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February 10, 2015

Novitas Solutions
Medical Policy Department
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Pittsburgh, PA 15219

RE: Future Local Coverage Article for Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (A53049)
Allergen Immunotherapy (DL35759)
Allergy Testing (DL35771)

Dear Members of the Contractor Advisory Committee,

Please accept these comments submitted by the American Academy of Allergy, Asthma & Immunology in response to the Future Local Coverage Article for Approved Drugs and Biologicals (A53049), and Proposed LCD for Novitas Medicare Contractor on Allergen Immunotherapy (DL35759) and Allergy Testing (DL35771).

Future Local Coverage Article for Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (A53049)

Regarding section Modifier EJ – subsequent dose in a series: "To distinguish between the initial dose of a drug and subsequent doses of that same drug used in a sequential series in the treatment of a condition, the modifier EJ should be used to identify the subsequent doses. Do not report an initial dose of a drug with the EJ modifier.":

The AAAAI requests clarification as to whether this proposed policy would impact the allergist for administration of Xolair.

Proposed Draft local coverage determination: Allergen Immunotherapy (DL35759)

Regarding the statement: "The build-up phase includes the initiation and subsequent rise of applicable antigen concentrations. Documentation of this phase should include the initial concentration, any changes/delay of progress and the reasoning for such delays, and the target concentration.":

The current Medicare manual, nationally, does not discuss the diluted doses any longer. It has been removed and it only addresses the issue of billing for 1 cc as the unit value. So does the language quoted above mean allergists will once again be able to charge for the build-up doses?

Continued.

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Regarding the section: “Unlike the maintenance phase injections, these injections do not require the EJ modifier to be appended.”

From this statement, it appears that EJ modifier is necessary on the injection codes 95115 and 95117. Please verify whether this is correct.

Regarding the section: “Maintenance Dose Interval: The frequency of maintenance dosing can be variable depending on the extract used. The Task Force notes for some antigens, the maintenance dose could be every 4-8 weeks. However, the frequency should be at least every two weeks for this dosing.”

This second sentence, “However, the frequency should be at least every two weeks for this dosing,” is misplaced and instead should apply to build-up dosing. In addition, maintenance dosing should be every 2-8 weeks, since initial maintenance dosing is often given every two weeks.

Regarding the section: “When billing maintenance dosing, the EJ modifier should be appended.”

This statement seems to indicate the EJ modifier on CPT 95165 doses would be necessary. The policy seems unclear regarding what is being tracked. Is it to be injections or doses being tracked? Is the EJ modifier necessary for both the injection and the allergens code 95165? Both codes are listed in this policy in Group 1 codes. Other Medicare contractors (Palmetto GBA) ask for this modifier for information only, and request it only for services related to end stage renal disease. In addition, it is unclear whether the EJ modifier is also necessary for maintenance Allergen Immunotherapy.

Regarding the section: “Allergen immunotherapy is not indicated and is considered investigational for…”:

We have several concerns in this area. First, sublingual immunotherapy is listed. Is this inclusive of the recently FDA approved sublingual tablets? Second, allergen immunotherapy for the management of skin and mucous membrane disease such as atopic dermatitis is not indicated, and is considered investigational. Earlier, however, it is noted, “Atopic dermatitis secondary to aeroallergen has been reported to be influenced by immunotherapy. (These rare issues will be reviewed through the redetermination process with documentation review.)” This creates an inconsistency between recognizing the influence of immunotherapy and saying that it is not indicated.

Regarding the diagnoses codes for medical necessity for allergen immunotherapy services, listed in (DL35759), we have several concerns related to Group 1 Codes:

- *The Group 1 Codes list omits the diagnosis for animal dander (477.2) and allergic asthma (493.00, 493.01, 493.01), as well as many of the diagnoses codes listed on the approved list for allergy testing.*
- *The current stinging insect diagnosis code (989.5) is not on the approved list for rush immunotherapy (95180).*

Proposed LCD for Novitas Medicare Contractor Allergy Testing (DL35771)

Regarding Allergy Sensitivity Testing:

Clarification is necessary regarding the number of sensitivity tests, and the statements, “All patients should not necessarily receive the same tests or the same number of sensitivity tests. Rather testing should be patient specific based on the history and physical examination.” Patients with allergic rhinitis, allergic conjunctivitis, and asthma will have symptoms that are caused by similar allergens, necessitating testing for similar allergens. In addition, significant numbers of patients do not know the cause of their symptoms.

Regarding “Intradermal tests are injection of small amounts … ”:

It is suggested that intradermal testing is not preferred for allergy testing. Clarification is necessary to indicate Prick Testing would be the preferred initial method of allergy sensitivity testing, and then, if indicated, intradermal testing could be utilized. Furthermore, it is stated, “Medicare considers percutaneous (scratch, prick or puncture) testing medically reasonable and necessary when IgE-mediated reactions occur to any of the following…” It would more appropriately read, “Percutaneous testing is the preferred method for evaluation for inhalant and food allergies. Intradermal testing is considered reasonable and necessary for drug and Hympenoptera allergies.”

The proposed LCD addresses patch testing and allows for only 29 patches. An allergist usually exceeds 29 patch tests, so it would be recommended that this LCD use the American Contact Dermatitis Core Services Guidelines and increase the units allowed to 80, with 50 or more units requiring submission of claim documentation to support medical necessity.

Regarding specific IgE in vitro Test (RAST, MAST, FAST):

RAST is archaic terminology as reference to the assay used in serum specific antibody testing. Rather, the assay is essentially ELISA.

Regarding: “In-vitro testing is considered reasonable and necessary only as a substitute for skin testing. It is not considered reasonable and necessary when done in addition to skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed.”:

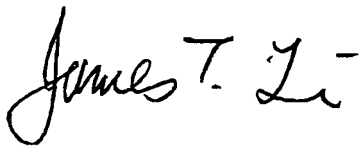
In vitro testing often complements skin testing, and is reasonable and necessary to perform when the history is suggestive, but the skin tests are negative, regardless of the allergen, and also can be used with other food allergens for prognostic purposes. In vitro testing may also be used if the history is strongly suggestive of severe anaphylaxis related to food ingestion. “In general, there is good concordance between results of the allergy diagnostic tests and clinical history. Exceptions (eg, a negative skin test or serum s-IgE test result with a positive clinical history) require additional analysis or use of a different method (eg, skin testing if the serum s-IgE test result is negative).”[1]

Regarding IgE (ELISA) being included in the not medically reasonable and necessary list:

The IgE (ELISA) test should not be on this list because it can be a medically reasonable and necessary test.

Thank you for consideration of these comments. The AAAAI would welcome the opportunity to further discuss or explain any of the issues raised herein, as well as feedback on changes made in consideration of this information. Questions may be directed to Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or 414-467-8409.

Sincerely,



James T. Li, MD, PhD, FAAAAI
President

[1] Cox L, Williams B, Sicherer S, et al. Pearls and pitfalls of allergy diagnostic testing: report from the American College of Allergy, Asthma and Immunology/American Academy of Allergy, Asthma and Immunology Specific IgE Test Task Force. Ann Allergy Asthma Immunol 2008;101:580-92.