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INFORMED CONSENT FOR SUBLINGUAL IMMUNOTHERAPY

Mile High Family Medicine is pleased to offer our allergy patients options for long-term allergy desensitization immunotherapy. Many patients are aware of allergy injections or shots but most do not know about a relatively new treatment known as sublingual immunotherapy also known as SLIT or allergy drops. The following information is offered in order to help you determine what the right treatment is for you.

History of Sublingual Immunotherapy

Allergy drops have been studied in controlled clinical trials over the past 20 years. Through clinical experience and increasing data the drops are indicated to be effective and safe for limited allergens. While allergy drops are widely used in many other countries, their use in the U.S. is investigational. The process of administering antigen drops under the tongue is not an approved method by the FDA and is not covered by insurance at this time.

It is important to understand that the medicines (antigens) used in sublingual drops are the same FDA approved medicines used in allergy shots. The difference is in the way the medicine is administered – a dropper that delivers the medicine under the tongue versus a syringe injecting the medicine into the tissue. The method of administration used in sublingual therapy is called an “off-label” use of an FDA approved biologic, which is both legal and very common.

Why Sublingual Immunotherapy?

- **Efficacy:** Sublingual drops are widely accepted as an effective treatment throughout the world. In fact, 50-75 percent of allergy sufferers in southern Europe are treated with allergy drops. The majority of the reported studies showed SLIT to be an effective treatment for patients with perennial allergic rhinitis and or mild to moderate asthma who are monosensitive to grass pollen, birch pollen, Parietaria, ragweed, or house dust mites.
- **Safety:** Safety is an important consideration for using SLIT. Allergy drops have been used around the world for more than 60 years, and numerous studies validate both the safety and effectiveness. In fact, the World Health Organization has endorsed sublingual immunotherapy as a viable alternative to injection therapy. The Cochrane Collaboration, the world’s most trusted international organization dedicated to reviewing healthcare treatments, recently concluded sublingual immunotherapy significantly reduced allergy symptoms and the use of allergy medications.
- **Convenience:** Sublingual therapy is convenient. You are able to take your allergy drops wherever, making it easy to be comply with your treatment.
- **Less medication:** Research confirms that most patients find they need less medication to control symptoms after beginning sublingual drops.

- Lower cost and fewer office visits: Compared to shots, sublingual drops cost less and require fewer office visits.
- The end benefit: Feeling better. Patients typically report fewer office visits and hospitalizations, and less time lost from work and school after taking their drops consistently.

Risks and Advantages of Sublingual Immunotherapy

- Sublingual drops are not approved by the FDA. As mentioned above, it is important to understand that the antigens used in sublingual drops are the same FDA approved antigens used in allergy shots. They are administered under the tongue rather than through an injection. This is an “off-label” use of an FDA-approved biologic, which is both legal and highly common.
- Sublingual drops have very infrequent side effects. Some patients may complain of itching in their mouths. Since the drops are swallowed, some patients may have some gastrointestinal symptoms. It requires a significant overdose to get more serious reactions such as swelling of the mucus membranes that could lead to anaphylaxis.
- Sublingual drops are NOT covered by health insurance carriers. Treatment with sublingual drops is an out-of-pocket expense. However, the cost is very comparable to the expense paid for co-pays to receive allergy shots.

Informed Consent

I have read or have had explained to me the above-information regarding Sublingual Immunotherapy and I understand the risks, benefits, and alternatives of allergy drops. I have had a chance to ask questions of my healthcare provider and I have been given ample time to consider my decision. I hereby give my consent to allow the person named below to be treated using sublingual immunotherapy.

Print Name of Patient

Signature of Patient

Date

Signature of Witness

Date

ACKNOWLEDGEMENT OF FINANCIAL RESPONSIBILITY FOR SUBLINGUAL IMMUNOTHERAPY

Sublingual immunotherapy is not covered by health insurance carriers. A specific billing/reimbursement code has not yet been established. As such, treatment with allergy drops will be an out-of-pocket expense.

The expense for sublingual immunotherapy is \$18 a week. Each vial will cost \$180. This payment is to be made in full when picking up the vial. It is important to remember that this will be a recurring expense every 10 weeks as treatment typically lasts for 3-5 years.

I, _____, have been notified by the provider that my health plan will not cover the services identified above. I agree to be personally and fully responsible for payment.

Signature of Patient

Date

Signature of Witness

Date