

Medicare Intravenous Immune Globulin (IVIG) Demonstration

(Updated October 24, 2017)

The Medicare Intravenous Immune Globulin (IVIG) Demonstration is being implemented 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 primary immune deficiency disease (PIDD).

Background

The IVIG Demonstration was initially authorized under section 101 of the “Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (P.L. 112-242)” as a three year demonstration. The statute authorizes an enrollment of up to 4000 Medicare beneficiaries and up to \$45 million to pay for services and costs to administer this demonstration. In addition, the statute mandates an independent evaluation and Report to Congress on the demonstration. The demonstration began October 1, 2014 and was initially scheduled to end on September 30, 2017. However, on September 29, 2017, the President signed legislation (Public Law No: 115-63) that extended the Medicare IVIG Demonstration through December 31, 2020.

Initiative Details

Under this demonstration, Medicare will provide a bundled payment under Part B for items and services that are necessary to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving home health care benefits. The demonstration only applies to situations where the beneficiary requires intravenous immune globulin for the treatment of PIDD, or is currently receiving subcutaneous immune globulin to treat PIDD and wishes to switch to intravenous immune globulin.

In order to participate in this demonstration, beneficiaries must complete and submit an application form. All applications must be signed by the beneficiary as well as his or her physician. Beneficiaries must meet specified eligibility requirements including being covered under the original Medicare fee-for-service program and not enrolled in a Medicare Advantage plan, have Part B, and require IVIG for the treatment of PIDD. Since the number of participants and funding for the demonstration are limited under the law, submission of an application does not guarantee that a beneficiary will be accepted to participate in the demonstration.

Services covered under the demonstration shall be provided and billed by the specialty pharmacies that provide the immune globulin drug, which is already covered under Medicare Part B. The new demonstration covered services will be paid as a single bundle and will be

subject to coinsurance and deductible in the same manner as other Part B services. Home health agencies are not eligible to bill for services covered under the demonstration but may still bill for services related to the administration of IVIG that are covered under the payment for a home health episode of care.

New applications for participation in the IVIG Demonstration are being accepted on a rolling basis until the demonstration reaches or is projected to reach the statutory limit on funding and/or enrollment. Completed applications received by the 15th of the month, if eligible, will have coverage effective the 1st of the next month. Completed applications received after the 15th of the month, if eligible, will have coverage effective the 1st of the second following month.

For More Information

For more information, please see the CMS Medicare IVIG Demonstration web site at: <http://innovation.cms.gov/initiatives/IVIG/>. For specific questions not answered in this fact sheet or on the website, please send an email to IVIGDemo@cms.hhs.gov