



ALABAMA BOARD OF MEDICAL EXAMINERS

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

*Under Alabama Law, this document is a public record,
and will be provided upon request*

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 appropriateness of treatment with neuromodulators, develop a treatment plan including ordering appropriate treatment product and dosage, administration by injection of 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 individual treatment plan as needed.

Botulinum toxin procedure: Dilution of a single-use, sterile 50u or 100u vacuum dried powder for reconstitution with 0.9% sodium chloride injection USP and injection of botulinum toxin according to the FDA approved package insert. Inject the diluted solution intramuscularly with a 30–33-gauge needle into the FDA approved muscles (frontalis, procerus, corrugator, orbicularis oculi). No more than 400u to be injected into a single patient in a 3-month period, according to the FDA package insert. No serious adverse events in post marketing research have been proven with the injection of botulinum toxin at a dose of 64u, or Botox unit equivalent, simultaneously for the purpose of cosmesis in the aforementioned muscles. **A limitation will be placed on the usage of no more than 64 botulinum toxin units, or Botox unit equivalent, per treatment session for the cosmetic temporary paralysis of facial muscles. Supervising/collaborating physician will be the only practitioner to purchase the product.**

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

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 means the approved collaborative practice site where a physician and/or APP (CRNP or PA) practices medicine and/or advanced practice nursing, whether as an individual, in a group, a professional corporation, or a professional association practice. **The administration of botulinum toxins cannot be performed in a non-medical setting, such as a private residence or event venue, and non-medical settings 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 pre-approved covering physician (MD/DO) who meets the same qualifications as the supervising/collaborating physician will be physically available on site when procedure is performed by 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 Board of Medical Examiners or Board of Nursing approved course.
- (3) Previous training in another state may be considered on a case-by-case basis to fulfill the required training.

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

_____ APP must observe 10 procedures and perform 50 procedures under direct physician supervision. 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 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/covering physician will intervene when indicated by this review and implement corrective action.

_____ 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 botulism 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 or supervising 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 APP.
- No more than 64 units, or Botox unit equivalent, may be injected per treatment session.
- No more than 400 units, or Botox unit equivalent, may be injected into a single patient in a 3-month period, in compliance with the FDA package insert, inclusive of all persons treating the patient.
- The APP may purchase botulinum-toxin for administration with physician awareness from an FDA approved manufacturer.
- No deviation from FDA approved protocol including dosage, location, and number of injections is allowed.
- Injection of botulism toxins are not to be performed on patients who are pregnant or breast feeding.
- Injection of botulism toxins are not to be performed on patients with glaucoma.

Physician Signature: _____ **License #** _____

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

APP Signature: _____ **License #** _____

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