

# BOTOX® chart documentation for Chronic Migraine patients

BOTOX® (onabotulinumtoxinA) for injection is indicated for the prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

## Important Limitations

Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in 7 placebo-controlled studies.

### Patient Information

Name: \_\_\_\_\_ Date: \_\_\_\_\_  
 Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
 DOB: \_\_\_ / \_\_\_ / \_\_\_\_\_ Sex:  Male  Female SSN: \_\_\_\_\_ Chart No.: \_\_\_\_\_

### Patient Assessment and History

Patient background: \_\_\_\_\_ Migraines since: \_\_\_\_\_  
 Chief complaints: \_\_\_\_\_  
 Number of headache days/month—Current: \_\_\_\_\_ Baseline: \_\_\_\_\_  
 Number of headache hours/days—Current: \_\_\_\_\_ Baseline: \_\_\_\_\_

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

Contraindications: \_\_\_\_\_  
 Allergies: \_\_\_\_\_  
 Diagnosis: \_\_\_\_\_

## IMPORTANT SAFETY INFORMATION, INCLUDING BOXED 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 underlying conditions 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 at lower doses.**

**Please see additional Important Safety Information on pages 2 to 4.**

## BOTOX® (onabotulinumtoxinA) Treatment Plan

Clinical rationale for BOTOX® treatment (medical necessity):

Dilution Table		Vial size/NDC No. <span style="font-size: small;">■ 200 Unit vial/NDC No.: 00023-3921-02</span>
Diluent* added to <b>200 Unit</b> vial (0.9% sodium chloride injection)	Resulting dose (Units per 0.1 mL)	Dilution (Units/mL)
1.0 mL	20.0 Units	_____
2.0 mL	10.0 Units	Lot number(s)
4.0 mL	5.0 Units	_____
8.0 mL	2.5 Units	Vial expiration date(s)
10.0 mL	2.0 Units	_____

**\*Preservative-free 0.9% sodium chloride injection, USP only.**

**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).**

**Note:** The product and diluent do not contain a preservative. Administer the 200 Unit vial of BOTOX® within 24 hours of reconstitution. During this period, BOTOX® solution should be stored in a refrigerator at 2°C to 8°C.

**Note:** For electronic billing, payers require an 11-digit NDC number [5-4-2 configuration] on the claim form. Therefore, an additional zero should be added to the beginning of the code [eg, 00023-3921-02].

### IMPORTANT SAFETY INFORMATION (continued) CONTRAINDICATIONS

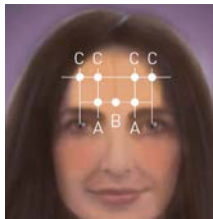
BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

### 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.**

## BOTOX® Dosing by Muscle for Chronic Migraine

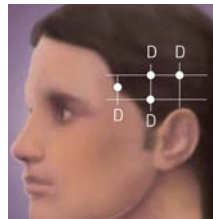


### A. Corrugator

BOTOX® dosage: 10 Units divided in  
**2 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_

### B. Procerus

BOTOX® dosage: 5 Units in  
**1 site** \_\_\_\_\_

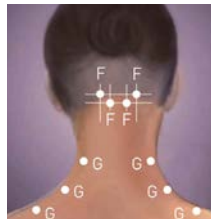
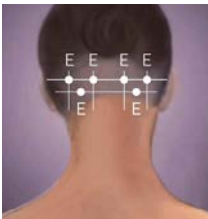


### C. Frontalis

BOTOX® dosage: 20 Units divided in  
**4 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_

### D. Temporalis

BOTOX® dosage: 40 Units divided in  
**8 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_



### E. Occipitalis

BOTOX® dosage: 30 Units divided in  
**6 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_

### F. Cervical Paraspinal

BOTOX® dosage: 20 Units divided in  
**4 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_

### G. Trapezius

BOTOX® dosage: 30 Units divided in  
**6 sites** Right: \_\_\_\_\_ Left: \_\_\_\_\_

Total Units injected: \_\_\_\_\_ Total Units discarded: \_\_\_\_\_ Total Units billed: \_\_\_\_\_

Chronic Migraine treatment response:

Physician signature: \_\_\_\_\_ Date: \_\_\_\_\_

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Spread of Toxin Effect

See Boxed Warning.

No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX® for chronic migraine at the labeled doses have been reported.

##### 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.

**Please see additional Important Safety Information on page 4.**