



ALABAMA STATE BOARD OF MEDICAL EXAMINERS

Botox Injection for Chronic Migraine Protocol

Purpose/Indication: Prevention of headaches in adults (18 years or older) with chronic migraine who have 15 or more headaches each month.

Definition of chronic migraine: Per the International Headache Society (IHS), chronic migraine is defined as a condition in which headaches occur on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of migraine headache. The term "episodic migraine" is used to describe migraine headaches with a frequency of 14 or fewer days per month.

Population Foci (CRNP): Adult Acute Care, Adult Health, Adult/Gerontology Acute Care, Adult/Gerontology Primary Care, Family, and Gerontology.

APP: _____ **License#** _____

Physician Attestation (s):

_____ Supervising/ collaborating physician trained in Botox injections for chronic migraines with at least **1** year experience performing Botox injections for chronic migraine pursuant to FDA approved protocols.

_____ The collaborating/supervising or covering physician will be physically available on site during training.

_____ Prior to approval for performing injections, the APP will receive three hours of didactic training, attend a half day course with a physician preceptor.

_____ APP must observe 10 procedures and perform 10 procedures under direct supervision. Following approval, the APP must perform no less than 10 treatments per year to maintain competency. (1 set of injections equals **1** procedure)

_____ The APP may only perform treatment on patients with a diagnosis of chronic migraines from a physician or an advanced practice provider (i.e., headache occurs 15 or more days per month for three months).

_____ Prior to each treatment, the APP will evaluate for contraindications by visually inspecting the injection sites, palpating the injection sites, and asking the patient to activate the muscle at the injection sites. The treatment is approximately 15 minutes and involves a 0.1 ml injection into 31 standardized sites on the patient's head and neck. The dosage and injection sites are the same for all patients receiving the treatment.

_____ The APP must discuss with the collaborating/supervising physician whether the patient is receiving one of the enumerated drugs that potentially interferes with neuromuscular transmission or whether the patient has pre-existing neuromuscular disorders. In addition, the treatment by the APP is contraindicated if the injection site is infected or if the patient has a hypersensitivity to Botox.

_____ On a quarterly basis, four patients are to be randomly chosen for discussion with the collaborating/supervising physician. The APP and physician will immediately discuss any adverse events.



ALABAMA STATE BOARD OF MEDICAL EXAMINERS

Botox Injection for Chronic Migraine Protocol

Description of skill/ procedure in detail:

1. Patient condition/ exam finding
 - a. Patient must have a diagnosis of Chronic Migraine, as defined on page 1, by a physician or advanced practice provider
2. FDA Approved Treatment Schedule
 - a. Fixed dosing of Onabotulinumtoxin A every 12 weeks
3. Pre-examination assessment of brow, forehead, and neck to evaluate the patient for conditions that may be affected or exacerbated by treatment. If any conditions are present, the should inform the physician prior to continuing treatment.
 - a. Visually inspect the muscle
 - b. Ask the patient to activate the muscle
 - c. Palpate the muscle
4. Onabotulinumtoxin A injection sites and order of injections using 0.1 mL (5 units) of Onabotulinumtoxin A per site. The procedure takes approximately 15 minutes to administer 31 injections in 7 head and neck muscle areas.
 - a. Corrugator
 - i. 10 units divided in 2 sites
 - b. Procerus
 - i. 5 units in 1 site
 - c. Frontalis
 - i. 20 units divided in 4 sites
 - d. Temporalis
 - i. 40 units divided in 8 sites
 - e. Occipitalis
 - i. 30 units divided in 6 sites
 - f. Cervical paraspinals
 - i. 20 units divided in 4 sites
 - g. Trapezius
 - i. 30 units divided in 6 sites
5. Expected results
 - a. A decrease in the frequency from baseline of headache days
6. After care
 - a. Report any adverse reactions to provider
7. Follow up
 - a. Fixed dose schedule every 12 weeks

No deviation from FDA approved protocol including dosage, location, and number of injections is allowed.

Physician Signature: _____ **License#** _____

Physician Name (Print): _____ **Date:** _____