

June 2, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: HCPCS Level II Public Meeting – Proposed HCPCS Coding Changes for Immune Globulin Products

Dear Administrator Oz:

The National Home Infusion Association (NHIA) appreciates the opportunity to provide oral comment for the Healthcare Common Procedure Coding System (HCPCS) Level II public meeting that is scheduled for June 1. These written comments are intended to elaborate on NHIA's positions and recommendations shared in the public comment meeting. NHIA is a trade association representing providers of home and alternate site infusion therapies, as well as manufacturers and suppliers of infusion products and services. As the leading voice for the home and alternate site infusion community, we write to share our feedback regarding CMS's proposed HCPCS coding changes for Immune Globulin (Ig) products. Our comments are focused on the Ig products commonly administered in the home and alternative site environments.

Background

CMS has proposed significant changes to HCPCS billing codes and billing units for immune globulin therapies that unless otherwise specified by CMS, are scheduled to become effective January 1, 2027. The proposed changes primarily involve revisions to existing immune globulin HCPCS codes and significant changes to billing units and descriptors for intravenous immune globulin (IVIG) products. Specifically, many immune globulin products (see Appendix A), which are currently billed in 500 mg increments, would transition to smaller 100 mg or 200 mg billing units, accompanied by entirely new HCPCS codes.

NHIA appreciates that CMS has requested public comment on the language used in the code descriptors for new HCPCS Level II codes that CMS established in the last quarter of 2025 and first quarter of 2026 "for Various FDA Approvals under a 505(b)(2) or Biologics License Application (BLA) Pathways and Products 'Not Otherwise Classified.'"

NHIA Position:

The proposed changes to HCPCS billing codes and billing units for immune globulin therapies would create significant operational, administrative, reimbursement, and patient care challenges across the healthcare system without providing material clinical benefit to patients or savings. For the reasons discussed below, NHIA strongly opposes these changes and respectfully requests that CMS not move forward with this proposal.

Summary of NHIA Recommendations to CMS on Proposed HCPCS Code Changes for Immune Globulin Products

1. Do Not Move Forward with the Proposed Changes
 - NHIA recommends CMS abandon the proposal entirely because it would create widespread disruption without meaningful patient benefit or cost savings.
2. Standardize Billing Units if Changes Proceed
 - If CMS abandons the proposal as recommended, then modify the units for Yimmugo to be consistent (500mg) with other IV products.
 - If CMS proceeds with modifying HCPCS billing units, NHIA recommends standardizing all immune globulin products to a consistent 100 mg billing unit across all products to reduce confusion and administrative complexity.
3. Evaluate Certain HCPCS Codes Separately
 - NHIA recommends that HCPCS codes J0850, J7504, and J7511 be excluded from the broader immune globulin proposal and evaluated independently because they are not therapeutically used in the same manner as other Ig products.
4. No Objection to Removing Route of Administration
 - NHIA does not oppose CMS's proposal to remove route-of-administration distinctions from the HCPCS code descriptors, noting this is consistent with existing CMS coding practices.
5. Delay the Implementation Timeline
 - NHIA recommends delaying implementation by an additional 18 months beyond the proposed January 1, 2027, effective date.
 - Provide at least six months of lead time before implementation of any new codes or billing units.
 - NHIA also requests additional stakeholder engagement and a second public comment opportunity if the proposal is revised.
6. Provide greater transparency regarding the rationale and intended benefits of the coding changes, and make all comments submitted to CMS related to this proposal publicly available.
7. Allow a one-year overlap period where both current and new HCPCS codes remain active simultaneously to support smoother transitions.

8. Require all payers to honor existing orders and prior authorizations during the transition period through automatic code crosswalk logic.
9. Publish clear HCPCS crosswalks for ASP well in advance of implementation.

NHIA Rationale:

Potential Patient Access Disruptions

NHIA notes that Ig therapies are life-sustaining treatments for patients with primary immunodeficiency (PI), chronic inflammatory demyelinating polyneuropathy (CIDP), multifocal motor neuropathy (MMN), myasthenia gravis, dermatomyositis, transplant-related conditions, and other serious diseases. In addition, patients with other immune-mediated neurologic and immunologic diseases may experience interruptions in care if authorizations, claims, or billing systems are delayed during implementation. Delays in therapy can result in hospitalization, irreversible loss of function, emergency care utilization, and significantly higher downstream healthcare costs.

Increased Risk of Denials, Delays, and Compliance Exposure

Simultaneously replacing HCPCS codes and modifying billing units creates substantial reimbursement and compliance risks. These could include increased claim denials and appeals activity during implementation, underpayments or payment delays if payer fee schedules and claims systems are not updated in a timely manner, and incorrect unit conversion by clearinghouses or billing systems. Compliance risks also could result from overbilling or underbilling resulting from inaccurate unit calculations, and an increased risk of RAC audits, payer recoupments, and fraud flagging exposure due to abnormal unit utilization patterns. EMRs retaining outdated code/unit information would no longer be accurate after implementation of the proposed changes.

These risks are especially concerning because immune globulin therapies are high-cost medications to treat chronic conditions frequently subject to prior authorization, utilization management, and audit review.

Significant Administrative and Operational Burden with No Corresponding Benefit

The proposed coding changes, if implemented, would create a cascade of widespread operational, reimbursement, claims processing, and systems disruptions for infusion pharmacies, physicians, manufacturers, payers, and patients receiving immune globulin therapies, for no meaningful benefit.

The proposed coding changes would require extensive operational updates for infusion pharmacies, physicians, hospitals, payers, and manufacturer systems. This policy will touch every system and process employed by entities that provide Ig products to patients, including but not limited to:

- Prior authorizations which would require review and potential reapproval to update to both HCPCS codes and approved billing units.
- Existing prior authorization templates and payer policy documents would become obsolete and require redevelopment.
- Payer contracts would require amendments to recognize and reimburse under the new coding structure.
- Medically Unlikely Edits (MUEs) would require reconfiguration and testing across payer claims systems.
- EMR/EHR systems, infusion software, revenue cycle platforms, and clearinghouses would require programming changes and validation testing.
- Charge description masters (CDMs), inventory systems, and billing platforms would require updates.
- Referral sources and physician offices would need to be educated regarding updated codes and billing requirements.
- Medicare Local Coverage Determinations and Policy Articles would require updating.
- Average Sales Price (ASP) publication for new HCPCS code may be delayed.
- Medicare and commercial payer policy alignment that may not occur simultaneously, creating operational complexity for organizations serving multiple payer types.

Note: Commercial payers frequently lag CMS implementation timelines when updating fee schedules and claims processing systems.

CMS Burden Reduction and Interoperability Goals

CMS's proposal appears difficult to reconcile with the agency's broader efforts to reduce administrative burden and advance interoperability through initiatives such as Patients Over Paperwork, administrative simplification policies, prior authorization and interoperability reforms, and electronic prior authorization requirements. Implementing broad HCPCS and billing unit changes without a clear transition strategy will create additional operational challenges for providers and potentially disrupt continuity of care. Additionally, many payers rely on HCPCS-based drug reimbursement to fulfill prior authorization requirements and

changes to HCPCS codes and billing units may invalidate existing authorizations and necessitate resubmission.

Manufacturer and Industry-Wide Impact

Manufacturers and support organizations would also face significant operational burden, including updates to rewriting and educating on drug specific billing and coding guides, copy assistance programs and bridge programs. Average Sales Price (ASP) reporting and publication, utilization tracking and trending, forecasting, and financial reporting will also be disrupted due to changes in units and reimbursement methodologies. It appears the current implementation timeline will at a minimum, create a quarterly gap where no ASP exists for the newly created codes. In addition, smaller providers and independent infusion organizations may experience disproportionate financial and operational strain due to limited IT and reimbursement resources.

Unnecessary Complexity from Proposed Unit Structure

The current HCPCS structure functions effectively for all stakeholders. SCIG products have a consistent unit of measure of 100 mg, and (except for Yimmugo) IVIg a consistent unit of measure of 500 mg. CMS's proposal introduces inconsistent billing units across immune globulin products, with some changing from 500 mg to 100 mg units and others from 500 mg to 200 mg units.

The lack of a standardized unit of measure increases the likelihood of data entry errors, unit conversion errors, medication dosing errors, authorization errors, billing denials, appeals activity, patient safety concerns, and inaccurate reimbursement.

In practice, intravenous immune globulin therapy is generally prescribed and operationalized in grams, not in fractional milligram increments. Most adult IVIG dosing ranges from approximately 30–90 grams per dose, with the most frequent dosing being between 30 and 50 grams, depending on diagnosis, route of administration, infusion schedule, and patient tolerance. SCIG dosing similarly occurs in clinically meaningful gram-based dosing patterns, with smaller doses administered more frequently.

The current 500 mg unit of measure (UOM) is functioning effectively and aligns with existing clinical and operational practices. While IVIG dosing can be prescribed on a grams-per-kilogram basis, doses (all of which are divisible by 500 mg) are typically rounded to the nearest available vial size to reduce waste. Therefore, the current UOM supports accurate billing without generating product waste.

The proposed modification of the UOM would introduce significant administrative burden by requiring new, less standardized system modifications for providers, suppliers, payers, and claims processing systems. These burdens would be incurred across the entire healthcare system

without evidence for improved program integrity or the creation of meaningful savings for the Medicare Trust Fund.

CMS should first demonstrate that a substantial and widespread billing problem exists before pursuing the changes proposed in this letter. Any policy change of this magnitude should be supported by clear evidence that the current 500 mg unit of measure is creating significant billing inaccuracies, reimbursement issues, or program integrity concerns that cannot be addressed through less disruptive means. We respectfully urge CMS to carefully evaluate the costs and operational impacts of this proposal relative to its anticipated benefits and to retain the current 500 mg UOM.

NHIA Recommendation Regarding Billing Units:

CMS should maintain the current 500 mg unit of measure. However, if CMS proceeds with the proposed changes to HCPCS billing units for immune globulin therapies, then the units should be standardized across all products to 100mg.

Furthermore, we recommend that CMS reevaluate the statement that only 999 units can appear on a claim line per date of service for Original Medicare using the CMS-1500 form. Box 24G on the CMS-1500 form allows 4 digits, or 9,999 units.

Certain Codes Should Be Evaluated Separately

NHIA's comments outlined above do not pertain to codes J0850, J7504, and J7511 as they are not therapeutically used in the same manner as other immune globulin products. These drugs and codes should be separated and evaluated independently because including them within the broader immune globulin proposal creates confusion and complicates stakeholder review. NHIA comments are focused on the other Ig HCPCS codes listed in Appendix A.

NHIA Recommendation Regarding Product Evaluation:

NHIA recommends that HCPCS codes J0850, J7504, and J7511 be evaluated separately from the other immune globulin products, as they are not used in the same therapeutic manner.

Route of Administration

CMS states that it has a long-standing practice of assigning dose descriptors in the smallest amount that could be billed in multiple units to accommodate a range of doses and support streamlined billing. In addition, to allow for multiple routes of administration for the same product, CMS typically creates codes for products themselves, without specifying a route of administration in the code descriptor. CMS proposes to modify the existing Ig HCPCS codes to

remove the route of administration from the HCPCS description. Providers and suppliers routinely use the JA and JB modifiers on claims to distinguish intravenous vs. subcutaneous routes of administration.

NHIA Recommendation Regarding Changes to the Route of Administration:

NHIA does not object to the proposal to remove the route of administration from the existing HCPCS descriptions, which will be consistent with its policies in this area.

Implementation Timeframe

A proposed effective date of January 1, 2027, adds significant administrative burden to an already busy time of year for patients and payers that calls for excess workflow for activities including annual insurance changes, formulary updates, and deductible resets. NHIA is concerned that providers will not have adequate resources to address the conversion should CMS move forward with the current timeline. Shifting to a mid-year (July 1, 2028) implementation would allow providers to sufficiently prepare and identify the resources needed. This extended timeline also ensures CMS can fully consider stakeholder input, solicit additional comment, and provide a minimum of 6 months lead-time from final determination to implementation.

NHIA Recommendation Regarding the Implementation Timeframe:

NHIA recommends CMS revisit the proposal and delay the implementation date an additional 18 months to allow for further stakeholder input, including a second comment opportunity should the proposal be revised.

Additional NHIA Recommendations:

Again, the proposed changes to HCPCS billing codes and billing units for immune globulin therapies would create significant operational, administrative, reimbursement, and patient care challenges across the healthcare system without providing clinical benefit to patients or savings. NHIA strongly opposes these changes and respectfully requests that CMS not move forward with this proposal.

If CMS moves forward with this proposal, NHIA additionally recommends that the agency:

- Provide additional transparency regarding the rationale for these changes so stakeholders can better understand the intended benefits and implementation goals associated with this significant operational investment.
- Make all comments CMS receives related to this proposal publicly available.

- Allow an overlap period where both existing and new HCPCS codes remain active simultaneously for a one-year period to allow for a smoother transition. While rare, there is precedent for a drug having two HCPCS codes with different units of measure, example: J1950 - Leuprolide Acetate, 3.75 mg and J9217 - Leuprolide Acetate, 7.5 mg.
- Require all payers to honor existing orders and prior authorizations during the transition period through automatic code crosswalk logic.
- Publish clear HCPCS crosswalks for ASP well in advance of implementation.

Summary

While standardization and modernization efforts are important, the proposed HCPCS coding and billing unit changes for immune globulin products would create substantial operational disruption and financial risk across the healthcare system, with little to no benefit to patients or CMS. CMS should abandon this proposal and work with affected stakeholders on any potential new coding changes.

For questions or additional information, please contact Bill Noyes, NHIA's Senior Vice President of Reimbursement Policy at bill.noyes@nhia.org .

Sincerely,

Connie Sullivan

Connie Sullivan, B.S. Pharm
President and
Chief Executive Officer

Appendix A

| Existing HCPCS Codes being Deleted | | New HCPCS Effective Jan. 1, 2027 | |
|---|--|---|---|
| HCPCS_Cd | HCPCS_Desc | HCPCS_Cd | HCPCS_Desc |
| J1459 | Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg | J1461 | Injection, immune globulin (privigen), 200 mg |
| J1552 | Injection, immune globulin (alyglo), 500 mg | J1578 | Injection, immune globulin (alyglo), 100 mg |
| J1553 | Injection, immune globulin (yimmugo), 100 mg | J1553 | Injection, immune globulin (yimmugo), 100 mg |
| J1554 | Injection, immune globulin (asceniv), 500 mg | J1579 | Injection, immune globulin (asceniv), 100 mg |
| J1556 | Injection, immune globulin (bivigam), 500 mg | J1581 | Injection, immune globulin (bivigam), 100 mg |
| J1557 | Injection, immune globulin, (gammplex), intravenous, non-lyophilized (e.g., liquid), 500 mg | J1582 | Injection, immune globulin, (gammplex), 100mg |
| J1561 | Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg | J1583 | Injection, immune globulin, (gamunex-c/gammaked), 200 mg |
| J1566 | Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg | J1584 | Injection, immune globulin, lyophilized (e.g., powder), not otherwise specified, 100 mg |
| J1568 | Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg | J1585 | Injection, immune globulin, (octagam), 200 mg |

| Existing HCPCS Codes being Deleted | | New HCPCS Effective Jan. 1, 2027 | |
|---|---|---|---|
| J1569 | Injection, immune globulin, (gammagard liquid, gammagard liquid erc), non-lyophilized, (e.g., liquid), 500 mg | J1586 | Injection, immune globulin, (gammagard liquid, gammagard liquid erc), 200 mg |
| J1572 | Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg | J1587 | Injection, immune globulin, (flebogamma/flebogamma dif), 200 mg |
| J1576 | Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg | J1588 | Injection, immune globulin (panzyga), 200 mg |
| J1599 | Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg | J1589 | Injection, immune globulin, non-lyophilized (e.g., liquid), not otherwise specified, 200 mg |