



## **LOW DOSE ALLERGY IMMUNOTHERAPY INFORMED CONSENT**

Low Dose Allergy (LDA) Immunotherapy employs mixtures of pollens, molds, other inhaled allergens, foods and food additives, chemical and/or bacterial extracts. LDA contains the enzyme beta-glucuronidase to activate the allergens and positively affect T-suppressor cells. The concentration of the various allergens is very low and reactions to the LDA injections are very mild, if any at all.

The Federal Drug Administration (FDA) does not approve LDA or any other immunotherapy treatment. College Pharmacy, a compounding pharmacy certified by the State of Colorado, compounds LDA under stringent Federal and State compounding regulations, for named patients by prescription only. The FDA allows physicians to prescribe and dispense medications under appropriate direction and oversight.

### **PROCEDURE**

Typically, previous allergy testing will be completed before LDA therapy is initiated. This may include a history & physical, skin, stool, saliva, blood or other testing which meets the criterion of the Wycoff Wellness Center. You will be expected to have read and followed the guidelines in the "LDA Patient Instruction Booklet."

Treatments will be given intradermally (under the skin) with one or more injections. Injections may be given every two months (7-8 weeks). The typical protocol involves an injection every two months for the first year (6 injections) and an injection every 3 months during the second year (4 injections). The need for LDA injections typically will lessen over time.

You will be required to wait in the office for 30 minutes (1/2 hour) after each treatment. You may be required to wait longer if you have any significant reaction(s) at the discretion of a Wycoff Wellness Center provider. These types of reactions are unusual.

## **DISCONTINUATION OF TREATMENT**

I am free to discontinue treatment at any time without prejudice, or when I feel I no longer require LDA therapy. I will incur no further costs related to LDA treatment after my decision to stop treatment.

## **AVAILABLE ALTERNATIVES**

I am aware or have been made aware of various alternatives to treat my condition(s). These alternative may include: a) receiving various types of prescriptions medications appropriate to my condition(s) such as antihistamines, decongestants, asthma medications or others; b) following certain strict dietary guidelines in an attempt to improve my condition(s); c) receive “standard” allergy immunotherapy injections; d) elect to be treated with sublingual (under-the-tongue) allergy drops; e) receive some type of “alternative” medical treatments which may be available to treat my illness(es), such as acupuncture, homeopathy, herbs and other, or; f) electing to do nothing for the treatment of my condition(s).

## **POTENTIAL RISKS (SIDE EFFECTS) AND BENEFITS**

Some patients may experience mild to moderate adverse symptoms from 1 to 21 days after LDA treatments. These usually consist of a worsening of your typical allergy symptoms or the occurrence of symptoms you have had in the past. A small minority of patients may have ill effect for up to 3 weeks after LDA treatments. Most adverse reactions, when and if they occur, will likely be less with the second treatment and usually subside by the third treatment. Patients with severe food intolerance may experience temporary worsening of their intolerance(s), or temporary intolerance to foods to which you appeared to be tolerant before treatment. If this temporary intolerance occurs, it generally will last for three to four weeks after the first 1 to 3 treatments. Patients with chemical sensitivity may experience a temporary worsening of the perception of chemicals or reactions to chemicals. Most temporary intolerances will disappear or improve dramatically after the second or third treatment. Local swelling, possibly with itching, is common with LDA treatments. This swelling should not be treated unless directed by a Wycoff Wellness Center provider.

You may benefit significantly from this treatment. The possible benefits are: 1) total relief of your symptoms; 2) partial relief of your symptoms or; 3) reduction or elimination of medication(s) used to currently treat these conditions.

You should not undergo allergy skin testing for at least 6 months after your last LDA injection. Allergy skin testing may cause you to not feel well for several days after the treatment, experience mild hives or even more severe allergic reactions.

## **SPECIAL WARNINGS**

**Patients who have any known or suspected autoimmune disease (e.g. rheumatoid arthritis, systemic lupus, scleroderma and others) a history of anaphylaxis or hives, or significant skin rashes must be cautioned that particular care must be taken to follow the protocols ordered by a Wycoff Wellness Center provider in preparation for LDA. If you have any of these problems, and your provider is unaware of this, you MUST advise him/or her when you sign this consent form.**

**Patients who stop LDA after having had an untreated or partially treated adverse reaction to one of the first 1-3 treatments may be at risk for considerable worsening of symptoms for up to a year or longer. To avoid this possibility, we advise that you make a commitment to a minimum of 6 treatments when before you start LDA immunotherapy.**

## **PREGNANCY**

LDA immunotherapy should not be given in you are pregnant or considering getting pregnant in the next few weeks. The effects of LDA on a pregnancy are unknown. Should you find you are pregnant when you are receiving LDA, treatments will be discontinued until after the delivery, and then only resumed when a Wycoff Wellness Center provider deems it safe to do so. Should you think you might become pregnant or try to become pregnant during LDA therapy, please discuss this with your provider.

## **OPPORTUNITY TO ASK QUESTIONS**

I have been given the opportunity to ask and have all of my questions answered by a Wycoff Wellness Center provider or staff person before signing this consent form.

## **COMPLICATIONS OR EMERGENCIES**

Significant adverse effects of LDA are not anticipated and are quite rare. You need to be aware that reactions may occur for up to 4 weeks after each treatment. If you feel you are experiencing an adverse affect, please contact our office during office hours.

If you are unable to reach our office or it is after hours, you should seek urgent or emergency care at the nearest urgent care or emergency department.

## **COPY OF THIS CONSENT FORM**

You are entitled to receive a copy of this consent form at the time it is signed. Please ask a member of the Wycoff Wellness Center staff to receive this copy.

**COSTS**

The costs of testing and treatment with LDA have been reviewed with me. A written estimate and explanation of all costs will be provided upon request.

Medical insurance may or may not cover LDA immunotherapy itself, associated medications or the nutritional supplements required as an adjunct to LDA. You will obtain a receipt with each LDA treatment performed which will include the cost of the injections, any associated testing and the charge for a nurse or provider visit. You may elect to submit this to your insurance. We do not have the ability to bill your insurance company for you. LDA immunotherapy does not have a billing code available for insurance reimbursement purposes at this time.

**WARRANTIES**

No warranties, expressed or implied, are made for the safety of the nutrients, medications, LDA itself or other products provided or required by this treatment or prescribed by the doctor.

**WAIVER OF LIABILITY**

I, \_\_\_\_\_ understand that my receiving Low Dose Allergy Immunotherapy (LDA) is completely voluntary. I may discontinue treatment at any time. I have been given the opportunity to ask and have answered all questions about the treatment I have chosen to have administered and understand the risks and benefits of this proposed treatment.

\_\_\_\_\_  
Patient's Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient's (or Guardian's) Signature

\_\_\_\_\_  
Wycoff Wellness Center Staff Witness Signature

LDA Vaccine recommended by WWC provider: \_\_\_\_\_