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| First Coast Service Options, Inc.  JN Open Meeting |
| Thursday, October 12, 1 p.m.  Topic:  DL37800– Allergen Immunotherapy |
| CORPORATE PARTICIPANTS  Patrick Mann, MD – First Coast Service Options/Novitas Executive Contractor Medical Director  David Sommers, MD, JD, LLM- Novitas Contractor Medical Director  Claudia Campos, MD, FACP- Novitas Contractor Medical Director  Gavin McKinnon, MD, CRC, CHCQM- Novitas Contractor Medical Director  Benita Jackson, MD, MPH, FACPM, CHCQM, CPHQ- First Coast Contractor Medical Director  Janice Green, RN, CPC – Novitas Medical Policy Nurse  PRESENTERS  No registered presenters |

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PRESENTATION

Monica McKenzie

Good Afternoon. I'm Monica McKenzie, your WebEx host for today's Open Meeting. Before we get started, I want to remind everyone that this meeting is being recorded. At this time, I'm going to turn things over to Contractor Medical Director Dr.Gavin McKinnon. Dr. McKinnon?

Dr. Gavin McKinnon

Good afternoon. I would like to welcome everyone to First Coast’s August Open meeting. My name is Dr. Gavin McKinnon. Joining me today are my Novitas and First Coast colleagues, Dr. Patrick Mann, Dr. Claudia Campos, Dr. Benita Jackson, and Dr. David Sommers.

Please be aware that First Coast Service Options, Inc. is recording this virtual Open meeting to comply with the CMS guidelines. By remaining logged in and connected via telephone or webinar, you acknowledge that you have been made aware that this virtual Open meeting is being recorded and that you consent uh and you are consenting to the recording. If you do not consent to being recorded, please disconnect from this virtual Open meeting.

We are holding today’s Open meeting to provide you with an opportunity to present your comments on revisions made in response to a reconsideration request. Open meetings allow interested parties the opportunity to present information and offer comments related to new proposed LCDs and/or the revised portion of a proposed LCD during the 45-day comment period.

The proposed LCD topic for today’s meeting is:

• DL37800 Allergen Immunotherapy

During today’s meeting, interested parties will make presentations of information related to the proposed LCDs. Please remember, today’s call is being recorded and we request that all formal comments be submitted in writing before the end of the comment period on November 11th. We encourage you to submit full text published evidence regarding, supporting your recommendations that have not been previously submitted.

At this time, I would like to turn it over to I would like to turn it over to Jan Green to provide a brief overview of the proposed LCD Allergen Immunotherapy.

Janice Green

Thank you, Dr. McKinnon and good afternoon, everyone. This Local Coverage Determination has been revised in response to a reconsideration request. Once this revision to the LCD becomes effective, the current First Coast LCD L37800 for Allergen Immunotherapy will be replaced with this revised policy. The related article will not be revised.

Allergen Immunotherapy is defined as the repeated administration of specific allergens to individuals with IgE-mediated conditions to provide protection against allergic symptoms and inflammatory reactions associated with natural exposure to these allergens.

A reconsideration request was received requesting to remove non-coverage language for ‘multiallergen subcutaneous immunotherapy’. After evidence was reviewed, it was determined that this was a valid request as literature indicates that this is considered the standard of practice in the United States. Therefore, the LCD has been revised accordingly.

The reconsideration request also requested the removal of non-coverage language for ‘allergen immunotherapy for cockroach hypersensitivity’ and referenced an article by Wood et al (2014). However, the quality of evidence provided is insufficient to support allergen immunotherapy for cockroach hypersensitivity. Further research is needed to clarify the utility and efficacy of allergen immunotherapy for cockroach sensitivity. Therefore, the LCD has not been revised as requested.

Finally, the reconsideration request requested the removal of non-coverage language for the following allergen immunotherapy routes of administration: ‘oral or sublingual for food immunotherapy and epicutaneous immunotherapy’. Per National Coverage Determination 110.9, antigens must be administered by injection to be considered for coverage by Medicare. Because coverage determinations that appear in NCDs supersede those found in LCDs, the LCD has not been revised as requested. Thank you and now I'll turn the meeting back over to Dr. McKinnon.

Dr. Gavin McKinnon

Thank you, Jan.

Since we have no presenters, I would like to thank everyone for their participation in today’s Open meeting and remind you to submit comments in writing before the end of the comment period on November 11, 2023. We encourage you to submit full text published evidence supporting your comments that have not been previously submitted. This meeting is adjourned.