

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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Intravenous Immune Globulin (IVIG) Demonstration - Implementation

Note: This article was revised on June 2, 2016, to make suppliers aware that a new contractor is administering this demonstration. See article SE1610 at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1610.pdf> for more information.

Provider Types Affected

This MLN Matters® Article is intended for suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for Intravenous Immune Globulin (IVIG) drugs and services to Medicare beneficiaries.

Suppliers do not need to apply to participate in the demonstration as long as they meet all Medicare as well as other national, state, and local standards and regulations applicable to the provision of demonstration covered services.

Provider Action Needed

In this article, the Centers for Medicare & Medicaid Services (CMS) alerts providers to a three year demonstration to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of Primary Immune Deficiency Disease (PIDD). CMS has designed the IVIG demonstration to pay a bundled payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of PIDD. The demonstration will begin paying for services as

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of October 1, 2014, and will continue for three years, as long as funding remains available.

Background

Depending on the circumstances, traditional fee-for-service (FFS) Medicare covers some, or all, components of home infusion services. By special statutory provision, Medicare Part B covers IVIG for persons with PIDD who wish to receive the drug at home. Medicare does not separately pay for any services or supplies to administer the drug if the person is not homebound, and is otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office, in an outpatient hospital setting, or to self-administer the drug subcutaneously. Beneficiaries may also alternate between settings or drug formulations, if necessary, to accommodate travel or other personal situations.

IVIG Demonstration

The "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012" authorized the demonstration under Part B of Title XVIII of the Social Security Act. The demonstration is limited to no more than 4,000 beneficiaries, and the \$45 million budget covers benefit costs, as well as administrative expenses for implementation and evaluation. Participation is voluntary and may be terminated by the beneficiary at any time.

Under this demonstration, Medicare will issue under Part B a bundled payment for all 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. In processing all services and supplies needed for the administration of IVIG, CMS is not making any changes to existing coverage determinations to receive the IVIG drug in the home or for services and supplies that are otherwise not covered under the traditional FFS Medicare Part B benefit.

The demonstration only applies to situations where the beneficiary requires IVIG for the treatment of PIDD, or is currently receiving subcutaneous immune globulin to treat PIDD and wishes to switch to IVIG. This demonstration does not apply if the immune globulin is intended to be administered subcutaneously. Only those beneficiaries with PIDD who are eligible to receive IVIG under the current Medicare benefit (have Part B, and have traditional FFS Medicare) will be eligible to enroll in the demonstration and have the services paid under the new demonstration.

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This demonstration will not change how subcutaneous administration of immune globulin (SCIG) is covered and paid for under the traditional Medicare FFS program. Also, nothing in this demonstration will impact how IVIG is paid by Medicare for beneficiaries who are covered under a home health episode of care.

Beneficiaries participating in the demonstration shall not be restricted in any way from receiving Medicare covered IVIG, and non-demonstration Medicare covered related services from different providers at different times should they so choose. For example, a beneficiary receiving services under the demonstration at home may choose to switch and receive them at a doctor's office or outpatient department at any time. The beneficiary may switch back to receiving services under the demonstration as long as they are otherwise still eligible, and funding remains available.

Beneficiaries under hospice shall not be excluded from this demonstration, and their demonstration claims shall be processed in the same manner as other Medicare (non-demonstration) claims for hospice patients.

Beneficiaries covered under a home health episode of care may apply to participate in the demonstration but will not be eligible to have services paid for under the demonstration until after the home health episode of care has ended. Similarly, beneficiaries who are participating in the demonstration and subsequently become eligible to receive services under a home health episode of care will not be eligible to have services paid for under the demonstration for the period of time they are covered under such episodes.

Providers/suppliers billing for the services and supplies covered under the demonstration must meet all Medicare as well as other national, state, and local standards and regulations applicable to the provision of services related to home infusion of IVIG.

Beneficiary Eligibility

In order to pay for the new demonstration covered services, the following requirements must be met:

1. The beneficiary must be enrolled in the demonstration on the eligibility file provided by NHIC, Corp., the implementation support contractor (as of July 1, 2016, Noridian Healthcare Solutions, LLC is the support contractor);
2. The beneficiary must be eligible to have the IVIG drug paid for at home (has a diagnosis of PIDD) under the traditional Medicare benefit;
3. The beneficiary must be enrolled in Medicare Part B and not be enrolled in a Medicare Advantage plan (i.e. have traditional FFS Medicare coverage);

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4. The beneficiary must not be covered on the date of service in a home health episode (In such circumstances, the services are covered under the home health episode payment.)
5. The place of service must be the beneficiary's home or a setting that is “home like”.

Billing Details

A new “Q” code has been established for services, supplies, and accessories used in the home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration:

Q2052 – (Long Description) - Services, supplies, and accessories used in the home under Medicare Intravenous immune globulin (IVIG) demonstration.

Q2052- (Short Description) - IVIG demo, services/supplies.

The code is for use with the IVIG demo only and the jurisdiction for this code is DME MAC.

The new demonstration service code (Q2052) must be billed as a separate claim line on the same claim for the IVIG drug itself.

Specialty pharmacies will bill for the IVIG drug itself when intended for home administration by beneficiaries who are not homebound and not covered under a home health benefit episode. For those beneficiaries participating in the demonstration, specialty pharmacies shall bill for the demonstration covered services on the same claim as the drug itself. Claims for the demonstration bundled service (Q2052) billed in the absence of the “J” code for the IVIG drug will not be payable. The new demonstration covered services will be paid as a bundle and will be subject to coinsurance and deductible in the same manner as other Part B services.

For 2014, the nationwide Medicare allowable for Q2052 will be \$300 each time the IVIG is administered. (The 2016 payment rate for Q2052 is \$336.05.) While this is expected to be approximately monthly, it can be more or less frequent depending upon a patient’s medical need.

As with all DMEPOS claims, specialty pharmacies will bill these claims to the appropriate DME MAC jurisdiction based on the beneficiary’s state.

The following “J” codes (as updated by CR 8724) represent immune globulin drugs that are administered intravenously and payable in 2014 under Medicare Part B for services rendered in the home (or home-like setting) for beneficiaries with PIDD: Privigen, (J1459), Bivigam (J1556), Gammaplex (J1557), Gamunex (J1561), Immune Globulin Not Otherwise Specified (J1566 and J1599), Octagam (J1568), Gammagard liquid (J1569), and Flebogamma (J1572). Immune globulin drugs covered under

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Medicare Part B for administration in the home for patients with PIDD are subject to change; coverage of any drugs under the demonstration shall not differ from drugs that are eligible for payment under Part B for beneficiaries not enrolled in the demonstration.

Note: If the claim for IVIG is not otherwise payable under Medicare Part B, the Q2052 claim line is not payable under the demonstration. The claim for Q2052 must have the same place of service code on the claim line as the IVIG (J code) for which it is applicable. In cases where the drug is mailed or delivered to the patient prior to administration, the date of service for the administration of the drug (the “Q2052” claim line) may be no more than 30 calendar days after the date of service on the drug claim line.

If multiple administrations of IVIG are submitted on a single claim, each date of service for the administration of the drug (Q2052) must be on a separate claim line. If these requirements are not met, the claim will not be processed and Medicare will return a Group Code of CO (Contractual Obligation), a Remittance Advice Remarks Code (RARC) of M51 (Missing/incomplete/invalid procedure code(s)) and a Claim Adjustment Remarks Code (CARC) of B15 (This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated).

If a claim is submitted with the HCPCS Q2052 code and the beneficiary is not enrolled in the demonstration on the date of service, the claim will be denied with a RARC of M138 (Patient identified as a demonstration participant but the patient was not enrolled in the demonstration at the time services were rendered. Coverage is limited to demonstration participants.), a CARC of 96 (Non-covered charge(s)), and a Group Code of CO.

Coverage of demonstration services shall be subject to the usual coordination of benefit process and the usual Medicare Secondary Payer process as well.

Questions and Answers Relating to Supplier Eligibility

Question: Is the DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) Supplier required to be certified to bill the A/B MACs in order to provide the nursing component of the Q2052 - Services, Supplies and Accessories Used in the Home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration?

Answer: No. The DMEPOS supplier must currently be able to bill the DME MACs (enrolled and current with the National Supplier Clearinghouse) and meet all

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regulatory and statutory requirements. If a state requires licensure to furnish certain items or services, a DMEPOS supplier: Must be licensed to provide the item or service; and may contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs or from any other federal procurement or non-procurement programs.

Question: Can the supplier/pharmacy contract or subcontract nursing services for the administration of the IVIG to bill the Q2052 - Services, Supplies and Accessories Used in the Home under the Medicare Intravenous Immune Globulin (IVIG) Demonstration?

Answer: Yes. If a state requires licensure to furnish certain items or services, a supplier/pharmacy: Must be licensed to provide the item or service; and may contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other federal procurement or non-procurement programs.

How Beneficiaries can apply for the IVIG Demonstration

To participate in this demonstration the beneficiary must complete and submit an application form. All applications must be signed by the beneficiary as well as his or her physician. **Submission of an application does not guarantee that a beneficiary will be accepted to participate in the demonstration.**

CMS has contracted with NHIC, Corp., DME MAC Jurisdiction A, (NHIC is being replaced by Noridian as of July 1, 2016) to help administer the demonstration. NHIC (Noridian, effective July 1, 2016) will review all applications for eligibility and will create and upload an enrollment file to be used by CMS' claims processing systems.

CMS conducted an initial enrollment period from 8/08/2014 – 9/12/2014.

Since the number of beneficiaries and funds available to implement this demonstration are limited, not all beneficiaries who are eligible may be accepted if more eligible beneficiaries apply than can be served with the funds available. If the number of eligible beneficiaries that apply during the initial enrollment period is below the statutory limits, then additional applications will continue to be accepted after the 9/12/2014 deadline on a rolling basis until enrollment and/or funding limits are reached. As of June 2016, Medicare is continuing to

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accept applications from beneficiaries on a rolling basis. This will continue as long as the funding or enrollment limitations are not reached or until the demonstration ends, whichever occurs sooner. The last date to submit an application for coverage prior to September 30, 2017 (when the demonstration is scheduled to end) is August 15, 2017.

Until June 24, 2016, the enrollment application and the application completion guide are available at: <http://www.medicarenhic.com> or through the IVIG Demo Hot Line at: (844)-625-6284.

As of June 24, 2016, the enrollment application and the application completion guide will be available at <http://med.noridianmedicare.com/web/ivig>.

Until June 23, 2016, completed applications may be submitted by fax or mail to NHIC, Corp. at the following address:

Applications may be mailed to:

NHIC, Corp.

IVIG Demo

P.O. Box 9140

Hingham, MA. 02043-9140

For overnight mailings:

NHIC, Corp

IVIG Demo

75 William Terry Dr.

Hingham, MA. 02043

Applications may be faxed to:

Fax 781-741-3533

As of June 24, 2016, completed applications may be submitted by fax or mail to Noridian.

Applications may be mailed to:

Noridian Healthcare Solutions, LLC

IVIG Demo

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PO Box 6788
Fargo ND 58108-6788

For overnight mailings:
Noridian Healthcare Solutions, LLC
IVIG Demo
900 42nd Street South
Fargo ND 58103

Applications may be faxed to:
Fax 701-277-2428

Additional Information

If you have any questions, please contact your DME MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

MLN Matters article SE1610 at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1610.pdf> contains details on submitting applications to Noridian, the new support contractor, as of July 1, 2016.

Document History

- July 31, 2014 - Initial issuance.
- August 28, 2014 - revised to amend some of the billing instructions, particularly with regard to date of service on the Q2052 claim line. Also, some questions and answers related to supplier eligibility are added to the article.
- June 2, 2016 - Revised to add a link to SE1610, which announces a new contractor administering the demonstration, and to update the article to reflect the new contractor's information.

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