

The Ontario Drug Policy Research Network (ODPRN) conducted multiple studies on the effectiveness, safety, and accessibility of allergen immunotherapy using multiple research methods.

What is allergen immunotherapy?

Allergen immunotherapy (AI) involves the regular administration of gradually increasing doses of allergen extracts (e.g., insect venom, grass, pollen) for patients suffering from allergic rhinitis (hay fever), allergic asthma, or stinging insect hypersensitivity. AI is most often used in patients with allergic rhinitis who have failed or cannot tolerate standard treatment options, such as intranasal steroids or antihistamines.

Immunotherapy can be administered as an injection (subcutaneous immunotherapy or 'SCIT') or as tablets under the tongue (sublingual immunotherapy or 'SLIT').

SCIT

SCIT - Aeroallergens

- Used for environmental allergies
- Should be administered by a doctor/nurse
- Each dose is personalized specifically for the patient
- The compounding of the serum is either done by commercial laboratories, pharmacies, or in the physician's office. There is no standardization which leads to variability in pricing and manufacturing practices.
- Effective in helping patients with allergic asthma and allergic rhinitis
- Can cause a severe allergic reaction (anaphylaxis) in some patients



SLIT

- For pollen aeroallergens only
- Commercially available as tablets for sublingual administration
- Can be taken at home
- Some SLIT products have been added to the Ontario Drug Benefit (ODB) formulary as Limited Use
- Effective in helping patients with allergic asthma and allergic rhinitis
- Can cause a severe allergic reaction (anaphylaxis) in some patients

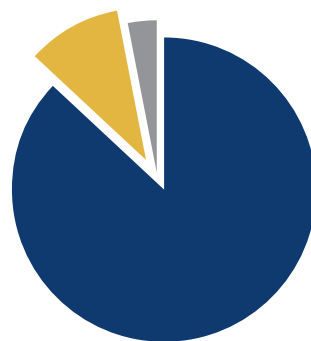


SCIT - Venom

- Used for allergies to insect stings (e.g., bees, wasps)
- It is effective for preventing whole body allergic reactions
- Some patients could develop local reactions, or more rarely, severe allergic reactions during therapy



Use of SCIT Allergen Immunotherapy



Out of 100 claims:

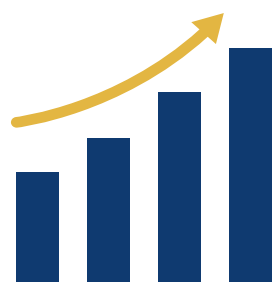
87 were for environmental

10 were for venom

3 were for mixed serum (environment and food)

- Environmental
- Venom
- Mixed (Environmental and Food)

It should be noted that 13% of allergen serums were characterized as possibly unstable, which may mean they won't work as well.

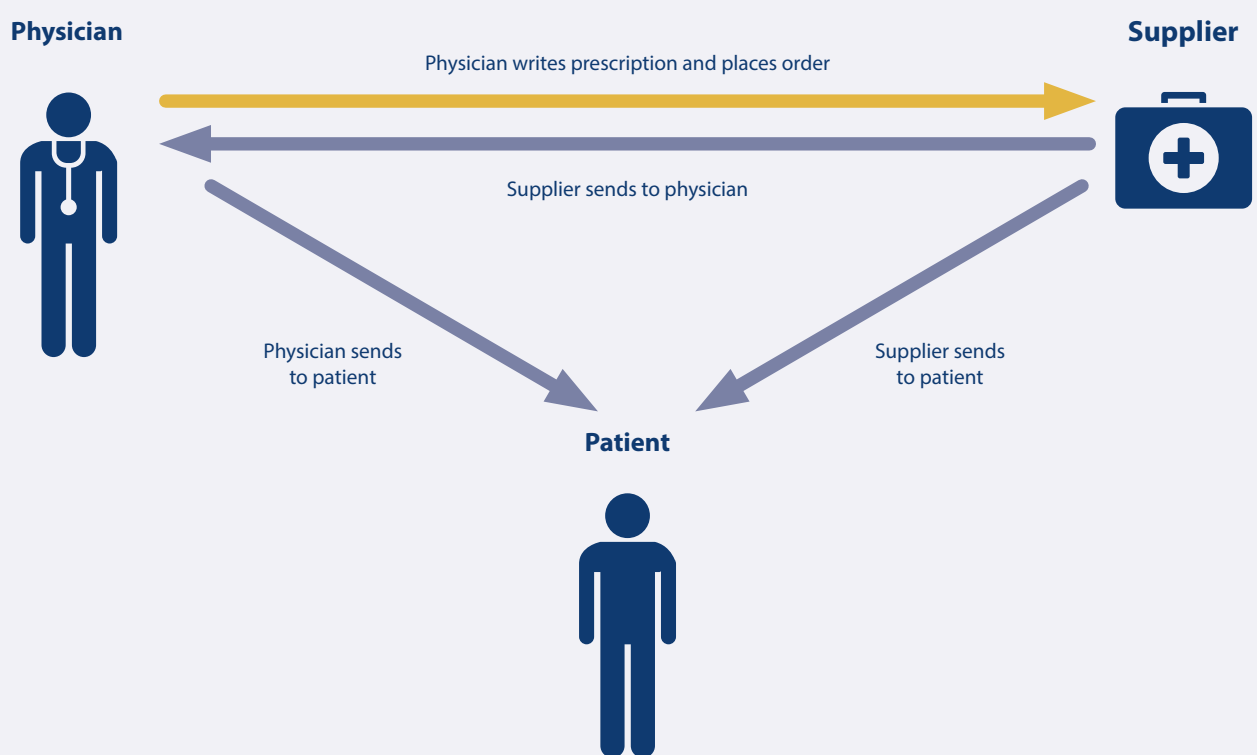


Use of immunotherapy is rising

- The introduction of SLIT to the Canadian market caused a 32% increase in costs for commercially available SLIT and Pollinex-R, from \$5.6 million in 2013 to \$7.4 million in 2014.
- Use in Canada for commercially available SLIT products and Pollinex-R has nearly doubled (92%) over the past 5 years, from 6,423 prescriptions to 12,311.
- Ontario comprises the majority of users as the ODB alone spent \$3,789,385 in fiscal year 2013/2014.

Distribution Process

Lack of standardization on how SCIT is dispensed (i.e. on-site, manufacturer, or pharmacy), has resulted in a variety of prices for the same products across the various dispensing outlets, whereas SLIT costs are consistent.



For SCIT therapy, the pricing can vary depending on whether or not the patient buys the treatment from the physician or directly from the supplier.

Recommendations for consideration

1

Recommendation 1:
Limit duration of therapy to 5 years for aeroallergens administered as SCIT



- Although the optimal duration of immunotherapy is unknown, 3-5 years of SCIT & 3 years of SLIT (before and during the allergy season) have been recommended.
- Patients receiving venom immunotherapy may require life-long administration.

2

Recommendation 2:
Require drug identification numbers (DIN) on all prescriptions for SCIT



- Only extracts with associated DINs should be used in the manufacturing of patient-specific serums. Whenever possible, standardized extracts should be utilized.
- The inclusion of DINs on the prescription will prevent the use of in-house manufactured allergen extracts that may not meet minimum manufacturing standards set out by Health Canada.
- Suppliers (including physician's offices) will need to include DINs for all SCIT products.

3

Recommendation 3:
Develop clinical criteria for use of SCIT



- Clinical criteria to include:
 - A diagnosis of: allergic rhinitis, allergic asthma, or history of insect sting allergy.
 - Documentation of previous therapy: nasal steroids and/or antihistamines (insect allergies exempt).

4

Recommendation 4:
Coverage of SLIT be limited to commercially available products



- Ontario currently provides coverage for two commercially available SLIT products (as tablets): Oralair and Ragwitek. Some clinicians use the allergen extracts to prepare patient-specific SLIT administered as drops - considered "off-label" use.
- It is recommended that patient-specific allergen extracts only be administered subcutaneously. Therefore, it is recommended that Ontario Public Drug Programs not provide coverage for patient specific allergen extracts for sublingual use.

5

Recommendation 5:
Develop pricing structure for patient-specific allergen immunotherapy



- Since there is currently no pricing structure, a maximum allowable claim cost (annual) is recommended for SCIT. However the amount would be different for environmental and venom immunotherapy, as venom is much more expensive.

6

Recommendation 6:
Provide guidance for safe manufacturing practices



- All manufacturing (including pharmacies and physician's offices) should follow established guidelines which set rules for sterility, sanitization, storage, handling, expiration dates, and proper combining and dosing.