Special Article

Guidance for the Evaluation by Payors of Claims Submitted Using Current Procedural Terminology Codes 95165, 95115, and 95117

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INTRODUCTION

This Guidance was jointly developed equally by the American Academy of Allergy Asthma and Immunology (AAAAI), the American Academy of Otolaryngic Allergy (AAOA), and the American College of Allergy, Asthma and Immunology (ACAAI) to advise insurance companies and other payors of the documentation that they should, and should not, require in their review of claims for payment for services covered by Current Procedural Terminology (CPT) codes 95165, 95115, and 95117. The goal of the Guidance is to assist payors to develop a process for reviewing claims submitted under these 3 codes in a manner that is efficient, fair, and not unduly burdensome. This document supersedes any document or manual published previously by the above organizations.

The Guidance is divided into 2 parts. The first part explains each of the 3 codes, the services that are covered by these codes, and the medical necessity of those services. The second part describes what the 3 organizations believe are reasonable requests for documentation and what we submit are unreasonable requests. It first addresses code 95165 and then codes 95115 and 95117.

THE 3 CURRENT PROCEDURAL TERMINOLOGY CODES AND THE SERVICES THAT THEY COVER

The Codes

For more than 100 years, allergists/immunologists and otolaryngologists have prescribed and provided patient-specific, disease-modifying allergen immunotherapy in treating allergic rhinitis, asthma, and atopic dermatitis. This therapy is covered by 3 different CPT codes. Specifically, CPT code 95165 is the code for the supervision of the preparation and provision of multiple allergen components and dilutions. The CPT code 95115 covers professional services in connection with a single injection of allergen immunotherapy, not including provisions of allergenic extracts. The CPT code 95117 applies when professional services are performed in connection with 2 or more injections of allergen immunotherapy, not including provision of allergenic extracts.

The Medical Necessity of the Procedures Covered by the Codes

All the procedures covered by these 3 codes are medically necessary for patients experiencing allergic rhinitis, asthma, or atopic dermatitis. Each patient is different. The physician must therefore make a sound professional judgment regarding an appropriate treatment plan, with consideration of national recommendations. The allergen immunotherapy plan may involve multiple allergen components and dilutions. Thus, the services covered by 95165 are essential to ensure that a patient with one of the conditions previously described will have a treatment plan, formulated in the reasonable judgment of a qualified physician specialist in light of the patient's specific medical condition, that is most likely to succeed in treating the patient's condition—with the least likelihood of complications or contraindications. Codes 95115 and 95117 describe the subcutaneous injection of patient-specific extract in accordance with the prescribed dosage schedule determined by the ordering physician. These injections are the approved method of delivery and are medically necessary for the proper treatment of the patient.

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Proper and Improper Documentation Requirements

The AAAAI, AAOA, and ACAAI recognize that insurance companies and other payors have a right to take reasonable steps to ensure that claims by physicians for payment for services are (1) for medically necessary services that were performed for the patient and (2) properly coded. In recent years, however, payors have increasingly demanded multiple, detailed documentation that is both highly burdensome to the physician and generally unnecessary. These demands have caused significantly delayed payment—or worse yet, nonpayment for entirely appropriate procedures.

In the first part of this section, we describe what the 3 organizations regard as reasonable and unreasonable requests for documentation of claims submitted under 95165. In the second part, we describe what we believe to be reasonable and unreasonable requests for documentation of claims submitted under 95115 and 95117. For each of the requests to which we object, we explain the basis for our objection.

95165

Reasonable Requests for Documentation

As previously noted, CPT code 95165 describes professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single or multiple antigens. It requires specification of the number of prescribed doses. Accordingly, we believe that the following requests by the payor for documentation are reasonable: (1) the identity of the physician who established the treatment plan; (2) the identity of the patient and a short description of the clinical indications for allergen immunotherapy; (3) a brief description of the treatment plan and the date on which it was formulated; and (4) a description of the response to allergy immunotherapy and the need for continued allergen immunotherapy at routine visits.

In addition, a signed and dated order for allergen extract listing the allergy extract ingredients (ie, antigens), concentrations (Allergy Unit, Bioequivalent Allergy Unit, and weight to volume), volumes of extract, and diluent (cubic centimeters or milliliters) should be available to document the contents of both the initial and refill allergy extracts vial. Initials of the allergen-extract compounding healthcare professional should also be included. The information described in this subsection is all that a payor should need to determine whether the service was medically necessary and appropriately coded.

Unreasonable Requests for Documentation

In addition to the information previously outlined, some insurers require that allergy extracts billed under 95165 must be based on a volume of 1 mL or on some other insurer-specific maximum. We submit that this requirement is contrary to the standard of practice and therefore inappropriate.

As previously noted, each patient is different. Depending on the unique immunotherapy protocol for each patient, dosages vary, and the number of doses should not be based on a 1-mL or other predetermined volume. Rather, depending on the condition of the patient and the composition of the appropriate allergen, the patient may receive injections of different volumes and require additional extract vials. For example, certain antigens cannot be compounded together owing to protease activity requiring separation of molds and cockroach antigen from pollens, dust mites, and animal dander. In addition, there are limits to the number of allergens that can be compounded in a vial. Thus, it is entirely appropriate for a physician to submit a claim under 95165 for extracts that are not based on a volume of 1 mL or on some other predetermined volume. Annual dose limits should allow these variations.

For many years, Medicare was the only payer that used 1 mL as the dose, and it is confusing when CPT and most insurance companies use the CPT definition of a dose. Centers for Medicare & Medicaid Services has also developed "medically unlikely edits (MUEs)," which it uses to determine the number of units it regards as billable for a particular service or procedure, including for 95165 based on a 1-mL dose.

For the reasons previously explained, it is often the standard of care to provide allergen extracts that are not 1 mL. Accordingly, we request that, in reviewing claims submitted under 95165, private payors not use MUEs or insurer-specific unit maxima but rather, in accordance with the language of CPT, respect the dosage determined by the physician if the information described in the previous subsection is provided by the submitting physician.

In addition to improper use of MUEs, several other unreasonable requests relating to claims submitted under 95165 have been rendered. In particular, compounding logs for each dilution and lot numbers are not necessary to document compliance with the requirements of 95165. Demands for these logs are unnecessary and simply make the claims process less efficient and more burdensome.

Similarly, the results of allergy skin testing are necessary only for billing skin testing codes. This information should not be required for every claim submitted under 95165. A demand for documentation of this information whenever a claim is submitted under 95165 is unnecessary and unduly burdensome. Such a demand should not routinely be made.

95115 AND 95117

Reasonable Requests for Documentation

Traditionally, allergen extracts are formulated for a patient under the supervision of an allergist. The formulation process for compounding allergen extracts involves prescribed amounts of extracts compounded in sterile 5-to-10 mL vials. The series of injections may start at a 10,000-fold (or higher) dilution of the final "maintenance vial" of concentration extract. A typical schedule is in increasing increments starting at 0.05 mL through 0.5 mL through each vial until the maintenance dose is reached.

In these circumstances, the following documentation would be reasonable to support a claim submitted under 95115 or 95117: (1) the date of the injection, the name, and birth date of the patient; (2) the dose administered, specifying volume, dilution, and number of injections; (3) the site(s) of the injection; for example, right arm; and (4) the initials or signature of the person administering the injection (whether actual or electronic).

This documentation is all that a payor should need to satisfy itself that an injection or injections were properly administered to the patient. As explained in the next subsection, demands for additional documentation call for unnecessary and unduly burdensome information.

Unreasonable Requests for Documentation

The AAAAI, AAOA, and ACAAI submit that the following documentation is unnecessary, and that provision of this information is often unduly burdensome: (1) date of vial expiration/"best use by"; (2) full planned dosing schedule; (3) specification

of subcutaneous administration; (4) signature of ordering healthcare professional; (5) credentials of the person administering the injection; (6) a history of injections; and (7) multiple audit requests.

We now explain the reasons for our position.

Initially, 95115 and 95117 cover professional services for the administration of allergen immunotherapy. The claim for payment therefore should, as previously noted, indicate that the injection was administered, and the name of the patient, the date of the injection, the site of the injection, a description of the dose administered, and a verification by the person who administered the injection. However, absent some strong reason to believe that the person giving the injection did not follow proper protocols, there is no justification for demanding the date of vial expiration. Such a demand serves no purpose other than to make the process more burdensome.

The same conclusion applies to demands for the fully planned dosing schedule, the credentials of the person administering the injection, and the history of injections. All these demands place a burden on the claimant to show that the injection was administered according to standards of care. However, the inescapable fact is that most injections are administered according to the planned dosing schedule by properly credentialed professionals and agree with the history of injections. To require this information on every claim submitted under these 2 codes imposes an entirely unnecessary and time-consuming burden—and for no legitimate reason except the rare instance in which the payor has good reason to believe that some wrong-doing is being perpetrated.

Similarly, there is no purpose in demanding specification of subcutaneous administration. All injections are subcutaneous. There is also no need to routinely require the signature of the ordering healthcare professional. It is quite burdensome to obtain the signature of the ordering professional every time that a claim is submitted. In addition, there are no work relative value units associated with 95115 or 95117. For a well-tolerated allergy injection encounter, a physician does not need to examine the patient and does not need to sign off on a treatment schedule that they have already prescribed and signed.

Finally, we are aware that in some instances, there have been multiple audit requests or that all claims are routinely audited. Claims should not be routinely audited unless the payor presents evidence that a provider has been chronically filing incorrect claims. Routine audits of all claims can interfere with patient care and ultimately cause delays in treatment. We do not object to follow-up audit requests when a response to the reasonable requests described above have not been provided. Nor do we object to follow-up requests when the payor has evidence suggesting that a particular injection has been administered improperly. However, absent these considerations, multiple audit requests impose undue burden, delay payment that should be timeously rendered, and cannot be justified.

CONCLUSION

The AAAAI, AAOA, and ACAAI recognize that it is reasonable for insurance companies and other payors to request documentation to show that a claim submitted under CPT code 95165, 95115, or 95117 is for a medically necessary service that has been performed and has been properly coded. Accordingly, in this Guidance, we have presented the documentation that in our judgment is reasonable for payors to request. This documentation is itself quite substantial.

At the same time, we respectfully submit that demands for several kinds of additional documentation that have been made by some insurers are unnecessary. These demands serve only to make the claims process less efficient and to impose an undue burden on the entity submitting the claim—at least when the payor has no sound reason to believe that a particular claimant has acted improperly. Whenever we have characterized a particular category of requested documentation as excessive, we have sought to explain the reasons for our position.

All 3 organizations would be pleased to meet with any payor that would like to discuss this Guidance. As noted at the outset, our goal is to work with payors to assist them in developing a process for review of claims under codes 95165, 95115, and 95117 that is efficient, fair, and not unduly burdensome.