

Updated Cost-Effectiveness of PTAH Oral Immunotherapy in Peanut Allergy

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OBJECTIVES

The Institute for Clinical and Economic Review (ICER) published a report of the cost-effectiveness of peanut allergy immunotherapy treatment AR-101 (Peanut (Arachis hypogaea) Allergen Powder-dnfp, “PTAH”) compared to avoidance alone in 2019. PTAH was approved by the FDA in 2020 and two-year extension trial data is now available.

Our objective was to replicate and update the previously developed ICER model for PTAH to include extension trial data and updates to drug costs.

METHODS

- We replicated the five-state 2019 ICER Markov model (Figure 1) estimating costs and outcomes from the payer perspective over a lifetime horizon.
- Year one estimates were derived from the 2019 ICER model.
- Year two clinical inputs were derived from the PALISADE extension trial and pooled extension trial safety results, and patients were assumed to stay at their desensitization level at end of year 2 for the remainder of the model.
- Costs were in 2022 dollars and a 3% discount rate was applied to costs and outcomes.
- The following inputs were included but not shown here: discontinuation during trial period, disutilities for severe AEs and epinephrine utilization, disutility duration, healthcare utilization costs, adverse event costs, and post-trial adverse event rates.
- The model includes functionality for modeling year 2 exit food challenge doses of 1000 mg and 2000 mg.

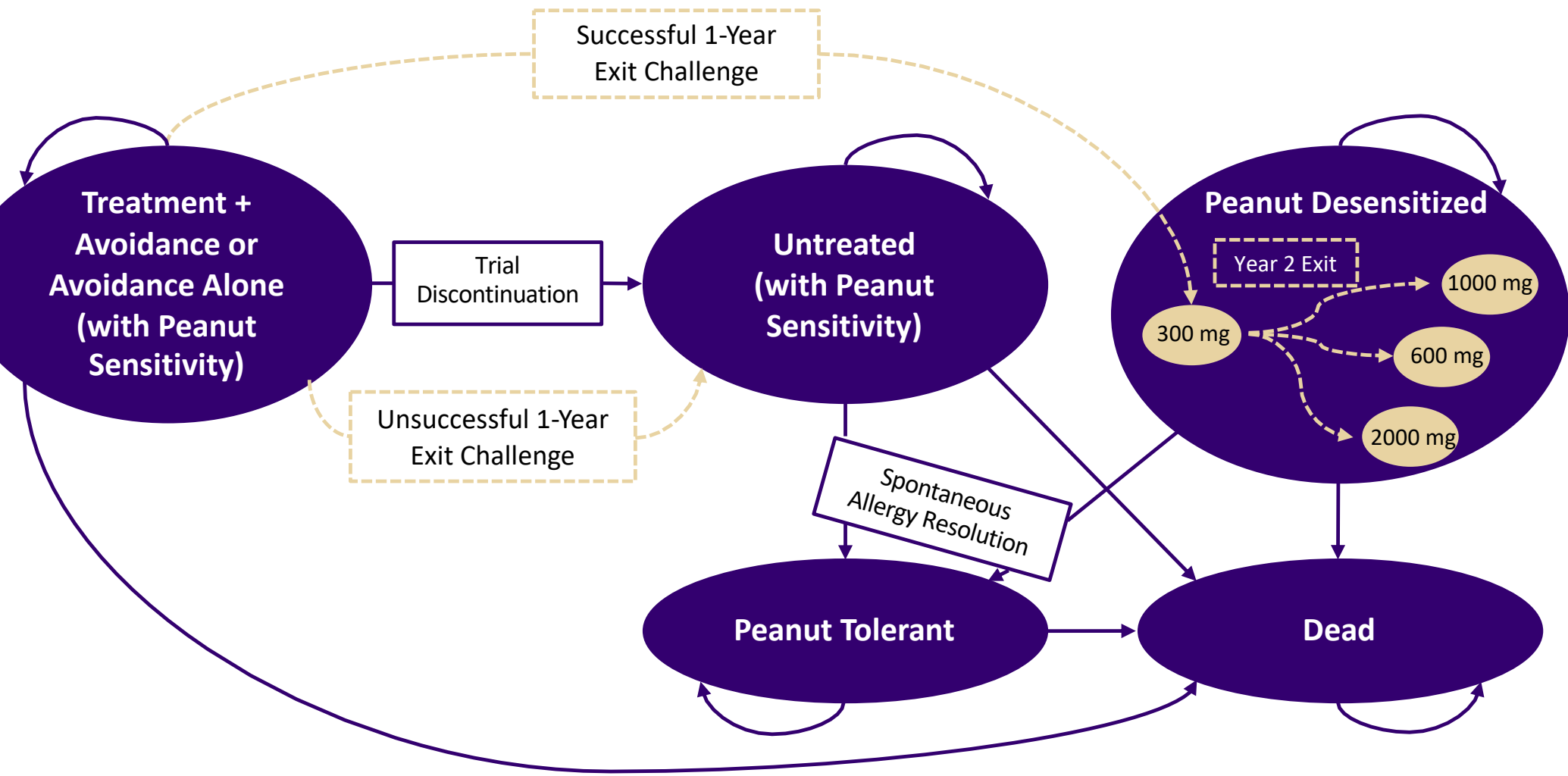


Figure 1. Model Structure – adapted from ICER 2019

REFERENCES

1. Tice JA et al. *Oral Immunotherapy and Viaskin Peanut for Peanut Allergy: Effectiveness and Value Final Evidence Report (ICER)*. July 10, 2019. 2. PALFORZIA [Peanut (Arachis hypogaea) Allergen Powder-dnfp] Prescribing Information. Aimmune Therapeutics; 2020. 3. PALISADE Group of Clinical Investigators. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med*. 2018 Nov 22;379(21):1991-2001. 4. Vickery BP et al. Continuous and Daily Oral Immunotherapy for Peanut Allergy: Results from a 2-Year Open-Label Follow-On Study. *J Allergy Clin Immunol Pract*. 2021 May;9(5):1879-1889.e13. 5. Fernandez-Rivas M et al. Open-label follow-on study evaluating the efficacy, safety, and quality of life with extended daily oral immunotherapy in children with peanut allergy. *Allergy*. 2022 Mar;77(3):991-1003. 6. Brown KR et al. Safety of peanut (Arachis hypogaea) allergen powder-dnfp in children and teenagers with peanut allergy: Pooled summary of phase 3 and extension trials. *J Allergy Clin Immunol*. 2022 Jun;149(6):2043-2052.e9. 7. Shaker M et al. The Health and Economic Outcomes of Peanut Allergy Management Practices. *J Allergy Clin Immunol Pract*. Nov-Dec 2018;6(6):2073-2080. 8. Shaker MS. An Economic Analysis of a Peanut Oral Immunotherapy Study in Children. *J Allergy Clin Immunol Pract*. Nov-Dec 2017;5(6):1707-1716. 9. REDBOOK Online, Accessed March 1, 2023.

KEY INPUTS

Parameter	Value
Time Horizon	Lifetime
Perspective	Payer
PTAH Cost Per Dose	\$38.44
PTAH – Clinical Parameters, Year 1	
300 mg successful challenge (compared to placebo)	68.5%
Epinephrine Utilization (annual rate)	0.24
AE – Anaphylactic reaction (events per year)	0.01
AE – Systemic allergic reaction (events per year)	0.23
Placebo – Clinical Parameters, Year 1	
300 mg successful food challenge	8.1%
Epinephrine Utilization (annual rate)	0.03
AE – Anaphylactic reaction (events per year)	0.00
AE – Systemic allergic reaction (events per year)	0.02
PTAH – Clinical Parameters, Year 2	
300 mg successful food challenge	100%
600 mg successful food challenge	96.2%
Epinephrine Utilization (annual rate)	0.34
AE – Anaphylactic reaction (events per year)	0.00
AE – Systemic allergic reaction (events per year)	0.20
Annual spontaneous resolution	1.10%
Utilities, Patients Aged 0-11	
Utility – on treatment/placebo with sensitivity	0.84
Reduction in disutility for each 100 mg desensitized	5.7%
Utility – peanut tolerant	0.94
Utilities, Patients Aged 12+	
Utility – on treatment/placebo with sensitivity	0.91
Reduction in disutility for each 100 mg desensitized	5.7%
Utility – peanut tolerant	1.0

KEY CONCLUSIONS

- PTAH is not cost-effective at the current price according to commonly accepted thresholds, when accounting for both Year 1 and Year 2 trial results.
- The results are highly dependent upon child utility values.
- Future development of this model will explore child utility values further and incorporate the societal perspective.

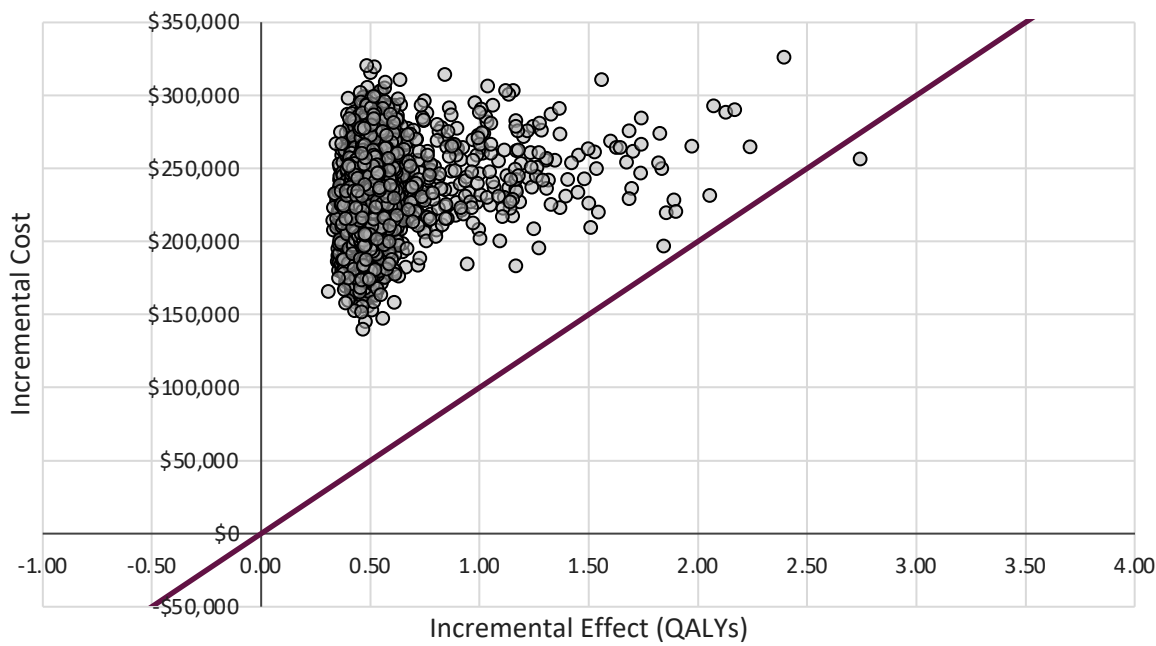
RESULTS

- The model estimated increased QALYs for the intervention arm vs. avoidance alone (26.56 vs. 26.06) and increased costs (\$247,000 vs. \$7,300) over the lifetime horizon using the 2-year trial results and a desensitization threshold of 600 mg. This yielded an incremental cost-effectiveness ratio of \$477,400/QALY based on deterministic results.
- The OWSA indicated that the utility values were primary drivers of the results, followed by the cost of PTAH.
- The probabilistic sensitivity analysis indicated that PTAH had a 0.02% chance of being cost-effective at a willingness-to-pay threshold of \$100,000/QALY.
- Based on this model, the price of PTAH would need to decrease by approximately 69% to meet a willingness-to-pay threshold of \$150,000/QALY.

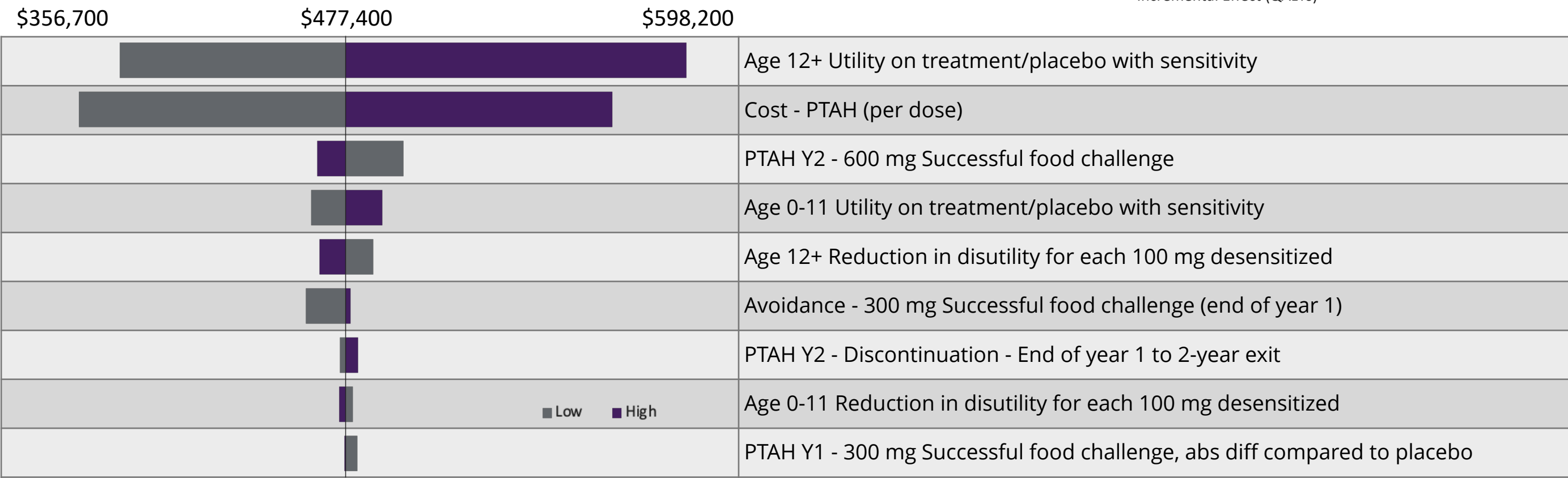
RESULTS SUMMARY

	Cost	QALYs
PTAH	\$247,000	26.56
Avoidance/Placebo	\$7,300	26.06
Difference	\$239,700	0.50
ICER	\$477,400/QALY	

PROBABILISTIC SENSITIVITY ANALYSIS



ONE-WAY SENSITIVITY ANALYSIS (OWSA)



CONCLUSION

- Model results indicate that PTAH is not cost-effective at the current price according to commonly accepted cost-effectiveness thresholds.
- The results are highly dependent upon child utility values, indicating that the assumptions used to derive these values could have significant implications for decision-making.
- Food allergy is a condition that affects both parents and children, so consideration of family spillover effects and the societal perspective is crucial and is in development for future versions of this model.