



June 3, 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 Association of Specialty Pharmacy (NASP) appreciates the opportunity to provide comments regarding the Centers for Medicare & Medicaid Services' (CMS) proposed HCPCS coding changes for immune globulin (Ig) products.

NASP represents the specialty pharmacy industry, including specialty pharmacies, pharmaceutical manufacturers, wholesalers and distributors, some PBMs, GPOs, patient advocacy organizations, cold chain management and logistics providers and data and technology companies that provide comprehensive high-touch patient care services for individuals with complex, chronic and rare medical conditions requiring to life-sustaining immune globulin therapies.

NASP is concerned about any policy decision that could impede patient access to medically necessary therapies by introducing significant changes to established operational processes without a clearly demonstrated and fully understood benefit to Medicare beneficiaries, providers, or the Medicare program.

While NASP appreciates CMS's efforts to evaluate and modernize HCPCS coding structures, we urge the Agency to carefully consider the potential downstream consequences of these proposed changes. Immune globulin therapies are critical treatments for patients with primary immunodeficiency disorders, chronic inflammatory demyelinating polyneuropathy (CIDP), multifocal motor neuropathy (MMN), myasthenia gravis, and numerous other serious immune-mediated conditions. For these patients, delays in therapy can result in disease progression, avoidable hospitalizations, increased healthcare utilization, and diminished quality of life.

The proposed changes would require substantial modifications across healthcare delivery systems, including updates to prior authorization processes, reimbursement systems, electronic medical records, claims adjudication platforms, payer policies, and provider workflows. Such changes create a



meaningful risk of disruptions in treatment access, particularly during implementation and transition periods.

NASP is particularly concerned that stakeholders have not been provided with sufficient information regarding the intended benefits of these changes and how those benefits outweigh the significant operational burden and patient access risks associated with implementation. Before moving forward, CMS should clearly articulate:

- The specific problem the proposed coding changes are intended to address;
- The anticipated benefits to Medicare beneficiaries, providers, and the Medicare program;
- The expected impact on patient access and continuity of care;
- The measures CMS will implement to mitigate disruptions during any transition period.

At present, it is not clear that the proposed changes will improve patient outcomes, reduce administrative burden, enhance program integrity, or generate meaningful savings. Conversely, there is substantial concern that implementation could increase complexity for providers and payers while creating barriers to timely treatment access for vulnerable patient populations.

NASP believes that any policy changes affecting specialty therapies should be evaluated through the lens of patient access and continuity of care. Changes that create additional administrative complexity without a corresponding and clearly demonstrated benefit risk undermining the shared goal of ensuring patients receive the therapies they need when they need them.

Accordingly, NASP urges CMS to carefully reconsider the proposal and engage in additional stakeholder dialogue before finalizing any changes. If CMS elects to proceed, we strongly recommend a phased implementation approach, extensive stakeholder education, transparent communication regarding expected benefits, and safeguards to ensure existing prior authorizations and patient treatment regimens are not disrupted.

NASP appreciates CMS's commitment to improving healthcare delivery and stands ready to work collaboratively with the Agency to identify solutions that promote efficiency while preserving patient access to critical specialty therapies.

Thank you for your consideration of these comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sheila Arquette", with a large, stylized flourish at the end.

Sheila M. Arquette, RPh
President & CEO