1. **Purpose**
   The purpose of this policy is to establish the criteria for the medical necessity of botulinum toxin injections.

2. **Definitions**
   Botulinum toxin injections are intramuscular injections of botulinum neurotoxins which are purified forms of Clostridium Botulinum exotoxins. The botulinum toxin acts by blocking release of acetylcholine at the neuromuscular junction thus reducing the tone of overactive muscles. There are several commercial products (consisting of either serotype-A or serotype-B) currently available for use. Each differs in its unit potency, side effects, and duration of action. The clinical goals for utilizing botulinum toxin injections are to result in a temporary chemodenervation of the effected muscle at the neuromuscular junction thus: reducing pain or increasing comfort, improving function, preventing or treating musculoskeletal complications, facilitating ease of care, and/or for improving the general appearance, mobility and/or phonation in patients presenting with spasticity or dystonia.

3. **Statement of Policy**
   3.1 The determination of medical necessity for the use of botulinum toxin injections is always made on a case-by-case basis.
   3.2 Botulinum toxin injections utilizing botulinum toxin-A **may be considered medically necessary** for the treatment of patients presenting with the following conditions:
      - Spasticity
      - Cervical Dystonia (spasmodic torticollis)
      - Focal Dystonia
         - Blephorospasm
         - Laryngeal dystonia/spasm
         - Hemifascial spasm
         - Upper extremity essential tremor
         - Upper or lower extremity focal dystonia
         - Motor tics
         - Strabismus
         - Vesicourethral spasm
         - Headache.
3.3 Repeat botulinum toxin injections are typically not indicated unless there is documented evidence that all types of improvement noted must be clinically meaningful and should include: functional improvement, clinically meaningful reduction in pain, reduction of the need for treatment of musculoskeletal complications, facilitating ease of care, and/or for improving the general appearance, mobility and/or phonation in patients presenting with spasticity or dystonia for a minimum of eight (8) weeks following the injection(s). Based on the typical response of properly administered botulinum toxin injections, injections are typically performed every three (3) months. Injections performed on a more frequent basis may be considered not medically necessary. In addition, more than four (4) injections per region per year may be considered not medically necessary.

3.4 The use of electrical muscle stimulation (95873) or needle electromyography (95874) may be considered medically necessary for guidance in conjunction with botulinum toxin injections (chemodenervation).

3.5 Botulinum toxin injections are not without risk, and can expose patients to potential serious complications. As a result, certain patients may not be optimal candidates for botulinum toxin injections. Optimal candidates include those:

- With a limited number of muscles that need treatment;
- Who do not have fixed contracture.

In patients who may not fulfill these criteria, the use of botulinum toxin injections may be considered not medically necessary.

3.6 Based on the limited evidence of efficacy and the increased side-effects profile, the use of botulinum toxin type-B may be considered medically necessary only in the management of patients who have become non-responsive to botulinum toxin type-A.

3.7 Botulinum toxin injections are considered not medically necessary for the treatment of:

- Myofascial trigger points
- Myofascial tender points (Myofascitis or Fibromyositis or Fibromyalgia)
- Neck Pain
- Low Back Pain.

Triad Healthcare, Inc. also considers the use botulinum toxin injections not medically necessary for cosmetic purposes as well as all other indications.
4. References

4.1. Scientific:

The following scientific references were utilized in the formulation of this medical policy. Triad Healthcare, Inc. will continue to review clinical evidence surrounding botulinum neurotoxin injections and may modify this policy at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to Triad Healthcare, Inc. so the information can be reviewed by the Academic Advisory Committee (AAC) and the Medical Quality Improvement Committee (MQIC) to determine if a modification of the policy is in order.

- Bakheit AM, Thilmann AF, Ward AB, et al. A randomized, double-blind, placebo-controlled, dose-ranging study to compare the efficacy and safety of three doses


Greene PE, Fahn S. Use of botulinum toxin type F injections to treat torticollis in patients with immunity to botulinum toxin type A. *Mov Disord* 1993; 8:479-483.


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- Scott AB. Botulinum toxin injection into extraocular muscles as an alternative to strabismus surgery. *Ophthalmology* 1980; 87:1044-1049.


4.2. Related Triad Medical Policies:

- **TMMP 15 – Minimal Clinical Progress / Improvement**
- **TMMP 18 - Medical Necessity**
- **TMMP 25 – Use of Electrodiagnostic Testing**
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Triad’s Medical Policies are not recommendations for treatment and providers are expected to exercise their clinical judgment in providing the most appropriate care. Health care providers and patients should not rely on these Medical Policies in making health care decisions. These Medical Policies are guidelines and do not constitute an authorization, certification, explanation of benefits or guarantee of payment. Applications of Triad’s Medical Policies are determined by the enrollee’s benefit documents and contracts and as such individual benefits must be verified. Determinations of medical necessity apply only if the benefit exists and no contract exclusions are applicable. In the event of a conflict, a participant’s benefit plan document shall supersede the information contained in Triad’s Medical Policies.