USE OF BOTULINUM NEUROTOXIN FOR THE TREATMENT OF SPASTICITY

This is a summary of the American Academy of Neurology (AAN) guidelines regarding recommended use and best practices for botulinum neurotoxin for spasticity.

Please refer to the full guideline for detailed findings and supporting evidence at www.aan.com.

RECOMMENDATIONS FOR USE OF BoNT IN ADULTS WITH SPASTICITY	
Strong evidence supports	Use of BoNT as a treatment option to reduce muscle tone and improve passive function **(Level A[†])**.
Good evidence supports	Consideration of BoNT to improve active function **(Level B)**.
Insufficient evidence supports	Optimum technique for muscle localization at the time of injection **(Level U)**.
Clinical context	There are no controlled studies comparing BoNT to other treatment modalities for spasticity. In adult spasticity, there is a lack of consensus on what constitutes meaningful functional gain following treatment for spasticity. There is also a need to confirm efficacy for active function in controlled trials.

RECOMMENDATIONS FOR THE USE OF BoNT IN CHILDREN WITH SPASTICITY DUE TO CEREBRAL PALSY (CP)	
Strong evidence supports	Injection of BoNT into calf muscles as a treatment option for *equinus varus deformity* in children with CP **(Level A)**.
Good evidence supports	Consideration of BoNT as a treatment option of *thigh adductor spasticity and for pain control* undergoing adductor-lengthening surgery **(Level B)**.
Good evidence supports	Injection of BoNT as a treatment option for children with *upper extremity spasticity* **(Level B)**.
Clinical context	Though clinicians, patients, and caregivers have found BoNT treatment for spasticity gratifying, the United States Food and Drug Administration has not approved BoNT for the treatment of spasticity in children or adults.

This guideline summary is evidence-based. The AAN uses the following definitions for the level of recommendations and classification of evidence for therapeutic intervention.

The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

†**Classification of Recommendations: A** = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.*) **B** = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.) **C** = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.) **U** = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven. (Studies not meeting criteria for Class I–III).

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if (1) all criteria are met and/or (2) the magnitude of effect is large (relative rate improved outcome > 5 and the lower limit of the confidence interval is > 2).

AAN Classification of Evidence for Therapeutic Intervention: Class I: Randomized, controlled clinical trial with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. The following are required: (a) concealed allocation; (b) primary outcome(s) clearly defined; (c) exclusion/inclusion criteria clearly defined; and (d) adequate accounting for drop-outs (with at least 80% of enrolled subjects completing the study) and cross-overs with numbers sufficiently low to have minimal potential for bias. **Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets b-d above OR a RCT in a representative population that lacks one criteria a-d. **Class III:** All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.** **Class IV:** Studies not meeting Class I, II, or III criteria, including consensus, expert opinion, or a case report.

** Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

This is an educational service of the American Academy of Neurology. It is designed to provide members with evidence-based guideline recommendations to assist with decision-making in patient care. It is based on an assessment of current scientific and clinical information and is not intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on the circumstances involved. Physicians are encouraged to review the full AAN guidelines carefully so they understand all recommendations associated with care of these patients.

Copies of this summary and additional companion tools are available at *www.aan.com* or through AAN Member Services at (800) 879-1960.

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