
Regulatory changes that affect coding for immunotherapy

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Background: During the past decade, a variety of federal regulations have had a significant impact on the way allergen immunotherapy is reimbursed and how *Current Procedural Terminology* (CPT) codes are used for this purpose. As mandated by the US Congress, the Centers for Medicare and Medicaid Services (CMS) through the Office of the Inspector General (OIG) targeted immunotherapy codes for scrutiny, because they are some of the most frequently used codes.

Objective: To examine how federal regulations have affected reimbursement for allergy immunotherapy and other allergy services.

Methods: A review was performed of the OIG survey of allergy immunotherapy and the OIG recommendations on CPT coding compliance guidelines.

Results: A preliminary survey found problems with medical appropriateness of allergen immunotherapy. For this reason, the OIG performed a more comprehensive study of 301 physicians using code 95165 to analyze by medical record and billing data whether the new billing rules were being correctly used and found that only 44% of physicians were following the new definition of a billable dose. In the early 1990s, the federal government served notice of its intent to more aggressively identify and prosecute health care providers who improperly billed and collected for medical services. Through the adoption of the 1991 US Sentencing Commission Guidelines, the government sought to enhance compliance by mandating lesser criminal penalties for violating organizations that nevertheless maintained and operated "effective compliance plans." In 2002, the OIG audited health care providers and recouped \$14.4 billion in improper payments by Medicare. Between January and June 2003, Medicare excluded 1,241 individual providers and health care entities due to fraudulent billing practices.

Conclusions: Federal regulations have significantly affected reimbursement for allergy immunotherapy and other allergy services. Allergists need to be aware of these changes and implement the new recommendations into their practices.

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INTRODUCTION

During the past decade, a variety of federal regulations have had a significant impact on the way allergen immunotherapy is reimbursed and how *Current Procedural Terminology* (CPT) codes are used for this purpose. As mandated by the US Congress, the Centers for Medicare and Medicaid Services (CMS) through the Office of the Inspector General (OIG) targeted immunotherapy codes for scrutiny, because they are some of the most frequently used codes. A preliminary survey found "medical inappropriateness" regarding recommendations for immunotherapy as recommended in the Practice Parameters.¹ This article examines how federal regulations have affected reimbursement for allergy immunotherapy and other allergy services by reviewing the OIG survey of allergy immunotherapy and the OIG recommendations on CPT coding compliance guidelines.

PROVISION OF ALLERGY EXTRACT

Because of rising health care costs, the US Congress mandated that CMS review all highly used codes whether they were high-cost budgetary items or simply frequently used

codes in terms of actual number of times the code was submitted. It was for the latter reason that 95165 was selected. Medicare spent \$98 million for allergy treatments in 2000.¹ As part of the overall Medicare budget, this represents a small percentage of the total. However, a preliminary study of only 18 patients completed in 2001 found "medical inappropriateness" in 12 of these cases.¹

For this reason, the OIG performed a more comprehensive study of 301 physicians using 95165. This included not only allergists but also otolaryngologists, pediatricians, family medicine physicians, and any others who used this code. The purpose was to analyze by medical record and billing data whether the new billing rules were being correctly used. Again, the OIG reported that only 44% of physicians were following the new definition of a billable dose. Fortunately, allergists were more aware of this new definition and more compliant with the rules than others, although significant errors still occurred. During the past 2 years, the Joint Council of Allergy, Asthma and Immunology (JCAAI) has notified its membership of these new regulations through direct mail, e-mail, and postings at www.jcaai.org.

For Medicare only, a billable dose was redefined as 1-mL aliquots of maintenance extract. Medicare may be billed for 10 mL only if the patient is provided with 10 mL of extract. Confusion arose regarding the difference in billable dose and treatment dose. Medicare did not attempt to specify what a

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treatment dose should be but rather stated how it would reimburse for a treatment dose (ie, by 1-mL aliquots up to 10 mL of extract). It is permissible to bill for 10 doses if a patient receives 0.5 mL as treatment and 10 mL is provided to the patient. The physician can still bill for 10 mL; it will just last for 20 injections. Also if the 2 vials are required for multiple antigens, the physician can bill for two 10-mL vials. As an example of preparing two 10-mL vials for a patient allergic to grass and molds, allergens that should not be mixed in the same vial, Medicare should be billed for 95165 (20-mL extract) regardless of the number of injections the patient receives from these 2 vials. Even if the patient receives 40 injections (0.05 mL each time), the billable amount of extract remains 20 units. Another major change was that dilutions of the concentrate could no longer be reimbursed. This applies only to Medicare patients. A charge can be submitted each time a maintenance dose is prepared; 95115 to 117 (administration of an allergy injection[s]) can still be billed.

The JCAAI was made aware of a 30% decrease in reimbursement from the 2003 to the 2004 CMS fee schedule for those allergists who use 95144 (provision of single-dose vials for allergy immunotherapy). After the CMS was asked to review this, notice was issued by CMS to correct this error. An unexpected outcome of the billing review was the finding of inappropriate medical use of immunotherapy. Specifically, our Practice Parameters were reviewed and applied to medical record audits. One of the more common inconsistencies was why immunotherapy was continued beyond 5 years without documentation of effectiveness or need for further treatment. It is not appropriate to treat more than 5 years if there is documentation for prolonged use. The JCAAI has available on its Web site examples of proper clinical documentation. Other findings were the presence of strong contraindications such as concomitant β -blocker therapy or severe asthma without proper documentation of the associated increased risks. Even more basic was the failure to specify why immunotherapy was clinically indicated as opposed to alternative medical therapies, such as medications or environmental control measures. For a more detailed review of this study, the reader is referred to www.oig.hhs.gov/publications/workplan.htm. Other studies indicate a 6-fold increased chance of getting sued for negligence or lack of medical necessity if established clinical standards of care are not followed.²

OIG COMPLIANCE

In the early 1990s, the federal government served notice of its intent to more aggressively identify and prosecute health care providers who improperly billed and collected for medical services. Through the adoption of the 1991 US Sentencing Commission Guidelines, the government sought to enhance compliance by mandating lesser criminal penalties for violating organizations that nevertheless maintained and operated "effective compliance plans."

In 2002, the OIG audited health care providers and recouped \$14.4 billion in improper payments by Medicare.²

Between January and June 2003, Medicare excluded 1,241 individual providers and health care entities due to fraudulent billing practices.² Although not required, the importance and necessity for allergists to develop a compliance plan cannot be overestimated. To aid the allergist in developing a compliance plan, the JCAAI provides the necessary forms on its Web site. In addition, an online interactive module for both office staff and physicians is available on OIG compliance at www.jcaailearn.org. The module consists of 6 parts: overview, front office, business office, compliance officer implementation, physician, and evaluation and management (E&M) coding modules. Completion of this program will greatly aid in the allergists' understanding of the OIG compliance regulations and potentially prevent troublesome and expensive encounters.

Each year the OIG announces its intent to look at specific areas in medical practices in its "work plan." For 2004, the areas identified were new patient consults vs new patient codes, E&M outliers, and use of modifier 25 and "incident to" physician services. Of particular importance to allergists is determination of the frequency of use of various E&M codes for a particular physician. At jcaai.org, a link to CMS coding frequency data by state and specialty is provided. It is recommended that each individual allergist use this information to perform a "coding analysis" of their practice to determine trends in CPT coding compared with benchmark norms for state and national allergy coding patterns. If a significant variation from the norm is found, then the reason it exists must be reviewed and documented. Is the physician undercoding or overcoding? Is there documentation that higher-level codes are justified? Again, the JCAAI provides an online coding module to help allergists improve their coding skills.

VENOM EXTRACTS

Through its review process of the yearly updated CMS free schedule, the JCAAI found that in 2004 Medicare was scheduled to reimburse for venom extract below the published cost of extract. Listed in their catalogs, the manufacturers' price is \$12.22 (1 venom) to \$23.39 (3 venom mixed vespids) per milliliter. Medicare stated it would reimburse at \$5.18 per milliliter. The JCAAI wrote a letter to CMS in September 2003 explaining this error and asking for correction. Medicare admits there is an error but is not certain where the error occurred. Medicare does not believe it has the statutory authority to "just fix it." This involves a convoluted process of Medicare "practice expense" circulations. Before 1999 Medicare based expense on actual historic charge data.

From 1999 throughout 2002, the "top down" method was adopted. "Top down" involves calculating a practice expense dollar "pool" for each individual specialty based on the previous year's charges. The pool is allocated proportionally by the number of times a code is used per year. Allocation is supposed to reflect the relative costs of a particular service. If an error occurs, reallocation can result in reductions of all other codes to compensate for increase in the one code. This

could negatively affect allergy reimbursement for more frequently used codes, and thus at this point the JCAAI has not further challenged the reimbursement. Because there was a discrepancy, CMS agreed to recalculate total practice expense allocated to allergy services. Direct costs will be considered. The JCAAI contracted with Doane Marketing Research (St Louis, MO) for an independent survey of allergy expenses. The survey was recently submitted to CMS and updates the 1995 practice expense data that CMS had been relying on. The new survey based on 2003 data shows that allergy practice expenses are higher than originally assumed. These data, if accepted by CMS, should result in a higher practice expense component used in the relative value units reimbursement calculations. This could potentially have a positive impact on reimbursement for allergy services.

SUBLINGUAL IMMUNOTHERAPY

In March 2003 a request was made to the American Medical Association *CPT* Advisory Committee for a code for sublingual immunotherapy (SLIT). At the time neither the allergy organizations nor otolaryngologists who provide allergy services supported this request. The options were that of a category III *CPT* code (an emerging technology code, usually nonreimbursable) or a category I code (existing procedural codes, reimbursable). Because there were no Food and Drug Administration (FDA)–approved licensed SLIT extracts in the United States, the JCAAI and its parent organizations could not support this option. In 2004 extract manufacturers submitted a request to the FDA for phase 1 and 2 studies for

SLIT. Approval was granted and clinical trials are ongoing. The JCAAI has agreed to further pursue a *CPT* code for SLIT.

CONCLUSION

Federal regulations have significantly affected reimbursement for allergy immunotherapy and other allergy services. Allergists should pay particular attention to new Medicare rules that govern billing and reimbursement for immunotherapy for both aeroallergens and venoms. A compliance plan is needed for all offices to carefully review coding and billing practices. New therapies such as SLIT are under review for provision of a new *CPT* code.

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