

September 4, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted electronically via Regulations.gov

RE: CY 2025 Payment Policies under the Medicare Physician Fee Schedule (PFS) and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure:

The undersigned organizations provide in-office drug administration services to Medicare beneficiaries and write in response to your proposal and request for information on non-chemotherapy administration, included as part of the aforementioned proposed rule.

Valuation of Services: Non-Chemotherapy Administration

We commend CMS for its proactive approach in addressing the challenges associated with the "Billing and Coding Articles" established by Medicare Administrative Contractors (MACs) that have led to the down-coding and restriction of payment for complex and non-chemotherapeutic drug administration services (CPT codes 96401-96549). CMS's efforts, including those listed below, have been instrumental in mitigating the negative impacts of such coding policies:

- issuing a Technical Direction Letter (TDL) on August 12, 2022, directing MACs to "pause" down-coding;
- releasing Transmittal 12397 on December 21, 2023, to publicly share the substance of the TDL;
- ensuring the retirement of "Billing and Coding Articles" that instructed physician practices to down-code; and
- soliciting public feedback through the Request for Information (RFI) in the CY 2024 Medicare PFS proposed rule.

Proposed Manual Changes

CMS proposes modifications to its Medicare Claims Processing Manual, Chapter 12, section 30.5, to include language currently consistent with CPT code definitions for the complex non-chemotherapy infusion code series stating that the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549. CMS explains that this would allow the MACs to consider:

- the need for staff with advanced practice training and competency, such as, a physician or other qualified health care professional to monitor the patient during these infusions due to the incidence of severe adverse reactions, and
- special considerations for preparation, dosage, or disposal for these infusion drugs.

We appreciate CMS's recognition that these complex services involve significant patient risks, necessitating frequent consultation with a physician or qualified healthcare professional. Multiple drugs used as response modifiers in Rheumatology, Allergy/Asthma/Immunology, Gastroenterology and other specialties share many of the complex monitoring needs and potentially debilitating or even fatal adverse effects as drugs used for Chemotherapy. The proposed updates to the Manual will provide MACs with the necessary clinical criteria to make informed payment determinations, thereby enhancing the consistency and appropriateness of reimbursements.

As previously highlighted in our responses to the CY 2024 Medicare PFS RFI, when Congress authorized the use of complex drug administration service codes for non-oncologic medications under the *Medicare Modernization Act (MMA)*, it did not intend for this to be limited to the drugs available at that time (e.g., infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab). Over the past two decades, numerous additional non-oncologic medications have emerged, requiring similar levels of supervision and specialized administration. ***We strongly support CMS' proposal and urge the Agency to expedite the Manual updates.***

Additional Recommendations

In addition to the proposed changes, we respectfully request CMS to consider the following actions:

- Establish clear documentation requirements that allow physicians to demonstrate in the medical record that the complex drug administration service code reported on their claims meets the revised criteria.
- Create a Medicare Learning Network (MLN) article to educate practices on the updated criteria and documentation requirements, and require MACs to post this resource on their respective websites.
- Prohibit program safeguard contractors, including MACs, from initiating retroactive program integrity audits or recoupments for complex drug administration services for dates of service from August 12, 2022, until the effective date of the Manual revisions.

We sincerely thank CMS for considering our concerns and acting on our recommendations. These efforts are critical in ensuring that Medicare beneficiaries continue to have access to the medications they need in the most cost-effective, high-quality, and safe setting—the physician's office.

Sincerely,

American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
Coalition of State Rheumatology Organizations
Digestive Health Physicians Association
Infusion Providers Alliance
National Infusion Center Association