

117TH CONGRESS
1ST SESSION

H. R. 3808

To provide for a demonstration project to further examine the benefits of providing coverage and payment for items and services necessary to administer intravenous immune globulin (IVIG) in the home, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2021

Mr. BLUMENAUER (for himself, Mr. SMITH of New Jersey, and Mr. BUTTERFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 provide for a demonstration project to further examine the benefits of providing coverage and payment for items and services necessary to administer intravenous immune globulin (IVIG) in the home, 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 IVIG Access
5 Enhancement Act”.

1 **SEC. 2. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION**
2 **PROJECT.**

3 (a) ESTABLISHMENT.—The Secretary of Health and
4 Human Services (in this section referred to as the “Sec-
5 retary”) shall establish and implement a demonstration
6 project under part B of title XVIII of the Social Security
7 Act to evaluate the benefits of providing payment for items
8 and services needed for the in-home administration of in-
9 travenous immune globulin for the treatment of chronic
10 inflammatory demyelinating polyneuropathy or multifocal
11 motor neuropathy.

12 (b) DURATION AND SCOPE.—

13 (1) DURATION.—Beginning not later than 1
14 year after the date of enactment of this Act, the
15 Secretary shall conduct the demonstration project
16 for a period of 5 years.

17 (2) SCOPE.—The Secretary shall, subject to
18 subsection (d), enroll not greater than 3,000 Medi-
19 care beneficiaries who have been diagnosed with
20 chronic inflammatory demyelinating polyneuropathy
21 or multifocal motor neuropathy for participation in
22 the demonstration project. Subject to subsection (d),
23 a Medicare beneficiary may participate in the dem-
24 onstration project on a voluntary basis and may ter-
25minate participation at any time.

1 (c) COVERAGE.—Except as otherwise provided in this
2 section, items and services for which payment may be
3 made under the demonstration program shall be treated
4 and covered under part B of title XVIII of the Social Se-
5 curity Act in the same manner as similar items and serv-
6 ices covered under such part.

7 (d) ELIGIBILITY.—In order to participate in the dem-
8 onstration project, a Medicare beneficiary must—

9 (1) be covered under the original Medicare fee-
10 for-service program under parts A and B of title
11 XVIII of the Social Security Act and not enrolled in
12 a Medicare Advantage plan under part C of such
13 Act;

14 (2) require intravenous immunoglobulin for the
15 treatment of chronic inflammatory demyelinating
16 polyneuropathy or multifocal motor neuropathy; and

17 (3) meet any other eligibility requirements spec-
18 ified by the Secretary.

19 (e) PAYMENT.—

20 (1) INTRAVENOUS IMMUNE GLOBULIN.—For in-
21 travenous immune globulin furnished under this sec-
22 tion, the Secretary shall make payment using the
23 payment methodology under section 1847A of the
24 Social Security Act (42 U.S.C. 1395w–3a).

25 (2) OTHER ITEMS AND SERVICES.—

1 (A) IN GENERAL.—The Secretary shall es-
2 tablish, subject to subparagraph (B), a per-visit
3 payment amount for items and services (other
4 than intravenous immune globulin) needed for
5 the in-home infusion of intravenous immune
6 globulin for the treatment of chronic inflam-
7 matory demyelinating polyneuropathy or
8 multifocal motor neuropathy based on the na-
9 tional per visit low-utilization payment amount
10 under the prospective payment system for home
11 health services established under section 1895
12 of the Social Security Act (42 U.S.C. 1395fff).

13 (B) LIMITATION.—In establishing the per
14 visit payment amount established under sub-
15 paragraph (A) for items and services described
16 in such subparagraph, the Secretary shall con-
17 sider—

18 (i) including a component for requisite
19 nursing care;

20 (ii) establishing an appropriate fur-
21 nishing fee for intravenous immune glob-
22 ulin similar to the separate payment for
23 clotting factors under section 1842(o)(5) of
24 the Social Security Act (42 U.S.C.
25 1395u(o)(5));

1 (iii) otherwise acknowledging the
2 length of infusions for individuals needing
3 in-home infusion of intravenous globulin
4 for treatment described in subparagraph
5 (A);

6 (iv) that, in total, such amount poten-
7 tially not being less than at least 2.5 times
8 the payment amount applied under the
9 demonstration project established under
10 section 101 of the Medicare IVIG Access
11 and Strengthening Medicare and Repaying
12 Taxpayers Act of 2012 (Public Law 112-
13 242) for items and services needed for the
14 in-home administration of intravenous im-
15 mune globulin for the treatment of pri-
16 mary immune deficiency diseases in rec-
17 ognition of the fact that patients with
18 chronic inflammatory demyelinating poly-
19 neuropathy or multifocal motor neuropathy
20 tend to have longer infusion times, require
21 more product, and have additional health-
22 care needs related to underlying neuromus-
23 cular challenges; and

24 (v) developing such amount in con-
25 sultation with stakeholders.

1 (f) WAIVER AUTHORITY.—The Secretary may waive
2 such requirements of title XVIII of the Social Security Act
3 as may be necessary to carry out the demonstration
4 project.

5 (g) FINAL EVALUATION AND REPORT.—Not later
6 than one year after the third year of the demonstration
7 project, the Secretary shall submit to Congress a report
8 that contains—

9 (1) a current and projected evaluation of the
10 impact of the demonstration project on access for
11 Medicare beneficiaries with chronic inflammatory
12 demyelinating polyneuropathy and Medicare bene-
13 ficiaries with multifocal motor neuropathy to items
14 and services needed for the in-home administration
15 of intravenous immune globin that also draws upon
16 information and data from the ongoing home infu-
17 sion demonstration project for primary immuno-
18 deficiency diseases (Public Law 112–242) and the
19 recent effort to provide an adequate coverage benefit
20 for therapies infused through durable medical equip-
21 ment (HCPCS CMS–1738–P); and

22 (2) a final analysis of the appropriateness of ex-
23 panding or extending the demonstration project, or
24 implementing a new methodology for payment for in-
25 travenous immune globulins in all care settings

1 under part B of title XVIII of the Social Security
2 Act (42 U.S.C. 1395k et seq.), or augmenting exist-
3 ing benefits to provide proper access for home infu-
4 sion of intravenous immune globulins, and, to the
5 extent such analysis determines such an expansion,
6 extension, or methodology appropriate, recommenda-
7 tions for such expansion, extension, or methodology,
8 respectively, along with an explanation of how CMS
9 intends to implement or otherwise provide such a
10 permanent benefit or mechanism for access during
11 the fifth year of the demo to ensure nondisruptions
12 in care for impacted patients.

13 (h) DEFINITIONS.—In this section:

14 (1) DEMONSTRATION PROJECT.—The term
15 “demonstration project” means the demonstration
16 project conducted under this Act.

17 (2) MEDICARE BENEFICIARY.—The term
18 “Medicare beneficiary” means an individual who is
19 enrolled for benefits under part B of title XVIII of
20 the Social Security Act.

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