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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: RAST Type Tests**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft **RAST Type Tests** LCD. The official notice period for the final LCD begins on November 17, 2008 and the final determination will become effective on January 1, 2009.

### *Comment:*

A commenter submitted literature and noted the following:

- 1. Recognition of the limitations of in-vitro allergy tests as compared to in-vivo skin testing.**  
Since clinical allergic responses require the presence of IgE binding to activated Mast Cells, the mere presence of specific IgE does not mean clinical allergy. In addition, patients may have barely detectable allergen specific IgE that may be misinterpreted as non-significant and still be at risk for a severe allergic response. It's like counting the cars (serum allergen specific IgE) on a busy highway and trying to correlate them to a nearby parking lot (Mast cell bound IgE in tissue). For this reason, trained allergists consider RAST type tests as supplemental to the "gold standard" of skin testing.
- 2. Potential for abuse of RAST testing by the "remote practice of allergy."**  
In this scenario, "patients" may have blood drawn and told they are allergic without ever seeing any physician, much less a trained allergist. There have been situations where they a set vials for immunotherapy is prescribed (and sold) by the lab. With the probable future FDA approval of sub-lingual immunotherapy it would be possible for this entire process to occur without at patient being physically seen by a physician.
- 3. CPT code 86001 -ALLERGEN SPECIFIC IGG QUANTITATIVE OR SEMIQUANTITATIVE, EACH ALLERGEN** is not recommended or considered as a valid test for the diagnosis of food sensitivity. There are certain very specific instances where they may be of value (cow's milk antibodies in Heiner's Disease) but should not be considered as a way to diagnose food allergy. We occasionally see large panels of IgG to food done, primarily by "alternative" practitioners,

and not by allergists. Page 49 of the above Parameters has a more detailed discussion including the following statement: *“Summary Statement 127. IgG and IgG subclass antibody tests for food allergy do not have clinical relevance, are not validated, lack sufficient quality control, and should not be performed.”*

*Response:*

These comments are greatly appreciated. Comment # 3 has been incorporated into the LCD.