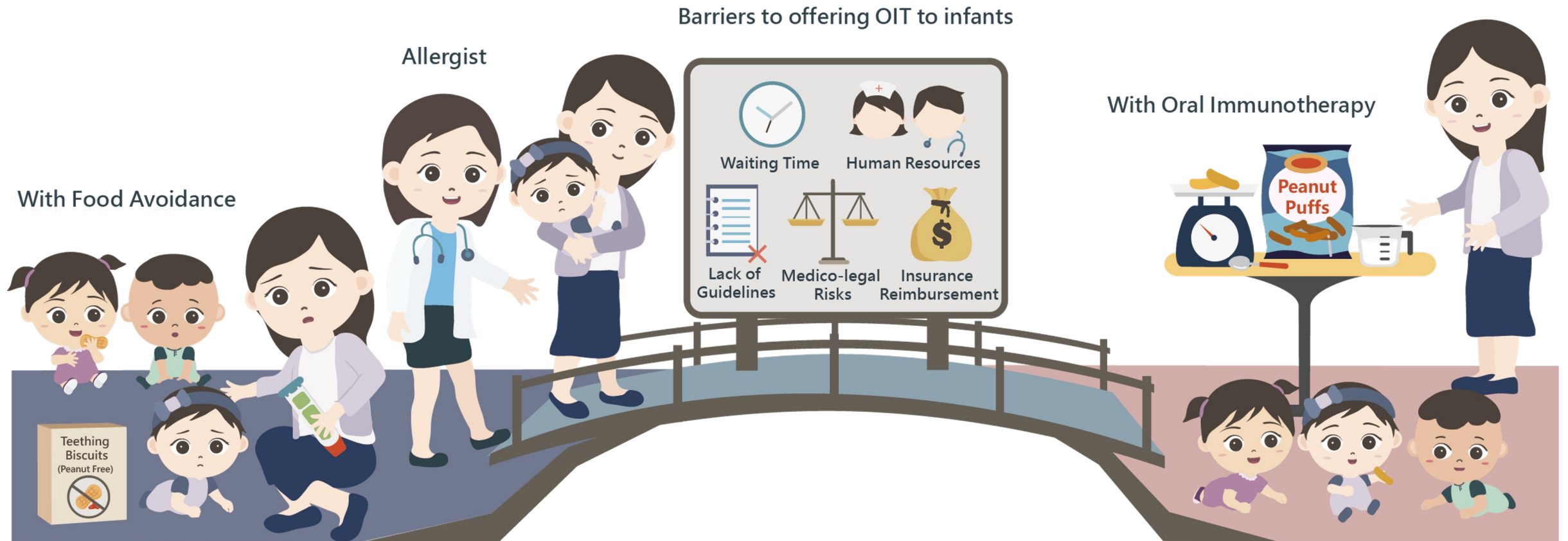


The Economics of Oral Immunotherapy

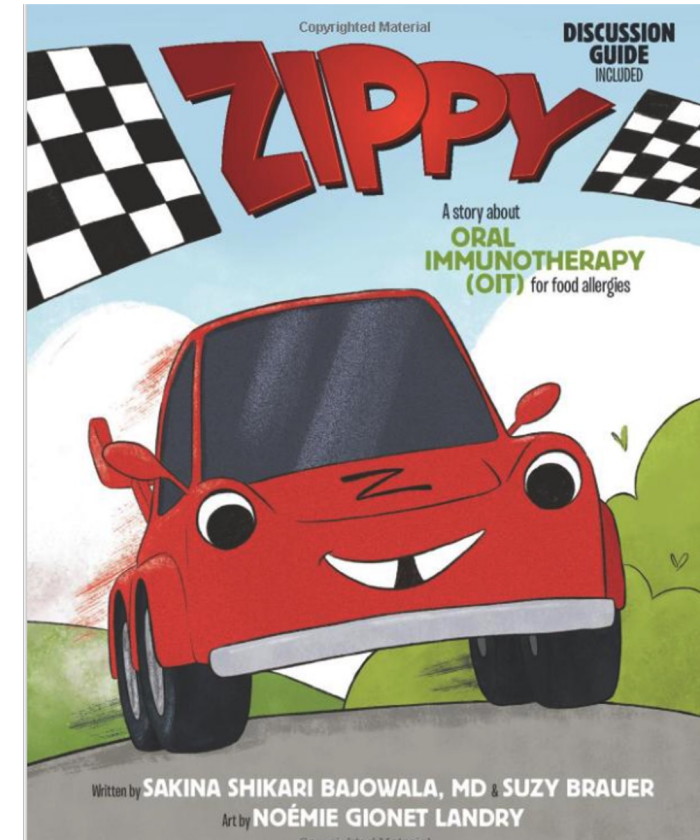
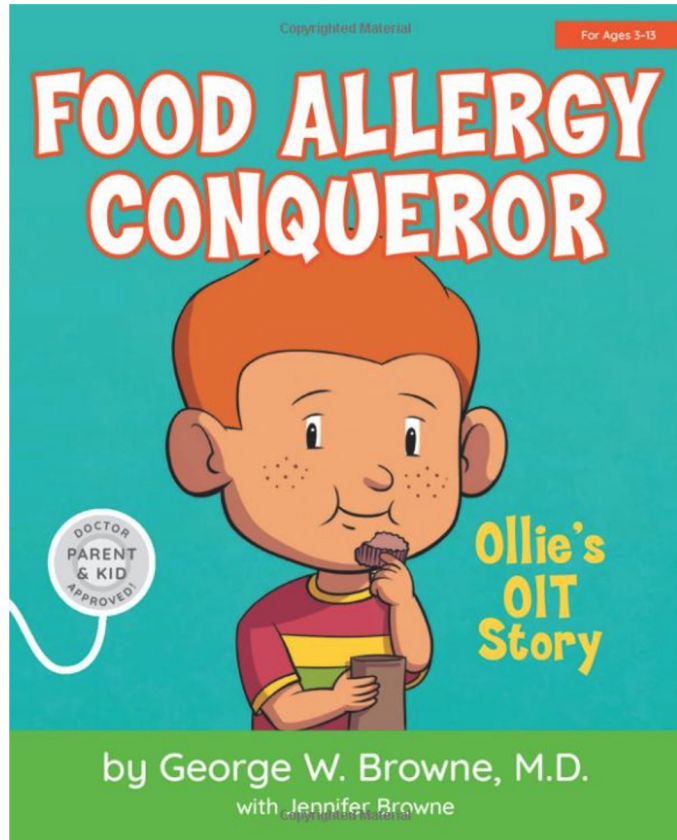
Dollars and Sense

Tina Dominguez, PA-C, MMS & Marcus Shaker, MD MSc
Latitude Food Allergy Care & Dartmouth Health

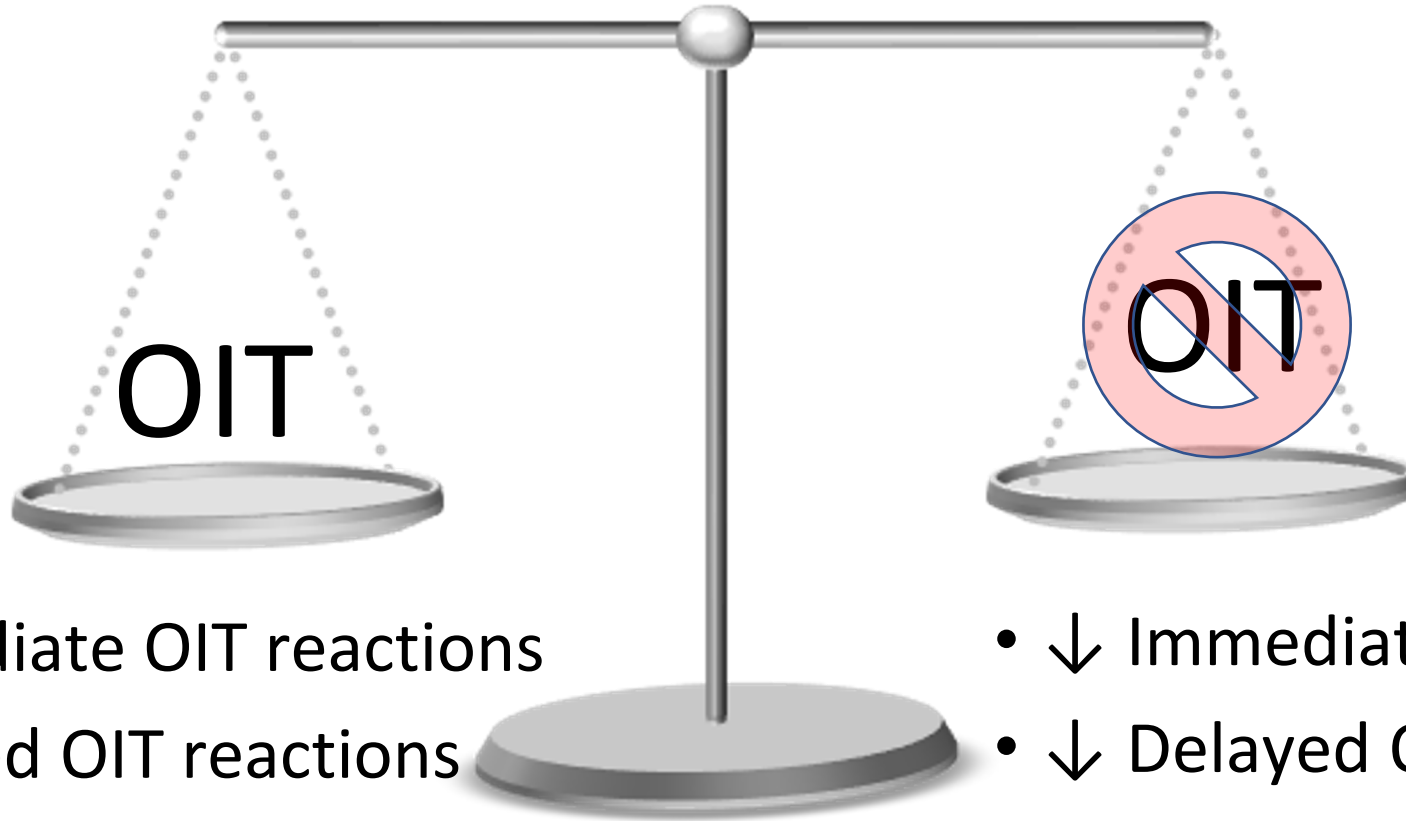
Benefits of OIT



Empowerment



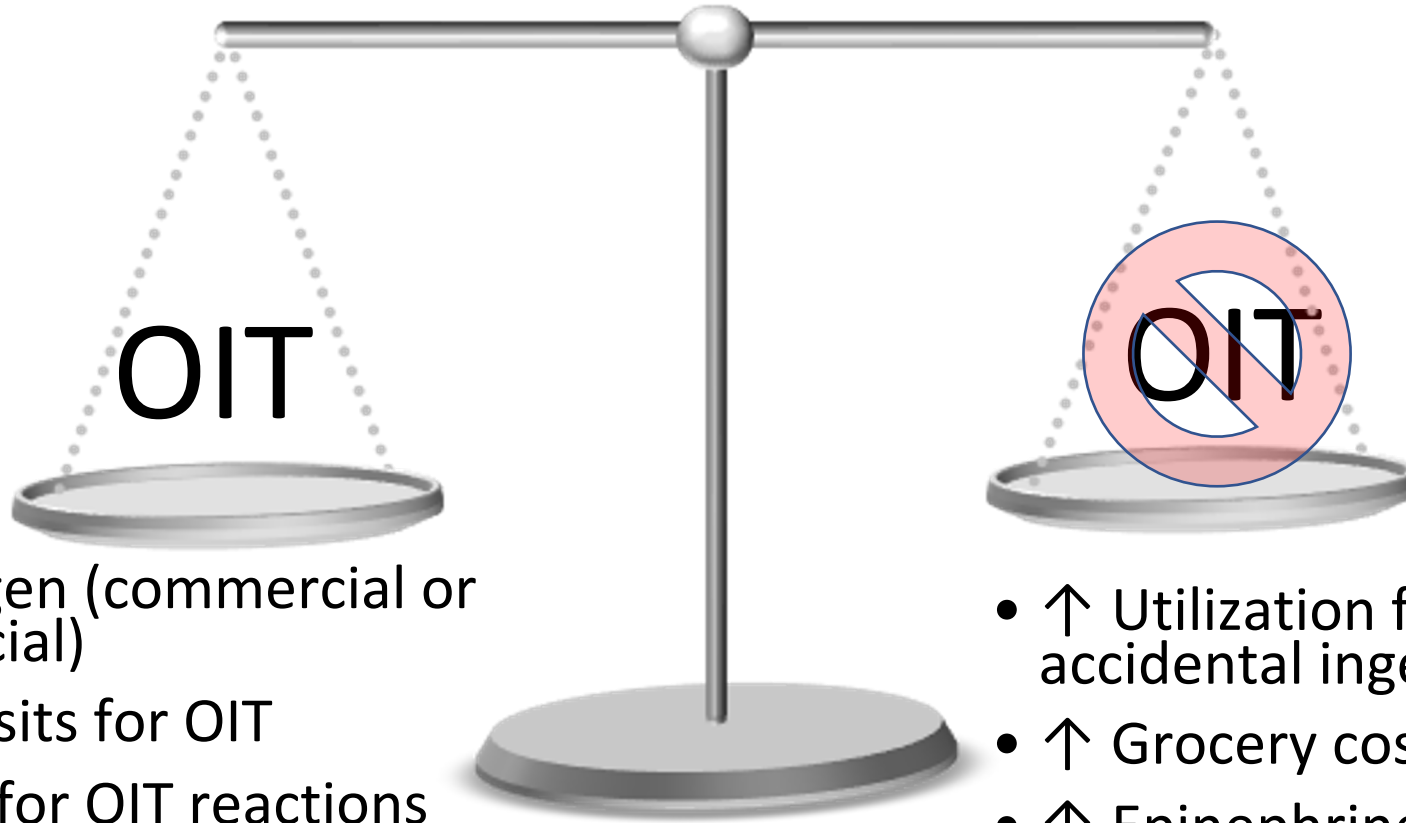
Risks of OIT



- ↑ Immediate OIT reactions
- ↑ Delayed OIT reactions
- ↓ Accidental food reactions

- ↓ Immediate OIT reactions
- ↓ Delayed OIT reactions
- ↑ Accidental food reactions

Costs of OIT



- ↑ Food allergen (commercial or non-commercial)
- ↑ Provider visits for OIT
- ↑ Utilization for OIT reactions
- ↓ Grocery costs
- ↓ Utilization for reactions from accidental ingestions

- ↑ Utilization for reactions from accidental ingestions
- ↑ Grocery costs
- ↑ Epinephrine costs (possible)
- ↑ Lifetime provider visits (possible)



Costs of (untreated) Food Allergy - Economic

- A 2013 study estimated annual food allergy costs exceeded \$4,000 per child in the US
- Most costs related to lost productivity and out of pocket costs, and most were borne directly by families
- Nearly 1/3 of costs related to allergen-free diets
- When considering peanut allergy alone, patients with food allergy experience almost double all-cause health costs

Costs of (untreated) Food Allergy – Social/Quality of Life

- About one-third of children with food allergies have been bullied due to their food allergy
- Bullying decreases QoL for children and parents



*Shemesh E, et al 2013
Annunziato et al 2014
Lieberman, Weiss et al 2010*

Value of OIT & Advocacy



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TABLE I. Six domains of health care quality¹¹

Domain	Description
Safe	Avoids harm from care that is intended to be helpful
Effective	Services based on scientific knowledge; avoidance of services that are not beneficial
Patient-centered	Care that is based on individual patient needs and values and guided by these needs and values
Timely	Reducing wait and delay as much as possible
Efficient	Avoiding waste of medical equipment, supplies, and time
Equitable	Consistent quality of care across personal characteristics



Measuring Value

Cost-Effectiveness

- With early OIT, cost savings reached \$12.3 to \$47 billion in the US and \$10.4 to \$13.6 billion in Canada
- Not only did OIT save money, at the same time it improved quality-adjusted life years
- Systemic reactions to OIT were less common than anaphylaxis from accidental reactions without OIT



National Library of Medicine
National Center for Biotechnology Information

☐ 1 **The Cost-Effectiveness of Preschool Peanut Oral Immunotherapy in the Real-World Setting.**

Cite Shaker M, Chan ES, Protudjer JLP, Soller L, Abrams EM, Greenhawt M.

Share *J Allergy Clin Immunol Pract.* 2021 Jul;9(7):2876-2884.e4. doi: 10.1016/j.jaip.2021.02.058. Epub 2021 Mar 18.

PMID: 33744474

BACKGROUND: Across North America, 1.4% to 4.5% of children and families live with **peanut** allergy (PA). Preschool **peanut oral immunotherapy** (POIT) has been shown to be safe and effective in the real-world setting. ...Models incorporated the natural hist ...

Item in Clipboard

☐ 2 **Estimation of Health and Economic Benefits of Commercial Peanut Immunotherapy Products: A Cost-effectiveness Analysis.**

Cite Shaker M, Greenhawt M.

Share *JAMA Netw Open.* 2019 May 3;2(5):e193242. doi: 10.1001/jamanetworkopen.2019.3242.

PMID: 31050778 **Free PMC article.**

IMPORTANCE: Commercial epicutaneous **peanut immunotherapy** (EPIT) and **peanut oral immunotherapy** (POIT) may offer significant quality-of-life improvements for patients with **peanut** allergy, but the **cost-effectiveness** of commerci ...

☐ 3 **An Economic Analysis of a Peanut Oral Immunotherapy Study in Children.**

Cite Shaker MS.

Share *J Allergy Clin Immunol Pract.* 2017 Nov-Dec;5(6):1707-1716. doi: 10.1016/j.jaip.2017.04.016. Epub 2017 Jun 9.

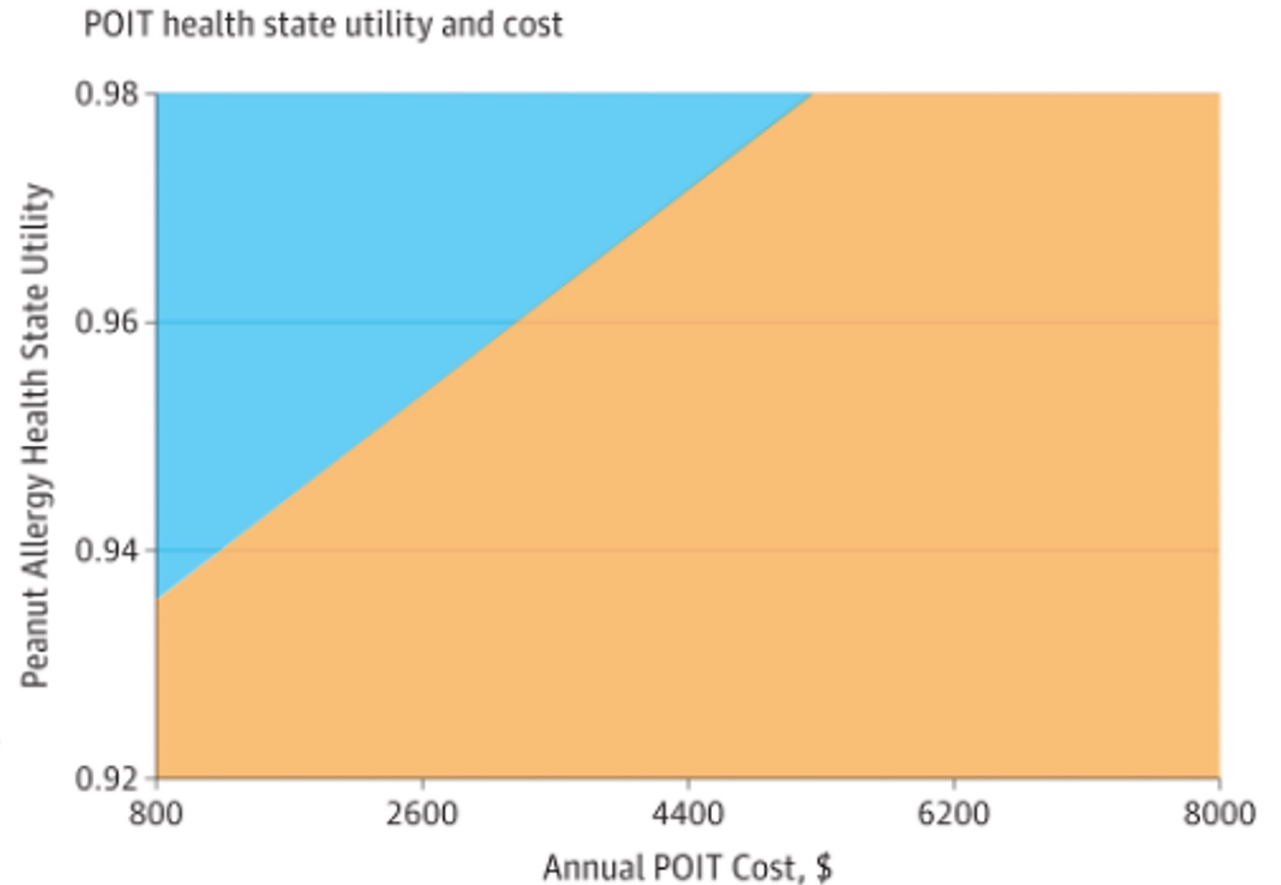
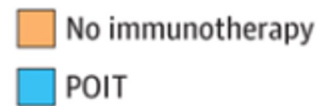
PMID: 28606784

BACKGROUND: **Peanut oral immunotherapy** (POIT) decreases the probability of accidental recurrent systemic reactions but reactions from the therapy itself are frequent. OBJECTIVE: The purpose of this economic **analysis** was to characterize the potential ...

Cost of Therapy By Benefit - What's it Worth?

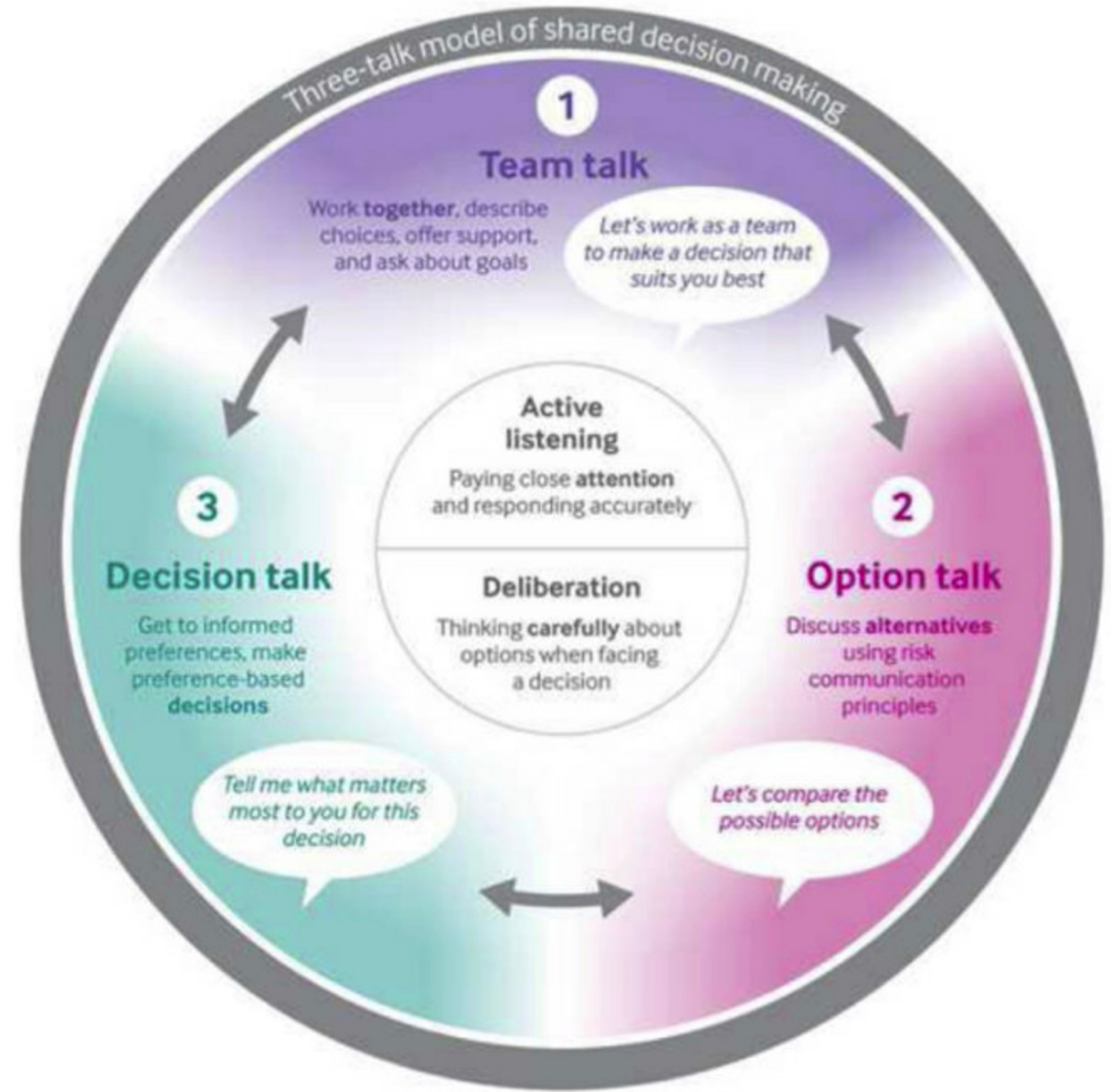
- As OIT allows 'free-eating', annual costs of therapy can reach \$5,235*

*Cost-effective care < \$100,000/QALY



Health State Utility: Quality of Life under conditions of risk and trade-off
(1 = perfect health; 0 = death)

Contextual Decisions, Shared Decisions





Reimbursement and Payment Models



E&M



Cash





- Cash only service - Cash pay price range:
 - One time all inclusive fee \$40K
 - \$6000 start up fee, then \$250 per visit
- Insurance plus fee in addition to billing insurance:
 - Program/ material fees:
 - Monthly fee while on dilutions
 - \$150 - \$300
 - One time fee:
 - \$5000 - 6000 (single or multi-allergen)
 - Based off of the number of foods:
 - 1st food \$2000 - \$4000
 - Each additional \$700 - \$1500
- HSA or FSA eligible in some states

For Perspective...

Table 8: PALFORZIA Office Dose Kit Packaging Presentations

Packaging Presentation	Kit Components (Blisters, Capsules, or Sachets)	Number of Doses per Kit	NDC Numbers (Kit Components)	NDC Number (Kit)
3 mg (Level 1)	Eighteen blisters, each containing: Three 1 mg capsules	18	71881-101-09 71881-122-01	71881-101-99
6 mg (Level 2)	Eighteen blisters, each containing: Six 1 mg capsules	18	71881-102-09 71881-122-01	71881-102-99
12 mg (Level 3)	Twelve blisters, each containing: Two 1 mg capsules One 10 mg capsule	12	71881-103-09 71881-122-01 71881-123-01	71881-103-99
20 mg (Level 4)	Twelve blisters, each containing: One 20 mg capsule	12	71881-104-09 71881-124-01	71881-104-99
40 mg (Level 5)	Twelve blisters, each containing: Two 20 mg capsules	12	71881-105-09 71881-124-01	71881-105-99
80 mg (Level 6)	Twelve blisters, each containing: Four 20 mg capsules	12	71881-106-09 71881-124-01	71881-106-99
120 mg (Level 7)	Twelve blisters, each containing: One 20 mg capsule One 100 mg capsule	12	71881-107-09 71881-124-01 71881-125-01	71881-107-99
160 mg (Level 8)	Twelve blisters, each containing: Three 20 mg capsules One 100 mg capsule	12	71881-108-09 71881-124-01 71881-125-01	71881-108-99
200 mg (Level 9)	Twelve blisters, each containing: Two 100 mg capsules	12	71881-109-09 71881-125-01	71881-109-99
240 mg (Level 10)	Twelve blisters, each containing: Two 20 mg capsules Two 100 mg capsules	12	71881-110-09 71881-124-01 71881-125-01	71881-110-99
300 mg (Level 11)	Fifteen 300 mg sachets	15	71881-111-09	71881-111-99


NDC, National Drug Code.





Palforzia


1 dose pack (Level 11 Maintenance) of Palforzia 300mg [Edit](#)

1

 Notice 

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\$1,114.20

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For Perspective...



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Average College Tuition and Fees

For the 2021-2022 academic year, the average price of tuition and fees came to: **\$38,070 at private colleges**. \$10,740 at public colleges (in-state residents) \$27,560 at public colleges (out-of-state residents)

<https://www.collegedata.com/resources/pay-your-way>

How Much Does College Cost? | CollegeData

[About featured snippets](#) [Feedback](#)

<https://www.ontocollege.com/average-college-tuition>

Average College Tuition by State - OnToCollege

	Public 4-year In-state tuition and fees	Public 4-year Out-of-state tuition and fees	Private 4-year Tuition and fees	Public ... In-stat...
United States	\$9,212	\$26,382	\$31,875	\$3,313
Alabama	10,138	25,782	16,119	4,770

[View 50 more rows](#)

E&M



- Codes were designed for general allergy visits and procedures
- No guidelines for billing OIT visits until recently
- Some insurances have started to deny claims
- This begs the question.....

E&M Change or Revision

- **New or reviewed Category I code must satisfy ALL of the below Criteria:**
 - FDA Approval
 - The procedure or services is performed by many qualified healthcare providers across the United States
 - The procedure or service is performed with frequency consistent with the intended clinical use
 - The procedure or service is consistent with current medical practice
 - The clinical efficacy of the procedure or service is documented in literature that meets the requirement for code change application



Time

- The total time used to select the level of office E/M is the sum of all time spent face-to-face **and** in non-face-to-face activities that are not separately reportable by the provider. *The non-face-to-face activities have to occur on the **day of the visit** for that time to be counted.*



Examples of non-face-to-face activities include:

- Preparing to see the patient (e.g. review of tests)
- Obtaining and/or reviewing separately obtained history
- Counseling and educating the patient/family/caregiver
- Ordering medications, tests, or procedures
- Referring and communicating with other health care professionals (when not separately reported)
- Documenting clinical information in the electronic or other health record
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
- Care coordination (not separately reported)

An Approach to the Office-Based Practice of Food Oral Immunotherapy

Richard L. Wasserman, MD, PhD^a, Jeffrey Factor, MD^b, Hugh H. Windom, MD^c, Elissa M. Abrams, MD^d,

TABLE E4. Approaches to OIT coding in 2020

Visit type	Code	Alternatives	Comments
Day 1	CPT 95076: ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug, or other substance); initial 120 min of testing; and CPT 95079: each additional 60 minutes of testing (list separately in addition to code for primary procedure)	CPT 95119: unlisted allergy/clinical immunology procedure	CPT 95180: as written, is not intended for oral administration. Some payers specifically prohibit its use for OIT. CPT 95119: because it is nonspecific, reimbursement will be unpredictable
Updosing visits	CPT Established Patient E/M Code (select appropriate E/M level) CPT 99354: prolonged evaluation and management service(s); first hour (list separately in addition to code for Evaluation and Management) CPT 99355: each additional 30 min (list separately in addition to code for prolonged service)	CPT 95119: unlisted allergy/clinical immunology procedure	CPT 95075: may not be appropriate because it specifies at least 2 doses for the ingestion challenge CPT 95180: is interpreted to require at least 2 doses and is not intended for oral administration CPT 95119: because it is nonspecific, reimbursement will be unpredictable CPT 99354 and CPT99355: required direct face-to-face visit contact

ICD-10-CM DIAGNOSIS CODING

International Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM) codes are used to identify the patient's condition and reason the patient is receiving treatment.

Potential ICD-10-CM Diagnosis Codes for Allergy and Reactions due to Peanuts¹

Z91.010	Allergy to peanuts
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter
T78.01XS	Anaphylactic reaction due to peanuts, sequela

Other Potential ICD-10-CM Diagnosis Codes Commonly Billed by Healthcare Professionals¹

T78.2XXA	Anaphylactic shock, unspecified, initial encounter
T78.2XXD	Anaphylactic shock, unspecified, subsequent encounter
T78.2XXS	Anaphylactic shock, unspecified, sequela
T78.40XA	Allergy, unspecified, initial encounter
T78.40XD	Allergy, unspecified, subsequent encounter
T78.40XS	Allergy, unspecified, sequela

Potential CPT Codes

Office Visit Evaluation and Management CPT® Codes²

» 99213**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision-making. When using time for code selection, 20-29 minutes of time is spent on the date of the encounter.
» 99214**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision-making. When using time for code selection, 30-39 minutes of time is spent on the date of the encounter.
» 99215**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision-making. When using time for code selection, 40-54 minutes of time is spent on the date of the encounter.

Ingestion Challenge Test/Rapid Desensitization Procedure CPT Codes²

95076*	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing
95079*	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)
95180	Rapid desensitization procedure, each hour (e.g., insulin, penicillin, equine serum)

E/M = Evaluation and Management
CPT = Current Procedural Terminology

*Recommended for billing for initial visit by the American Academy of Allergy, Asthma & Immunology (AAAAI) and American College of Allergy, Asthma and Immunology (ACAAI).

**Recommended for billing for Up-Dosing services by the AAAAI and ACAAI. These specialty societies indicate that Up-Dosing services are most appropriately coded using an E/M code plus prolonged service code(s) if needed. Please note: both specialty societies also disclaim that Allergy practices should follow health plan and payer policies and guidelines where available even though they may differ from the guidance provided.

Potential CPT Codes

Unlisted Allergy/Clinical Immunology CPT Codes²

95199

Unlisted allergy/clinical immunologic service or procedure

Prolonged Service, Requiring Direct Patient Contact²

» 99415**

Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service)

» 99416**

Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service)

Prolonged Service, With or Without Direct Patient Contact²

» 99417**

Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes of total time (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management service)

E/M = Evaluation and Management
CPT = Current Procedural Terminology

**Recommended for billing for Up-Dosing services by the AAAAI and ACAAI. These specialty societies indicate that Up-Dosing services are most appropriately coded using an E/M code plus prolonged service code(s) if needed. Please note: both specialty societies also disclaim that Allergy practices should follow health plan and payer policies and guidelines where available even though they may differ from the guidance provided.

Hybrid models





Take Home Points

OIT has emerged as a patient preference-sensitive treatment option

OIT can lead to empowerment and improved quality of life

Cost saving associated with OIT can reach billions of dollars when considering long-term outcomes

Coding and billing options include cash, E&M, time, and hybrid approaches