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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare IVIG Access Enhancement Act''.

SEC. 2. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish and implement a demonstration project under part B of title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of chronic inflammatory demyelinating polyneuropathy or multifocal motor neuropathy.

(b) DURATION AND SCOPE.—

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

(2) SCOPE.—The Secretary shall, subject to subsection (d), enroll not greater than 3,000 Medicare beneficiaries who have been diagnosed with chronic inflammatory demyelinating polyneuropathy or multifocal motor neuropathy for participation in the demonstration project. Subject to subsection (d), a Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time.

(c) COVERAGE.—Except as otherwise provided in this section, items and services for which payment may be made under the demonstration program shall be treated and covered under part B of title XVIII of the Social Security Act in the same manner as similar items and services covered under such part.

(d) ELIGIBILITY.—In order to participate in the demonstration project, a Medicare beneficiary must—

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

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

(3) meet any other eligibility requirements specified by the Secretary.

(e) PAYMENT.—

(1) INTRAVENOUS IMMUNE GLOBULIN.—For intravenous immune globulin furnished under this section, the Secretary shall make payment using the payment methodology under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a).

(2) OTHER ITEMS AND SERVICES.—

(A) IN GENERAL.—The Secretary shall establish, subject to subparagraph (B), a per-visit payment amount for items and services (other than intravenous immune globulin) needed for the in-home infusion of intravenous immune globulin for the treatment of chronic inflammatory demyelinating polyneuropathy or multifocal motor neuropathy based on the national per visit low-utilization payment amount under the prospective payment system for home health services established under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

(B) LIMITATION.—In establishing the per visit payment amount established under subparagraph (A) for items and services described in such subparagraph, the Secretary shall consider—

(i) including a component for requisite nursing care;

(ii) establishing an appropriate furnishing fee for intravenous immune globulin similar to the separate payment for clotting factors under section 1842(o)(5) of the Social Security Act (42 U.S.C. 1395u(o)(5));

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

(iv) that, in total, such amount potentially not being less than at least 2.5 times the payment amount applied under the demonstration project established under section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Public Law 112–242) for items and services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency diseases in recognition of the fact that patients with chronic inflammatory demyelinating polyneuropathy or multifocal motor neuropathy tend to have longer infusion times, require more product, and have additional healthcare needs related to underlying neuromuscular challenges; and

(v) developing such amount in consultation with stakeholders.

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

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

(1) a current and projected evaluation of the impact of the demonstration project on access for Medicare beneficiaries with chronic inflammatory demyelinating polyneuropathy and Medicare beneficiaries with multifocal motor neuropathy to items and services needed for the in-home administration of intravenous immune globin that also draws upon information and data from the ongoing home infusion demonstration project for primary immunodeficiency diseases (Public Law 112–242) and the recent effort to provide an adequate coverage benefit for therapies infused through durable medical equipment (HCPCS CMS–1738–P); and

(2) a final analysis of the appropriateness of expanding or extending the demonstration project, or implementing a new methodology for payment for intravenous immune globulins in all care settings

under part B of title XVIII of the Social Security Act (42 U.S.C. 1395k et seq.), or augmenting existing benefits to provide proper access for home infusion of intravenous immune globulins, and, to the extent such analysis determines such an expansion, extension, or methodology appropriate, recommendations for such expansion, extension, or methodology, respectively, along with an explanation of how CMS intends to implement or otherwise provide such a permanent benefit or mechanism for access during the fifth year of the demo to ensure nondisruptions in care for impacted patients.

(h) DEFINITIONS.—In this section:

(1) DEMONSTRATION PROJECT.—The term ''demonstration project'' means the demonstration project conducted under this Act.

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

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