ALABAMA BOARD OF MEDICAL EXAMINERS

P.O. Box 946 / Montgomery, AL 36101-0946 / (334) 242-4116

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Cosmetic Botulinum Toxin Injection Protocol for Advanced Practice Providers (APPs)

Submit completed form and protocol template to APPDept@albme.gov.
Skills_Protocol_Template.pdf

Purpose/Indication: To evaluate patients for treatment appropriateness with neuromodulators, development of individualized treatment plans including selection of the appropriate neuromodulator treatment product and dosage, administration by injection of an FDA approved, brand-name botulinum-toxin A ("Botox"), prabotulinumtoxinA-xvfs ("Jeuveau"), incobotulinumtoxinA ("Xeomin"), abobotulinumtoxinA ("Dysport"), and daxibotulinumtoxinA-lanm ("Daxxify") for cosmetic purposes according to the treatment plan, follow up to evaluate treatment effectiveness with intervention as needed to correct adverse reactions, and to adjust the treatment plan as clinically indicated.

Population Foci Exclusions (CRNP): Neonatal, Pediatric Primary, Pediatric Acute, Psychiatric-Mental Health CRNPs, and Certified Nurse-Midwives.

Practice Site: The administration of botulinum toxins must be performed in a medical setting, such as a hospital, ambulatory surgical center, or the private clinical office of a physician or Advanced Practice Provider (APP), including Certified Registered Nurse Practitioners (CRNPs) and Physician Assistants (PAs). A private clinical office refers to an approved collaborative practice site where a physician and/or an APP (CRNP or PA) practices medicine or advanced practice nursing, whether as an individual, in a group, a professional corporation, or a professional association practice. **The administration of botulinum toxins is prohibited in non-medical settings, including private residences and event venues. Such locations cannot be designated as a principal practice site.**

APP: _____ License # _____

Physician Attestation(s):

Physician Training Requirement: The supervising/collaborating physician must be qualified under one of the following conditions: (Mark the applicable condition)

_____I am currently board certified by an American Board of Medical Specialties or the American Osteopathic Association in plastic surgery, facial plastic surgery, or dermatology.

_____ I have completed not less than eight (8) hours of training in the injection of cosmetic injectables, including the administration by injection of botulinum-toxin-A and its safety protocols, have actively practiced as an injector in Alabama, or in another state, for more than 12 months, and performed not less than 25 procedures (1 (one) set of injections equals 1 (one) procedure.) (Attach documentation of training).

Physician Responsibilities: The supervising/collaborating physician shall be responsible for ensuring the occurrence of the following conditions:

_____ The collaborating/supervising or covering physician (MD/DO) who meets the same qualifications as the supervising/collaborating physician must be physically available on site when the procedure is performed by the APP.

_____ Prior to approval for performing injections, the APP will have received:

(1) 10 hours of didactic training which may include lectures, and/or a course determined by the supervising/ collaborating physician. Training must include: injectable safety; education in anatomical structures, such as nerves and blood vessels which must be avoided when injecting neuromodulators, Board rules; and

(2) Successful completion and certification from a course approved by the Board of Medical Examiners or the Board of Nursing The course must include no less than four (4) hours of training and must not be completed exclusively through online or remote modalities. The curriculum must incorporate in-person instruction and hands-on clinical training.

(3) Previous training in another state may be considered on a case-by-case basis to fulfill the required training.

_____ The collaborating/supervising physician must evaluate the competency of the APP after completion of certification and training before the APP begins administering botulinum toxins. Maintenance of competency training and procedures must be documented and readily retrievable.

_____ APP must observe 10 procedures and perform 50 procedures under the direct supervision of the collaborating/supervising or covering physician. Following approval, the APP must perform no less than 25 procedures per year to maintain competency. (1(one) set of injections equals 1(one) procedure). Supervised practice must be submitted to the Board within one (1) year of approval to train, or the approval to train will lapse.

Quality Assurance Monitoring Required: Documented evaluation of the clinical practice (high risk/problem prone skill) against defined quality outcome measures, using a meaningful selected sample of patient records and a review of all adverse events [BME 540-X-8-.08(8); BME 540-X-7-.23(10)]

- All final procedures and reports will be logged for physician (MD/DO) review as dictated by the existing practice setting guidelines.
- The results of the botulinum-toxin injections will be reviewed at least quarterly with the collaborating/supervising or covering physician and documented as part of the Quality Assurance Plan. Any adverse events will be recorded, included in all quality monitoring reviews, and reported to the site's designated safety officer. Examples of adverse events could include, but are not limited to, infection, ptosis, and arterial aneurysm. The collaborating/supervising or covering physician will intervene when indicated by this review and implement corrective action.

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QA-Plan-template-sample-Revision-8-24-2018.pdf

_____ **Failure to conduct quarterly skill competency evaluations and/or implement timely corrective action when indicated could result in Board action on the physician's medical license.**

_____ By signing this form, I, the collaborating/supervising physician (MD/DO) certify that I have read and understand the requirements listed above and attest that the requirements have been met or will be met in order for the APP to begin performing the procedure of administering botulinum toxins.

- Training may not begin until the CRNP receives written approval from the Board of Nursing and the collaborating physician receives written approval from the Board of Medical Examiners.

- Training for the PA may not begin until the PA and supervising physician receives written approval from the Board of Medical Examiners.

_____ Prior to providing the treatment, and annually thereafter, the APP must discuss with the collaborating/supervising physician any patient who is receiving a drug that potentially interferes with neuromuscular transmission and any patient who 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.

Limitations:

- The collaborating/supervising or covering physician is required to be physically present on-site during the APP's training for this procedure. The collaborating, supervising, or covering physician must remain on-site at all times while these procedures are being performed by the APP.
- No more than 100 units, or Botox unit equivalent, may be injected for cosmetic purposes within a 3-month period.
- No more than 400 units, or Botox unit equivalent, may be injected into a single patient within a 3-month period, in compliance with the FDA package insert, inclusive of all providers treating the patient and inclusive of treatment for migraines and hyperhidrosis.
- The APP may purchase botulinum-toxin with physician approval from an FDA approved manufacturer.
- Cosmetic botulinum toxin A shall be limited to FDA approved anatomical areas.
- Injection of botulinum toxins are not to be performed on patients who are pregnant or breast feeding.
- Injection of botulinum toxins are not to be performed on patients with glaucoma.

Physician Signature: _____ License # _____

Physician Name (Print): _____ Date: _____

APP Signature: _____ License # _____

APP Name (Print): _____ Date: _____