BOTOX® (onabotulinumtoxinA) Treatment Record for Cervical Dystonia

Patient name: _____

Clinical rationale for BOTOX® treatment (medical necessity):

Clinical rationale for EMG (if applicable):

Comments:

Dilution Table

200-Unit Vial		100-Unit Vial	
Diluent to Add (0.9% Sodium Chloride Injection Only)	Resulting Dose (Units per 0.1 mL)	Diluent to Add (0.9% Sodium Chloride Injection Only)	Resulting Dose (Units per 0.1 mL)
1 mL	20 Units	1 mL	10 Units
2 mL	10 Units	2 mL	5 Units
4 mL	5 Units	4 mL	2.5 Units
8 mL	2.5 Units	8 mL	1.25 Units
10 mL	2 Units	10 mL	1 Unit

Treatment date _____

Dilution (Units/mL) _____

Lot number(s) _____

Vial expiration date(s) _____

Note: These dilutions are calculated for an injection volume of 0.1 mL. A decrease or increase in the BOTOX® dose is also possible by administering a smaller or larger injection volume—from 0.05 mL (50% decrease in dose) to 0.15 mL (50% increase in dose). BOTOX® should only be reconstituted in preservative-free 0.9% sodium chloride injection, USP. Because the product and diluent do not contain a preservative, use within 24 hours once opened and reconstituted. During the 24 hours, BOTOX® solution should be stored in a refrigerator at 2ºC to 8ºC.

Indication

Cervical Dystonia

BOTOX® for injection is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

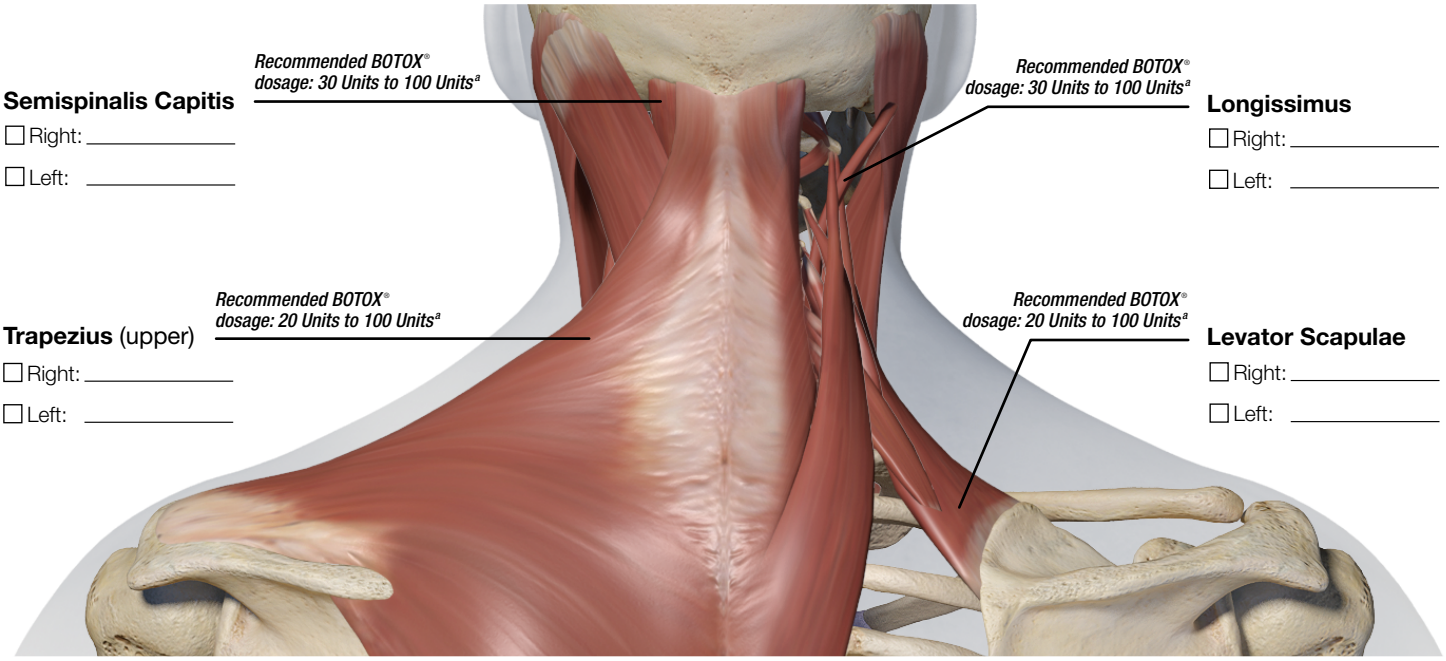
WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

Please see additional Important Safety Information about BOTOX® on following pages.

BOTOX® (onabotulinumtoxinA) Patient Injection Record[1,2]

Be sure to indicate which side was treated by selecting the right or left checkbox, and fill in number of Units injected.



Total Units injected: _____ Total Units discarded: _____

[a]Charles et al., 2010

Lines indicate muscle location, and do not point out sites for injection.

Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient's neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history.

Cervical dystonia dosing information

- BOTOX® dosing in initial and sequential treatment sessions should be tailored to each individual patient based on his or her head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history. The initial dose for a patient without prior use of BOTOX® should be at a lower dose, with subsequent dosing adjusted based on individual response[1]
- The recommended dilution is 200 Units/2 mL, 200 Units/4 mL, 100 Units/1 mL, or 100 Units/2 mL with preservative-free 0.9% Sodium Chloride Injection, USP. Limiting the total dose injected into the sternocleidomastoid muscle to 100 Units or less may decrease the occurrence of dysphagia. In general, no more than 50 Units per site should be administered. Localization of the involved muscles with electromyographic guidance may be useful[1]
- In treating adult patients for 1 or more indications, the maximum cumulative dose should not exceed 400 Units in a 3-month interval[1]

IMPORTANT SAFETY INFORMATION (continued)

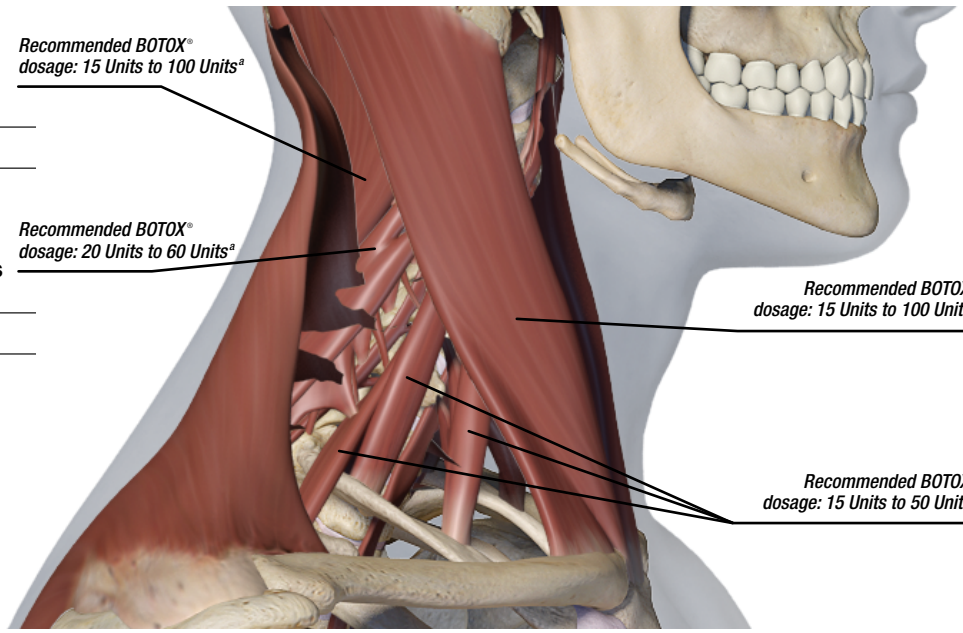
CONTRAINDICATIONS

BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

Please see additional Important Safety Information about BOTOX® on following pages.

BOTOX® (onabotulinumtoxinA) Patient Injection Record[1,2] (continued)

Be sure to indicate which side was treated by selecting the right or left checkbox, and fill in number of Units injected.



Splenius Capitis

Recommended BOTOX® dosage: 15 Units to 100 Units[a]

☐ Right: _____

☐ Left: _____

Splenius Cervicis

Recommended BOTOX® dosage: 20 Units to 60 Units[a]

☐ Right: _____

☐ Left: _____

Recommended BOTOX® dosage: 15 Units to 100 Units[a]

Sternocleidomastoid

☐ Right: _____

☐ Left: _____

Recommended BOTOX® dosage: 15 Units to 50 Units[a]

Scalene Complex

☐ Right: _____

☐ Left: _____

Total Units injected: _____ Total Units discarded: _____

[a]Charles et al., 2010

Lines indicate muscle location, and do not point out sites for injection.

Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient's neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history.

Cervical dystonia dosing information (continued)

- An understanding of standard electromyographic techniques may be useful for the treatment of cervical dystonia. Physicians administering BOTOX® must understand the relevant neuromuscular and structural anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures and disease, especially when injecting near the lungs[1]
- Clinical improvement generally begins within the first 2 weeks after injection, with maximum clinical benefit at approximately 6 weeks post injection. In clinical studies, most subjects were observed to have returned to pretreatment status by 3 months post treatment[1]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Spread of Toxin Effect

See Boxed Warning.

Please see additional Important Safety Information about BOTOX® on following page.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® (onabotulinumtoxinA) injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Increased Risk of Clinically Significant Effects With Pre-Existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX® (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties

Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

ADVERSE REACTIONS

Adverse reactions to BOTOX® (onabotulinumtoxinA) are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Cervical Dystonia

The most frequently reported adverse reactions following injection of BOTOX® for cervical dystonia include dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

Post Marketing Experience

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

DRUG INTERACTIONS

Co-administration of BOTOX® and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX®.

For more information on BOTOX®, please see the accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

1. BOTOX® Prescribing Information, April 2017.

2. Charles D, Gill CE. Neurotoxin injection for movement disorders. *Continuum Lifelong Learning Neurol.* 2010;16(1):131-157.

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