

# Treatment Options for Food Allergy: A Decision Guide for Caregivers

Starting a food allergy therapy like oral immunotherapy (OIT) or omalizumab (brand name: Xolair® or its biosimilar, Omlyclo®) is a big decision. This guide can help you to talk with your allergist about the best options for you or your child.

It may also help to talk with family and friends. Showing them this guide may help you reach a decision. Your family knows you and your concerns, and they can support you in making the best decision.

The best choice will be the one you feel most comfortable with, and you and/or your child will stay with long-term. One of the options is to continue with allergen avoidance and not start treatment at this time. You may be able to start treatment in the future.

When you are ready to decide, make an appointment with your allergist. Please ask any questions and share any concerns you have about these choices with your allergist. Your allergist will go over the treatment schedule and how they will measure your or your child's progress.

**Do not try any type of food allergy treatment at home without talking with your allergist.**

## This decision aid is for you if any of the following apply:

- Your allergist or primary care doctor diagnosed you or your child with one or more food allergies.
- You or your child with the diagnosed food allergy is at least age 6 months or older.
- You or your child had an allergic reaction to food, including anaphylaxis.
- You are curious about food allergy treatment choices for you or your child.
- You are concerned about the risk of an accidental allergic reaction to food for you or your child.
- You or your child are willing to do a treatment that either involves eating the food allergen on a regular basis or getting shots once or twice a month.

### Definitions and pronunciations to help you talk about this decision:

**Allergen [ah-ler-jin]:** thing that causes allergic reaction (like food)

**Oral immunotherapy [ih-myoo-no-theh-ruh-pee]:** a treatment that involves eating a small amount of food allergen to help the immune system learn to tolerate the food

**Omalizumab [oh-muh-liz-uh-mab]:** a prescription injection (shot) that works by blocking an immune response to food to help prevent severe allergic reactions if a person accidentally eats their allergen

**Xolair [ZOH-lair]:** a brand name for omalizumab

**Omlyclo [ahm-lih-cloh]:** an interchangeable biosimilar to Xolair

**Anaphylaxis [anna-fih-LACK-sis]:** a severe allergic reaction that needs prompt treatment with epinephrine

**Epinephrine [eh-puh-neh-fruhn]:** a prescription medicine that treats anaphylaxis

**Eosinophilic esophagitis [EE-oh-sin-oh-FILL-ick uh-sof-uh-JIE-tis]:** a delayed type food allergy that causes swelling in the esophagus (part of your throat)

## What are the current options for managing food allergy?

1. Allergen avoidance (remove the food allergen from the diet)
2. Food oral immunotherapy (eat small amounts of allergen with allergist's guidance)
3. Omalizumab injections (a medicine that helps block allergic reactions)

For all of these options, you (or your child) will still need to carry epinephrine and have it with you in case of emergency.





## Comparison of Options for Managing Food Allergy

	Avoidance	OIT	Omalizumab (Xolair or Omlyclo)
<b>What the treatment is and how often it is taken</b>	<p>Every day: Continue to strictly avoid eating any amount of the food allergen.</p> <p>You may worry about accidentally eating the food allergen.</p> <p>Only some people outgrow their food allergy. The chance this happens depends on the food allergen.</p> <p>Not a treatment or a cure.</p>	<p>Every day: Eat small, increasing amounts of the food allergen up to a certain target level, under the direction of your allergist.</p> <p>The allergist will increase the dose in office every few weeks to a top target dose.</p> <p>The person must eat the dose every day or they will lose protection.</p> <p>You may still have to avoid eating any extra of the food allergen besides the dose.</p> <p>For most people, OIT is not a cure.</p>	<p>Get shots once or twice a month.</p> <p>The first 3 shots are supervised in the allergy clinic. After that, the shots can usually be done at home.</p> <p>You must continue the shots or you will lose protection.</p> <p>Some people may be able to eat some amounts of their allergen in their diet.</p> <p>If you are doing OIT, your allergist may have you use omalizumab for a few months to help limit side effects and to make the OIT reach the target faster and then stop omalizumab.</p> <p>Not a cure.</p>
<b>Time it takes for treatment to work</b>	Right away.	Around 6-12 months for most people	Around 4-5 months, but results are better if used longer.
<b>Eligible ages</b>	Any age.	Any age. Works very well in infants and toddlers. Less clear how well OIT works in adults.	Any age over 1 year.
<b>Number of allergist visits needed</b>	Usually, once a year for follow-up and testing.	<p>Updosing visits every 1 to 4 weeks to increase the dose until the top dose is reached (around 6-12 months).</p> <p>Routine follow-up visits with allergist to follow progress.</p>	<p>The first 3 shots are done at the allergy clinic. After that, you can do the shots yourself at home or continue to go to clinic.</p> <p>Routine allergist follow-up visits to follow progress are recommended.</p>
<b>How long to stay on treatment</b>	Probably long-term.	Unknown if treatment can be stopped.	Unknown if treatment can be stopped.
<b>Benefits</b>	<p>No risk of side effects related to treatment.</p> <p>Some people and their families do well with allergen avoidance.</p>	<p>Increases how much food the person can eat before they have an allergic reaction.</p> <p>May make allergic reactions less severe.</p> <p>May prevent allergic reactions if the food allergen is accidentally eaten.</p> <p>May improve quality of life and reduce anxiety by end of treatment.</p> <p>Works for the specific food(s) that are treated.</p>	<p>Increases how much food most people can eat before they have an allergic reaction.</p> <p>May make allergic reactions less severe.</p> <p>May prevent allergic reactions if the food allergen is accidentally eaten.</p> <p>May improve quality of life and reduce anxiety by end of treatment.</p> <p>Works for one or more foods.</p> <p>Also treats asthma, chronic hives, and nasal polyps.</p>




	Avoidance	OIT	Omalizumab (Xolair or Omlyclo)
<b>Risks and side effects</b>	<p>You must avoid all sources of the food and carry epinephrine at all times.</p> <p>Some people have poor quality of life and anxiety related to living with a food allergy and managing it by avoiding the allergen(s).</p> <p>Accidental reactions can occur and could be severe.</p> <p>If you accidentally eat your allergen, there is a chance it will lead to anaphylaxis (7% or 7 out of 100).</p>	<p>There is a risk of having an allergic reaction during treatment, needing epinephrine. This risk gets lower the longer the treatment goes but does not go away.</p> <p>Dose-related reactions such as stomach aches, nausea, and vomiting (around 80% or 80 out of 100 people have this).</p> <p>Anaphylaxis from the dose (around 20% or 1 out of 5 people have this).</p> <p>Eosinophilic esophagitis (around 3% or 3 out of 100 people will get this).</p> <p>Higher chance of side effects with doses if taken on an empty stomach, when sick, on your period, when tired, or too close to exercise or a hot shower (chances vary).</p> <p>May be hard for some people and families to fit into their daily life.</p> <p>You must avoid all additional sources of the food and always carry epinephrine. Some may be able to put small amounts of the food back in their diets.</p>	<p>There is a very small risk having an allergic reaction to the treatment, needing epinephrine. This risk is highest with the first 3 doses.</p> <p>May have pain, redness or swelling at shot site (15% or 15 out of 100 people will have this)</p> <p>Fever (around 6% or 6 out of 100 people will have this)</p> <p>Anaphylaxis from the shot (0.2% or 2 out of 1,000 people will have this)</p> <p>13 out of 100,000 (or 0.013%) of older adults had a slight increase in heart and circulation problems, but it is unclear if omalizumab caused these.</p> <p>You must avoid all sources of the food and always carry epinephrine. Some may be able to put small amounts of the food back in their diets.</p>
<b>Duration of side effects</b>	No direct side effects.	<p>Mild symptoms can be treated and get better with time without stopping OIT.</p> <p>Severe symptoms may need epinephrine and to stop OIT.</p>	<p>Mild symptoms can be treated and get better with time without stopping omalizumab.</p> <p>Severe symptoms may need epinephrine and to stop omalizumab.</p>
<b>Cost</b>	No extra costs over normal food allergy care.	<p>Insurance may not pay for OIT visits, food, or medicine costs.</p> <p>Commercial insurance: May be covered or partially covered but will vary by plan.</p> <p>Without insurance: Costs and access vary widely by clinic.</p> <p>Check with your doctor if you must pay cash for OIT.</p>	<p>Insurance may not pay for shot visits or medicine costs.</p> <p>Commercial insurance: May be covered or partially covered but will vary by plan.</p> <p>Without insurance: The self-pay price is high.</p> <p>Specialty pharmacies may not take cash payments.</p> <p>You may be eligible to get Xolair for free if you meet certain income limits.</p>
<b>What happens if you stop treatment</b>	You may react every time they eat any bit of the food allergen.	<p>1-2 missed doses a week likely has no effect.</p> <p>Protection may drop if several doses are missed in a row (time on OIT dependent).</p> <p>Protection may be fully lost after a few months of stopping OIT.</p>	<p>Protection may drop if you miss several doses in a row.</p> <p>If the therapy is stopped, protection goes away after a few months.</p>

## What Does the Research Show

### Out of 100 people who start OIT, about:

Benefits	Reactions and Side Effects
<p><b>80</b> will be able to eat more food before a reaction occurs</p> 	<p><b>98</b> may have a reaction caused by the OIT dose (this includes things like itching, hives, stomach pain, or lip swelling). <b>Most of those reactions (4 out of 5) will be mild or moderate.</b></p>
<p><b>30</b> may grow out of their allergy with OIT, depending on the person's age</p> 	<p><b>20</b> may have an allergic reaction from OIT and need to use epinephrine, depending on age</p> 
	<p><b>18</b> may stop OIT because of side effects</p> 

### Out of 100 people who start omalizumab (Xolair or Omlyclo), about:

Benefits	Reactions and Side Effects
<p><b>78</b> will be able to eat a half a serving of one allergenic food before a reaction occurs</p> 	<p><b>15</b> will develop mild symptoms at the shot-site including pain, soreness, warmth, swelling</p> 
<p><b>66</b> will be able to eat a portion of two allergenic foods before a reaction occurs</p>	<p><b>6</b> will develop a fever within a few days of the shot</p> 
<p><b>37</b> will be able to eat a portion of three allergenic foods</p>	

### Out of 1,000 people who start omalizumab, about:

**Less than 1 (0.13)** may develop a slight risk of heart or circulatory issues but it is not clear omalizumab causes this

**2** may develop anaphylaxis to omalizumab

#### OIT vs omalizumab

In the only (small) study comparing these, people with multiple food allergies who used omalizumab were 2 times more likely tolerate small amounts of food allergen than people who did multi-food OIT.

[View citations at aafa.org/cite](https://aafa.org/cite)

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Tool developed in collaboration with other experts and stakeholders.

## Review your wants and needs

There are several factors to consider before making a choice to continue allergen avoidance, start OIT, or start omalizumab (Xolair or Omlyclo). Knowing what your hopes for treatment are will help you with your decision and will help your allergist answer questions about the options.

Place a checkmark in the second column on how much each reason matters **to you** on a scale from 0 to 5. **'0' means it is not important. '5' is very important.**

<b>How important are these issues to consider for your decision?</b>	<b>Not important</b>	<b>Very important</b>
Lower risk of a severe allergic reaction to eating the food allergen		
Being safe from accidental exposures		
Avoiding the use of epinephrine*		
Being able to eat the food allergen		
Having to carry epinephrine despite treatment		
Avoiding eating the food allergen		
Avoiding a daily treatment		
Avoiding having to get any shots for treatment		
Avoiding skin reactions due to treatment		
Avoiding stomach reactions due to treatment		
Having fewer doctor visits		
Lower risk of severe allergic reactions caused by the treatment itself		
Having no rules around when to take the dose		
Having to avoid certain activities before/after treatment		
Treatment is covered by your insurance		

\*All current options still have a risk of a severe allergic reaction, which requires epinephrine for treatment

**What additional concerns below affect your choice to start treatment** Check all that apply.  
Discuss these with your allergist.

- Other medical conditions this therapy may affect
- Avoiding side effects that may need additional treatment
- Long-term risks and benefits with this treatment
- Being afraid of needles and/or getting a shot
- How quickly the treatment will start to work
- How well the treatment will protect against allergic reactions
- How long the treatment needs to continue
- Being afraid of eating the allergen as part of the treatment

**After reading about your choices between OIT, omalizumab, or continuing to avoid the food, answer the questions below.**

**Quality of Life**

- |  |     |    |
|--|-----|----|
| Are you clear about which option best fits your lifestyle?   | Yes | No |
| Do you have enough information to determine which option has the highest chance to make your quality of life better? | Yes | No |
| Do you know enough about the benefits and side effects of each option?   | Yes | No |

**Values**

- |  |     |    |
|--|-----|----|
| Are you clear about which benefits and side effects matter most to you/your child? | Yes | No |
|--|-----|----|

**Support**

- |   |     |    |
|---|-----|----|
| Do you have enough support and advice from other people to make a choice? | Yes | No |
|---|-----|----|

**Certainty**

- |  |     |    |
|--|-----|----|
| Do you feel sure about the best choice for you/your child?               | Yes | No |
| Do you wish there were other choices besides avoidance, OIT, and Xolair? | Yes | No |

**Goals**

- What are your goals?
- How do you hope your/your child's life will change?
- What benefits do you think you/your child will gain?
- What risks do you think you/your child are willing to take?
- What are your/your child's questions and concerns?

**Decision**

**What do you/your child want to do:**

**Continue avoidance**

**Start OIT**

**Start omalizumab (Xolair or Omlyclo)**



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