

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**ALLERGEN IMMUNOTHERAPY  
FOR MEDICARE BENEFICIARIES**



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Inspector General

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# *Office of Inspector General*

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## OBJECTIVE

To determine (1) if allergen immunotherapy and related services met Medicare coverage and documentation requirements, and (2) if allergen immunotherapy provided to Medicare beneficiaries was of a quality that met professionally recognized standards of health care.

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## BACKGROUND

In 2001, Medicare allowed approximately \$130 million for allergen immunotherapy and related services. By 2003, this amount had grown to \$171 million. Allergen immunotherapy—commonly known as allergy shots—is intended to reduce the patient’s reactions to particular allergens. Title XVIII of the Social Security Act (the Act) limits Medicare coverage to services that are medically necessary (section 1862(a)(1)(A)) and supported by documentation (section 1833(e)). Title XI of the Act requires that services provided to Medicare beneficiaries be of a quality that meets professionally recognized standards of health care (section 1156(a)(2)). Federal regulations (42 CFR § 1001.2) define “professionally recognized standards of health care” as “. . . Statewide or national standards of care . . . that professional peers of the individual or entity . . . recognize as applying to those peers practicing or providing care within a State.”

The Joint Task Force on Practice Parameters, which represents 95 percent of the allergist/immunologists in the United States, publishes standards of care for the diagnosis and treatment of allergies. These standards specify medical necessity criteria, contraindications, and the proper duration of allergen immunotherapy. They also outline procedures for administering allergy tests, preparing and delivering injections, and providing follow-up care. Because, to our knowledge, there exist no competing local or State standards for allergen immunotherapy, we considered the Joint Task Force standards to be “professionally recognized standards of health care” under section 1156(a)(2) of the Act.

As part of “Medicare Antigen Preparation” (OEI-09-00-00530), published in 2000, the Office of Inspector General evaluated a probe sample of allergy services. Based on medical review, most beneficiaries in the sample received substandard and poorly documented care. These concerns led us to contract with practicing allergists and otolaryngologists to review the medical records of a random cluster

sample of 400 Medicare immunotherapy patients and 1,434 allergen immunotherapy and related services they received in 2001. We also contracted with a certified professional coder to determine if each service was documented adequately and billed with the correct code.

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## FINDINGS

**Sixty-two percent of the allergen immunotherapy and related services allowed by Medicare in 2001 did not meet program requirements, resulting in \$75 million in improper payments.** Our medical reviewers found that 31 percent of allergen immunotherapy and related services allowed by Medicare in 2001 were not medically necessary (and, therefore, noncovered). These services generally were not indicated or were provided as part of an immunotherapy regimen that lasted longer than clinically acceptable. Furthermore, 7 percent of allergen immunotherapy and related services were billed with an incorrect code and 29 percent were undocumented. Six percent had multiple errors, yielding an overall error rate of 62 percent, resulting in \$75 million in improper payments.<sup>1</sup>

**In the absence of national guidance, some carriers have adopted policies that diverge from professionally recognized standards of health care.** National Medicare coverage and payment guidelines regarding allergen immunotherapy are very limited. In the absence of national guidelines, carriers have implemented policies that are sometimes inconsistent with Joint Task Force standards. For instance, at least one carrier allows reimbursement for injections given at home, although the standards clearly state that, because of the risk of adverse reactions, shots should be delivered only in a clinical setting.

**The care provided to approximately 70 percent of Medicare beneficiaries who received allergen immunotherapy in 2001 was inconsistent with professionally recognized standards of health care.** In addition to the service-level review, our reviewers also examined the entire course of treatment for each beneficiary in our sample. In approximately 70 percent of cases, the reviewers found that some aspect of the beneficiary's allergy testing or treatment departed significantly from one or more of the Joint Task Force standards. For

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<sup>1</sup> Difference due to rounding.

example, 20 percent of beneficiaries on allergen immunotherapy did not have conditions for which allergy shots were appropriate or did not have allergy tests that showed reactions to any potential allergens. Treatment for 13 percent was contraindicated by concomitant conditions or the use of beta-blockers. Nearly 22 percent of beneficiaries received shots for longer than is acceptable, because they were not experiencing any clinical benefit or had been receiving shots for many years without being reassessed. Other examples include identified situations wherein beneficiaries received allergy tests that lacked proper controls, injections that were delivered in a nonclinical setting, and follow-up care that was too infrequent to adequately monitor the patient or involved unnecessary repeat allergy tests.

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## RECOMMENDATIONS

The large number of payment errors we found indicates that allergen immunotherapy is a significant Medicare vulnerability. That vulnerability has expanded as Medicare allowances for allergen immunotherapy and related services have increased since we conducted our inspection. To address this growing problem, we recommend that the Centers for Medicare & Medicaid Services (CMS):

**Require carriers to educate physicians who provide allergen immunotherapy to Medicare beneficiaries about coverage, coding, and documentation requirements.**

**Develop national coverage criteria for allergen immunotherapy based on professionally recognized standards of health care.**

In addition to these recommendations, we have forwarded information on the medically unnecessary, miscoded, and undocumented services identified in our sample to CMS for appropriate action.

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## AGENCY COMMENTS

In its comments to our draft report, CMS stated that it is prepared to develop and disseminate educational materials and develop new coverage criteria for allergen immunotherapy services. CMS has identified two possibilities for developing national coverage criteria for allergen immunotherapy: adapting criteria directly from current professional society standards or opening a National Coverage Determination. CMS states that either option would require up to 12 months to fully implement, and that educating physicians on existing

## E X E C U T I V E   S U M M A R Y

coding, documentation, and coverage requirements depends on the course chosen for developing national coverage criteria.

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### **OFFICE OF INSPECTOR GENERAL RESPONSE**

We appreciate CMS's support for our recommendations to increase physician education and to develop national coverage criteria based on professionally recognized standards of health care. Since the CMS letter identifies various methods for implementing the recommendations, we request that CMS provide to us an action plan that clarifies the specific steps it intends to take to fully implement the recommendations.



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## OBJECTIVE

To determine (1) if allergen immunotherapy and related services met Medicare coverage and documentation requirements, and (2) if allergen immunotherapy provided to Medicare beneficiaries was of a quality that met professionally recognized standards of health care.

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## BACKGROUND

### **Allergies: What are they, and how are they diagnosed and treated?**

One in six Americans suffers from allergies—hypersensitive immune reactions to substances that are harmless to nonallergic people. Specific allergy triggers, or *allergens*, vary among sufferers, but commonly include animal dander, molds, pollens, and foods. Allergy symptoms range from mild respiratory irritation to anaphylaxis, a systemic and potentially fatal allergic reaction.

An allergist<sup>2</sup> uses allergy tests, along with his or her knowledge of possible environmental exposures and the patient’s history, to diagnose allergies and determine the substances to which a patient is allergic.<sup>3</sup> Prick and intradermal skin tests are the most widely used diagnostic tests, although blood tests and skin endpoint titration are sometimes used, particularly by otolaryngic allergists. Skin tests must be administered with positive and negative controls to properly interpret the patient’s reactions.<sup>4</sup>

Several treatment options for allergies exist. If less costly measures are ineffective, the physician may start the patient on a program of allergy shots. In this treatment, also called allergen immunotherapy, a physician administers gradually increasing amounts of an extract containing one or more allergens until the patient reaches a maintenance dose. The patient’s symptoms should generally improve within 1 year of shots at the maintenance dose. If not, the physician should explore other treatment options. Since many patients experience

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<sup>2</sup> Two types of specialist generally provide allergy care: allergist/immunologists and otolaryngic allergists. Both must undergo specialized training and examination. Allergist/immunologists provide the majority of Medicare allergy services.

<sup>3</sup> Joint Task Force on Practice Parameters. “Practice Parameters for Allergy Diagnostic Testing.” *Annals of Allergy, Asthma, & Immunology*. (1995;75:543-625)

<sup>4</sup> Joint Task Force on Practice Parameters. “Allergen immunotherapy: a practice parameter.” *Annals of Allergy, Asthma, & Immunology*. (2003;90:S1-S40)

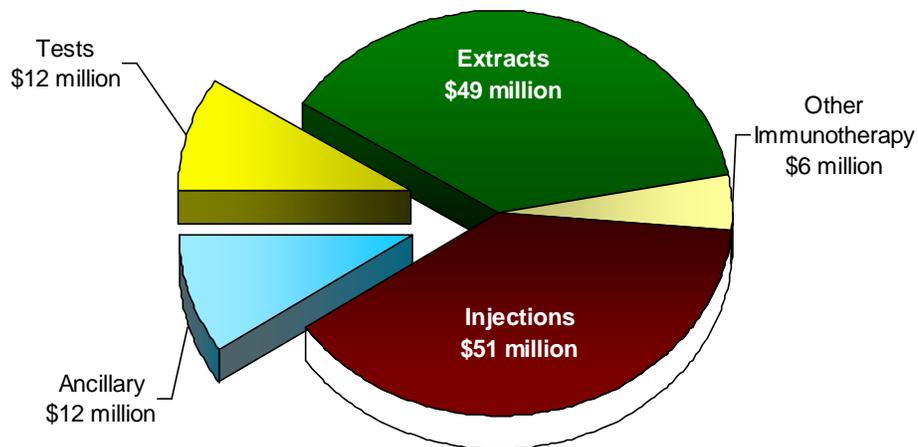
a prolonged asymptomatic period after several years of successful immunotherapy, the physician should reevaluate the beneficiary’s need for continued treatment after 3 to 5 years of maintenance shots.<sup>5</sup>

Allergy shots are generally safe, but involve a small risk of triggering adverse events, including anaphylaxis, and should be given only in a clinical setting appropriate for managing such reactions. Providers must be especially careful with the elderly, because older adults are more likely to have health problems or use medications that increase the risks associated with allergy shots. In particular, the use of beta-blockers can make anaphylaxis more severe and difficult to treat should it occur. Severe, uncontrolled asthma and significant cardiovascular disease also reduce a patient’s chance of surviving a systemic reaction to allergy shots. Immunotherapy for patients with such conditions is appropriate only if the benefits of treatment clearly outweigh the increased risks, e.g., the patient has a life-threatening venom allergy.<sup>6</sup>

**Medicare coverage of and requirements for immunotherapy services**

According to the National Claims History Data File, Medicare allowed \$130 million for allergen immunotherapy and related services provided to 202,359 beneficiaries in 2001. As shown in Figure 1, \$49 million was allowed for preparing allergen extracts and \$51 million for injections, which are treated as distinct services for Medicare reimbursement.<sup>7</sup> In

FIGURE 1  
Medicare reimbursement  
for allergen  
immunotherapy and  
related services



Source: CMS National Claims History Data File, 2001

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

<sup>7</sup> Normally, Medicare pays 80 percent of allowed charges, and the beneficiary pays the remaining 20 percent as coinsurance.

addition, Medicare allowed \$12 million for allergy tests furnished to beneficiaries on allergy shots in 2001 and another \$12 million for ancillary services, such as office visits, billed by the provider of an immunotherapy service.

Provisions of the Social Security Act (the Act) and related regulations govern Medicare reimbursement of allergy services. Section 1862(a)(1)(A) of the Act, implemented by 42 CFR § 411.15(k), limits Medicare coverage to services that are medically necessary. Section 1833(e) of the Act, as reflected in 42 CFR § 424.5(a)(6), requires that providers furnish sufficient information to determine the amount due. In addition, section 1156(a)(2) of the Act requires that providers ensure that all health care services they bill to Medicare, including allergy services, are of a quality that meets professionally recognized standards of health care. “Professionally recognized standards of health care” are defined by 42 CFR § 1001.2 as “. . . Statewide or national standards of care . . . that professional peers of the individual or entity . . . recognize as applying to those peers practicing or providing care within a State.”

The only national rules specific to Medicare coverage of allergen immunotherapy appear in the National Coverage Determinations Manual. Section 110.9 of the manual precludes reimbursement for allergen immunotherapy delivered via antigen drops placed under the tongue. Sections 110.11 and 110.13 limit certain types of testing and treatment for food allergies. Other Medicare manual sections provide rules for proper billing of allergy services, but contain no additional restrictions on coverage. In the absence of national rules, many carriers have instituted Local Medical Review Policies (LMRP) that address allergy services.

The Joint Task Force on Practice Parameters develops standards for the diagnosis and treatment of allergies that embody generally accepted practices within the profession. The three societies that make up the Joint Task Force—the *American Academy of Allergy, Asthma, and Immunology*, the *American College of Allergy, Asthma, and Immunology*, and the *Joint Council of Allergy, Asthma, and Immunology*—represent an estimated 95 percent of the allergist/immunologists practicing in the United States, according to the chair of the Task Force. In 1995, the Task Force published “Practice Parameters for Allergy Diagnostic Testing,” which outlines the proper use of clinical and laboratory tests for allergies. “Allergen immunotherapy: a practice parameter [sic],” which was published in

1996 and updated in 2003, provides standards for evaluating and treating allergic patients. The Joint Task Force standards specify medical necessity criteria for, contraindications to, and the appropriate duration of allergen immunotherapy. They also outline proper procedures for administering allergy tests, preparing and delivering injections, and providing follow-up care. Because, to our knowledge, there exist no competing local or State standards for allergen immunotherapy, we considered the Joint Task Force standards to be “professionally recognized standards of health care” under section 1156(a)(2) of the Act. Appendix A lists the specific standards that are related to the findings in this report.<sup>8</sup>

#### **Prior Office of Inspector General work**

As part of “Medicare Allergen Preparation” (OEI-09-00-00530), published in 2002, we evaluated a probe sample of a small number of allergy services rendered to Medicare beneficiaries in 2000 and 2001. Seventeen of the twenty-seven services reviewed as part of this probe were inadequately documented or not medically necessary. Beneficiaries of the 12 services determined to be medically unnecessary had allergy test results that did not demonstrate the need for immunotherapy, had contraindications, or were on allergy shots for extended periods without clinical justification.

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## METHODOLOGY

Our primary methodology involved medical review of a sample of allergy services randomly selected from the Medicare 2001 National Claims History Date File. Because our objective required us to address both beneficiary- and service-level issues, we used a two-stage cluster sample to select records for the medical review. As diagramed in Figure 2 on the next page, we first defined the beneficiary universe as all Medicare beneficiaries on allergen immunotherapy in 2001, i.e., for whom at least one allergen immunotherapy service was allowed.<sup>9</sup> From this universe

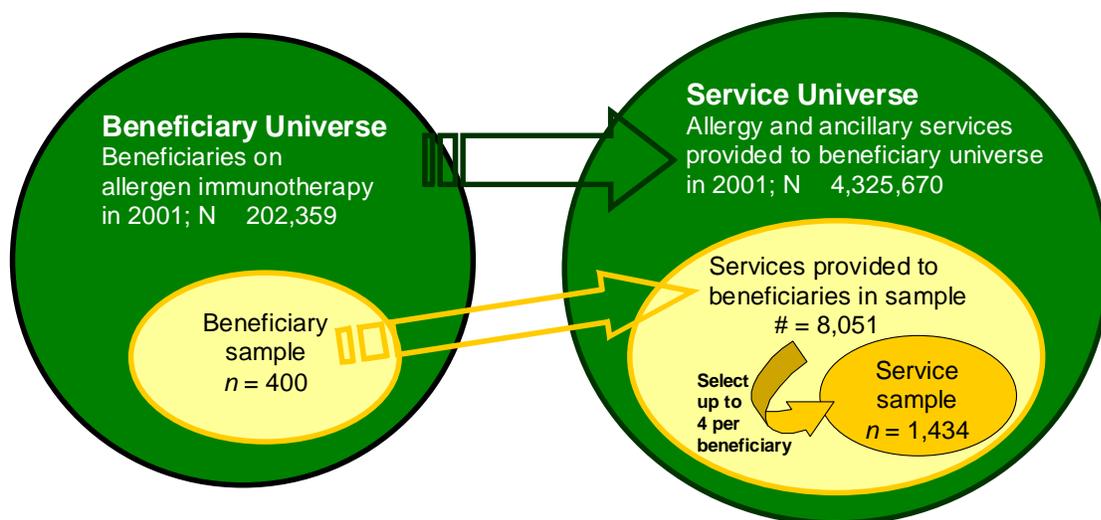
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<sup>8</sup> The 2003 update clarified and expanded the standards that had been published in 1996. The allergy specialists who conducted the medical review for this study stated that the standards were considered “good practice” for many years prior to either publication.

<sup>9</sup> In defining the beneficiary universe, we regarded services listed under the heading “Allergen Immunotherapy” in the 2001 Current Procedural Terminology (CPT, codes 95115 through 95199) as “allergen immunotherapy services,” except code 95180, *Rapid desensitization procedure, each hour*. We excluded CPT code 95180 because it is sometimes used to bill for an emergency procedure, rather than ongoing immunotherapy.

of 202,359 beneficiaries, we selected 400 to create the beneficiary sample. Next, we defined the service universe as all Part B allergy and ancillary services allowed in 2001 for members of the beneficiary universe.<sup>10</sup> The service universe comprised 4,325,670 services, with \$130,388,941 allowed. To obtain the service sample, we randomly selected four services billed for each sampled beneficiary. Since some beneficiaries had fewer than 4 services allowed in 2001, our sample contained 1,434 services.

FIGURE 2  
Graphical  
representation of the  
sample



Source: Office of Evaluation and Inspections, 2004

After selecting the cluster sample, we requested medical records from all providers who billed at least one allergy service in 2001 on behalf of the sampled beneficiaries. We requested that each provider send all records related to each beneficiary’s allergy treatment, including the patient’s history and the results of allergy tests. We made at least two follow-up requests to each provider who did not respond to our initial request, for a total of three contacts. Our overall response rate was 96 percent, because eight physicians did not respond to our repeated requests for records, and we chose not to contact eight others.<sup>11</sup>

<sup>10</sup> For the service universe, we regarded services listed under the CPT headings “Allergy Testing” and “Allergen Immunotherapy” (CPT codes 95001 through 95199) as “allergy services” and services billed by the provider of an allergy service as “ancillary services.”

<sup>11</sup> One was under criminal investigation, one did not maintain records in English, two could not be located, and four had recently provided records for another allergy study.

## I N T R O D U C T I O N

We contracted with allergist/immunologists and otolaryngic allergists to review the records using a protocol we developed in collaboration with the medical reviewers.<sup>12</sup> The protocol had two parts. First, the reviewers determined if the beneficiary's allergy care as a whole met Joint Task Force standards. Then, the reviewers determined if each individual service in the sample was medically necessary. If the physician reviewer found that the beneficiary was an appropriate candidate for immunotherapy, a Certified Professional Coder then determined if each service was documented adequately and billed according to the definitions in the 2001 CPT Manual. We did not share the results of our review with the Medicare carriers that paid for the services.

Along with the medical and coding reviews, we analyzed legislation, Medicare regulations, and Medicare and carrier LMRPs related to allergy services and compared them to the Joint Task Force standards.

Because we reviewed only allergy and related services provided in 2001, our results cannot be extrapolated to other periods. Accordingly, we make no inferences to subsequent years. However, to our knowledge, the Centers for Medicare & Medicaid Services (CMS) has made no national policy changes that would impact the incidence of allergen immunotherapy payment errors since 2001.

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

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<sup>12</sup> A physician of the same specialty as the beneficiary's primary provider of allergen services reviewed each record.

## ► FINDINGS

### Sixty-two percent of the allergen immunotherapy and related services allowed by Medicare in 2001 did not meet program requirements, resulting in \$75 million in improper payments

Medicare allowed approximately \$130 million in 2001 for allergen immunotherapy and related services. According to our medical review, 31 percent of these services were not

medically necessary (and, therefore, noncovered). An additional 7 percent were miscoded and 29 percent were undocumented. Six percent had multiple errors, yielding an overall error rate of 62 percent.<sup>13</sup> Figure 3 groups the improperly paid services in our sample by the type of error and gives statistical projections of these errors to the population.

**Figure 3: Medically Unnecessary, Miscoded, and Undocumented Allergen Immunotherapy and Related Services**

Type of Error	Sample		Projected	
	Services	Allowed Amount	Services (Proportion)	Allowed Amount (Millions)
<b>Medically unnecessary</b>				
- Not indicated	208	\$ 7,170.58	0.15	\$ 17
- Excessive duration	315	\$ 10,566.99	0.24	\$ 22
- (Both not indicated and excessive duration)	(77)	(\$ 1,965.31)	(0.08)	(\$ 6.5)
<b>Total medically unnecessary</b>	<b>446</b>	<b>\$ 15,772.26</b>	<b>0.31</b>	<b>\$ 33</b>
<b>Total miscoded (net)</b>	<b>129</b>	<b>\$ 2,577.84</b>	<b>0.07</b>	<b>\$ 4.3</b>
<b>Undocumented</b>				
- Nonresponse	29	\$567.13	0.03	\$2.2
- Missing documentation	404	\$23,311.64	0.26	\$42.5
<b>Total undocumented</b>	<b>433</b>	<b>\$23,837.85</b>	<b>0.29</b>	<b>\$45</b>
<b>(Overlapping errors)</b>	<b>(101)</b>	<b>(\$ 3,591.27)</b>	<b>(0.06)</b>	<b>(\$ 6.4)</b>
<b>Total</b>	<b>907</b>	<b>\$ 38,596.68</b>	<b>0.62</b>	<b>\$ 75</b>

Source: Medical Review of Year 2001 Allergen Immunotherapy and Related Services by Practicing Allergy Specialists. Lines may not sum to totals due to rounding.

*Medically unnecessary.* Medical reviewers determined that 31 percent of the allergen immunotherapy and related services Medicare allowed in 2001 were not medically necessary because immunotherapy was not indicated or the beneficiary had been on allergy shots for an excessive length of time. Immunotherapy services were more likely (34 percent)

<sup>13</sup> Confidence intervals for all statistics appear in Appendix B.

to be medically unnecessary than allergy tests (5 percent) or ancillary services (11 percent).

*Medically unnecessary: Not indicated.* There was no clinical basis for approximately 15 percent (\$17 million) of the allergen immunotherapy and related services that Medicare beneficiaries received. Medical reviewers determined that the allergy test results for 74 percent of these cases (i.e., of the 15 percent that did not have a clinical basis) did not indicate that the beneficiaries had any allergies, and 3 percent were not supported by any allergy test. The rest were not medically necessary because patient histories did not demonstrate that allergy shots were likely to alleviate the beneficiaries' complaints or had never been completed.

*Medically unnecessary: Excessive duration.* According to our reviewers, 24 percent (\$24 million) of allergen immunotherapy and related services were provided to beneficiaries for whom allergy shots were indicated originally, but whose duration of treatment exceeded Joint Task Force standards. The reviewers found some of these services to be medically unnecessary because the beneficiaries had not experienced any clinical benefits after 1 year of maintenance treatment. Other services were deemed unnecessary because the beneficiaries had been on immunotherapy for extended periods of time without evidence that such an extended course of immunotherapy was needed.

*Miscoded.* In 2001, Medicare allowed approximately \$13 million for allergen immunotherapy and related services that were billed with a code that did not accurately reflect the service provided.<sup>14</sup> If these services had been coded properly, Medicare would have allowed only \$9 million, yielding an overpayment of \$4 million. The most common error was billing CPT code 95117 (two or more injections of an allergen extract) when the documentation showed only one shot was provided. Other problems included billing for a greater volume of extract than was actually prepared or billing preparation of a multi-dose extract vial as preparation of a more expensive, single-dose vial. In several instances, physicians coded nonallergy services—including two lupron

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<sup>14</sup> The Certified Professional Coder reviewed only services provided to Medicare beneficiaries who were appropriate candidates for allergen immunotherapy. Our projections for "miscoded" services, therefore, are actually projections for "miscoded services provided to beneficiaries who were appropriate candidates for allergen immunotherapy." As a result, it is likely that we have underestimated the amount of money associated with miscoded allergy services.

injections, a vitamin B12 injection, and an echocardiogram—as allergy shots.

*Undocumented.* We did not receive substantiating documentation for 433 of the 1,434 services in our sample (29 percent). Despite repeated attempts, physicians did not provide any medical records for 29 of the services in our sample. The physicians who rendered another 404 of the services sent records that did not substantiate that any service was performed on the date claimed. Based on these findings, we estimate that Medicare allowed approximately \$45 million in 2001 for undocumented allergen immunotherapy and related services. Although some cases of missing documentation may be attributable to billing errors (e.g., putting the wrong date on the claim form), others may represent services not rendered. In any case, claims for services that lack sufficient documentation to show that care was provided do not meet the requirements of section 1833(e) of the Act.

Services billed with codes describing the preparation of immunotherapy extracts were undocumented most frequently. Although the Joint Task Force stresses the importance of documenting the contents of allergen extracts, 62 percent of these services lacked any substantiating documentation.

**In the absence of national guidance, some carriers have adopted policies that diverge from professionally recognized standards of health care**

As stated in the background, Medicare has little national coverage policy addressing allergen immunotherapy. In the absence of national guidance, many carriers have instituted LMRPs that

address allergy-related issues. Some local, and even national, policies contradict the Joint Task Force standards. For example, section 110.11 of the National Coverage Decisions Manual prohibits a particular, nontraditional, kind of immunotherapy for food allergies, but does not restrict the use of traditional immunotherapy for this purpose. The Joint Task Force standards, on the other hand, state that current scientific evidence does not support the use of any allergen immunotherapy modality in managing food allergies.

Another example concerns patients who self-administer their allergy shots. Although the Joint Task Force standards clearly and strongly state that immunotherapy should not be given at home because of the risk of adverse reactions, no national Medicare policy addresses the issue. Most LMRPs are consistent with the Joint Task Force and

indicate that shots should be provided in a setting appropriate for managing potential adverse reactions. However, one local policy states, “. . . it is expected that when the patient is stable on chronic therapy, [allergen immunotherapy] injections may be self-administered.”<sup>15</sup>

**The care provided to approximately 70 percent of Medicare beneficiaries who received allergen immunotherapy in 2001 was inconsistent with professionally recognized standards of health care**

In addition to examining the medical necessity and documentation of individual allergy services, our reviewers also assessed each beneficiary’s

entire course of immunotherapy. Since national Medicare coverage rules for allergen immunotherapy are very limited, we compared beneficiaries’ treatment to the Joint Task Force standards for allergy testing and allergen immunotherapy. Overall, 30 percent of beneficiaries received care that met all Joint Task Force standards examined, 26 percent received care that did not meet standards related to one of the areas listed below, and 44 percent received care that did not meet standards related to two or more of these areas:<sup>16</sup>

- clinical indications for immunotherapy (20 percent),
- contraindications (13 percent),
- duration of immunotherapy (22 percent),
- allergy diagnostic testing (15 percent),
- preparation and provision of injections (22 percent), and
- follow-up care (44 percent).

**Approximately 20 percent of beneficiaries who received allergen immunotherapy services in 2001 had no clinical need for treatment**

“Allergen immunotherapy should be considered for patients who have demonstrable evidence of [reactivity] to clinically relevant allergens,” but the medical records for one in five beneficiaries lacked evidence that allergen immunotherapy was medically necessary.<sup>17</sup> According to the

<sup>15</sup> Cahaba Government Benefit Administrators, Allergen Immunotherapy, L5390.

<sup>16</sup> In addition to the 16 beneficiaries for whom we did not receive records, 12 beneficiaries who were not actually on allergen immunotherapy in 2001 appeared in our sample, mostly as a result of billing errors. Hence, except where otherwise noted, we used a denominator of 372 beneficiaries on immunotherapy for the percentages in this finding.

<sup>17</sup> “Allergen immunotherapy: a practice parameter.”

patient histories that were available (9 percent of beneficiaries did not have a history in their record), 3 percent of beneficiaries on allergy shots had medical problems for which immunotherapy is not appropriate treatment. For example, several patients received allergy shots for chronic hives or angioedema (a type of swelling), although no clinical studies support treating these conditions with immunotherapy according to the Joint Task Force standards. Whether or not immunotherapy was appropriate for their complaints, 17 percent of Medicare immunotherapy patients did not show sufficient reactivity on their allergy tests to warrant treatment. The medical records for four of these beneficiaries contained no indication that they had ever received an allergy test.

**Thirteen percent of beneficiaries received immunotherapy despite contraindications that should have precluded it**

Approximately 13 percent of beneficiaries on immunotherapy had conditions for which our reviewers believed the attendant risk outweighed the potential benefit of allergy shots. The most common contraindications included taking beta-blockers and having compromised lung function. Other contraindications included a recent heart attack or arrhythmia, bypass surgery, chronic heart failure, prostate cancer, and previous stroke. Nearly 28 percent of the beneficiaries who received medically unnecessary immunotherapy also had contraindications.

**Approximately 22 percent of Medicare immunotherapy patients continued treatment well beyond clinical norms without justification**

The Joint Task Force standards state that if a patient has not experienced clinical improvement after 1 year of maintenance-dose immunotherapy, the physician should pursue other treatment options. Although approximately 9 percent of beneficiaries experienced no clinical benefit after several years of immunotherapy, they continued to receive shots on a regular basis. For example, one beneficiary remained on immunotherapy for 39 years, but still had significant allergy symptoms and needed numerous medications.

The practice parameter also states that the physician and patient should reevaluate the need for continued immunotherapy every 3 to 5 years. Seventeen percent of Medicare immunotherapy patients received shots for longer periods, with no indication in the medical record that the physician had ever considered discontinuing immunotherapy. At least 10 percent of Medicare beneficiaries had been

on allergy shots for 20 years or more without a reevaluation. In one extreme case, a beneficiary received continuous immunotherapy for 47 years; the treating physician did not try new medications that had been developed during the 47 years, which may have eliminated the need for the shots. Also, the physician never attempted a trial cessation of immunotherapy, which our reviewers believed should have occurred in such a prolonged course of treatment.

**Fifteen percent of beneficiaries on immunotherapy received inappropriate allergy tests**

Based on “Practice Parameters for Allergy Diagnostic Testing,” approximately 6 percent of Medicare beneficiaries on immunotherapy received allergy tests to allergens to which they reported no exposure or for which allergen immunotherapy was not indicated. Some physicians administered skin tests for substances, such as bacteria or smog, for which skin testing is of unproven diagnostic value. Others tested beneficiaries with allergens to which they had little or no history of exposure. A few other beneficiaries received tests for multiple cross-reactive allergens when a test for a single representative member of the allergen group would have sufficed.<sup>18</sup> Approximately 2 percent were tested to an excessive number of potential allergens, especially foods. “This is a record for me: 141 prick skin tests and 91 intradermal tests,” wrote one reviewer.

For the results of skin tests to be meaningful, they must be performed with appropriate controls and the test reagents must be provided at the correct strength.<sup>19</sup> Physicians used incorrect procedures, however, to test about 1 of every 10 Medicare beneficiaries on immunotherapy in 2001. The most common error was performing skin tests with no negative or positive controls, rendering accurate interpretation impossible. Physicians used reagents that were too strong for other tests, resulting in a high probability of false positive results. Physicians tested approximately 6 percent of beneficiaries using serial endpoint titration, a technique used primarily by otolaryngologists. Our reviewers stated that the physicians for 27 percent of these patients performed the technique or interpreted the results incorrectly.

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<sup>18</sup> See Summary Statement 26 from “Allergen immunotherapy: a practice parameter” in Appendix A.

<sup>19</sup> “Practice Parameters for Allergy Diagnostic Testing.”

**Twenty-two percent of beneficiaries received allergy shots that were prepared improperly, provided too frequently, or delivered in an inappropriate setting**

Approximately 8 percent of all Medicare immunotherapy patients received an allergen extract that was not prepared according to Joint Task Force standards. More than half of these extracts combined incompatible allergens or contained an excessive number of allergens, both of which can reduce treatment efficacy. Others contained allergens to which the beneficiary had tested negative or that had no correlation to the beneficiary's allergy history. Some beneficiaries (2 percent overall) received extracts containing allergens, such as foods and poison ivy, for which immunotherapy is not indicated.

Patients on a maintenance schedule should generally receive injections at 2- to 4-week intervals, but allergy shots were provided too frequently to approximately 11 percent of Medicare beneficiaries. Providers for these beneficiaries generally did not increase the amount of time between shots after a maintenance dosage was reached, which should normally be attempted, according to Joint Task Force standards. For example, one beneficiary received weekly shots for 28 years, without any indication that the physician ever tried longer intervals between shots.

At least 7 percent of beneficiaries received their allergy shots at home despite Joint Task Force standards that state "immunotherapy injections should not be administered at home because of the risk of inadequate recognition and treatment of systemic reactions."<sup>20</sup> These beneficiaries administered their own shots or were treated by family members. According to the progress notes in her medical record, one beneficiary received shots "on the rode [sic]" in her mobile home. An additional 3 percent of beneficiaries received shots away from their allergy specialists' offices, but in locations that were not identified in their medical records.

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<sup>20</sup> "Allergen immunotherapy: a practice parameter."

## F I N D I N G S

### **Some Medicare immunotherapy patients did not receive adequate follow-up care**

The Joint Task Force standards advise physicians to evaluate their immunotherapy patients every 6 to 12 months, but 24 percent of beneficiaries on allergy shots did not have regular follow-up visits with their allergy specialists. For example, one medical record showed that the patient had not seen her allergy specialist in more than 10 years. Another beneficiary, on immunotherapy for approximately 20 years, had no documented follow-up visits to his allergist.

Even when conducted, followup was inappropriate for 27 percent of beneficiaries. For example, approximately 7 percent of patients had routine periodic skin tests without clinical justification—one beneficiary was inappropriately retested every time she had an exacerbation of her symptoms and another had skin tests at least nine times during a 6-year period. Other providers made no note of the beneficiary's response to immunotherapy or did not respond appropriately to changes in the beneficiary's symptoms or the results of reevaluations.



## R E C O M M E N D A T I O N S

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Allergen immunotherapy services, while valuable, often are provided in an inappropriate manner and result in a significant number of improper Medicare payments. As allowances for allergen immunotherapy and related services have increased from \$130 million in 2001 to approximately \$171 million in 2003, so has Medicare's vulnerability to related payment errors. Also, current national Medicare policy on immunotherapy is limited, and some national and local policies do not reflect current professionally recognized standards of health care. Therefore, we recommend that CMS:

**Instruct its carriers to educate physicians who provide allergen immunotherapy to Medicare beneficiaries about existing coding, documentation, and coverage requirements**

**Develop national coverage criteria for allergen immunotherapy that are based on professionally recognized standards of health care**

In addition to these recommendations, we have forwarded information on the medically unnecessary, miscoded, and undocumented services identified in our sample to CMS for appropriate action.

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## AGENCY COMMENTS

In its comments to our draft report, CMS stated that it is prepared to develop and disseminate educational materials and develop new coverage criteria for allergen immunotherapy services. CMS has identified two possibilities for developing national coverage criteria for allergen immunotherapy: adapting criteria directly from current professional society standards or opening a National Coverage Determination. CMS states that either option would require up to 12 months to fully implement, and that educating physicians on existing coding, documentation, and coverage requirements depends on the course chosen for developing national coverage criteria. The complete text of CMS's comments are included starting on page 26.

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## OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate CMS's support for our recommendations to increase physician education and to develop national coverage criteria based on professionally recognized standards of health care. Since the CMS letter identifies various methods for implementing the

## R E C O M M E N D A T I O N S

recommendations, we request that CMS provide to us an action plan that clarifies the specific steps it intends to take to fully implement the recommendations.

## Professionally Recognized Standards of Care

We compared the findings of our medical review with the professionally recognized standards of health care found in the 2003 version of “Allergen immunotherapy: a practice parameter” and “Practice Parameters for Allergy Diagnostic Testing.” Although “Allergen immunotherapy” was updated in 2003, our contracted allergy specialists stated that the standards therein were considered “good practice” for many years prior, and are, therefore, applicable to services provided in 2001.

“Allergen immunotherapy” expresses the standards as a series of “summary statements,” each addressing a single topic related to immunotherapy. “Allergy Diagnostic Testing” consists primarily of similar one- or two-sentence guidelines. The particular summary statements and guidelines relevant to our analysis are quoted below.

**“Allergen immunotherapy: a practice parameter”**

Summary Statement 9. Immunotherapy is effective for treatment of allergic rhinitis, allergic asthma, and stinging insect hypersensitivity. Therefore, immunotherapy merits considerations in patients with these disorders.

Summary Statement 10. Clinical studies to date do not support the use of allergen immunotherapy for food hypersensitivity, chronic urticaria, and/or angioedema. Therefore, allergen immunotherapy for patients with these conditions is not recommended.

Summary Statement 11. Clinical parameters, such as symptom scores and medication use, may be useful measures of the efficacy of immunotherapy in a clinical setting. Routine periodic skin testing or in vitro IgE antibody testing of patients receiving immunotherapy is not recommended.

Summary Statement 14. Patients taking  $\beta$ -adrenergic blocking agents may be at increased risk when receiving immunotherapy, because [beta]-receptor blockade can make treatment of anaphylaxis more difficult. Therefore, [beta]-adrenergic blocking agents are relative contraindications for immunotherapy.

Summary Statement 15. Medical conditions that reduce the patient’s ability to survive a systemic reaction are relative contraindications for allergen immunotherapy. Examples include severe asthma

uncontrolled by pharmacotherapy and significant cardiovascular disease.

*Summary Statement 16.* Allergen immunotherapy should be administered in a setting where procedures that can reduce the risk of anaphylaxis are in place and where the prompt recognition and treatment of anaphylaxis are assured.

*Summary Statement 17.* Allergen immunotherapy should be considered for patients who have demonstrable evidence of specific IgE antibodies to clinically relevant allergens. The decision to begin allergen immunotherapy depends on the degree to which symptoms can be reduced by avoidance and medication, the amount and type of medication required to control symptoms, and the adverse effects of medications. Patients who wish to avoid or reduce the long-term use of medications are good candidates for immunotherapy.

*Summary Statement 18.* Patients with severe, poorly controlled asthma are at higher risk for systemic reactions to immunotherapy injections.

*Summary Statement 21.* The components of a clinically relevant vaccine (and, therefore, a vaccine that is most likely to be effective) should be selected on the basis of a careful history of relevant symptoms, knowledge of possible environmental exposures, and correlation with positive tests for specific IgE antibodies.

*Summary Statement 22.* The immunotherapy vaccine should contain only clinically relevant allergens.

*Summary Statement 23.* Immediate-type skin testing has been the primary diagnostic tool in clinical studies of allergen immunotherapy. Therefore, in most patients, skin testing should be used to determine whether the patient has specific IgE antibodies. Appropriately interpreted and well performed [sic] in vitro tests for specific IgE antibodies may also be used.

*Summary Statement 24.* Immunotherapy is effective for pollen, fungi (molds), animal dander, dust mite, cockroach, and Hymenoptera sensitivity. Therefore, immunotherapy should be considered as part of the management program in patients who have symptoms related to exposure to these allergens and in whom the presence of specific IgE antibodies has been established.

*Summary Statement 25.* In the mixing of an allergen vaccine, the following factors must be considered: (1) the cross-reactivity of the

allergens, (2) the optimal dose of each constituent, and (3) enzymatic degradation of the allergens.

*Summary Statement 26.* The selection of allergens for immunotherapy should be based in part on the cross-reactivity of clinically relevant allergens. Many related pollen contain allergens that are cross-reactive. When pollen allergens are substantially cross-reactive, selection of a single pollen within the cross-reactive genus or subfamily may suffice. When pollen allergens are not substantially cross-reactive, testing for and treatment with multiple locally prevalent pollen [sic] may be necessary.

*Summary Statement 27.* The efficacy of immunotherapy depends on achieving an optimal therapeutic dose of each of the clinically relevant constituents in the vaccine.

*Summary Statement 28.* Separation of aqueous extracts (vaccines) with high proteolytic enzyme activities (e.g., fungi, dust mites, cockroach, and insect venoms) from other extracts (vaccines) is recommended.

*Summary Statement 43.* When the patient has reached a maintenance dose, the interval between injections can often be progressively increased as tolerated to 4 to 6 weeks.

*Summary Statement 44.* Clinical improvement usually is observed within 1 year after the patient reaches a maintenance dose.

*Summary Statement 45.* Patients should be evaluated at least every 6 to 12 months while they receive immunotherapy.

*Summary Statement 46.* A decision to continue or stop immunotherapy should be made after 3 to 5 years.

*Summary Statement 47.* The vaccine contents, informed consent for immunotherapy, and administration of vaccines should be carefully documented.

*Summary Statement 48.* The preferred location for the administration of allergen immunotherapy is the office of the physician who prepared the patient's vaccine.

*Summary Statement 49.* Generally, patients at high risk of systemic reaction should receive immunotherapy in the office of the physician who prepared the patient's vaccine.

Summary Statement 50. Regardless of location, allergen immunotherapy should be administered under the supervision of an appropriately trained physician and personnel.

Summary Statement 51. Immunotherapy injections should not be administered at home because of the risk of inadequate recognition and treatment of systemic reactions.

Summary Statement 55. In older adults, medications and co-morbid medical conditions may increase the risk from immunotherapy. Therefore, special consideration must be given to the benefits and risks of immunotherapy in older adults.

**“Practice Parameters for Allergy Diagnostic Testing”**

- To properly interpret allergy skin tests that detect immediate hypersensitivity, both positive (histamine) and negative (diluent) controls need to be performed.
- The appropriate clinical indications for retesting may include changing symptoms, new exposures, 3 to 5 years of venom immunotherapy or evaluation of newly discovered, purified, or standardized allergens.
- Avoidance measures and extract formulations for immunotherapy should be based on the skin tests coupled with adequate clinical correlation, i.e., integrating with the history and physical findings obtained by face-to-face contact with the patient.
- A prick/puncture skin test wheal response of at least 3 mm (with equivalent erythema) > than the diluent control done at the same time is required as proof of the presence of allergen specific IgE.
- The larger the prick/puncture skin test reaction, the more likely it is to be of clinical significance. However, the presence of a positive prick/puncture skin test per se does not establish whether clinical sensitivity currently is present.
- As a general rule, the starting test dose of intracutaneous extract solutions in patients with a preceding negative prick/puncture test should range between 100 and 1,000 fold dilutions of the prick/puncture test solution.
- Any reaction larger than the negative control may indicate the presence of specific IgE antibody. However, given the lower

specificity of intracutaneous testing, small positive reactions may not be clinically relevant.

- The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intracutaneous tests, which are ordinarily performed when prick/puncture tests are negative. Under special circumstances and in certain geographic areas, a greater number of prick/puncture and/or intracutaneous tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required.
- The number of prick/puncture tests performed for suspected food hypersensitivity may vary from less than 20 to as many as 80 tests, depending on the clinical situation.
- . . . for such agents as newsprint, formaldehyde, tobacco smoke, smog, cotton, sugar, and human dander, there is insufficient evidence to justify their use as allergen test reagents.

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Statistical Confidence Intervals

Statistic	N	Point Estimate	95% Confidence Interval
Percentage of immunotherapy-related services that should not have been paid	1,434	0.62	0.56 to 0.67
Amount that Medicare should not have allowed	1,434	\$75 million	\$68 million to \$82 million
Percentage of services that were not medically necessary	1,434	0.31	0.26 to 0.37
Amount allowed for medically unnecessary services	1,434	\$33 million	\$26 million to \$39 million
Percentage of immunotherapy services that were not medically necessary	1,243	0.34	0.28 to 0.40
Percentage of allergy tests that were not medically necessary	32	0.05	< 0.11
Percentage of ancillary services that were not medically necessary	127	0.11	0.04 to 0.19
Percentage of services for which immunotherapy was not indicated	1,434	0.15	0.10 to 0.20
Amount allowed for services where immunotherapy was not indicated	1,434	\$17 million	\$12 million to \$22 million
Of services for which immunotherapy was not indicated:			
-the percentage for which allergy tests did not show reactivity	208	0.74	0.56 to 0.91
-the percentage for which no allergy test was documented	208	0.03	< 0.08
-the percentage for which the patient's history did not indicate immunotherapy	208	0.35	0.18 to 0.53
Percentage of services that were allowed for beneficiaries on immunotherapy too long	1,434	0.24	0.18 to 0.30
Amount allowed for services provided to beneficiaries on immunotherapy too long	1,434	\$22 million	\$17 million to \$28 million
Percentage of services that were miscoded	1,434	0.07	0.05 to 0.10
Excess amount allowed for miscoded services	1,434	\$4.3 million	\$2.4 million to \$6.1 million
Total amount allowed for miscoded services	1,434	\$13 million	\$8.8 million to \$17 million

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Statistical Confidence Intervals, continued			
Statistic	N	Point Estimate	95% Confidence Interval
Percentage of services that were undocumented	1,434	0.29	0.24 to 0.34
Amount allowed for undocumented services	1,434	\$45 million	\$37 million to \$52 million
Percentage of extract preparations that were undocumented	357	0.62	0.52 to 0.72
Total percentage of beneficiaries whose care did not meet standards	372	0.70	0.65 to 0.75
Percentage of beneficiaries whose care met standards	372	0.30	0.25 to 0.35
Percentage of beneficiaries whose care failed standards in one area	372	0.26	0.22 to 0.31
Percentage of beneficiaries whose care failed standards in multiple areas	372	0.44	0.39 to 0.49
Percentage of beneficiaries on shots who had no demonstrated need for treatment	372	0.20	0.16 to 0.24
Percentage of beneficiaries who had contraindications	372	0.13	0.10 to 0.17
Percentage of beneficiaries on immunotherapy too long	372	0.22	0.18 to 0.26
Percentage of beneficiaries whose allergy tests did not meet standards	372	0.15	0.11 to 0.19
Percentage of beneficiaries whose allergy shots were prepared or delivered inappropriately	372	0.22	0.18 to 0.27
Percentage of beneficiaries who received inadequate follow-up care	372	0.44	0.39 to 0.49
Percentage of beneficiaries who did not have a patient history in their record	372	0.09	0.06 to 0.12
Percentage of beneficiaries who had complaints for which immunotherapy is not appropriate	372	0.03	0.01 to 0.04
Percentage of beneficiaries whose allergy tests did not indicate a need for treatment	372	0.17	0.14 to 0.21

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Statistical Confidence Intervals, continued			
Statistic	N	Point Estimate	95% Confidence Interval
Percentage of with contraindications who:			
- were on beta-blockers	50	0.36	0.23 to 0.49
- had compromised lung function	50	0.18	0.07 to 0.29
Of beneficiaries whose treatment was unnecessary, the percentage that also had contraindications	74	0.28	0.18 to 0.39
Percentage of beneficiaries who should have terminated immunotherapy because it did not benefit them clinically	372	0.09	0.06 to 0.11
Percentage of beneficiaries who were on immunotherapy too long without justification	372	0.17	0.13 to 0.20
Percentage of beneficiaries on immunotherapy longer than 20 years	372	0.10	0.07 to 0.13
Percentage of beneficiaries who were tested to inappropriate allergens	372	0.06	0.03 to 0.08
Percentage of beneficiaries who were tested to too many allergens	372	0.02	0.01 to 0.04
Percentage of beneficiaries who were tested with incorrect procedures	372	0.10	0.07 to 0.14
Percentage of beneficiaries who were tested with skin endpoint titration	372	0.06	0.04 to 0.08
Percentage of skin endpoint titrations that were performed or interpreted incorrectly	22	0.27	0.09 to 0.46
Percentage of beneficiaries whose shots contained inappropriate allergens	372	0.08	0.06 to 0.11
Percentage of beneficiaries whose shots contained allergens for which immunotherapy is not indicated	372	0.02	0.01 to 0.04
Percentage of beneficiaries who received shots too frequently	372	0.11	0.08 to 0.14

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Statistical Confidence Intervals, continued			
Statistic	N	Point Estimate	95% Confidence Interval
Percentage of beneficiaries who received shots at home	372	0.07	0.05 to 0.10
Percentage of beneficiaries who received shots in an undetermined location	372	0.03	0.01 to 0.04
Percentage of beneficiaries whose treatment was not monitored	372	0.24	0.19 to 0.28
Percentage of beneficiaries who were monitored, but received inappropriate follow-up	312	0.27	0.22 to 0.32
Percentage of beneficiaries who received inappropriate repeat skin tests	372	0.07	0.05 to 0.10

Pairwise T - Tests for medically unnecessary services by type of service

Comparison	Test Result	P-value (Bonferroni threshold = 0.016667)
Allergy tests versus allergen immunotherapy	-6.59	0.00 ( <i>significant at 95% confidence</i> )
Allergy tests versus ancillary services	-1.37	0.17 ( <i>not significant at 95% confidence</i> )
Allergen immunotherapy versus ancillary services	5.10	0.00 ( <i>significant at 95% confidence</i> )

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

NOV 17 2005

Administrator  
Washington, DC 20201

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Mark B. McClellan, M.D., Ph.D. *MM*  
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report "Allergen Immunotherapy for Medicare Beneficiaries," (OEI-09-00-00531)

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 GENERAL

Thank you for the opportunity to review and comment on the subject draft report. CMS is prepared to develop and disseminate materials to better educate physicians on coding, documentation, and coverage requirements for allergen immunotherapy services. CMS is also prepared to develop new coverage criteria from either current professional standards or through the national coverage determination process in order to reduce and eliminate medically unnecessary, miscoded, and undocumented services.

The OIG report explains the results of a medical review by practicing allergy specialists of a random sample of 400 Medicare allergen immunotherapy and related services allowed in 2001. This review was conducted to determine if services related to immunotherapy met Medicare coverage and documentation requirements and if allergen immunotherapy provided to Medicare beneficiaries was of a quality that met professionally recognized standards of care.

OIG Recommendation

Instruct its carriers to educate physicians who provide allergen immunotherapy to Medicare beneficiaries about existing coding, documentation, and coverage requirements.

CMS Response

The Centers for Medicare & Medicaid Services (CMS) interprets this to mean that CMS should remind/notify physicians about the existing national policy surrounding current coding, documentation, and coverage requirements as it relates to allergen immunotherapy. In order to do this, the appropriate CMS staff – the Office of Clinical Standards and Quality (OCSQ) - responsible for this issue should determine whether or not to proceed with such physician outreach/education, possibly through a *Special Edition Medlearn Matters* article. A determination by OCSQ on the immediate education piece will most likely depend on the CMS response to the second recommendation, which we discuss below. Once OCSQ advises as to how to proceed with an education program, CMS staff (OCSQ and the Center for Medicare Management) will work

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together to determine the best method for disseminating information to the physician community.

OIG Recommendation

Develop national coverage criteria for allergen immunotherapy that are based on professionally recognized standards of health care.

CMS Response

CMS has identified two ways in which to develop new coverage criteria in order to reduce and eliminate medically unnecessary, miscoded, and undocumented allergen immunotherapy services. The first option is to adapt coverage criteria directly from current professional society standards. The second option would require opening a national coverage determination (NCD) in order to use available data to develop national coverage criteria, obtain public input, and implement the coverage policy. An NCD can be opened either on the initiative of CMS staff or based upon an outside request. Either of these options would take up to 12 months from the initiation of an NCD to completely develop and implement new coverage criteria.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Paul A. Gottlober, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Deborah Harvey, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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