ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

Allergen Immunotherapy Products

FINAL BUDGET IMPACT ANALYSIS

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Conflict of Interest Statement

No study members report any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock options, expert testimony, grants or patents received or pending, or royalties) that may present a potential conflict of interest in the Allergen Immunotherapy Drug Class Review.

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Contents

Conflict of Interest Statement 2
Acknowledgments 2
Study Team 2
Introduction 4
Data Sources 4
Ontario Public Drug Program Allergen Program Data 4
Methods 4
Table 1: Assumptions used to populate budget impact analysis 5
Table 2: Calculation of costs for patient-specific allergen immunotherapy 6
Results 6
Table 3: Budget impact of introduction of standardized pricing, assuming removal of unstable components of claims 6
Table 4: Budget impact of introduction of standardized pricing, assuming duplication of unstable components of claims 7
Conclusion 7

Introduction

Allergen Immunotherapies are a class of therapies used to help decrease symptoms related to allergies for a variety of allergens. Allergen immunotherapy can be divided into two forms of therapy, which consists of sublingual immunotherapy (SLIT) and subcutaneous immunotherapy (SCIT). Most SCIT therapies are uniquely compounded for each patient (with the exception of Pollinex-R which is available as a commercially formulated product). Currently in Ontario, all publicly-funded SCITs (both patient-specific serums and Pollinex-R) are paid for through the Allergy Products program.

The objective of this report is to describe the potential budget impact of several potential approaches to standardizing costs related to uniquely compounded SCIT therapies in Ontario

Data Sources

Ontario Public Drug Program Allergen Program Data

We were supplied information on spending of patient-specific allergen extracts and Pollinex-R from the Ontario Public Drug Programs (OPDP) Allergy Products program. This data included claim summary information from April 1, 2010 to March 31, 2015. Information included total cost paid, number of claims, and number of users by fiscal year. Additionally, we received a random sample of 100 allergen extract claim submissions that were de-identified. These claims contained information related to the cost of the allergen extracts, dose and type of extract, number of extracts, and date of claim.

Methods

A budget impact analysis was developed that leveraged prior prescription patterns for SCITs in Ontario to estimate the impact of various potential policy changes on total cost to the Ontario Public Drug Program. The main inputs for this analysis were:

1. **Volume of prescribing**: the total number of claims expected was based on claims data from the OPDP allergen program for fiscal year 2013-14.
2. **SCIT Therapy Type**: We used a random sample of detailed information on 100 claim submissions to estimate the proportion of SCITs for environmental, venom and other allergens. These proportions were applied to overall volume of prescribing to estimate the number of claims of each type
3. **Unstable combinations**: Guidelines suggest that certain allergens should not be combined in SCIT therapy. We identified the proportion of claims that included unstable combinations from the random sample of 100 submissions and applied this to the overall number of claims to estimate the number of unstable combinations. We then modeled unstable claims in two ways:
    a. No change: this situation assumes that the unstable aspect of the claim would be removed, and so these SCIT claims would still be dispensed; however they would only contain stable components

b. Duplicated claims: this situation assumes that the SCIT therapy would be separated into two separate claims so that the patient receives therapy for both allergens in separate products. We assume that this would then double the number of allergen claims for these unstable combinations since they would now result in two separate claims.

4. **Costs**: We used the mean cost per claim from the random sample of 100 submissions to estimate the costs for environmental and venom SCITs separately. We applied the costs for environmental SCITs to the "Other" group since these SCITs all had a combination of environmental and food allergens, and so would be reimbursed at the cost of environmental SCITs.
5. **Proportional cost per claim:** Based on discussions with the Research Team, we estimated costs for environmental SCIT at $130 and for venom SCIT at $410. These costs were derived based on the wholesale cost of the allergen extracts, preparation time for compounding the patient-specific extracts, mark-up and dispensing fee (see Table 2).

The assumptions that are described above are detailed in **Table 1**

Table 1: Assumptions used to populate budget impact analysis

	Actual Amounts (2013/14) (MOH Data)	Environment Allergen	Venom Allergen	Other Allergens*
Claims (% of total)		87%	10%	3%
Claims	16,947	14,744	1,695	508
% Unstable combinations		11%	None (0%)	67%
Number Unstable Claims		1,695	0	339
Claims (assume unstable combos dispensed as 2 separate claims)		16,439	1,695	847
Cost per claims	$211.15 (average for all claims)			
Minimum (from sample)		$106.50	$106.50	$106.50
Mean (from sample)		$223.75	$336.85	$223.75
Estimated Research Team Costs		$130.00	$410.00	$130.00
Current Total Cost	$3,578,359			
Estimated Total Costs				
Based on Sample	$3,983,595			
Based on proportional costs	$3,578,359			

**Combinations of environmental and food allergens*

We estimated the potential costs, and budget impact of the following policies:

1. Introduction of standardized pricing according to several potential costs (minimum and the research team's estimate of appropriate cost) for environmental and venom SCITs. Minimum costs were $106 for both types of SCITs and the estimated appropriate cost was $130 for environmental SCITs and $410 for venom allergens.
2. Restriction on SCIT components to avoid dispensing of unstable combinations. This would result in either:
    a. Removal: SCIT components being reduced to remove problematic allergen
    b. Duplication: Two SCIT products dispensed with allergens separated to avoid unstable combination.

Table 2: Calculation of costs for patient-specific allergen immunotherapy

Component[a]	Environmental SCIT	Venom SCIT
Cost of ingredients	$35.00/5mL multidose vial for most allergen extracts (ALK-Canada) x 3 extracts[b,c] = $105	$370 (maintenance treatment for wasp)
Compounding charge	0.55 x 15 minutes (estimate) = $8.25	None
Upcharge	8% of ($105 + 8.25) = $9.06	8% ($29.60)
ODB dispensing fee	$8.00	$8.00
TOTAL	**$130.31**	**$407.60**

[a]The basic formula for billing extemporaneous preparations in a pharmacy is: [cost of ingredients] + [compounding charge (= compounding time in minutes x $0.55/minute)] + [upcharge (8%) on ingredients + compounding charge] + [ODB dispensing fee] = total.
[b]Based on average number of allergens in sample.
[c]Assuming that a full multi-dose vial will be billed. If only a portion of the multivial is billed (e.g., 20%), then the cost is reduced to $47.00.

Results

The results of the BIA for each of the policies described above are provided in **Tables 3 and 4.**

Table 3: Budget impact of introduction of standardized pricing, assuming removal of unstable components of claims

Cost Assumption	Total Cost	Budget Impact	% Change
Minimum Costs	$1,804,856	-$1,773,504	↓50%
Mean Costs	$3,983,562	$405,203	↑11%
Potential Appropriate Costs	$2,677,626	-$900,733	↓25%
Actual Ontario Costs (2013/14)	$3,578,359		

Table 4: Budget impact of introduction of standardized pricing, assuming duplication of unstable components of claims

Cost Assumption	Total Cost	Budget Impact	% Change
Minimum Costs	$2,021,438	-$1,556,921	↓44%
Mean Costs	$4,438,589	$860,229	↑24%
Potential Appropriate Costs	$2,941,999	-$636,360	↓18%
Actual Ontario Costs	$3,578,359		

Conclusion

The potential budget impact of new policies addressing costs of SCITs and restrictions on unstable combinations is varied, and relies heavily on the assumptions regarding costs per claim reimbursed. For example, if costs are restricted to the minimum amount currently reimbursed by the OPDP, this could lead to savings of over $1.5M/year. However, reimbursing all claims at the current mean cost would lead to an increase in costs of approximately $860,000.