BEAUTOX BAR

Clinical Policies and Procedures

Purpose

To ensure safe and effective treatment of patients undergoing injection treatments such as BOTOX® Cosmetic and JUVÉDERM® at Beautox Bar LLC. The following policies and procedures have been created and practiced.

Policy

A Registered Nurse (RN), or Health Care Provider with current state licensure shall be able to assess, consult, and treat clients with BOTOX® Cosmetic JUVÉDERM®, and competitive brands of injectables at Beautox Bar LLC clinics.

i. Setting

The Registered Nurse (RN) or Health Care Provider can perform the administration of BOTOX® Cosmetic, JUVÉDERM®, and competitive brand injectables in various settings and locations, such as but not limited to:

- Beautox Bar LLC clinic locations
- Client home
- Client work place with written permission

All treatment procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

ii. Supervision

The Registered Nurse (RN) or Health Care Provider shall function under the general supervision of the Medical Director who is immediately available for consultation by phone and is physically available as medically necessary. The Medical Director is under contract with the Beautox Bar LLC.

Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's Beautox Bar LLC treatment record and the chart. All adverse reactions such as lid ptosis, diplopia, lower eyelid retraction, and weakening of the lacrimal pump shall be consulted with a Registered Nurse any serious reactions will be reported to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

iii. Patient Conditions

The Registered Nurse (RN), or Health Care Practitioner will not knowingly treat any clients who have:

- Allergies to eggs, egg products, albumin, and/or
- Significant autoimmune or neurological diseases, and/or
- Pregnant clients.

The Registered Nurse (RN), or Physician Assistant will only treat patients after completing all proper certifications for BOTOX® Cosmetic, JUVÉDERM®, and competitive brands.

BOTOX® Cosmetic and JUVÉDERM® Filler Procedure

The Registered Nurse (RN), or Health Care Practitioner will:

- Complete the Beautox Bar LLC patient health history and intake form with all new clients.
- Clients with a history of allergies of human albumin, clients with significant neurological and/or autoimmune diseases, or pregnant clients will be denied treatment.
- Upon passing medical screening, clients will be fully informed of risks, benefits, and potential adverse reactions, including the off label cosmetic use of JUVÉDERM®, and JUVÉDERM® for areas on the face that is discussed and agreed upon with the client.
- BOTOX® Cosmetic must be stored in a freezer (-5 degrees C or lower) until ready for use. Once reconstituted, it must be refrigerated (2-8 degrees C), not refrozen. Reconstituted BOTOX® Cosmetic should be clear, colorless, and free of particulate matter.
- JUVÉDERM® and competitive brand injectable fillers must be stored at room temperature.
- Vacuum will be released, using a 21/22-gauge, 2.5 inch length-needle prior to reconstitution. If no vacuum is present the BOTOX® Cosmetic vial will be sent back to the manufacturer and a new vial shall be used following the same procedure.
- Once BOTOX® Cosmetic is reconstituted, Beautox Bar LLC will administer the BOTOX® Cosmetic injection within 24 hours after reconstitution in the vial. During this time, reconstituted BOTOX® Cosmetic solution will be stored in a refrigerator at 2°C to 8°C.
- BOTOX® Cosmetic should be reconstituted using 2.5 ml of preserved or unpreserved saline (0.9%) as a diluent, resulting in a 2.5 – 3.3 units per 0.1 cc. A 3-5cc syringe containing non-preserved saline is attached to the 21/22 gauge needle (at a 45 degree 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 BOTOX® Cosmetic.
- JUVÉDERM® Ultra injectable gel is a highly crosslinked formulation that can be injected using a 30-G needle for more versatility in contouring and volumizing of facial wrinkles and folds. Prior to treatment with JUVÉDERM® Ultra injectable gel, the patient's medical history should be obtained and the patient should be fully apprised of the indications, contraindications, warnings, precautions, treatment responses, adverse reactions, and method of administration. Patients also should be advised that supplemental "touch-up" implantations may be required to achieve and maintain maximum correction.
- BOTOX® Cosmetic is gently drawn up into a 1 ml tuberculin syringe using a 21/22 gauge needle. The injection is to be administered with a 30-gauge (1/2 inch) needle or a 32-Ultra fine gauge needle upon request.
- Clients are injected while in a seated position.
- Clients are asked to demonstrate dynamically the function of the muscle groups to be injected.
- Prior to administration the Registered Nurse (RN), or Health Care Practitioner 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 in the forehead and periorbital region in the upper face. Mid-facial application (Corrugator and procerus muscles for frown lines, frontalis muscle for horizontal forehead lines, and orbicularis oculi muscle for crow's feet.) Mid-facial BOTOX® Cosmetic may be added for lifting of the corners of the mouth, vertical lip lines, elevation of the tip of the nose smoothening of dimpled chin skin and softening of neck cords.

- In an effort to reduce the complications of ptosis the following steps should be adhered to:
    - Administer at least 1 cm above the central eyebrow and 1.5 cm – 2 cm form the lateral canthus.
    - Ensure the injected dose is accurate and kept to a minimum.
    - Avoid injections near the levator superioris, particularly in clients with larger brows.
    - Medical corrugator injections should be placed 1 cm above the bony supraorbital ridge.
- If mild lid ptosis should occur the nurse will instruct the client that this will resolve within a few weeks and in the use of Vasocon to assist in alleviating the ptosis. Ptosis or any other complications shall be reported to the Medical Director and documented in the Beautox Bar LLC client record.
- Syringe is inserted perpendicular to the skin and completed at a depth just beneath the dermis, 2.0 units to 5 units of BOTOX® Cosmetic is injected into each site.
- After each injection the skin may be massaged moderately and pressure held with a gauze.
- When the 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 clinic immediately.
- Typically, the initial doses of reconstituted BOTOX® Cosmetic induce chemical denervation of the injected muscles 3-5 days after procedure, increasing in intensity during the first week.

Beautox Bar LLC will not knowingly treat any clients who are knowingly pregnant, trying to get pregnant, lactating, or have any medical contraindication as noted in the health history form.

Beautox Bar LLC will not exceed the following per patient per day:
Botox®: 100 Units
Cosmetic Filler: 2 syringes

Beautox Bar LLC will not exceed the following repeat treatments in the same area:
Botox®: 2 months
Cosmetic Filler: After bruising and swelling are gone

Beautox Bar LLC Standard Mixture:
Botox®: 1 to 2.5cc of preservative saline in 100 units for facial use
Botox®: 4cc of NS in 100 units for hyperhidrosis

iv. Record Keeping

The Registered Nurse (RN), or Health Care Provider shall be responsible for maintaining Beautox Bar LLC treatment 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 of treatment.

v. Competencies & Documentation

The Medical Director, Registered Nurse and/or Health Care Provider shall:

- Document (on the appropriate form) the initial evaluation and final determination recording satisfactory completion of training and competence.
- Evaluate the competence of the Registered Nurse (RN), or Health Care Provider as needed if indicated by client dissatisfaction of efficacy issues.
- The evaluation shall be maintained in the personnel file of the Registered Nurse, or Health Care Provider at the appropriate administrative office.

Requirement for Education of Clinical Personnel

- Mechanism - Basic Theory - Storage/Prep - Safety, Efficacy, Complications
- Assessment of Area to be Treated - Safe Application Technique (8 hours hands-on)
- Complications and their management

Development and Approval of Standardized Procedure

Beautox Bar LLC policies and procedures for the administering of cosmetic injectables such as BOTOX® Cosmetic, JUVÉDERM®, and competitive injectable brands has been developed jointly by the Medical Director and Beautox Bar LLC officers.

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