BOTULINUM TOXIN TREATMENTS

CLINICAL POLICIES AND PROCEDURES

PURPOSE

To ensure safe and effective treatment of clients undergoing Botulinum Toxin – Type A administration at the [INSERT PRACTICE NAME], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Botox® following the guidelines set herein. In the state of California, the medical director or a physician assistant must perform a good faith examination prior to the use of Botox®.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Botox® in various settings and locations, such as but not limited to:

- § Physician Office
- § Satellite clinic / health care office(s)
- § MedSpa Setting authorized by the Medical Director
- § Health Club Setting[1] authorized by the Medical Director

All Botulinum Toxin Type A (i.e. Botox®, Xeomin®, Dysport®) administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as ptosis, diplopia, lower eyelid retraction, and weakening of the lacrimal pump shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with allergies to eggs, egg products, albumin, any clients with significant autoimmune or neurological diseases, or pregnant clients. The Registered Nurse

[RN], Physician Assistant or licensed medical personnel will only treat the upper 1/3 of the face and will not treat any portion of the face below mid-cheek areas.

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

BOTULINUM TOXIN, TYPE A PROCEDURE

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- **Complete assessment and a medical history questionnaire with all new clients.**
- **Clients with a history of allergies to human albumin, clients with significant neurological and autoimmune diseases, or pregnant clients will be denied treatment.**
- **Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.**
- **Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) shall be stored in a freezer [-5 degree C or lower] or refrigerator [2-8 degree C] until ready for use. Once reconstituted, it must be refrigerated [2-8 degree C], not refrozen. Reconstituted Botox should be clear, colorless and free of particulate matter.**

- **Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) shall only be reconstituted just prior to use and should be used within the first 4 hours according to the manufacturer. However, medical papers suggest it can be refrigerated up to 30 days without any loss of efficacy. Gently rotate the vial and record the date and time of reconstitution on the label.**

- **Vacuum will be released, using a 21/22-gauge, 2.5 inch length-needle prior to reconstitution. If no vacuum is present the Botox vial will be sent back to the manufacturer and a new vial shall be used following the same procedure.**

- **Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) should be reconstituted using 2.5 ml of non-preserved saline[1] [0.9%] as a diluent, resulting in a 4.0 units per 0.1cc. A 3-5cc syringe containing non-preserved saline is attached to the 21/22 gauge needle [at a 45° angle] and SLOWLY injected into the vial. Allow the saline to flow down the sides of the vial, thus minimizing air bubble formation and not damaging the delicate neurotoxin and protein associated with the Botulim Toxin.**

- **Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) is gently drawn up into a 1ml tuberculin syringe using a 21/22 gauge needle. The injection is to be administered with a 30 or 31-gauge [½ inch needle].**

- **Clients are injected while in a reclined or seated position.**

- **Clients are asked to demonstrate dynamically the function of the muscle groups to be injected.**

- **Prior to administration the Registered Nurse [RN], Physician Assistant or licensed medical personnel will map out points of injection according to landmarks and location of muscle belly. The only areas of administration will be the corrugator, procerus, frontalis, and orbicularis oculi muscles. [Corrugator and procerus muscles for frown lines, frontalis muscle for horizontal forehead lines, and orbicularis oculi muscle for crow's feet.]**

Note: increased toxin dose may be necessary in older and male clients.

- **In an effort to reduce the complications of ptosis the following steps should be adhered too:**
  - **a. Administer at least 1cm above the central eyebrow and 1.5cm-2cm from the lateral canthus.**
  - **b. Ensure the injected volume/dose is accurate and kept to a minimum.**
  - **c. Avoid injection near the levator superioris, particularly in patients with larger brows.**
  - **d. Medial corrugator injections should be placed 1cm above the bony supraorbital ridge.**

If mild ptosis should occur the nurse will instruct the client that this will resolve within a

few weeks and in the use of [over the counter] Vasocon to assist in alleviating the ptosis which will alleviate the immediate condition temporarily. The prescription drug Iopodine™ may also be prescribed by the attending physician or Medical Director if determined after examination of the patient. Ptosis or any other complications[2] shall be immediately reported to the Medical Director and documented in the client record.

- **Syringe is inserted perpendicular to the skin and completed at a depth just beneath the dermis, 0.1cc of Botox is injected into each site.**

- **After each injection a cold compress consisting of a clean 4x4 gauze dipped in ice water is applied and gently massaged for a few seconds over the injection site.**

- **When procedure is completed the client will be educated to perform the dynamic facial expressions for the next hour, not to rub or manipulate the injection sites, not to lie down for a period of 4 hours, and to report any problems or complications to the office immediately.**

16. Typically, the initial doses of reconstituted Botulinum Toxin – A induce chemical denervation of the injected muscles one to two days after procedure, increasing in intensity during the first week.

[1] Allergan & Merz Pharma recommends using 2.5ml of non-preserved saline resulting in 4.0 units per 0.1cc. Galderma (Dysport) recommends 3.0ml of non-preserved saline resulting in 10.0 units per 0.1cc.

[2] The RN shall be familiar with all general adverse reactions that can be associated with the administration of Botulinum Toxin Type A products. Refer to the manufacturer's publication within the product insert, "Adverse Reactions-General" enclosed with each vial of product.

PRE-PROCEDURE QUESTIONAIRE FOR BOTOX INJECTIONS

Patient Name: _____ Date: _____

History

Do you have:

Hypersensitivity to Botulinum A toxin products ▫ Yes ▫ No

Infection at the proposed injection site(s) ▫ Yes ▫ No

Bleeding Disorders ▫ Yes ▫ No

Cardiac Disease ▫ Yes ▫ No

Active Skin Disease ▫ Yes ▫ No

Do you or a family member have:

Amyotrophic Lateral Sclerosis ▫ Yes ▫ No

Motor Neuropathy ▫ Yes ▫ No

Myasthenia Gravis ▫ Yes ▫ No

Lambert-Eaton Syndrome ▫ Yes ▫ No

Facial Nerve Palsy ▫ Yes ▫ No

Are you:

Pregnant ▫ Yes ▫ No

Breast-feeding ▫ Yes ▫ No

Medications

Do you take or have recently been on any of the following medications:

Warfarin or Anti-Platelet Agents ▫ Yes ▫ No

Quinidin ▫ Yes ▫ No

Aminoglycosides ▫ Yes ▫ No

Magnesium Sulfate ▫ Yes ▫ No

Curare-like Nondepolarizing Blockers ▫ Yes ▫ No

Anticholinesterases ▫ Yes ▫ No

Lincosamides ▫ Yes ▫ No

Succinylcholine Chloride ▫ Yes ▫ No

Polymyxins ▫ Yes ▫ No

Physical

Glabellar lines smoothed out by physically spreading them apart ▫ Yes ▫ No

Skin infection at site of injection ▫ Yes ▫ No

Evidence of muscular atrophy ▫ Yes ▫ No

Evidence of petechia or bruising ▫ Yes ▫ No

Facial Asymmetry ▫ Yes ▫ No

Ptosis ▫ Yes ▫ No

Deep dermal scarring ▫ Yes ▫ No

Thick sebaceous skin ▫ Yes ▫ No

Dermatochalasis (excessive redundant skin) ▫ Yes ▫ No

Physician/P.A. Signature: _____ Date: _____

BRIEF MEDICAL HISTORY AND INFORMED CONSENT

Name_____Phone_____Age_____Ht_____Wt_____
Address_____City/
State_____Zip_____

MEDICATIONS:_____

ALLERGIES:_____

Women: Are you Pregnant?_____
Physician's
Name_____\
Circle any of the following illnesses you have or have ever had in the past:
Myesthenia Gravis Hepatitis Eye Disease Autoimmune Disease
Vision Problems Numbness Muscle Weakness Amyotrophic Lateral Sclerosis (ALS)

Explain: _____

Previous Hospitalizations/Operations:

_____
I understand the information on this form is essential to determine my medical and cosmetic needs and the provision of treatment. I understand that if any changes occur in my health I will report it to the office as soon as possible. I have read and understand the above medical questionnaire. I acknowledge that all answers have been recorded truthfully and will not hold any staff member responsible for any errors or omissions that I have made in the completion of this form.
Patient
Signature_____Date_____

CONSENT TO BOTULINUM TOXIN "A" TREATMENT

Botox® a neurotoxin produced by the bacterium Clostridium A. Botox® can relax the muscles on areas of the face and neck that cause wrinkles associated with facial expressions. Treatment with Botox can cause your facial expression lines or wrinkles to essentially disappear. Areas most frequently treated are: a) glabellar area of frown lines, located between the eyes; b) crow's feet (lateral areas of the eyes); and c) forehead wrinkles. Botox is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Clients may feel a slight burning sensation while the solution is being injected. The procedure takes

about 15-20 minutes and the results last 3-6 months. With repeated treatments, the results may tend to last longer.

RISKS AND COMPLICATIONS

It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to : 1) Post treatment discomfort, swelling, redness, and bruising, 2) Post treatment bacterial, viral, and/or fungal infection requiring further treatment, 3) Allergic reaction, 4) Minor temporary drop of eyelid(s) in approximately <1% of injections, this usually lasts 2-3 weeks, 5) Occasional numbness of the forehead lasting up to 2-3 weeks, 6) Transient headache, and 7) Flu-like symptoms may occur.

PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE

I am not aware that I am pregnant, have any significant Neurologic disease, or have any allergies to the toxin ingredients, or to human albumin.

RESULTS

I am aware that when small amounts of purified botulinum ("BOTOX®") are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 3-4 days and usually lasts 3-6 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual. I understand that I will not be able to "frown" while the injection is effective but that this will reverse after a period of months at which time re-treatment is appropriate. I understand that I must stay in the erect posture and that I must not manipulate the area of the injection for the four hours post-injection period.

I hereby voluntarily consent to treatment with Botulinum Toxin Type A injection for the condition known as: Facial Dynamic Wrinkles. The procedure has been explained to me. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure.

_____ _____

Patient Signature Date Witness Signature
Date

Enclosures: BOTOX® (botulinum toxin type A) package insert, NDC # 0023-1145-01

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of Botox®. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

§ Mechanism of Action of the Botulinum Toxin, Type A Products
§ Basic Theory of Treatment for Cosmetic Purposes
§ Facial Anatomy
§ Storage, preparation, and dilution of Botulinum Toxin A
§ Safety, efficacy, and complication issues
§ Assessment and identification of areas to be treated
§ Safe application of injection techniques [minimum 8-hours hands on training]

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

§ Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

§ Evaluate of the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

§ The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of Botulinum Toxin, Type A products have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse or Other Authorized Healthcare Personnel Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

BOTULINUM TOXIN, TYPE A POST TREATMENT INSTRUCTIONS

- Avoid lying down for several hours following treatment.
- Facial exercise in the area of treatment is recommended [frown/smile 1 hour].
- Avoid manipulation of the area the first four-hours after procedure.

Note: These measures should minimize the possibility of ptosis.

- Treatment effect may take 3-8 days to appear.
- **The benefits may last 3-6 months, the average is 4 months.**
- A touch-up may be necessary in 1-2 weeks.
- Contact the practitioner as soon as possible after the eight [8^{th}] day if you have not received the desired effect.