## National Government Services, Inc JK and J6 Open Meeting Transcript

Moderator: Dr. Ella Noel March 13, 2025, 12:00 pm ET 11m 13s

## Noel, Ella

Are we ready to show the slides Crystal? OK, looks like we're ready to start the J6 JK Open meeting today. Next slide. Next slide please.

## Bennett, Crystal M.

One second, I need to get them to advance.

## Noel, Ella

OK.

And then if you can advance.

OK, this call is being recorded and transcribed. If you do not want to be recorded, please drop from the call. If you stay on the call, we assume that means that you are OK with being recorded. Next slide.

This slide welcomes the CMDs for J6 and JK. These are our contract medical directors. We have Dr. Ola Awodele, Dr. Marc Duerden, Dr. Janet Lawrence, Dr. Gina Mullen, Dr. Greg McKinney and myself Dr. Ella Noel. Next slide.

Today, we're going to talk about a proposed LCD. It is DL40048 Allergen Immunotherapy with Subcutaneous Immunotherapy. Next slide.

This slide lists the clinical indications for allergen immunotherapy. These clinical indications must be met to be considered reasonable and necessary for allergen immunotherapy. There must be symptoms of allergic rhinitis, allergic conjunctivitis, allergic asthma, or any combination of these disorders after natural exposure to aeroallergens and demonstratable evidence of clinical relevant specific IgE and at least one of the following: poor response to pharmacotherapy, allergen avoidance, or both, for a minimum of 28 consecutive days, unacceptable adverse effects of medications, avoidance of long term pharmacotherapy and its side effects and possible prevention of asthma in patients with allergic rhinitis. Next slide.

Limitations of immunotherapy. These are not considered to be reasonable or necessary. First line treatment for allergic rhinitis and allergic conjunctivitis in the absence of previous medical treatment and environmental avoidance. Absence of clinically relevant IV excuse me, IgE. That would be a different open meeting. Atopic dermatitis. Sublingual immunotherapy. Subcutaneous immunotherapy during pregnancy. Treatment for food sensitivities. A presumption of failure can be made when after 12 to 24 months of therapy, a person does not experience a noticeable decrease of symptoms and increase intolerance to the offending allergen and a reduction in medication usage. Treatment will not be reimbursed after a 2-year period when there is no apparent clinical benefit. For those patients who have had an equivocal testing on IgE specific antibodies but have a strong clinical suspicion of allergic rhinitis and have a positive reaction to nasal allergen channel, subcutaneous immunotherapy may be considered on a case-by-case basis as reasonable and necessary. Next slide.

Provider requirements. Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient when: the antigens are prepared by a physician who is a Doctor of Medicine or Osteopathy, and the physician who prepared the antigens has examined the patient and determine a plan of treatment and a dosage regimen; and because the major risk of allergen immunotherapy is anaphylaxis, subcutaneous immune therapy should therefore be administered under the supervision of an appropriately trained physician who can recognize early symptoms and signs of anaphylaxis and administer emergency medications where necessary. In addition, subcutaneous immunotherapy should be administered only in facilities equipped to treat anaphylaxis. It may be appropriate to permit patient self-administration at home for a patient with a history of life-threatening anaphylaxis who cannot receive immunotherapy in a healthcare facility. This requires careful consideration of potential benefits and risks and should be made on an individual patient basis with appropriate informed consent. Next slide.

Documentation. Clear and accurate recording of the initial prescription for an allergen immunotherapy extract is essential to ensure that it is mixed in an identical fashion each time it is filled. In addition, these forms allow transmission of the information to any clinician who may undertake the allergy care of the patient. It is recommended that the following information be contained in the form patient information including name, patient number, birth date, telephone number and picture, if available to reduce the risk of an extract being given to a wrong patient. Preparation information, including name of the person preparing and the date of the preparation. allergen immunotherapy extract content, including for each allergen, common name or genus, and species extract manufacturer, concentration of manufacturers extract, volume of the manufacturer's extract added and the type of diluent of any, used volume of

diluent added, lot number and expiration date of each individual component. Next, thank you.

Are there any further comments on the allergen immunotherapy with subcutaneous immunotherapy from the those in attendance. Please raise your hand using the app so that we know if there is any questions. It does not appear that anyone has any questions that is in the audience. If not, comments are closed at this time. If you have any written comments, please forward them to us. Next slide.

The comment period is from February 13th to March 29. If you click on the public comments button on the proposed LCD in the Medicare coverage database. And we would like those sent to Part B LCD comments at Anthem com. And if you need to send them through the regular Postal Service, send them to National Government Services Incorporated, LCD comments, PO Box 7108 Indianapolis IN 46207-7108 and again the comment period is officially from February 13<sup>th</sup> to March, I believe it was 29<sup>th</sup>.

I'd like to thank you all for joining us and have a good day. The meeting is closed.

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