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Practice Parameter

Sublingual immunotherapy
A focused allergen immunotherapy practice parameter update

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Disclosures: A summary of interests disclosed on work group members' conflict of interest disclosure statements (not including information concerning family member interests) can be found in the article's online repository. Completed conflict of interest disclosure statements are available on request. In terms of the 2 workgroup chairs, Linda Cox, MD served as a consultant for Greer (not ongoing), a member of the Data Safety Monitoring Committee for Circassia and BioMay, and a member of an Adjudication Committee for Medimmune and Genentech, and Michael Nelson MD, PhD, had no conflict of interest. The Joint Task Force on Practice Parameters (JTFPP) recognizes that experts in a field are likely to have interests that could come into conflict with the development of a completely unbiased and objective practice parameter. To take advantage of that expertise, a process has been developed to prevent potential conflicts from influencing the final document in a negative way. At the workgroup level, all the sections are reviewed by all workgroup members to determine whether the content is appropriate and without apparent bias. If a section is deemed to have apparent bias, it will be appropriately revised without the section author's involvement to remove potential bias. In addition, the entire document is then reviewed by the Joint Task Force on Practice Parameters (JTFPP), and any apparent bias is removed at that level. In a final stage of review, the practice parameter is sent for review and comment to invited experts reviewers and the American Academy of Allergy, Asthma, and Immunology and American College of Allergy, Asthma, and Immunology general membership via posting the document on their website.

Disclaimer: The American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) have jointly accepted responsibility for establishing Sublingual Immunotherapy: A Practice Parameter. This is a complete and comprehensive document at the current time. The medical environment is changing, and not all recommendations will be appropriate or applicable to all patients. Because this document incorporated the efforts of many participants, no single individual, including members serving on the Joint Task Force on Practice Parameters (JTFPP), are authorized to provide an official AAAAI or ACAAI interpretation of these practice parameters. Any request for information or interpretation of this practice parameter by the AAAAI or ACAAI should be directed to the executive offices of the AAAAI and the ACAAI. These parameters are not designed for use by the pharmaceutical industry in drug development or promotion. The JTFPP understands that the cost of diagnostic tests and therapeutic agents is an important concern that may appropriately influence the workup and treatment chosen for a given patient. The JTFPP recognizes that the emphasis of our primary recommendations regarding a medication may vary, for example, depending on third-party payer issues and product patent expiration dates. However, because a given test or agent's cost is so widely variable, and there is a paucity of pharmacoeconomic data, the JTFPP generally does not consider cost when formulating practice parameter recommendations. In extraordinary circumstances, when the cost benefit of an intervention is prohibitive as supported by pharmacoeconomic data, commentary may be provided. These parameters are not designed for use by pharmaceutical companies in drug promotion. The JTFPP is committed to ensuring that the Practice Parameters are based on the best scientific evidence that is free of commercial bias. To this end, the parameter development process includes multiple layers of rigorous review. These layers include the work group convened to draft the parameter, the task force reviewers, and peer review by members of each sponsoring society. Although the JTFPP has the final responsibility for the content of the documents submitted for publication, each reviewer comment will be discussed and reviewers will receive written responses to comments when appropriate. To preserve the greatest transparency regarding potential conflicts of interest, all members of the JTFPP and the practice parameters work groups will complete a standard potential conflict of interest disclosure form, which will be available for external review by the sponsoring organization and any other interested individual. In addition, before confirming the selection of a work group chairperson, the JTFPP will discuss and resolve all relevant potential conflicts of interest associated with this selection. Finally, all members of parameter work groups will be provided a written statement regarding the importance of ensuring that the parameter development process is free of commercial bias.

Previously published Practice Parameters of the Joint Task Force on Practice Parameters for Allergy & Immunology are available at http://www.AAAAI.org, http://www.ACAAI.org, or http://www.allergyparameters.org.

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Classification of Recommendations and Evidence

Recommendation Rating Scale

Statement	Definition	Implication
Strong recommendation (StrRec)	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate (Mod)	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Weak (Weak)	An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation (NoRec)	No recommendation means there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit vs harm; patient preference should have a substantial influencing role.

*See Strength of Recommendation definitions below.

Category of Evidence

Ia Evidence from meta-analysis of randomized controlled trials
Ib Evidence from at least one randomized controlled trial
IIa Evidence from at least one controlled study without randomization
IIb Evidence from at least one other type of quasi-experimental study
III Evidence from nonexperimental descriptive studies, such as comparative studies
IV Evidence from expert committee reports or opinions or clinical experience of respected authorities or both

*Strength of Recommendation**

A Directly based on category I evidence
B Directly based on category II evidence or extrapolated recommendation from category I evidence
C Directly based on category III evidence or extrapolated recommendation from category I or II evidence
D Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence
LB Laboratory based
NR Not rated

Methods and Overview of the Guideline Development Process

The sublingual immunotherapy (SLIT) practice parameters contain systematically developed statements with recommendations intended to optimize patient care and assist physicians and/or other health care practitioners and patients to make decisions regarding this therapy. This guideline is based on 2 published systematic reviews of the literature[1,2] and publications identified by the workgroup's comprehensive literature search and the US Food and Drug Administration (FDA)–approved SLIT tablets' product information.[3,4]

Systematic Literature Review and Other Sources

Both the systematic reviews evaluated the efficacy and safety of SLIT and subcutaneous (SCIT) allergen immunotherapy.[2] Both