

117TH CONGRESS
2D SESSION

H. R. 9358

To amend title XVIII of the Social Security Act to provide a review process for adverse national coverage determinations with respect to drug coverage under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 29, 2022

Ms. BARRAGÁN (for herself and Mr. JOYCE of Pennsylvania) 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 provide a review process for adverse national coverage determinations with respect to drug coverage under the Medicare program.

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 “Access to Innovative
5 Treatments Act of 2022”.

1 **SEC. 2. PROVIDING A REVIEW PROCESS FOR ADVERSE NA-**
2 **TIONAL COVERAGE DETERMINATIONS WITH**
3 **RESPECT TO DRUG COVERAGE UNDER THE**
4 **MEDICARE PROGRAM.**

5 (a) IN GENERAL.—Section 1862(l) of the Social Se-
6 curity Act (42 U.S.C. 1395y(l)) is amended—

7 (1) by redesignating paragraphs (5) and (6) as
8 paragraphs (7) and (8), respectively; and

9 (2) by inserting after paragraph (4) the fol-
10 lowing new paragraphs:

11 “(5) REVIEW OF NATIONAL COVERAGE DETER-
12 MINATIONS FOR DRUGS AND BIOLOGICALS.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (D), not later than 30 days after receiv-
15 ing a request for a review of a specified na-
16 tional coverage determination (as defined in
17 subparagraph (E)), the Secretary shall initiate
18 such a review in accordance with the provisions
19 of this paragraph.

20 “(B) PUBLIC COMMENT PERIOD.—Begin-
21 ning on the date of the initiation of a review of
22 a specified national coverage determination
23 under subparagraph (A), the Secretary shall
24 provide for a 30-day public comment period as
25 to whether such determination should be af-
26 firmed, reversed, or otherwise modified.

1 “(C) FINAL DECISION.—Not later than 30
2 days after the conclusion of the 30-day period
3 described in subparagraph (B) with respect to
4 a specified national coverage determination, the
5 Secretary shall—

6 “(i) make a final decision as to wheth-
7 er such determination should be affirmed,
8 reversed, or otherwise modified;

9 “(ii) include in such final decision
10 summaries of the public comments received
11 and responses to such comments;

12 “(iii) make available to the public the
13 clinical evidence and other data used in
14 making such decision when such decision
15 differs from the recommendations of the
16 Medicare Coverage Advisory Committee;
17 and

18 “(iv) in the case of a final decision
19 under clause (i) to reverse or modify such
20 determination, the Secretary shall assign a
21 temporary or permanent code (whether ex-
22 isting or unclassified) and implement the
23 coding change as applicable.

24 “(D) LIMITATION ON SUCCESSIVE RE-
25 VIEWS.—Subparagraph (A) shall not apply with

1 respect to a request for a review of a specified
2 national coverage determination if the Secretary
3 has made a final decision with respect to a pre-
4 vious review of such determination under this
5 paragraph during the 2-year period ending on
6 the date of the receipt of such request. Nothing
7 in the preceding sentence shall be construed to
8 limit the authority of the Secretary to review or
9 reconsider a national coverage determination if
10 determined appropriate by the Secretary.

11 “(E) SPECIFIED NATIONAL COVERAGE DE-
12 TERMINATION DEFINED.—In this paragraph,
13 the term ‘specified national coverage determina-
14 tion’ means a national coverage determination
15 made with respect to a drug or biological ap-
16 proved under section 505(c) of the Federal
17 Food, Drug, and Cosmetic Act or licensed
18 under section 351 of the Public Health Service
19 Act under which coverage of such drug or bio-
20 logical under this title was denied or otherwise
21 limited in a manner inconsistent with such ap-
22 proval or licensure.

23 “(6) PROHIBITION ON APPLICATION OF CER-
24 TAIN EXISTING NATIONAL COVERAGE DETERMINA-
25 TIONS TO NEWLY-APPROVED DRUGS AND

1 BIOLOGICALS.—The Secretary may not, with respect
2 to a drug approved under section 505(e) of the Fed-
3 eral Food, Drug, and Cosmetic Act or a biological
4 licensed under section 351 of the Public Health
5 Service Act, apply a national coverage determination
6 that was made prior to the date of such approval or
7 licensure (as applicable) to the extent that such ap-
8 plication would result in a denial or other limit of
9 coverage under this title for such drug or biological
10 in a manner inconsistent with such approval or li-
11 censure.”.

12 (b) NONRELIANCE ON CERTAIN NCDs UNDER PART
13 D.—Section 1860D–2(e)(3) of the Social Security Act (42
14 U.S.C. 1395w–102(e)(3)) is amended by adding at the end
15 the following new sentence: “In determining whether pay-
16 ment would not be made with respect to a covered part
17 D drug if section 1862(a) applied to this part, a prescrip-
18 tion drug plan or MA–PD plan may not base such deter-
19 mination on a national coverage determination made with
20 respect to such drug if such determination is a specified
21 national coverage determination (as defined in section
22 1862(l)(5)).”.

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