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STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING JUVEDERM VOLBELLA XC® INJECTIONS

I. POLICY

A. Circumstances under which the clinicially trained RN, PA and or NP may perform Volbella injections.

1. Setting:
   - a Brentwood: Doctor's Office, Suite J-5, 1280 Central Blvd,
   - b. Alameda: Alameda Hospital, 4th Floor Doctor's Offices

2. Supervision:
   - a. The physician or NP who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Volbella. The patient's Medical History Questionnaire will be discussed in-depth with patient.
   - b. The employee RN will then treat the patient with Volbella, providing that the patient meets criteria, and Medical History Questionnaire has been completed.
   - c. The physician will review the treatment rendered and sign the chart upon review.

3. Patient Conditions:
   - a. Consultation regarding patient's chief complaint completed.
   - b. guardian may authorize treatment.
   - . c. Informed consent given and consent form completed.
   - d. age >= 21
   - e. the area to be injected includes perioral rhytids, body of lips and vermillion border of upper and lower lips either intradermal or subcuteneous but not intramascular or deep to the muscle

4. Contraindications:
   - a. Pregnancy.
   - b. For patients with severe allergies including gram positive organisms and lidocaine allergy manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
   - c. facial infection, including active acne and herpes simplex
   - d. coagulatopathy, anticoagulation, non steroidal use and vitamin E useage within 10 days of injection

5. Precautions:
   - a. Injection should be limited to 1ml per upper or lower lip or a maximum of 2mls.
   - b. Patient is aware of potential adverse events following injection of Volbella. These inlcude bruising, redness, swelling, facial nerve injury and hematoma, avascular necrosis of the lip,asymmetry, tenderness, itching and dry lips

c. above complications are ususally self limiting within 14 days of injection or less.
d. no intravascular injection should be performed in superior or inferior labial areas re the deep side of the orbicularis muslce
e. Volbella is packaged for single patient use

II. PROTOCOL

A. Definition:

The administration of the Volbella XC is for perioral rhytids, lip thinness and/or lack of volume and lack of vermillion border definition. Volbella may be used for the correction of age related changes or to improve the lips of a patient over 21 with the above listed familial problems who want fullness. Normal anatomy refers to 1 to 1.6 upper to lower lip vertical height and 1mm upper lip projection greater than lower lip. The compound utilizes Vycross technology referring to tight cross linking to low cohesivity, lowest molecular weight hyaluronic acid Juvederm gel and show continued improvement of lip lines and volume between 58-75% up to > =1 year and at 1 year >90% felt the lips felt normal. Volbella is a strepococcus equi bacteria formulated to a concentration of 15mg/ml and 0.3% lidocaine in a buffer made up in a 0.55ml syringe with 30g syringe.

B. Assessment:

1. Subjective: The above patient conditions have been met.
2. Objective: The patient presents with soft tissue deficits as described in A. definition above.

C. Plan:

1. Storage:
   a. Store Volbella XC at room temperature up to 77º F. Refrigeration is not needed. Do not freeze and protect from sunlight.
   Volbella must be used prior to expiration date on the package. Volbella XC is packaged sterile in 1ml syringes and sold by the box. Volume to inject of Volbella will vary according to patient's scheduled requirements.
2. Test Implant:
   a. Volbella XC does not require a test implant.
3. Treatment:
   a. Patient will remove all make-up from treatment area.
   b. wash lips with soap and then alcohol or betadine prep
   c. place gloves on
   d. Define areas to be treated, and in this order: 1,2,3
      1- peri-oral rhytids
      2- body of lip: ideally from base of tubercle inferiorly then laterally and medially to tip of tubercle
      3- vermillion border
   e. Injection Technique:
      remove tip cap and place the 30 g needle
      Inject thread technique or depot technique

Inject areas 1, then 2, then 3

e. Post treatment: cleanse with alcohol and massage antibiotic ointment to provide appropriate contour

f. Vollbella comes with a patient record label that is part of the syringe label. Remove it by pulling the flap marked with three small arrows. This label is to be attached to patient records to ensure traceability of the product.

4. <u>Emergency Treatments</u>:

a. If blanching continues inject 15 units (0.15mls) or > hyaluronidase (150U/ml)

b. **if visual loss noted:**

i. inject small bleb of local anesthetic into the lower lid just over the orbital rim and lateral to the pupillary line

ii. advance a 25 gauge needle on 1ml syringe in the inferolateral quadrant 1 inch posteriorly inject 150 - 200 units hyaluronidase: 1-1.5mls

iii. alternative technique is to inject all around the inside of the orbital rim into peribulbar intra orbital muscle: 1cm deep x 10 injections of 0.1ml or 15U

c. for severe allergic reactions call 911, and institute epipen, steroids and benedryl in resusitation brief case in MD's room by tall cabinet

5. <u>Patient Education:</u>

a. See Volbella® postcare sheet and give copy to patient.

b. Avoid strenuous exercise, extensive sun exposure and extensive heat.

c. Avoid all alcoholic beverages for 4 hours following injection.

d. Instruct patient not to massage treatment sites for 4 days.

e. Inform patient that bruising could occur and last 7-10 days.

f. Inform patient redness and slight swelling may occur at the injection site.

g. Patient to call us should any concerns or questions arise.
h. Reinjection should be at least 4 weeks after the current injection

6. Follow-up:
   a. Patient may leave with ice to reduce swelling and discomfort.
   b. Subsequent treatment scheduled upon patient's desire for further additional correction.
7. Documentation:

   The following information must be recorded with each treatment.
   a. Number and size of syringes used
   b. Syringe lot numbers
   c. Specific areas treated
   d. Amount of material used
   e. Patient response to treatment.
   f. Procure physician review and sign-off of all patient charts within 7 working days post procedure.

III. REQUIREMENTS FOR RN

A. Education:

Graduate of RN program with current California RN license.

B. Training:

1. Training by Dr Rex Moulton-barrett and the Allergan Training nurse under the supervision of Dr Rex Moulton-Barrett for Registered Nurse employees of Dr Moulton-Barrett specifically trained in Volbella XC product knowledge and proper technique.
2. Formal education from product company to gain knowledge, experience and proficiency in the proper administration of product.
3. Understanding the relevant anatomy. It is imperative not to inject Volbella XC into the parotid gland and duct, infra-orbital neurovascular bundle, and vessels present in the antero-medial cheek, including those in the glabella and nose. Doing so can result in vascular embolization, occlusion of vessels, ischemia/infarction, and blindness.

C. Evaluation:

1. Successful completion of in-service education, training and demonstration of competency to MD, including proctoring of (at least) 1 treatment.

. On-going evaluation:

2. Random MD visits during treatment sessions. MD will observe treatment quarterly.
3. Annual performance evaluation by Dr Moulton-Barrett