

PHYSICAL MEDICINE ASSOCIATES OF N.W. OHIO, INC.

939 W. Market St., Ste. 1

Lima, OH 45805

Phone: 419-228-5434

Fax: 419-228-4620

Kurt A. Kuhlman, D.O.

Xavier D. DiSabato, D.O.

Jodi M. Wilhelm, C.N.P.

Kathy M. Harvey, C.N.P.

Vicki S. Casey, C.N.P.

Consent for Botulinum Toxin Injections

This consent form is designed to provide the information necessary when considering whether or not to undergo botulinum toxin (Botox, Dysport, Xeomin) treatment for a wide variety of medical conditions including spasticity (muscle tightening), chronic headaches, cervical dystonia (neck muscle spasms), focal dystonia (uncontrolled spasm of specific muscles), axillary hyperhidrosis (excessive armpit sweating), sialorrhea (drooling), blepharospasm (uncontrollable blinking or twitching of the eyelid), Raynaud's (cold fingers), cosmetic treatment of facial and neck wrinkles, etc.

Injection of botulinum toxin causes weakness of the targeted muscles, which can last approximately 3 to 6 months. It can also be injected into glandular tissue, such as the parotid glands to stop them from producing excessive saliva. A small needle is used to inject the botulinum toxin into the desired muscle/gland. EMG as well as ultrasound are also frequently used to make sure the botulinum toxin is injected into the correct area. Treatment effects typically last 3 to 6 months depending upon the exact medical condition.

Dr. Kuhlman has been injecting botulinum toxin since 1995. He is a national expert, and is a paid consultant for AbbVie, the maker of Botox, to train other physicians. He personally trained all of the providers at Physical Medicine Associates to properly inject Botox.

Side effects of botulinum toxin can vary depending on which condition is being treated. The most common side effects of botulinum toxin injections are mild and temporary and include the following:

1. Localized burning or stinging pain during the injection.
2. Bruising.
3. Redness.
4. Tenderness.
5. Headache.
6. Anxiety.
7. Muscle weakness close to where the Botox was injected.
8. Flu-like symptoms such as fever, nausea or achy muscles.

Common side effects with botulinum toxin when treating specific medical conditions include the following:

1. **Spasticity:** Muscle pain in the area injected, redness, bruising, swelling, bleeding, fatigue, bronchitis, upper respiratory infection such as common cold.
2. **Chronic migraine headaches:** Neck pain, temporary headache, drooping eyelids, small bruises, head heaviness, neck weakness.
3. **Cervical dystonia:** Neck pain, neck weakness, headache, dizziness, dry mouth, trouble swallowing, hoarseness, upper respiratory infection, bruising, localized pain, anxiety.
4. **Axillary hyperhidrosis:** Itching, headache, sweating in other parts of body, tenderness.
5. **Sialorrhea:** Dry mouth, mild tenderness.
6. **Blepharospasm:** Drooping eyelid, dry eyes, double vision, irritated red or watery eyes, being more sensitive to light, swollen eyelid, facial asymmetry.
7. **Cosmetic treatment of wrinkles:** Droopy eyelid, droopy eyebrow, facial asymmetry, asymmetric smile, difficulty talking and swallowing, excessive or inadequate reduction of wrinkles, anxiety, mild bruising, vasovagal episode with loss of consciousness.

Serious side effects of botulinum toxin:

1. **Corneal ulceration** (open sore on the surface of the eye) can rarely occur when receiving treatment for blepharospasm (uncontrolled blinking or twitching of the eyelids).
2. **Distal spread:** When the Botox causes weakness in a different part of the body from where it was injected. This is most common in children or in adults who have received high doses of Botox in the lower limbs causing weakness in other parts of the body: Arm weakness, blurred vision, hoarseness, trouble swallowing.
3. **Problems breathing, swallowing or talking.** This is most common when injected into the muscles around the neck. It can also occur when a person develops distal spread.
4. **Immediate hypersensitivity reaction** can occur but is extremely rare.

Autoantibodies against botulinum toxin: Rarely, a person who has received multiple treatments of botulinum toxin can develop antibodies against the botulinum toxin making it less effective.

Who should not receive botulinum toxin? If you have a severe muscle or nerve condition such as ALS (Lou Gehrig's disease), myasthenia gravis or Lambert-Eaton syndrome. Additionally, if you are pregnant or plan to become pregnant or are breast-feeding, it is unknown if botulinum toxin can harm your baby. You may have more than expected bleeding if you are taking blood thinners. Please let us know if you have had problems with botulinum toxins products in the past.

What to do if you have a potential side effect? Realize that most side effects are mild and temporary and will completely resolve usually within a few weeks. However, if you have any concerns please contact our office.

Precertification: Your insurance company may require precertification/preauthorization for botulinum toxin injections. This can take several weeks for them to make this determination. We will not schedule an appointment until this has been completed.

PATIENT RESPONSIBILITY: Failure to submit current insurance information will result in cancellation of scheduled appointments until authorization and eligibility can be obtained. If a patient's insurance plan has changed and the patient fails to notify the office, any denied claim will become the responsibility of the patient. All botulinum toxin balances must be paid in full prior to the next scheduled injection or the appointment will be cancelled. **PATIENT'S INITIALS:** _____

Specialty pharmacy: Many insurance companies use a specialty pharmacy to ship the botulinum toxin directly to our office. Some specialty pharmacies may require a copayment.

PATIENT RESPONSIBILITY: The patient must contact the specialty pharmacy to ensure the medication is received by our office 7 days prior to your scheduled appointment. If it is not received, your appointment will be rescheduled. **PATIENT'S INITIALS:** _____

Botox savings program: For those with commercial insurance, there are programs available that will help pay for your botulinum toxin co-pays and deductibles. We will assist you with this.

Consent to treat: My signature below certifies that I fully read this consent form and understand the information provided to me regarding the proposed procedure. I have been adequately informed about the procedure including the potential benefits, limitations, and alternative treatments, and I have had questions and concerns answered to my satisfaction. I understand that results are not guaranteed and I accept the risk, side effects and possible complications inherent in undergoing botulinum toxin treatments.

Patient's name _____

Patient's signature _____ Date _____