



The American Academy  
of Otolaryngic Allergy



February 25, 2021

Juan L. Schaening Perez, MD  
Executive Contractor  
Florida First Coast Options, Inc.

Attn: Medical Affairs  
2020 Technology Parkway  
Suite 100  
Mechanicsburg, PA 17050

Email: [ProposedLCDComments@fcso.com](mailto:ProposedLCDComments@fcso.com)

RE: Proposed Local Coverage Determination (LCD) Allergen Immunotherapy (DL37800)

Dear Dr. Schaening Perez:

As healthcare providers skilled in the care of patients with allergies and concerned with the provision of allergen immunotherapy for their treatment, the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology and the American Academy of Otolaryngic Allergy offer the following collective comments regarding the First Coast Proposed Local Coverage Determination for Allergen Immunotherapy (DL37800).

We agree with many of the recommendations regarding medical necessity and coverage for allergen immunotherapy and we commend the MAC for its attention to these issues. However, we have a number of serious concerns about some portions of the proposed LCD.

### **1. Multiallergen Immunotherapy**

Of most concern is the proposed LCD's policy's determination that, "*Multiallergen subcutaneous immunotherapy*," is, "*not considered medically reasonable and necessary*." Virtually all allergists in the United States prescribe multiallergen immunotherapy, as indicated in the Allergen Immunotherapy Practice Parameter and as addressed in summary statement 72<sup>1</sup>. While it is understood that immunotherapy should be prescribed only for relevant antigens, multiallergen immunotherapy reflects the standard of care, and is supported by extensive evidence and decades of patient outcomes. A review article on multiallergen immunotherapy by Harold Nelson, MD (one of the Chief Editors of *Allergen immunotherapy: A practice parameter third update*<sup>1</sup>) stated (for allergic rhinitis and asthma)

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<sup>1</sup> Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. J Allergy Clin Immunol. 2011;127(1 Suppl):S1-55.

“The findings of the current review strongly suggest that the simultaneous delivery of multiple unrelated allergens can be clinically effective with the proper identification of relevant allergens, and treatment with adequate doses for a sufficient period of time is essential.”<sup>2</sup> Multiple other studies report similar findings.<sup>3</sup>

Multiallergen immunotherapy has been the standard of care for decades. It consists of testing patients for sensitivity to specific allergens, based on a detailed history, and mixing and preparing allergen extracts that include the relevant antigens. This is the way that allergen immunotherapy (AI) is delivered throughout the United States. The practice parameters cited in the proposed LCD make it clear that AI consisting of mixtures of relevant allergens is clinically appropriate and effective.<sup>4</sup>

Based on the above, we respectfully request that the words “multiallergen immunotherapy” on page 5 be deleted.

## **2. Allergen Immunotherapy for Cockroach Sensitivity**

We also take exception to the statement that cockroach sensitivity is not an indication for immunotherapy since it has been proven to be effective.<sup>5</sup> Therefore, we request that “cockroach hypersensitivity” be removed from the list of non-covered indications on page 5.

## **3. Oral Immunotherapy for Food**

This policy also indicates, “*Allergen immunotherapy is not considered medically reasonable and necessary for,*” and continues, “*The following routes of administration,*” and lists, “*Oral or sublingual for food immunotherapy*” and “*Epicutaneous Immunotherapy.*” The Food and Drug Administration (FDA) has recently approved Palforzia® for oral desensitization for peanut allergies. Further, the FDA will soon review epicutaneous desensitization for food. Therefore, we recommend that these routes of administration be removed from the list of non-approved routes of administration on page 5 of the proposed LCD. Alternatively, we recommend that the language be revised as follows:

- *Oral or sublingual for food immunotherapy unless the antigen is approved by the FDA for desensitization for food*
- *Epicutaneous immunotherapy unless the antigen is approved by the FDA for desensitization for food*

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<sup>2</sup> Nelson HS. Multiallergen immunotherapy for allergic rhinitis and asthma. *Journal of Allergy and Clinical Immunology*, Volume 123, Issue 4, 763 – 7699

<sup>3</sup> Nelson HS. *Exp Rev Clin Pharm*. 2016

<sup>4</sup> See, for example, summary statements 70, 72, 73, 77-79.

<sup>5</sup> Wood RA, et al. Development of cockroach immunotherapy by the Inner-City Asthma Consortium. *J Allergy Clin Immunol*. 2014; 133:846–52.

We thank you for your consideration of these collective comments. To discuss these comments further, please contact Sheila Heitzig, AAAAI Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071. She will facilitate further communication with leadership.

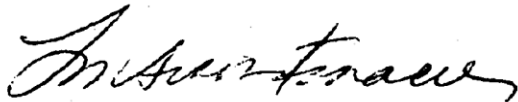
Sincerely,

A handwritten signature in black ink, appearing to read "Mary Beth Fasano". The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.

Mary Beth Fasano, MD, MSPH, FAAAAI  
President, American Academy of Allergy, Asthma & Immunology

A handwritten signature in black ink, appearing to read "Wesley D. Vander Ark". The signature is cursive and somewhat stylized, with a prominent "W" and "V".

Wesley D. Vander Ark, MD, FAAAAI  
President, American Academy Of Otolaryngic Allergy

A handwritten signature in black ink, appearing to read "Luz S. Fonacier". The signature is cursive and elegant, with a large initial "L" and a long, sweeping underline.

Luz S. Fonacier, MD, FAAAAI  
President, American College of Allergy, Asthma & Immunology