BOTOX® (onabotulinumtoxinA) Treatment Record for Adult Focal Spasticity

Indications

Adult Spasticity:

Adult Upper Limb Spasticity

BOTOX® for injection is indicated for the treatment of upper limb spasticity in adult patients to decrease the severity of increased muscle tone in elbow, wrist, finger, and thumb flexors (biceps, flexor carpi radialis, flexor carpi ulnaris, flexor digitorum profundus, flexor digitorum sublimis, adductor pollicis, and flexor pollicis longus).

Adult Lower Limb Spasticity

BOTOX® is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

Limitations of Use

Safety and effectiveness of BOTOX® have not been established for the treatment of other upper or lower limb muscle groups. BOTOX® has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture. Treatment with BOTOX® is not intended to substitute for usual standard of care rehabilitation regimens.

Patient Information

Name: _____ Date: _____

Address: _____ City: _____ State: ____ Zip: _____

DOB: ____/____/____ Sex: ☐ Male ☐ Female SSN: _____ Chart No.: _____

Patient Assessment and History

Patient background: _____

Chief complaints: _____

Current or previous drug name(s)/therapy	Currently taking (Y/N)	Results (effectiveness, tolerability, duration of trial, etc.)

Contraindications: _____

Allergies: _____

Diagnosis: _____

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 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.

Patient Assessment and History (continued)

Ashworth Scale Score

✔	Score	Severity	Definition
	0	None	No increase in muscle tone
	1	Mild	Slight increase in muscle tone, giving a "catch" when the limb was moved in flexion or extension
	2	Moderate	More marked increase in muscle tone but affected limb is easily flexed
	3	Severe	Considerable increase in tone—passive movement difficult
	4	Very severe	Limb rigid in flexion or extension

The expanded Ashworth Scale allows investigators to score half-point increments between each of the above categories. This is considered to allow more accurate recording of the patient's condition. The Modified Ashworth Scale (MAS) uses a similar scoring system as the Ashworth Scale.

BOTOX® (onabotulinumtoxinA) Treatment Plan

Clinical rationale for BOTOX® treatment (medical necessity):

Clinical rationale for EMG (if applicable):

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.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

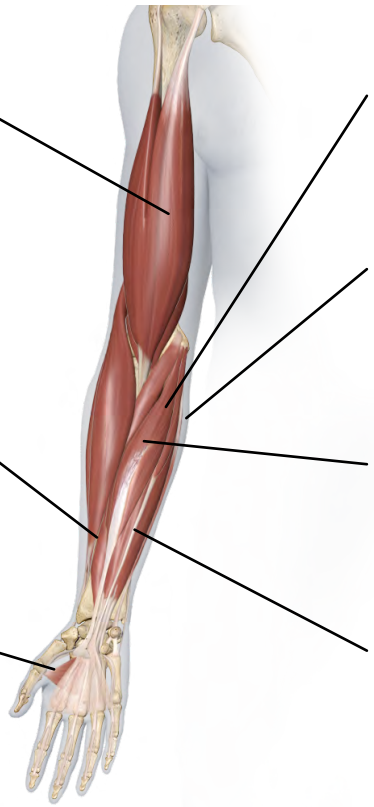
BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

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

BOTOX® (onabotulinumtoxinA) Patient Injection Record for Adult Upper Limb Spasticity

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

The recommended dose for treating adult upper limb spasticity ranges from 75 Units to 400 Units divided among 7 muscles (biceps brachii, flexor pollicis longus, adductor pollicis, flexor carpi radialis, flexor carpi ulnaris, flexor digitorum profundus, flexor digitorum superficialis [flexor digitorum sublimis]).



Biceps Brachii

Recommended BOTOX® *dosage: 100 Units to 200 Units*

Divided in 4 sites

☐ Right: _____ ☐ Left: _____

Flexor Pollicis Longus

Recommended BOTOX® *dosage: 20 Units*

1 site

☐ Right: _____ ☐ Left: _____

Adductor Pollicis

Recommended BOTOX® *dosage: 20 Units*

1 site

☐ Right: _____ ☐ Left: _____

Flexor Carpi Radialis

Recommended BOTOX® *dosage: 12.5 Units to 50 Units*

1 site

☐ Right: _____ ☐ Left: _____

Flexor Carpi Ulnaris

Recommended BOTOX® *dosage: 12.5 Units to 50 Units*

1 site

☐ Right: _____ ☐ Left: _____

Flexor Digitorum Profundus (hidden)

Recommended BOTOX® *dosage: 30 Units to 50 Units*

1 site

☐ Right: _____ ☐ Left: _____

Flexor Digitorum Superficialis (Flexor Digitorum Sublimis)

Recommended BOTOX® *dosage: 30 Units to 50 Units*

1 site

☐ Right: _____ ☐ Left: _____

Total Units injected: _____ Total Units discarded: _____

Other Notes: _____

Lines indicate muscle location, and do not point out sites for injection.
Per the BOTOX® package insert, in treating adult patients for one or more indications, the maximum cumulative dose of BOTOX® should not exceed 400 Units in a 3 month interval.

Adult upper limb spasticity treatment response:

Physician signature: _____ Date: _____

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS

Lack of Interchangeability Between Botulinum Toxin Products

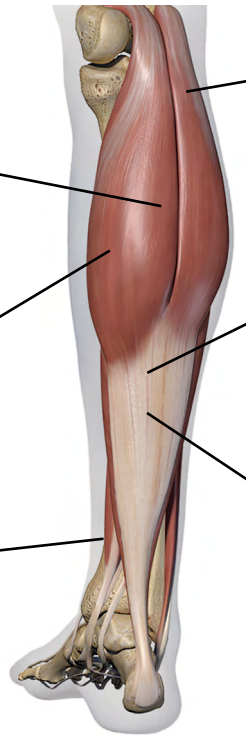
The potency Units of BOTOX® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX® cannot be compared to nor converted into Units of any other botulinum toxin products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

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

BOTOX® (onabotulinumtoxinA) Patient Injection Record for Adult Lower Limb Spasticity

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

The recommended dose for treating adult lower limb spasticity is 300 Units to 400 Units divided among 5 muscles (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).



Tibialis posterior (hidden)
Recommended BOTOX® *dosage: 75 Units*
Divided in 3 sites
☐ Right: _____ ☐ Left: _____

Gastrocnemius (medial head)
Recommended BOTOX® *dosage: 75 Units*
Divided in 3 sites
☐ Right: _____ ☐ Left: _____

Flexor digitorum longus
Recommended BOTOX® *dosage: 50 Units*
Divided in 2 sites
☐ Right: _____ ☐ Left: _____

Gastrocnemius (lateral head)
Recommended BOTOX® *dosage: 75 Units*
Divided in 3 sites
☐ Right: _____ ☐ Left: _____

Soleus (hidden)
Recommended BOTOX® *dosage: 75 Units*
Divided in 3 sites
☐ Right: _____ ☐ Left: _____

Flexor hallucis longus (hidden)
Recommended BOTOX® *dosage: 50 Units*
Divided in 2 sites
☐ Right: _____ ☐ Left: _____

Total Units injected: _____ Total Units discarded: _____

Other Notes: _____

Lines indicate muscle location, and do not point out sites for injection.
Per the BOTOX® package insert, in treating adult patients for one or more indications, the maximum cumulative dose of BOTOX® should not exceed 400 Units in a 3 month interval.

Adult lower limb spasticity treatment response:

Physician signature: _____ Date: _____

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Spread of Toxin Effect

See Boxed Warning.

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.

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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*).

Pulmonary Effects in Patients With Compromised Respiratory Status Treated for Spasticity

Patients with compromised respiratory status treated with BOTOX® for adult spasticity should be monitored closely.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX® (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX® (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%). In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX® (2% at 300 Units to 400 Units total dose) compared to placebo (1%).

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*.

Adult Upper Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX® for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Adult Lower Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX® for lower limb spasticity include arthralgia, back pain, myalgia, upper respiratory tract infection, and injection site pain.

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX® are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

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 other agents interfering with neuromuscular transmission (eg, aminoglycosides, 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 and also 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.