



April 24, 2026

Director Ryan Howe
Deputy Director Molly MacHarris
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via email to Ryan.Howe@cms.hhs.gov and molly.macharris@cms.hhs.gov

Dear Director Howe and Deputy Director MacHarris:

On behalf of The Allergy & Asthma Alliance (the “Alliance”), we want to thank CMS for holding productive discussions regarding Medicare coverage and billing for allergy immunotherapy, a vital and proven clinically effective treatment for individuals with allergic rhinitis and allergic asthma. We have enjoyed our conversations with CMS staff to date, appreciate CMS’ willingness to discuss our issues, and your dedication to ensuring that Medicare beneficiaries have full access to allergy immunotherapy.

As you may recall, the Alliance is comprised of seven member organizations with provider networks delivering the highest level of care and clinical expertise to individuals living with allergies, asthma, and other allergic diseases. Collectively, Alliance members practice at 457 locations across 27 states and the District of Columbia, serving over 1.1 million patients annually.

Allergy Immunotherapy

To quickly recap our previous conversations, allergy immunotherapy is the only proven therapy for asthma, allergic rhinitis, and allergic conjunctivitis that is disease-modifying and offers patients a possible cure. CMS pays for allergy testing of Medicare beneficiaries and for their treatment through allergy immunotherapy, more commonly known as allergy shots.

During allergy immunotherapy, a provider creates a vial, or multiple vials for the most allergic patients, containing the specific antigen mix for a given patient at the optimal treatment concentration known as “maintenance level.” This maintenance level concentration mix has been prospectively determined from the patient’s specific history and skin testing responses. The treatment regimen begins with a “build-up” phase, during which patients receive increasing concentrations of antigen generally up to three times per week. To prevent anaphylaxis during build-up, doses are smaller and may have to be adjusted throughout the build-up phase. This phase typically lasts three to six months, after which, the patient transitions to maintenance

therapy. Maintenance therapy means that the patient has reached the highest concentration of antigens, which is the dosage the patient will receive for the remainder of their allergy immunotherapy. Upon reaching maintenance level, the patient continues to receive injections on a less frequent but regular basis, generally one or two injections per month for three to five years.

CMS' Definition of a Dose

In 2000, CMS redefined an allergy immunotherapy dose from a clinical dose administered to a patient as specifically defined by the AMA's CPT, to "a 1cc aliquot" and adopted confusing language regarding reimbursement for the series of lower concentration doses prepared from the patient's anticipated maintenance level concentration, or the build-up doses.¹ A Department of Health and Human Services (HHS) Office of Inspector General (OIG) report in 2002 found that CMS did not have accurate data on the dose change when they made this calculation, yet the policy has remained in effect for 25 years.²

Since the Medicare policy went into effect in 2001, providers have been forced to maintain a dual definition of the units for CPT code 95165; one for Medicare and one for all other payers, resulting in confusion in the marketplace regarding coverage, billing, and reimbursement. The OIG confirmed that Medicare's 1cc aliquot dose was inaccurately calculated and that most immunotherapy providers actually used an average dose of .5cc.³ Medicare did not change its definition of a dose in response to the OIG and stated that the agency hoped providers would not respond by changing their doses to match the definition and should just consider this a "billing dose." No matter how many doses are prescribed, prepared, and provided to Medicare patients, providers have been required by Medicare to bill in 1cc billing dose units.

Medicare's 1cc aliquot dose has been a concern for years and is now creating reimbursement-driven changes to medical practice, rather than changes that align with clinical practice. This definition, increasingly adopted by commercial payers and Medicaid plans, will negatively impact the delivery of medically necessary and cost-effective patient care to Medicare beneficiaries. When this policy was implemented, few Medicare beneficiaries received allergy immunotherapy – in fact, most practices report that less than 5% of patients receiving treatment at that time were Medicare beneficiaries. Today, however, Medicare beneficiaries often comprise more than 20% of an individual practice's allergy immunotherapy patients.

CMS Program Integrity

The Alliance understands and agrees that Medicare must maintain program integrity by preventing waste, fraud and abuse. Currently, Medicare utilizes a medically unlikely edit (MUE) of 30 doses per claim to flag potential overutilization. The Alliance believes a more appropriate policy, which aligns with common clinical practice, is an annual limit on doses of medically necessary treatment. The annual limit of doses in the first year of treatment would be higher to account for the build-up phase, then reduced in subsequent years when the beneficiary is

¹ 65 Fed. Reg. 65393 (Nov. 1, 2000).

² HHS Office of Inspector General, "Medicare Antigen Preparation." OIE-09-00-00530 (Oct. 2002). Available at: <https://www.govinfo.gov/content/pkg/GOVPUB-HE-PURL-gpo67228/pdf/GOVPUB-HE-PURL-gpo67228.pdf>.

³ Id.

receiving a maintenance dose. Please see the attached addendum (“95165 Units BuildUp and Maintenance Vials”), which is intended to illustrate the build-up and maintenance phases of allergy immunotherapy based on clinical practice parameters and professional society recommended best practices.

Recommendations for CMS

Given our joint efforts to ensure Medicare beneficiary access to allergy immunotherapy and to correct the currently flawed definition and coverage policy, the Alliance respectfully requests that CMS propose the following regulatory changes in the forthcoming Calendar Year (CY) 2027 Medicare Physician Fee Schedule (MPFS) notice of proposed rulemaking:

1. Rescind the definition of an allergy immunotherapy “dose” for purposes of CPT code 95165 and formally adopt the definition established by the Joint Task Force (JTF) on Practice Parameters and applied in practice, which is a single injection from a multidose vial.⁴
 - a. Under this definition, an allergy immunotherapy dose would be defined as “the actual amount of allergen administered in the injection.”
2. Rescind the National Correct Coding Initiative (NCCI) Medically Unlikely Edit (MUE) of 30 for CPT code 95165 and instead adopt a reasonable annual limit on doses billed under this code.
 - a. Under this new limit, we recommend a limit of up to 160 doses per year during the first year of therapy (i.e., the build-up phase) and up to 130 doses per year thereafter (i.e., the maintenance phase). We have enclosed a graphic that helps illustrate the build-up and maintenance phases.

Conclusion

As we have discussed, CMS’ definition of a dose does not reflect clinical standards of care and imposes a billing structure that is inconsistent with real-world practice. This inconsistency places a significant administrative burden on providers, who must navigate varying payer definitions of a dose under CPT code 95165. If CMS formally adopts the appropriate definition of a dose, much needed regulatory certainty would be delivered to providers after nearly 25 years of ambiguity, ensuring that Medicare beneficiaries who comprise an increasing percentage of our patient population continue to have access to allergy immunotherapy.

We thank CMS in advance for your consideration of our request and we look forward to continuing to work with CMS to ensure meaningful access to care for Medicare beneficiaries.

⁴ Cox L, Nelson H, Lockey R. et al. Allergen Immunotherapy: A practice parameter third update. Joint Task Force Report. (2010) J. Allergy Clin Immunol. Jan. 2011. 127; 1: Supp. S1-S55. Available at: <https://www.jacionline.org/action/showPdf?pii=S0091-6749%2810%2901503-4>. The Joint Task Force (JTF) on Practice Parameters was formed in 1989 and is comprised of members from the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma and Immunology. Practice parameters are designed to assist clinicians in providing high quality assessment and treatment that is consistent with the best available scientific evidence and clinical consensus. The allergy immunotherapy dose is defined as “the actual amount of allergen administered in the injection.”

Sincerely,

The Allergy & Asthma Alliance

Alliance Members

Allergy & ENT Associates

Allergy Partners

AllerVie Health

Family Allergy & Asthma

SENTA Partners

Tennessee Society of Allergy, Asthma and Immunology

The Allergy, Asthma & Sinus Center

Attachment