



April 11, 2025

Submitted Electronically (mehmet.oz@cms.hhs.gov)

The Honorable Mehmet Oz
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Definition of a Dose for Purposes of Allergen Immunotherapy (CPT Code 95165)

Dear Administrator Oz:

The Advocacy Council of the American College of Allergy, Asthma and Immunology (“ACAAI”), together with its sponsoring organization—the ACAAI, write to urge the Centers for Medicare and Medicaid Services (“CMS”) to rescind the agency’s definition of a “dose” for purposes of allergen immunotherapy described by Current Procedural Terminology (“CPT”) code 95165. Since 2001, CMS has defined a “dose” as “a 1cc aliquot,” regardless of the amount actually administered to the patient. *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001*, 65 Fed. Reg. 65376, 65393 (Nov. 1, 2000). This arbitrary definition deviates from standard clinical practice and contradicts the definition of a “dose” set forth in the American Medical Association’s (“AMA’s”) CPT book. This creates a significant administrative and economic burden on allergy practices - particularly small and rural practices. **Therefore, on behalf of the more than 6,000 allergists-immunologist and allied health professional that we serve, we respectfully request a meeting to discuss the need to rescind Medicare’s definition of an allergen immunotherapy dose.**

Background

Allergen immunotherapy, administered through subcutaneous injections, is a proven clinically effective treatment for individuals with allergic rhinitis, allergic conjunctivitis, allergic asthma, and hymenoptera sensitivity. The efficacy of allergen immunotherapy is well-established in medical literature. In fact, allergen immunotherapy is the only proven therapy for asthma, allergic rhinitis, and allergic conjunctivitis that is disease-modifying and offers patients a possibility for cure.

Allergen immunotherapy is tailored to the unique needs of the patient. Treatment begins with a build-up phase during which a patient receives increasing concentrations of antigen. Depending on the number of antigens a patient is sensitive to and the types of antigens, the allergists may prepare two or three separate vials, each with different antigens. During the initial or build-up phase, patients typically receive injections up to three times per week. Usually, by the end of 3-6 months, a patient is on a maintenance dose and receives injections once a week and, ranging from six to twelve months later, up to once a month. Maintenance injections are administered

subcutaneously, and fewer doses are required once a patient has reached maintenance therapy.

“Dose” Under CPT Code 95165

Allergen immunotherapy is described by three CPT codes. CPT codes 95115 and 95117 describe the subcutaneous injection of allergen extracts. CPT Code 95165 describes “professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).” The AMA’s CPT book requires physicians to bill by the dose and to indicate on the claim the number of doses prepared. The CPT code book defines a dose as “the amount of antigen(s) administered in a single injection from a multiple dose vial.” Under standard practice, the number of doses billed is based on the total number of doses the allergist expects to administer based on the prescribed dosage and frequency schedule.

In 2001, CMS redefined an allergen immunotherapy “dose” - deviating from standard clinical practice and the CPT code book’s definition. Medicare defines a “dose” as “a 1cc aliquot,” regardless of the amount administered to the patient. In addition, CMS implemented a Medically Unlikely Edits (“MUE”) of 30 for CPT code 95165. Accordingly, Medicare’s approach reflects a misunderstanding of the way allergen immunotherapy is prepared and provided. Requiring allergists to bill by the cc, rather than by the number of clinical doses, is inconsistent with CPT and with the way that immunotherapy is administered. This creates a confusing inconsistency with what is documented in the patient’s clinical medical records. In addition, all practitioners billing allergy extract have had to maintain a dual definition of the units for CPT code 95165, one for Medicare and one for all other payers. This creates an administrative burden on allergy practices, particularly small practices.

We applaud the Trump Administration’s emphasis on rescinding regulations and guidance documents that burden American businesses—particularly small and rural business. We believe that the elimination of Medicare’s definition of a “dose” for purposes of CPT code 95165 would align with the Trump Administration’s priorities. *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001*, 65 Fed. Reg. 65376, 65393 (Nov. 1, 2000). In addition, we ask that the MUE be updated to alleviate this restriction on allergists. We respectfully request a meeting with you to discuss this request.

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We appreciate your attention to this matter. To schedule the meeting, please contact Susan Grupe, ACAAI’s Director of Advocacy Administration, at suegrupe@acaai.org.

Sincerely,



James M. Tracy, DO, FACAAI
President, ACAAI



Travis A. Miller, MD, FACAAI
Chair, Advocacy Council