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

What's Changed?

- Updated 2022 and 2023 payment rates for Q2052 (page 4)
- Added claims adjustment language for updated payment rates (page 5)

You'll find substantive content updates in dark red.

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

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

The IVIG demonstration started in October 2014 and will end on December 31, 2023. CMS automatically re-enrolled all patients enrolled in the demonstration as of November 15, 2020. They don't need to take any action. Suppliers continue to provide and get paid for demonstration services to these patients on or after January 1, 2021.

We're accepting new enrollment into the demonstration according to existing requirements. Check the IVIG demonstration website for more information. Applications are available in the "Additional Information" section of that website.

What's the IVIG Demonstration?

The Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 authorized the demonstration under Medicare Part B of Title XVIII of the Social Security Act. Participation is voluntary, and patients may end participation at any time.

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 Primary Immune Deficiency Disease (PIDD).

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This demonstration is for patients with PIDD who wish to get the drug at home.

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

- Requires IVIG for the treatment of PIDD
- Gets 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 patients with PIDD who are eligible to receive IVIG infusions under the current Medicare benefit (have Part B and traditional Fee-for-Service (FFS) Medicare) are eligible to enroll in the demonstration.

Under this demonstration, we make a bundled Part B payment for all items and services that are necessary to provide IVIG in the home for the treatment of PIDD. Patients 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, patients participating in the demonstration who 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.

We won't restrict patients participating in the demonstration 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 patient getting services under the demonstration at home may choose to switch and get them:

- At their doctor's office
- In an outpatient setting
- In an infusion center

Supplier Eligibility & Participation

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 provide 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's currently excluded from the Medicare Program, any state health care programs, or from any other federal procurement or non-procurement programs

Patient Eligibility & Participation

In order to participate in the demonstration-covered services, patients must meet the following requirements:

- Be eligible to have the IVIG drug paid for at home under Part B FFS
- Have a diagnosis of PIDD
- Not be 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's "home like"

To participate in this demonstration, the patient 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 we'll accept the patient into the demonstration.

We contract with Noridian Healthcare Solutions, LLC, to help manage 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.

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 or enrollment. We'll notify patients within 12 business days of receipt of a complete application of their status and effective date of their coverage under the demonstration.

Completed applications we get:

- By the 15th of the month, if eligible, will have coverage effective the 1st of the next month
- After the 15th of the month, if eligible, will have coverage effective the 15th of the next month

For example, if we get an application on September 15, coverage will be effective October 1. If we get an application on September 20, coverage will be effective October 15.

Patients may send applications by fax or mail to Noridian.

Mail 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

Fax: 701-277-2428

Billing & Coding Requirements

We 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. The HCPCS code Q2052 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.

Specialty pharmacies will bill for the IVIG drug when the drug is for home administration by patients who aren't:

- Homebound
- Under a covered home health patient episode

Specialty pharmacies will bill for the demonstration-covered services on the same claim as the IVIG drug for patients participating in the demonstration. **Claims for the demonstration bundled service (Q2052) billed in the absence of the "J" code for the IVIG drug aren't payable**. We'll 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 2023, the updated nationwide Medicare allowable rate for Q2052 is $408.23 each time the IVIG is administered. (The updated 2022 payment rate is $392.25, and the 2021 payment rate for Q2052 was $381.57.) While we expect this to be approximately monthly, it can be more or less frequent depending upon a patient's medical need. Specialty pharmacies will bill these claims to the appropriate DME MAC jurisdiction based on the patient's state.

Updated 2022 and 2023 payment rates reflect the national per-visit payment amount for home health agencies (HHAs) that submit required quality data. This is the same process we used before 2022. Your MAC will adjust all claims with HCPCS code Q2052 and demonstration number 71 with a date of service on and after January 1, 2022, paid prior to updating the payment rates for 2022 and 2023. You don't need to take any action. The rate adjustments for these claims are:

- $392.25 for 2022 (increased from previous rate of $384.59 — difference of $7.66)
- $408.23 for 2023 (increased from previous rate of $392.56 — difference of $15.67)

The following "J" codes represent immune globulin drugs that are given intravenously and payable under Part B for services you provide in the home (or home-like setting) for patients with PIDD:

- Privigen (J1459)
- Asceniv (J1554)
- 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 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 patients who aren't enrolled in the demonstration.

Note: If the claim for IVIG isn't otherwise payable under 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 before administration, the date of service for the administration of the drug (the "Q2052" claim line) can't be 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, we 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 patient 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 benefits process and the usual Medicare Secondary Payer process as well.

Resources

Noridian

- Beneficiary Information
- Provider and Supplier Information

CMS

- Beneficiary FAQs
- Supplier FAQs