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3 **Addendum guidelines for the**
4 **prevention of peanut allergy in the**
5 **United States**

6

7 **Summary of the National Institute of Allergy and**
8 **Infectious Diseases-sponsored expert panel**

9

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80 **INTRODUCTION**

81

82 Food allergy is an important public health problem because it affects children and
83 adults, it may be severe and even life-threatening, and it may be increasing in prevalence.
84 Beginning in 2008, the National Institute of Allergy and Infectious Diseases (NIAID),
85 working with other organizations and advocacy groups, led the development of the first
86 clinical guidelines for the diagnosis and management of food allergy. These guidelines,¹
87 which were published in 2010, did not offer strategies for the prevention of food allergy
88 due to a lack of definitive studies at the time.

89

90 In February 2015, the *New England Journal of Medicine* published the results of
91 the “Learning Early about Peanut Allergy” (LEAP) trial. This landmark clinical trial
92 showed that introduction of peanut products into the diets of infants at high risk of
93 developing peanut allergy was safe and led to an 81 percent relative reduction in the
94 subsequent development of peanut allergy. The LEAP trial results, combined with other
95 emerging data, strongly suggested that peanut allergy can be prevented through
96 introduction of peanut-containing foods beginning in infancy. This growing body of
97 evidence raised the need for clinical recommendations focusing on peanut allergy
98 prevention.

99

100 To achieve this goal and its wide implementation, NIAID invited the members of
101 the 2010 Guidelines Coordinating Committee and other stakeholder organizations to
102 develop this addendum on peanut allergy prevention to the 2010 Guidelines for the
103 Diagnosis and Management of Food Allergy in the United States.

104

105 **DEVELOPMENT OF THE 2017 ADDENDUM TO THE 2010 GUIDELINES FOR** 106 **THE DIAGNOSIS AND MANAGEMENT OF FOOD ALLERGY**

107

108 **Coordinating Committee**

109

110 The NIAID established a Coordinating Committee (CC), whose members are
111 listed in Appendix A, to oversee the development of the addendum; review drafts of the
112 addendum for accuracy, practicality, clarity, and broad utility of the recommendations in
clinical practice; review and approve the final addendum; and disseminate the addendum.

113 The CC members represented 26 professional organizations, advocacy groups, and
114 federal agencies.

115 **Expert Panel**

116 In June 2015, the CC convened an Expert Panel (EP) that was chaired by Joshua
117 Boyce, MD. The 26 panel members, listed in Appendix B, were specialists from a variety
118 of relevant clinical, scientific, and public health areas. Panel members were nominated
119 by the CC organizations, and the composition of the panel received unanimous approval
120 by the CC member organizations.

121 The charge to the EP was to use the literature review prepared by the NIAID, in
122 conjunction with consensus expert opinion and EP-identified supplementary documents,
123 to develop evidence-based recommendations for the early introduction of dietary peanut
124 to prevent peanut allergy. The new guidelines are intended to supplement and modify
125 Guidelines 37 to 40 in Section 5.3.4 of the 2010 Guidelines:¹ “Prevention of Food
126 Allergy.”

127 **Literature review**

128 NIAID staff conducted a literature search of PubMed, limited to the years 2010
129 (January) to 2016 (June). Sixty four publications (original research articles,
130 editorials/letters, and systematic reviews) were deemed relevant and placed into 2 tiers:
131 tier 1 contained 18 items, considered highly relevant to the early introduction of peanut or
132 other allergenic foods; and tier 2 contained 46 items on related topics such as food allergy
133 or eczema prevention.

134 **Assessing the quality of the body of evidence**

135 For the tier 1 references, the EP assessed the quality using the Grading of
136 Recommendations Assessment, Development and Evaluation (GRADE) approach.

137 **Preparation of the addendum**

138 Draft versions of the addendum were reviewed by the CC members, open to
139 public comment, revised accordingly, and approved by the EP and the CC.

140

141 **DEFINING THE STRENGTH OF EACH CLINICAL GUIDELINE**

142 The EP has used the verb “recommends” or “suggests” for each clinical
143 recommendation. These words convey the strength of the recommendation, defined as
144 follows:

- 145 • *Recommend* is used when the EP strongly recommended for or against a particular
146 course of action.
- 147 • *Suggest* is used when the EP weakly recommended for or against a particular
148 course of action.

149

150 **ADDENDUM GUIDELINES**

151 The EP came to consensus on the following 3 definitions used throughout the addendum
152 guidelines.

- 153 • *Severe eczema* is defined as persistent or frequently recurring eczema with typical
154 morphology and distribution assessed as severe by a health care provider and
155 requiring frequent need for prescription-strength topical corticosteroids,
156 calcineurin inhibitors, or other anti-inflammatory agents despite appropriate use
157 of emollients.
- 158 • *Egg allergy* is defined as a history of an allergic reaction to egg and a skin prick
159 test (SPT) wheal diameter of 3 mm or greater with egg white extract, or a positive
160 oral egg food challenge result.
- 161 • A *specialist* is defined as a health care provider with the training and experience
162 to (1) perform and interpret SPTs and oral food challenges (OFC) and (2) know
163 and manage their risks. Such persons must have appropriate medications and
164 equipment on site.

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170 **TABLE I: Summary of addendum guidelines 1, 2, and 3**

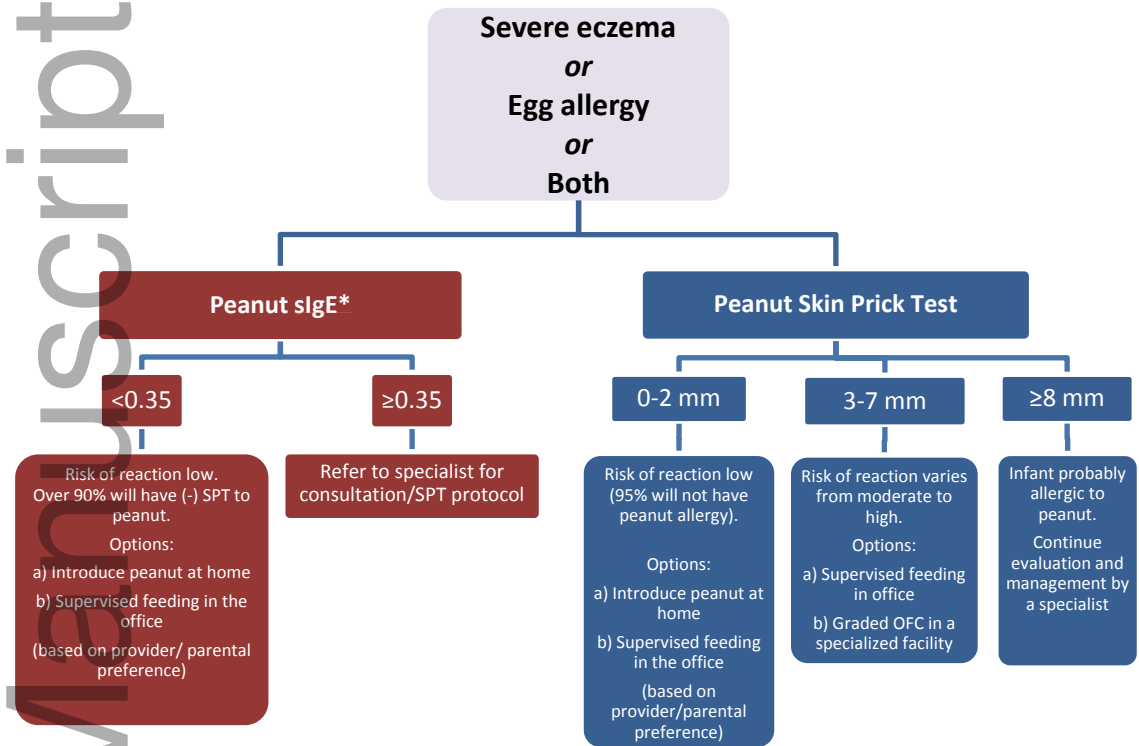
Addendum guideline	Infant criteria	Recommendations	Earliest age of peanut introduction
1	Severe eczema, egg allergy, or both	Strongly consider evaluation by sIgE and/or SPT and, if necessary, an oral food challenge. Based on test results, introduce peanut-containing foods	4 to 6 months
2	Mild-to-moderate eczema	Introduce peanut-containing foods	Around 6 months
3	No eczema or any food allergy	Introduce peanut-containing foods	Age appropriate and in accordance with family preferences and cultural practices

171

172 **Addendum guideline 1**

173 The EP recommends that infants with severe eczema, egg allergy, or both have
 174 introduction of age-appropriate peanut-containing food as early as 4 to 6 months of age to
 175 reduce the risk of peanut allergy. Other solid foods should be introduced before peanut-
 176 containing foods to show that the infant is developmentally ready. The EP recommends
 177 that evaluation with peanut-specific IgE (peanut sIgE) measurement, SPTs, or both be
 178 strongly considered before introduction of peanut to determine if peanut should be
 179 introduced and, if so, the preferred method of introduction. To minimize a delay in
 180 peanut introduction for children who may test negative, testing for peanut sIgE may be
 181 the preferred initial approach in certain health care settings, such as family medicine,
 182 pediatrics, or dermatology practices, in which skin prick testing is not routine.

183 Alternatively, referral for assessment by a specialist may be an option if desired by the
 184 health care provider and when available in a timely manner.
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*To minimize a delay in peanut introduction for children who may test negative, testing for peanut-specific IgE may be the preferred initial approach in certain health care settings. Food allergen panel testing or the addition of sIgE testing for foods other than peanut is not recommended due to poor positive predictive value.

FIG

1:

Recommended approaches for evaluation of children with severe eczema and/or egg allergy before peanut introduction

Important considerations for skin prick testing

SPT reagents, testing devices, and methodology can differ significantly among health care providers in the United States or elsewhere. The EP recommends that specialists should adjust their SPT categorization criteria according to their own training and experience.

Health care providers conducting oral food challenges in infants with 3 mm or greater SPT responses should be aware that the probability of a positive challenge increases with wheal size.

If the decision is made to introduce dietary peanut based on the recommendations of addendum guideline 1, the total amount of peanut protein to be regularly consumed per week should be approximately 6 to 7 grams over 3 or more feedings.

Quality of evidence. Moderate.

The designation of the quality of evidence as “moderate” (as opposed to “high”) is based on the fact that this recommendation derives primarily from a single randomized, open-label study: the LEAP trial. However, it should be noted that the assessment of the LEAP trial’s primary outcome was based on a double-blind, placebo-controlled OFC. Furthermore, confidence in this recommendation is bolstered by the large effect size demonstrated in the LEAP trial and prior epidemiological data that peanut allergy is relatively infrequent in Israel, where early childhood consumption of peanut is common.

Contribution of expert opinion. Significant.**Additional comments.**

- 1) *Breast-feeding recommendations:* The EP recognizes that early introduction of peanut may seem to depart from recommendations for exclusive breast-feeding through 6 months of age. However, it should be noted that data from the nutrition analysis of the LEAP cohort indicate that introduction of peanut did not affect the duration or frequency of breast-feeding, and did not influence growth or nutrition.
- 2) *Age of peanut introduction:* For children with severe eczema, egg allergy, or both, the EP recommends that introduction of solid foods begins at 4 to 6 months of age,

227 starting with solid food other than peanut. However, it is important to note that the
228 infants in the LEAP trial were enrolled between 4 and 11 months of age and
229 benefitted from peanut consumption regardless of age at entry. Therefore, if the
230 4- to 6-month time window is missed for any reason, including developmental
231 delay, infants may still benefit from early peanut introduction.

- 232 3) *Considerations for family members with established peanut allergy:* The EP
233 ■ recognizes that many infants eligible for early peanut introduction under this
234 guideline will have older siblings or caregivers with established peanut allergy.
235 The EP recommends that in this situation caregivers discuss with their health care
236 providers the overall benefit (reduced risk of peanut allergy in the infant) versus
237 risks (potential for further sensitization and accidental exposure of the family
238 member to peanut) of adding peanut to the infant's diet.
- 239 4) *Children identified as allergic to peanut:* For children who have been identified as
240 allergic to peanut, the EP recommends strict peanut avoidance. This may include
241 those children who fail the supervised peanut feeding or the OFC, or those
242 children who, upon further evaluation by a specialist, are confirmed as being
243 allergic to peanut. These children should be under long-term management by a
244 specialist.

245

246 **Addendum guideline 2**

247 The EP suggests that infants with mild-to-moderate eczema should have introduction
248 of age-appropriate peanut-containing food around 6 months of age, in accordance with
249 family preferences and cultural practices, to reduce the risk of peanut allergy. Other solid
250 foods should be introduced before peanut-containing foods to show that the infant is
251 developmentally ready. The EP recommends that infants in this category may have
252 dietary peanut introduced at home without an in-office evaluation. However, the EP
253 recognizes that some caregivers and health care providers may desire an in-office
254 supervised feeding, evaluation, or both.

255 **Quality of evidence.** Low.

256 The quality of evidence is low because this recommendation is based on extrapolation
257 of data from a single study.

258 **Contribution of expert opinion.** Significant.

259

260 **Addendum guideline 3**

261 The EP suggests that infants without eczema or any food allergy have age-appropriate
262 peanut-containing foods freely introduced in the diet together with other solid foods and
263 in accordance with family preferences and cultural practices.

264 **Quality of evidence.** Low.

265 **Contribution of expert opinion.** Significant.

266

267 **Reference**

268 1. Boyce JA, Assa'ad A, Burks AW, Jones SM, Sampson HA, Wood RA, et al.
269 Guidelines for the diagnosis and management of food allergy in the United States:
270 report of the NIAID-sponsored expert panel. J Allergy Clin Immunol
271 2010;126(suppl):S1-58.

272 **APPENDIX A. COORDINATING COMMITTEE MEMBER**

273 **ORGANIZATIONS AND REPRESENTATIVES**

274

275 **Academy of Nutrition and Dietetics**

276 <http://www.eatright.org/>

277 Alison Steiber PhD, RD

278

279 **Allergy & Asthma Network Mothers of Asthmatics (AANMA)**

280 <http://www.allergyasthmanetwork.org/main/>

281 Tonya A. Winders, MBA

282

283 **American Academy of Allergy, Asthma & Immunology (AAAAI)**

284 <https://www.aaaai.org/home.aspx>

285 Hugh A. Sampson, MD

286 David Fleischer, MD

287

- 288 **American Academy of Family Physicians (AAFP)**
289 <http://www.aafp.org/home.html>
290 Jason Matuszak, MD
291
- 292 **American Academy of Dermatology (AAD)**
293 <https://www.aad.org/>
294 Lawrence F. Eichenfield, MD, FAAD
295 Jon Hanifin, MD
296
- 297 **American Academy of Emergency Medicine (AAEM)**
298 <http://www.aaem.org/>
299 Joseph P. Wood, MD, JD
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- 301 **American Academy of Pediatrics (AAP)**
302 <https://www.aap.org>
303 Scott H. Sicherer, MD, FAAP
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- 305 **American Academy of Physician Assistants (AAPA)**
306 <https://www.aapa.org/>
307 Gabriel Ortiz, MPAS, PA-C, DFAAPA
308
- 309 **American College of Allergy, Asthma and Immunology (ACAAI)**
310 <http://acaai.org/>
311 Amal Assa'ad, MD
312
- 313 **American College of Gastroenterology (ACG)**
314 <http://gi.org/>
315 Steven J. Czinn, MD, FACG
316
- 317 **American Partnership for Eosinophilic Disorders (APFED)**
318 <http://apfed.org/>

319 Wendy Book, MD

320

321 **American Society for Nutrition (ASN)**

322 <http://www.nutrition.org/>

323 George J. Fuchs, III, MD

324

325 **Asthma and Allergy Foundation of America (AAFA)**

326 <http://www.aafa.org/>

327 Meryl Bloomrosen, MBA, MBI

328 David R. Stukus, MD

329

330 **Canadian Society of Allergy and Clinical Immunology (CSACI)**

331 <http://www.csaci.ca/>

332 Edmond Chan, MD, FRCPC

333

334 **Eunice Kennedy Shriver National Institute of Child Health & Human Development
(NICHD)**

336 <https://www.nichd.nih.gov>

337 Gilman Grave, MD

338

339 **European Academy of Allergy and Clinical Immunology (EAACI)**

340 <http://www.eaaci.org/>

341 Antonella Muraro, MD, PhD

342

343 **Food Allergy Research & Education (FARE)**

344 <https://www.foodallergy.org/>

345 James R. Baker, MD

346 Mary Jane Marchisotto

347

348 **National Eczema Association (NEA)**

349 <http://nationaleczema.org/>

350 Julie Block

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352 **National Heart, Lung, and Blood Institute (NHLBI)**

353 <http://www.nhlbi.nih.gov/>

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356 **National Institute of Allergy and Infectious Diseases (NIAID)**

357 <http://www.niaid.nih.gov/>

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359 Alkis Togias, MD

360 Marshall Plaut, MD

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362 **National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)**

363 <http://www.niams.nih.gov/>

364 Ricardo Cibotti, PhD

365

366 **National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**

367 www.niddk.nih.gov

368 Frank Hamilton, MD, MPH

369 Margaret A. McDowell, PhD, MPH, RD (retired)

370 Rachel Fisher, MS, MPH, RD

371

372 **North American Society for Pediatric Gastroenterology, Hepatology and Nutrition**

373 **(NASPGHAN)**

374 <http://www.naspghan.org/>

375 Glenn Furuta, MD

376

377 **Society of Pediatric Nurses (SPN)**

378 <http://www.pedsnurses.org/>

379 Michele Habich, DNP, APN/CNS, CPN

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381 **United States Department of Agriculture (USDA)**

382 <http://www.usda.gov/>

383 Soheila J. Maleki, PhD

384

385 **World Allergy Organization (WAO)**

386 <http://www.worldallergy.org/>

387 Lanny J. Rosenwasser, MD

388 **APPENDIX B: EXPERT PANEL, JUNE 2015**

389

390 **Chair**

391 **Joshua A. Boyce, MD**

392 Professor of Medicine and Pediatrics

393 Harvard Medical School

394 Director, Inflammation and Allergic Disease Research Section

395 Director, Jeff and Penny Vinik Center for Allergic Disease Research

396 Specialty: Allergy/pediatric pulmonology

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398 **Panelists**

399 **Maria Acebal, JD**

400 Board of Directors, Food Allergy Research & Education

401 Member of NIAID Advisory Council

402 Former CEO of Food Allergy and Anaphylaxis Network

403 Specialty: Advocacy

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405 **Amal Assa'ad, MD**

406 Professor, University of Cincinnati Department of Pediatrics

407 Director, FARE Center of Excellence in Food Allergy

408 Director of Clinical Services, Division of Allergy and Immunology

409 Associate Director, Division of Allergy and Immunology

410 Cincinnati Children's Hospital Medical Center

411 Specialty: Allergy/pediatrics

412

413 **James R. Baker Jr, MD**

414 CEO and Chief Medical Officer

415 Food Allergy Research & Education, McLean VA

416 Founding Director, Mary H. Weiser Food Allergy Center, University of Michigan

417 Professor of Internal Medicine, Division of Allergy and Clinical Immunology

418 University of Michigan Health System

419 Specialty: Allergy/advocacy/education

420

421 **Lisa A. Beck, MD**

422 Professor, Department of Dermatology

423 University of Rochester Medical Center

424 School of Medicine and Dentistry

425 Specialty: Dermatology

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427 **Julie Block**

428 President and CEO

429 National Eczema Association

430 Specialty: Advocacy/education

431

432 **Carol Byrd-Bredbenner, PhD, RD, FAND**

433 Professor of Nutrition/Extension Specialist

434 Rutgers University, School of Environmental and Biological Sciences

435 Specialty: Nutrition/health communication/behavioral science

436

437 **Edmond S. Chan, MD, FRCPC**

438 Clinical Associate Professor

439 Head, Division of Allergy and Immunology

440 Department of Pediatrics

441 BC Children's Hospital

442 University of British Columbia

443 Specialty: Allergy/pediatrics

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445 **Lawrence F. Eichenfield, MD**

446 Professor of Pediatrics and Dermatology

447 Chief, Pediatric and Adolescent Dermatology

448 Rady Children's Hospital, San Diego

449 University of California, San Diego School of Medicine

450 Specialty: Dermatology/pediatrics

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454 University of Colorado School of Medicine

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458 **George J. Fuchs III, MD**

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461 Chief, Gastroenterology, Nutrition & Hepatology

462 Kentucky Children's Hospital

463 Specialty: Gastroenterology/pediatrics

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465 **Glenn T. Furuta, MD**

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470 Specialty: Gastroenterology/pediatrics

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473 Assistant Professor of Pediatrics

- 474 Allergy Section
475 University of Colorado School of Medicine
476 Children's Hospital Colorado, Aurora, CO
477 Specialty: Allergy/pediatrics
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- 479 **Ruchi Gupta, MD, MPH**
480 Associate Professor of Pediatrics and Medicine
481 Director, Food Allergy Outcomes Research Program
482 Ann and Robert H. Lurie Children's Hospital of Chicago
483 Northwestern Medicine, Northwestern University
484 Specialty: Pediatrics
485
- 486 **Michele Habich, DNP, APN/CNS, CPN**
487 Advanced Practice Nurse
488 Northwestern Medicine, Central DuPage Hospital
489 Specialty: Nursing/pediatrics/education
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- 491 **Stacie M. Jones, MD**
492 Professor of Pediatrics
493 University of Arkansas for Medical Sciences
494 Chief, Allergy and Immunology
495 Arkansas Children's Hospital
496 Specialty: Allergy/pediatrics
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- 498 **Kari Keaton**
499 Facilitator, Metro DC Food Allergy Support Group
500 Specialty: Advocacy/education
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- 502 **Antonella Muraro, MD, PhD**
503 President of European Academy of Allergy and Clinical Immunology (EAACI)
504 Professor of Allergy and Pediatric Allergy

505 Head of the Veneto Region Food Allergy Centre of Excellence for Research and
506 Treatment

507 University Hospital of Padua, Italy

508 Specialty: Allergy/pediatrics

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510 **Lanny J. Rosenwasser, MD**

511 Immediate Past President, World Allergy Organization

512 Professor of Medicine

513 University of Missouri-Kansas City-School of Medicine

514 Specialty: Allergy/pediatrics

515

516 **Hugh A. Sampson, MD**

517 Professor of Pediatrics, Allergy and Immunology

518 Icahn School of Medicine at Mount Sinai

519 Director, Jaffe Food Allergy Institute

520 Specialty: Allergy/pediatrics

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522 **Lynda C. Schneider, MD**

523 Professor of Pediatrics

524 Harvard Medical School

525 Director, Allergy Program

526 Boston Children's Hospital

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529 **Scott H. Sicherer, MD**

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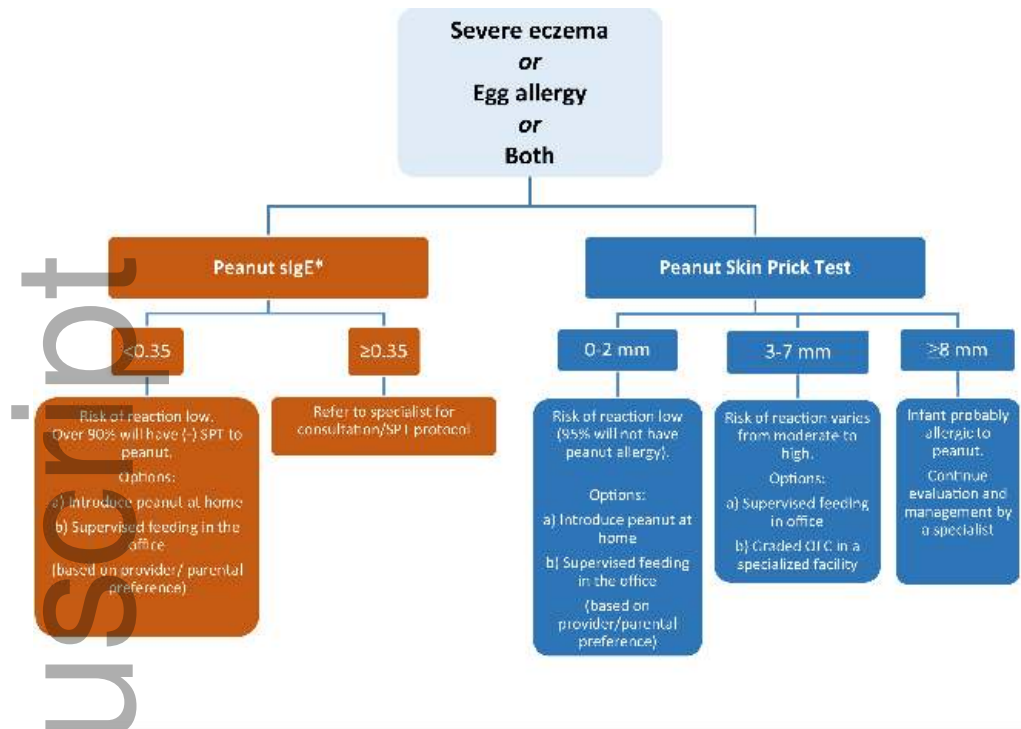
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535 **Robert Sidbury, MD, MPH**

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552 Assistant Professor of Pediatrics
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562 Specialty: Allergy/dietitian/pediatrics
563 **Abbreviations used**
564 CC: Coordinating Committee
565 EP: Expert Panel
566 GRADE: Grading of Recommendations Assessment, Development and Evaluation

- 567 LEAP: Learning Early about Peanut Allergy
- 568 NIAID: National Institute of Allergy and Infectious Diseases
- 569 OFC: Oral food challenge
- 570 sIgE: Specific Immunoglobulin E
- 571 SPT: Skin prick test

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* To minimize a delay in peanut introduction for children who may test negative, testing for peanut-specific IgE may be the preferred initial approach in certain health care settings. Food allergen panel testing or the addition of sIgE testing for foods other than peanut is not recommended due to poor positive predictive value.

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