the  
16          3-year period that begins—

17           “(A) except as provided in subparagraph  
18          (B), on the date that the Secretary, pursuant to  
19          subsection (c)(2)(A), updates the payment sys-  
20          tem under section 1886(d) to recognize the  
21          unique temporary or permanent code or codes  
22          assigned under subsection (c)(1) to such break-  
23          through device; or

24           “(B) in the case of a device that has not  
25          received approval or clearance as a break-

1 through device by the Food and Drug Adminis-  
2 tration before such payment system is updated  
3 under subsection (c)(2)(A) to recognize the  
4 unique temporary or permanent code or codes  
5 assigned under subsection (c)(1) to such device,  
6 on the date of such approval or clearance.

7 Nothing in this paragraph shall be construed to af-  
8 fect the authority of the Secretary to use claims  
9 data to establish new diagnosis or procedure codes  
10 for breakthrough devices or to identify appropriate  
11 diagnosis-related groups for the assignment of  
12 breakthrough devices under annual rulemaking to  
13 carry out section 1886(d)(5)(K).

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

21 “(A) except as provided in subparagraph  
22 (B), on the date that the Secretary, pursuant to  
23 subsection (c)(2)(B), updates the payment sys-  
24 tem under section 1833(t) to recognize the  
25 unique temporary or permanent code or codes

1 assigned under subsection (c)(1) to such break-  
2 through device; or

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

11 Nothing in this paragraph shall be construed to af-  
12 fect the authority of the Secretary to use claims  
13 data to establish new ambulatory payment classifica-  
14 tion groups for breakthrough devices or to revise  
15 such groups to take into account breakthrough de-  
16 vices under annual rulemaking to carry out section  
17 1833(t).

18 “(3) OTHER PAYMENT SYSTEMS.—

19 “(A) IN GENERAL.—In the case of a  
20 breakthrough device that is furnished and for  
21 which payment may be made under the pay-  
22 ment system established under section 1834,  
23 1834A, 1848, 1881(b)(14), 1886(j), 1886(m),  
24 1886(s), or 1895, or any other provision of this  
25 title (other than sections 1833(i), 1833(t), and

1 1886(d)), the Secretary shall provide for an ad-  
2 ditional payment for such breakthrough device  
3 under such applicable payment system or an  
4 adjustment to such applicable payment system,  
5 as the case may be. The payment basis for such  
6 additional payment or adjustment, as the case  
7 may be, shall equal an amount that the Sec-  
8 retary determines covers the costs of such  
9 breakthrough device.

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

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

1 tablish under the annual rulemaking authority  
2 under the provisions referred to in subpara-  
3 graph (A).

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

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



1       “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH  
2 DEVICES.—

3               “(1) COVERAGE OF SPECIFIED BREAKTHROUGH  
4 DEVICES.—

5                       “(A) IN GENERAL.—Subject to the suc-  
6 ceeding provisions of this subsection and not-  
7 withstanding any other provision of law, the  
8 Secretary shall provide for coverage and pay-  
9 ment pursuant to this section of a specified  
10 breakthrough device (as defined in subpara-  
11 graph (B)).

12                       “(B) SPECIFIED BREAKTHROUGH DEVICE  
13 DEFINED.—In this section, the term ‘specified  
14 breakthrough device’ means a breakthrough de-  
15 vice with respect to which no Medicare benefit  
16 category exists.

17               “(2) PERIOD OF TRANSITIONAL COVERAGE.—

18                       “(A) IN GENERAL.—Subject to subpara-  
19 graph (C), the provisions of subsection (b)(1)  
20 (relating to the transitional coverage period and  
21 payment for breakthrough devices, including the  
22 use of the most recently available data and in-  
23 formation on costs) shall apply to a specified  
24 breakthrough device in the same manner as  
25 such provisions apply to a breakthrough device.

1           The Secretary may use methodologies under ex-  
2           isting payment systems established under this  
3           title, may provide for appropriate adjustments  
4           to such methodologies, or may establish a new  
5           payment methodology under this title, to pro-  
6           vide for payment for a specified breakthrough  
7           device to ensure the payment basis for such  
8           payment covers costs of the specified break-  
9           through device.

10           “(B) REPORT.—

11           “(i) IN GENERAL.—With respect to  
12           each specified breakthrough device, the  
13           Secretary shall submit to Congress a re-  
14           port on the coverage of and payment for  
15           such specified breakthrough device under  
16           this section that includes the following in-  
17           formation:

18           “(I) The manner in which cov-  
19           erage is provided and payment is  
20           made for the specified breakthrough  
21           device, including how such device was  
22           classified (such as an item of durable  
23           medical equipment or otherwise) and  
24           the payment methodology the Sec-

1           retary applied with respect to such de-  
2           vice.

3           “(II) The impact of the avail-  
4           ability of the specified breakthrough  
5           device to Medicare beneficiaries, in-  
6           cluding impacts on the quality of pa-  
7           tient care, patient outcomes, and pa-  
8           tient experience.

9           “(III) The impact of the avail-  
10          ability of the specified breakthrough  
11          device to Medicare beneficiaries on  
12          program expenditures under this title.

13          “(IV) Such other information as  
14          the Secretary determines to be appro-  
15          priate.

16          “(ii) DEADLINE.—

17                 “(I) IN GENERAL.—Except as  
18                 provided in subclause (II), the Sec-  
19                 retary shall submit a report required  
20                 under this subparagraph no later than  
21                 the end of the transitional period of  
22                 coverage and payment applicable to  
23                 such specified breakthrough device.

24                 “(II) EXTENSION TO GENERATE  
25                 ADDITIONAL DATA.—If the Secretary

1 determines that additional data or evi-  
2 dence is required to complete a report  
3 required under this subparagraph  
4 with respect to a specified break-  
5 through device, the deadline under  
6 this clause may be extended for an  
7 additional two years.

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

17 “(i) two years; or

18 “(ii) the amount of additional time re-  
19 quired for the submission of the report  
20 with respect to such device.

21 “(3) COVERAGE AND PAYMENT AFTER THE  
22 TRANSITIONAL PERIOD.—The Secretary may con-  
23 tinue to provide for coverage of and payment for a  
24 specified breakthrough device after the end of the  
25 transitional period of coverage and payment for

1 breakthrough devices through the national coverage  
2 determination process if the Secretary determines  
3 that the specified breakthrough device—

4 “(A) improves the quality of care and pa-  
5 tient outcomes;

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

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

9 (b) STUDY OF LIMIT ON 510(k) BREAKTHROUGH  
10 DEVICES.—

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

19 (2) MATTERS EXAMINED.—In conducting the  
20 study described in paragraph (1), the Secretary  
21 shall—

22 (A) determine the number of medical de-  
23 vices cleared under such section 510(k) during  
24 the 5-year period beginning on the date of the  
25 enactment of this Act;

1           (B) determine the number of such devices  
2           that were not included as breakthrough devices  
3           for purposes of such section 1899C by reason  
4           of the limitation under subsection (a)(2) of such  
5           section; and

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

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

18          (c) CLARIFICATION REGARDING CERTAIN PAY-  
19          MENTS.—

20               (1) IPPS NEW TECHNOLOGY PAYMENT.—Sec-  
21          tion 1886(d)(5)(K) of the Social Security Act (42  
22          U.S.C. 1395ww(d)(5)(K)) is amended by adding at  
23          the end the following new clause:

24          “(x) During the period with respect to which a new  
25          medical service or technology is eligible for an additional

1 payment under this subsection by reason of this subpara-  
2 graph, any local coverage determination (as defined in sec-  
3 tion 1869(f)(2)(B)) that would affect the coverage of, or  
4 the additional payment under this subsection for, such  
5 new medical service or technology shall have no force or  
6 effect in law or regulation.”.

7 (2) OPPTS PASS-THROUGH PAYMENT.—Section  
8 1833(t)(6) of the Social Security Act (42 U.S.C.  
9 1395l(t)(6)) is amended by adding at the end the  
10 following new subparagraph:

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

23 (3) EFFECTIVE DATE.—This subsection, and  
24 the amendments made by this subsection, shall apply  
25 with respect to items and services furnished on or

1 after the date of the enactment of this Act, including  
2 any such item or service that is eligible on such date  
3 for an additional payment under section 1886(d) of  
4 the Social Security Act (42 U.S.C. 1395ww(d)) by  
5 reason of paragraph (5)(K) of such section or under  
6 section 1833(t)(6) of such Act (42 U.S.C.  
7 1395ww(t)(6)), or that would have been so eligible  
8 on such date but for a local coverage determination  
9 that limits or denies coverage of and such additional  
10 payment for the item or service.

11 (d) CONFORMING AMENDMENTS.—

12 (1) INPATIENT PROSPECTIVE PAYMENT SYS-  
13 TEM.—Section 1886(d)(5)(K) of the Social Security  
14 Act (42 U.S.C. 1395ww(d)(5)(K)), as amended by  
15 subsection (c)(1), is amended by adding at the end  
16 the following new clause:

17 “(xi) Effective for discharges occurring on or after  
18 October 1, 2020, in the case of a new medical service or  
19 technology that is a breakthrough device (as defined in  
20 section 1899C(a)), the additional payment established for  
21 such breakthrough device under this subparagraph shall  
22 be made for the 3-year period applicable to such break-  
23 through device under section 1899C(d)(1). In determining  
24 the amount of the additional payment for a breakthrough  
25 device under this subparagraph during such 3-year period,



1 the Secretary shall apply section 412.88(b) of title 42,  
2 Code of Federal Regulations (or any successor regulation),  
3 as if the reference to ‘50 percent’ in such section were  
4 a reference to ‘80 percent’.”

5 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-  
6 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.  
7 13951(t)(6)(C)) is amended by adding at the end the  
8 following new clause:

9 “(iii) SPECIAL RULE FOR BREAK-  
10 THROUGH DEVICES.—Notwithstanding  
11 clause (i) or (ii), or any other provision of  
12 this paragraph to the contrary, in the case  
13 of a breakthrough device (as defined in  
14 section 1899C(a)) that is furnished on or  
15 after January 1, 2021, payment under this  
16 paragraph for such breakthrough device  
17 shall be made for the 3-year period appli-  
18 cable to such breakthrough device under  
19 section 1899C(d)(2). The provisions of this  
20 clause shall also apply for purposes of  
21 transitional pass-through payment under  
22 section 1833(i)(2)(D).”

23 (3) COMPETITIVE BIDDING PROGRAM.—Section  
24 1847(a) of such Act (42 U.S.C. 1395w-3(a)) is  
25 amended—

1 (A) in paragraph (2)(A)—

2 (i) by striking “and excluding drugs”

3 and inserting “excluding drugs”; and

4 (ii) by inserting before the period at

5 the end the following: “, and excluding

6 breakthrough devices (as defined in section

7 1899C(a))”; and

8 (B) in paragraph (7), by adding at the end

9 the following new subparagraph:

10 “(C) BREAKTHROUGH DEVICES.—A break-

11 through device described in paragraph (2)(A)

12 that is furnished during the transitional cov-

13 erage period (as defined in section

14 1899C(b)(1)(B)) applicable to such device

15 under section 1899C.”.

16 (e) EFFECTIVE DATE.—This section, and the amend-

17 ments made by this section, shall take effect on the date

18 of the enactment of this Act and, unless otherwise speci-

19 fied in this section (or in an amendment made by this sec-

20 tion), shall apply to breakthrough devices (as defined in

21 section 1899C(a) of the Social Security Act, as added by

22 subsection (a)), approved or cleared on or after July 1,

23 2019, or, in the case of a specified breakthrough device

- 1 (as defined in such section as so added), approved or
- 2 cleared on or after December 1, 2018.

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