

STANDARDIZED PROCEDURE
ONABOTULINUM TOXIN TYPE A (BOTOX) INJECTIONS (Adult)

I. Definition:

The goal of onabotulinum toxin type A (BOTOX) injections per the PREEMPT protocol is to reduce headache frequency and/or severity that can last for a few weeks to a few months. This can be helpful for patients who have chronic migraine as well as other types of headache in selected patients whose headaches are not adequately controlled with medication, are unable to tolerate pills, and/or are non-adherent to taking pills on a regular basis.

A trial of two rounds of injections spaced three months apart is done. If this is helpful in providing headache relief, the patient will continue to receive injections every 3 months. If ineffective after the second round, no further Botox injections will be given.

Onabotulinum toxin type A injections may be performed by an Advanced Health Practitioner (AHP) who has been adequately trained and supervised in this procedure.

II. Background Information

A. Setting: This procedure is done in the outpatient setting. The population (adults) for the Advanced Health Practitioner is determined by the approval of the privileges requested on the AHP privilege Request Form.

B. Supervision:

The necessity of the procedure will be determined by the AHP in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician.

Direct supervision by an attending physician or his/her designee will not be necessary once competency is determined, as provided for in this procedure.

The AHP will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance of the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications:

Patients with chronic migraine

D. Precautions/Contraindications:

1. Hypersensitivity to any botulinum toxin preparation
2. Infection at the site(s) of procedure
3. Inflammation or excessive weakness or atrophy at proposed injection site(s)

III. Materials

For reconstitution:

1. One 200-unit Botox (onabotulinum toxin type A) vial
2. One vial of 10 mL preservative-free 0.9% sodium chloride
3. One 18G 1½-inch needle

4. One 5 mL syringe
5. Two alcohol wipes

For injections:

1. One pair of gloves
2. Four 1 mL syringes
3. Four 30G 1/2-inch needles
4. Four alcohol wipes
5. Two 2x2-inch gauze

IV. Procedure

A. Pretreatment evaluation

Patients with chronic migraine whose headaches are not adequately controlled with medication, who are unable to tolerate pills and/or who are non-adherent to taking pills.

B. Set up

Gather the necessary supplies.

C. Patient preparation

Review the potential benefits and side effects with the patient. Obtain consent from patient for the procedure.

Onabotulinum toxin type A injections, done according to the PREEMPT protocol, can provide headache relief for a few weeks to a few months. There is the potential for inefficacy, and patients will be advised of this. Potential side effects include a sensation of tightness across the forehead and inability to frown, eyebrow asymmetry, eyelid ptosis, shoulder weakness or pain. Side effects typically self-resolve within 1-3 months.

D. Reconstitute the medication

1. Record the expiration dates and lot numbers of the medications and check that the medications are not expired.
2. Clean the rubber stopper of the vial of preservative-free 0.9% sodium chloride (saline) and the 200 unit Botox vial with an alcohol swab.
3. Attach the 18G needle to the 5-mL syringe and draw up 4 mL of saline.
4. Using a 45-degree angle, insert the needle of the syringe containing saline into the Botox vial and allow the vacuum to pull the saline into the vial. Do not use the Botox vial if the vacuum does not pull all the saline into the vial.
5. Leave the reconstitution needle with the attached syringe in the bottle while gently rotating the vial to mix the Botox with the saline.

E. Prepare the injection syringe

1. Remove the reconstitution syringe and replace it with a 1-mL injection syringe.
2. Withdraw 1 mL of the reconstituted solution into the 1-mL injection syringe. The vial may be tilted slightly to withdraw a full 1 mL. Do not invert the Botox vial when withdrawing the solution into the 1-mL injection syringe.
3. Disconnect the first 1-mL injection syringe from the needle. Keep the reconstitution needle inserted into the vial.
4. Attach a 30G, 1/2 inch needle for injection to the syringe.

5. Repeat the Botox withdrawal procedure with three additional 1 mL injection syringes. Upon completion of the reconstitution of Botox, there should be four 1 mL injection syringes, each filled with 1 mL and 50 units of Botox solution and each with a 30G ½ inch needle attached.
6. The same technique may be used with two 100 Unit vials, but 2 mL saline should be added into each vial.

F. Perform Procedure (taken from the Allergan “Reconstitution and Injection Workshop Guide” for onabotulinumtoxinA injections)

1. Have the patient lie supine.
2. Prior to injection, wipe the areas with alcohol wipes.
3. Each injection volume will be 0.1 mL, containing 5 units.
4. General guidelines:
 - a. Insert the needle into the muscle with the bevel up, at a 45-degree angle.
 - b. After the needle is inserted into the muscle, pull the plunger back slightly to ensure no blood return, then push the plunger to administer the Botox injection.
 - c. Injections to the muscles in the face should be superficial to avoid hitting the periosteum because the muscle may be thin.
 - d. Do not inject too deep into the cervical paraspinal and trapezius muscles, as this may lead to neck weakness or neck or shoulder pain.
 - e. The needle should be inserted through the epidermis/dermis payer, which may feel more rigid when penetrated. The injection should be given when there is a decrease in resistance.
 - f. Pinching the skin may help adjust depth of needle insertion and reduce pain.
 - g. Do not rub the area after injection.
5. Perform **1 injection** of 0.1 mL (5 units) each to the **right and left corrugator muscles** (~1.5 cm above the medial superior edge of the orbital ridge). Inject at a 45-degree angle, away from the medial aspect of the muscle to avoid ptosis of the eyelid.
6. Perform **1 injection** of 0.1 mL (5 units) to the **procerus muscle** (approximately midway between the 2 corrugator injections, ~1.5 cm above the medial aspect of the supraorbital ridge between the eyes).
7. Perform **2 injections** of 0.1 mL to the **right and left frontalis muscles** (a total of **20 units** divided into 4 sites). Visually, draw a line up from the medial edge of the supraorbital ridge. The medial injection sites are parallel and ~1.5 cm above the corrugator injection site. The lateral injection sites are parallel and ~1.5 cm lateral to the medial injection sites. Injecting too low can result in eyebrow ptosis.
8. Perform **4 injections** of 0.1 mL to the **right and left temporalis muscle** (a total of **40 units** divided into 8 sites).
 - a. Injection 1: Find the tragus of the ear, move your finger vertically up the side of the head ~3 cm and inject at that location.
 - b. Injection 2: Move ~1.5 to 3 cm up from the first injection, still in line with the tragus. Once your finger is in line with the frontalis injections, stop and make the second injection.
 - c. Injection 3: Move ~1.5 to 3 cm forward towards the face, from the first and second injections. Inject halfway between injections 1 and 2, and in line with the corrugator injections.
 - d. Injection 4: Move ~1.5 cm back from the second injection, and in line with the midportion of the ear, and inject.
 - e. Repeat the 4 injections on the other side.
9. Have the patient sit up.

10. Perform **3 injections** of 0.1 mL to the **right and left occipitalis muscle** (a total of **30 units** divided into 6 sites). Angle the needle upward to avoid injecting any additional Botox into the neck region. Stay superior to the supranuchal ridge for these injections.
 - a. Injection 1: To locate the first occipitalis injection site, palpate the occipital protuberance and find the inion, or most prominent point, of the occipital protuberance. Palpate the nuchal ridge and locate the mastoid process behind the ear. Place your thumb on the midpoint of the occipital protuberance and your index finger on the mastoid process. Divide the space between your thumb and index finger in half. Injection just above the nuchal ridge at this midpoint.
 - b. Injection 2: Measure a diagonal finger's breadth up and out (toward the tip of the ear) for the second injection (at the 10 o'clock position).
 - c. Injection 3: Measure a diagonal finger's breadth up and medial for the third injection (at the 2 o'clock position).
11. Perform **2 injections** of 0.1 mL to the **right and left cervical paraspinal muscles** (a total of **20 units** divided into 4 sites). Angle the needle upward to avoid injecting any additional Botox into the neck region. Be sure not to inject too deep to avoid patient discomfort. Injection sites will typically be located within the hairline. All injection sites should be sub-occipital.
 - a. Injection 1: Measure ~1 cm left of the midline of the cervical spine and ~3 cm inferior to the inion, or most prominent point, of the occipital protuberance.
 - b. Injection 2: Measure ~1.5 cm diagonally up at a 45-degree angle toward the superior margin of the ear from the first injection.
12. Perform **3 injections** of 0.1 mL to the **right and left trapezius muscles** (a total of **30 units** divided into 6 sites). Injections should be kept in the supraclavicular portion of the trapezius to avoid the inferomedial trapezius and rhomboid muscles.
 - a. Injection 1: Divide the upper portion of the trapezius muscle, from the inflection point of the neck to the acromion, in half. The first injection is located at this midpoint.
 - b. Injection 2: Move ~3 cm laterally from the midpoint down along the trapezius toward the shoulder. The injection should be approached from the supraclavicular aspect of the muscle to avoid the acromion and the deltoid muscle, as this may produce potential shoulder weakness.
 - c. Injection 3: Move ~3 cm medially up along the trapezius from the midpoint. Make sure not to inject too high in the neck as this may cause neck pain or weakness.

G. Follow-up

The patient will be requested to provide an update a month after the procedure of any headache improvement either via MyChart, a follow-up appointment or by telephone.

V. Documentation

A. Documentation is in the electronic medical record.

Record the indication for the procedure, site of injection, medication used, lot numbers and expiration dates, and any complications. The outcome will be documented based on patient's update a month after the procedure, or at the next clinic appointment.

B. All adverse effects/events are reviewed with the supervising physician or designee.

VI. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Advanced Health Practitioner will demonstrate knowledge of the following:
 - a. Medical indications and contraindications of the procedure.
 - b. Benefits and potential side effects of the procedure.
 - c. Related anatomy and physiology.
 - d. Consent process (if applicable).
 - e. Steps in performing the procedure.
 - f. Documentation of the procedure.
3. The Advanced Health Practitioner will observe the supervising physician/designee perform each procedure three times and perform the procedure three times under direct supervision.
4. The supervising physician will document the Advanced Health Practitioner's competency prior to performing the procedure without supervision.
5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued Proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
2. Each candidate will be initially proctored and signed off by the supervising physician/designee. The Advanced Health Practitioner must perform this procedure at least three times per year. In cases where this minimum is not met, the supervising physician or designee must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred a copy of the procedure note will be submitted.

VII. Responsibility

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at (415) 353-4380.

VIII. History of Policy

Written September 2014.

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Approved December 2014 by the Executive Medical Board and Governance Advisory Council