

## Intravenous Immune Globulin Demonstration (Demonstration Ends on December 31, 2023)

### INTRODUCTION

This fact sheet educates Medicare suppliers on the Intravenous Immune Globulin (IVIG) demonstration and gives information on:

- Supplier eligibility and participation
- Beneficiary eligibility and participation
- Billing and coding requirements

The IVIG demonstration began in October of 2014 and has been extended twice by Congress. The demonstration will now end on December 31, 2023. All beneficiaries enrolled in the demonstration as of November 15, 2020, are automatically re-enrolled in the demonstration for the extension period, and don't need to take any action. Suppliers can continue to provide and be paid for demonstration services to these beneficiaries on or after January 1, 2021.

In accordance with the existing requirements of the demonstration, CMS is continuing to accept new enrollment into the demonstration. You may also check the [IVIG demonstration website](#) for more information, and applications can be found under "Additional Information".

### BACKGROUND

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. Participation is voluntary and the beneficiary may end participation at any time.

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 Primary Immune Deficiency Disease (PIDD) who wish to get the drug at home. Medicare doesn't separately pay for any services or supplies to give the drug if the person isn't homebound, and is otherwise getting services under a Medicare Home Health episode of care. As a result, many beneficiaries chose to get the drug at their doctor's office, in an outpatient hospital setting, or to self-apply the drug under the skin. Beneficiaries may also alternate between settings or drug formulations, if necessary, to accommodate travel or other personal situations.

The purpose of this demonstration is to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of PIDD. We designed the IVIG demonstration to pay a bundled payment for items and services needed for the in-home IVIG administration for the treatment of PIDD. The demonstration is set to end on December 31, 2023.

Under this demonstration, Medicare makes a bundled Part B payment for all items and services that are necessary to give IVIG in the home. We make the payment for enrolled beneficiaries who aren't otherwise homebound and getting home health care benefits. We aren't changing existing coverage determinations to get the IVIG drug in the home. There are no policy changes for services and supplies that Medicare doesn't cover under the FFS Medicare Part B benefit.

The demonstration only applies to situations where the beneficiary wants to switch to IVIG and currently:

- Requires IVIG for the treatment of PIDD
- Receives under the skin immune globulin to treat PIDD and wishes to switch to IVIG

This demonstration doesn't apply if the immune globulin is given under the skin. Only those beneficiaries with PIDD who are eligible to receive IVIG under the current Medicare benefit (have Part B and traditional FFS Medicare) are eligible to enroll in the demonstration and have Medicare pay for the services under the demonstration.

This demonstration doesn't change how Medicare covers and pays for under the skin administration of immune globulin (SCIG) under FFS. Also, nothing in this demonstration will impact how Medicare pays for IVIG for beneficiaries who are under a Medicare home health episode of care.

Medicare won't restrict beneficiaries participating in the demonstration in any way from getting Medicare covered IVIG, and non-demonstration Medicare covered related services from different providers at different times should they so choose. For example, a beneficiary getting services under the demonstration at home may choose to switch and get them at a doctor's office or outpatient department at any time. The beneficiary may switch back to getting services under the demonstration as long as they're still eligible, and funding remains available.

Beneficiaries under hospice aren't excluded from this demonstration. We'll process their demonstration claims 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. They won't be eligible to have services paid for under the demonstration until after the home health episode of care ends. Similarly, beneficiaries who are participating in the demonstration and then become eligible to get services under a home health episode of care won't be eligible to have services paid for under the demonstration for the period of time they're covered under such episodes.

## SUPPLIER ELIGIBILITY & PARTICIPATION

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Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 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
- Be enrolled and current with the National Supplier Clearinghouse
- Be able to bill the DME Medicare Administrative Contractors (MACs)

If a state requires licensure to give certain items or services, a DMEPOS supplier:

- Must be licensed to provide the item or service
- May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law
- Can't 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

## BENEFICIARY ELIGIBILITY & PARTICIPATION

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In order to pay for the new demonstration covered services, the beneficiary must meet the following requirements:

- Be enrolled in the demonstration
- Be eligible to have the IVIG drug paid for at home under FFS
- Have a diagnosis of PIDD
- Have active Medicare Part B and aren't enrolled in a Medicare Advantage plan
- Can't be in a home health episode of care on the date of service (In such circumstances, the home health episode payment covers the services.)
- Get the service in their home or a setting that is "home like"

To participate in this demonstration, the beneficiary must complete and submit an application form. They must sign the application and have their physician sign as well. Submission of an application doesn't guarantee that Medicare will accept the beneficiary into the demonstration.

CMS contracts with Noridian Healthcare Solutions, LLC, to help administer the demonstration. Noridian reviews all applications for eligibility and will create and upload an enrollment file for use by Medicare's claims processing systems.

An enrollment application and the application completion guide are available at <http://med.noridianmedicare.com/web/ivig>.

The initial enrollment period ended on November 15, 2020. However, under the most recent extension, we're accepting new applications for participation on a rolling basis until November 15, 2023, or until the demonstration reaches, or is projected to reach, the statutory limit on funding and/or enrollment. We'll notify beneficiaries within 10 calendar days of receipt of a complete application, of their status and the effective date of their coverage under the demonstration.

- Completed applications we receive by the 15th of the month, if eligible, will have coverage effective the 1st of the following month.
- Completed applications we receive after the 15th of the month, if eligible, will have coverage effective the 15th of the following month.

For example, if an application is received on September 15th, coverage will be effective October 1st. If an application is received on September 20th, coverage will be effective October 15th.

Beneficiaries may send applications by fax or mail to Noridian.

You may mail applications to:

Noridian Healthcare Solutions, LLC  
IVIG Demo  
PO Box 6788  
Fargo ND 58108-6788

For overnight mailings:

Noridian Healthcare Solutions, LLC  
IVIG Demo  
900 42nd Street South  
Fargo ND 58103

You may fax applications:

Fax 701-277-2428

## **BILLING & CODING REQUIREMENTS**

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We had established a "Q" code for services, supplies, and accessories used in the home under the 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 demonstration only. Both the HCPCS code Q2052 and the demonstration number of 71 must be on the claim or the claim will reject. The jurisdiction for this code is DME MAC.

You must bill Q2052 as a separate claim line on the same claim for the IVIG drug itself.

Specialty pharmacies will bill for the IVIG drug itself when the drug is for home administration by beneficiaries who aren't homebound and aren't under a covered home health benefit episode. For those beneficiaries participating in the demonstration, specialty pharmacies will 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 aren't payable. Medicare will pay for the demonstration covered services as a bundle. Coinsurance and deductible will apply in the same manner as for other Part B services.

For 2021, the nationwide Medicare allowable rate for Q2052 is \$381.57 each time the IVIG is administered. (The 2020 payment rate for Q2052 is \$374.20.) While we expect this 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 represent immune globulin drugs that are given intravenously and payable under Medicare Part B for services provided 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)
- Flebogamma (J1572)

Immune globulin drugs covered under Medicare Part B for administration in the home for patients with PIDD are subject to change. Coverage of any drugs under the demonstration won't differ from drugs that are eligible for payment under Part B for beneficiaries who aren't enrolled in the demonstration.

**Note:** If the claim for IVIG isn't otherwise payable under Medicare Part B, the Q2052 claim line isn't 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's 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 you submit multiple administrations of IVIG on a single claim, each date of service for the administration of the drug (Q2052) must be on a separate claim line. If you don't follow these requirements, Medicare won't process the claim and will return:

- Group Code of CO (Contractual Obligation)
- Claim Adjustment Reason 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.)
- Remittance Advice Remark Code (RARC) of M51 (Missing/incomplete/invalid procedure code(s))

If you submit a claim with the HCPCS Q2052 code and the beneficiary isn't enrolled in the demonstration on the date of service, we'll deny the claim with the following messages:

- Group Code of CO
- CARC of 96 (Non-covered charge(s))
- RARC of M138 (Patient identified as a demonstration participant but the patient wasn't enrolled in the demonstration at the time services were provided. Coverage is limited to demonstration participants.)

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

## RESOURCES

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### Noridian Resources

- [Beneficiary-Information](#)
- [Provider-and-Supplier-Information](#)

### CMS Resources

- [Beneficiary FAQs](#)
- [Supplier FAQs](#)

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