

103^D CONGRESS
1ST SESSION

H. R. 1787

To amend title XVIII of the Social Security Act to provide for uniform coverage of anticancer drugs under the medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 21, 1993

Mr. LEVIN introduced the following bill; which was referred jointly to the Committees on Ways and Means and Energy and Commerce

A BILL

To amend title XVIII of the Social Security Act to provide for uniform coverage of anticancer drugs 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 “Medicare Cancer Cov-
5 erage Improvement Act of 1993”.

6 **SEC. 2. UNIFORM MEDICARE COVERAGE OF ANTICANCER**
7 **DRUGS.**

8 (a) IN GENERAL.—Section 1861(t) of the Social Se-
9 curity Act (42 U.S.C. 1395x(t)) is amended—

1 (1) by inserting “(1)” after “(t)”;

2 (2) by striking “(m)(5) of this section” and in-
3 serting “(m)(5) and paragraph (2)”;

4 (3) by adding at the end thereof the following
5 new paragraph:

6 “(2)(A) For purposes of paragraph (1) the term
7 ‘drugs’ includes any drugs or biologics used in an
8 anticancer chemotherapeutic regimen for a medically ac-
9 cepted indication (as described in subparagraph (B)).

10 “(B) The term ‘medically accepted indication’ means
11 any use of a drug approved by the Food and Drug Admin-
12 istration which is included under paragraph (1), which for
13 a given condition—

14 “(i) is included (or approved for inclusion) in
15 one or more of the following compendia: the Amer-
16 ican Hospital Formulary Service-Drug Information,
17 the American Medical Association Drug Evaluations,
18 and the United States Pharmacopoeia-Drug Infor-
19 mation; or

20 “(ii) is supported by peer reviewed medical lit-
21 erature appearing in publications which have been
22 specifically approved for purposes of this paragraph
23 by the Secretary.”.

24 (b) EFFECTIVE DATE.—The amendments made by
25 subsection (a) shall apply with respect to items furnished

1 on or after the first day of the first month that begins
2 after the date of the enactment of this Act.

3 **SEC. 3. ORAL CANCER DRUGS.**

4 (a) COVERAGE OF CERTAIN SELF-ADMINISTERED
5 ANTICANCER DRUGS.—Section 1861(s)(2) of the Social
6 Security Act (42 U.S.C. 1395(s)(2)) is amended—

7 (1) by striking “and” at the end of subpara-
8 graph (O);

9 (2) by adding “and” at the end of subpara-
10 graph (P); and

11 (3) by adding at the end the following new sub-
12 paragraph:

13 “(Q) an oral drug (which is approved by the
14 Food and Drug Administration) prescribed for use
15 as an anticancer chemotherapeutic agent for a given
16 indication, and containing an active ingredient (or
17 ingredients), which is the same indication and active
18 ingredient (or ingredients) as a drug which the car-
19 rier determines would be covered pursuant to sub-
20 paragraph (A) or (B) if the drug could not be self-
21 administered;”.

22 (b) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to items furnished on or after Jan-
24 uary 1, 1994.

1 **SEC. 4. STUDY OF MEDICARE COVERAGE OF PATIENT CARE**
2 **COSTS ASSOCIATED WITH CLINICAL TRIALS**
3 **OF NEW CANCER THERAPIES.**

4 (a) STUDY.—The Secretary of Health and Human
5 Services shall conduct a study of the effects of expressly
6 covering the patient care costs for medicare beneficiaries
7 enrolled in clinical trials of new cancer therapies, where
8 the protocol for the trial has been approved by the Na-
9 tional Cancer Institute or meets similar scientific and ethi-
10 cal standards, including approval by an Institutional Re-
11 view Board. The study shall include—

12 (1) an estimate of the cost of such coverage,
13 taking into account the extent to which medicare
14 currently pays for such patient care costs in prac-
15 tice;

16 (2) an assessment of the extent to which such
17 clinical trials represent the best available treatment
18 for the patients involved and of the effects of partici-
19 pation in the trials on the health of such patients;

20 (3) an assessment of whether progress in devel-
21 oping new anticancer therapies would be assisted by
22 medicare coverage of such patient care costs; and

23 (4) an evaluation of whether there should be
24 special criteria for the admission of medicare bene-
25 ficiaries (on account of their age or physical condi-

1 tion) to clinical trials for which medicare would pay
2 the patient care costs.

3 (b) REPORT.—The Secretary of Health and Human
4 Services shall submit a report on the study required by
5 subsection (a) (including recommendations as to the cov-
6 erage of patient care costs of medicare beneficiaries en-
7 rolled in clinical trials of new cancer therapies) to the
8 Committee on Finance of the Senate and the Committee
9 on Ways and Means and the Committee on Energy and
10 Commerce of the House of Representatives, not later than
11 2 years after the date of enactment of this Act.

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