Alabama Board of Nursing
Cosmetic Botulinum Toxin Injection Protocol

COSMETIC BOTULINUM TOXIN INJECTION PROTOCOL: The CRNP scope of practice includes: evaluation of patients for treatment appropriateness with neuromodulators, development of a treatment plan including ordering appropriate neuromodulators 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, following up to evaluate treatment effectiveness with intervention as needed to correct adverse reactions, and adjustment of the individual treatment plan as needed.

PHYSICIAN REQUIREMENTS:

The collaborating physician must be qualified under one of the following conditions:

1. Board certified by a board recognized by the American Board of Medical Specialties or the American Osteopathic Association in plastic surgery, facial plastic surgery, or dermatology.

2. 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].

APPLICATION LINK: Cosmetic Botulinum Toxin Injection Protocol Application

POPULATION FOCI EXCLUSIONS: Neonatal, Pediatric/ Pediatric Acute, and Psychiatric-Mental Health CRNPs, and Certified Nurse- Midwives

LIMITATIONS:

- Cosmetic Botulinum toxin procedures are limited to the following practice settings: 1) Hospital, 2) Physician's Office, or 3) Ambulatory Surgical Center. **The administration of botulinum 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.**
- The collaborating or covering physician (MD/DO) who meets the same qualifications as the collaborating physician must be physically available on site when the procedure is performed by the CRNP.
- 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 collaborating physician may purchase botulinum toxin for administration by the CRNP.
- 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.

- No deviation from FDA approved protocol, including dosage, location, and number of injections, is allowed.
- Injections of botulinum toxins are not to be performed on patients who are pregnant or breastfeeding, or patients with glaucoma.

EDUCATION/ COURSE REQUIREMENTS:

- Prior to approval for performing injections, the CRNP will have received:

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

2. Successful completion of and certification from a course approved by the Board of Medical Examiners or the Board of Nursing.

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

Training Requirements for Skill(s) or Procedure(s)

- The collaborating physician is required to be physically present on site during the CRNP training for this procedure.
- The collaborating physician must evaluate the competency of the CRNP after completion of the certification and training before administering botulinum toxins. Maintenance of competency training and procedures must be documented and readily retrievable.

Supervised practice must be submitted to the Board within one (1) year of approval to train, or the approval to train will lapse.

Skills/Procedures	Observation (if indicated)	Number Required for Initial	Annual Maintenance Requirement
Cosmetic Botulinum Toxin Injection [1 (one) set of injections equals 1(one) procedure]	Observe **10** procedures	**50** procedures under the direct supervision of the physician	No less than **25** procedures annually to maintain competency

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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 is 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 simultaneous injection of botulinum toxin at a dose of 64u or Botox unit equivalent 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.

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 [ABN Administrative Code § 610-X-5-.01(13)].

- All final procedures and reports will be logged for physician (MD/DO) review in accordance with established protocols and institutional policies.

- 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.

NOTES:

- Prior to providing the treatment, and annually thereafter, the CRNP must discuss with the collaborating 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 is contraindicated if the injection site is infected or if the patient has a hypersensitivity to Botox.

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