ALABAMA BOARD OF MEDICAL EXAMINERS

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Cosmetic Botulinum Toxin Injection Protocol for Certified Registered Nurse Practitioners and Physician Assistants

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.

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: Hospital, Physician Office, or Ambulatory Surgical Center. **The administration of botulism toxins must be performed in a medical setting and cannot be performed in a non-medical setting such as a private residence or event venue.**

CRNP or PA: _____ **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 ("ABMS") board 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 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 CRNP/PA.

_____ Prior to approval for performing injections, the CRNP/PA will have received:

(1) 10 hours of didactic training which may include lecture, hands on training, 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.

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

_____ CRNP/PA must observe 10 procedures and perform 50 procedures under direct physician supervision. Following approval, the CRNP/PA must perform no less than 25 procedures per year to maintain competency. (1 (one)set of injections equals 1(one) procedure).

Quality Monitoring and Adverse Outcome Review: All final procedures and reports will be logged for physician (MD/DO) review as dictated by the existing practice setting guidelines. Quality will be monitored using the qualitative and quantitative data through the Supervised/Collaborative Practice Quality Assurance Plan.

QAPlanSupervisedPractice.pdf

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

_____ All cases regarding adverse events will be reviewed with the supervising/collaborating physician (MD/DO) and documented as part of the Supervised/Collaborative Practice Quality Assurance Plan. Any adverse event will be recorded and reported to the site-designated safety officer. Examples of adverse events could include but are not limited to infection, ptosis, and arterial aneurysm. The CRNP/PA and physician will immediately discuss any adverse events.

_____ The results of botulinum-toxin injections are reviewed at least quarterly by the supervising/collaborating or covering physician to assess staff skill competency regarding procedural technique and proper administration for improved outcomes and patient safety. The supervising/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) and the CRNP/PA, 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 CRNP/PA to begin performing the procedure of administering botulism toxins.

_____ Prior to providing the treatment, and annually thereafter, the CRNP/PA 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 CRNP/PA 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 CRNP/PA'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 CRNP/PA.
- 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.
- Only the supervising/collaborating physician may purchase botulinum-toxin for administration by the CRNP/PA.
- 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:** _____

CRNP/PA Signature: _____ **License #** _____

CRNP/PA Name (Print): _____ **Date:** _____