

# BOTOX<sup>®</sup> Billing and Coding for Chronic Migraine



## Indication

### Chronic Migraine

BOTOX<sup>®</sup> for injection is indicated for the prophylaxis of headaches in adult patients with Chronic Migraine ( $\geq 15$  days per month with headache lasting 4 hours a day or longer).

### Limitations of Use

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.

## IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

### WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX<sup>®</sup> 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<sup>®</sup> on following pages.

# Common codes for BOTOX® indications

DRUG CODES		
CODE TYPE	CODE	CODE DEFINITION
HCPCS II	J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-3921-02	BOTOX® 200 Unit vial
PROCEDURE CODE		
CPT®*	64615	Chemodeneration of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
DIAGNOSIS CODES		
Please see full Indications and Important Limitations on following pages.		
Diagnosis ICD-10-CM	G43.709	Chronic migraine without aura, not intractable, without status migrainosus
	G43.719	Chronic migraine without aura, intractable, without status migrainosus
	G43.701	Chronic migraine without aura, not intractable, with status migrainosus
	G43.711	Chronic migraine without aura, intractable, with status migrainosus

**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 10-digit NDC code listed on the box [eg, 00023-1145-01].

Contact payers to confirm their reporting preferences and determine which procedure code to use. Check payer guidelines regarding the definition of site, coding, and use of modifiers.

\*CPT® codes and descriptors are copyrighted by the AMA. These include uses that are outside labeled indications. The procedure codes and diagnosis codes are for illustrative purposes only, as the practitioner must determine the proper coding for the treatment provided.

This piece is being provided in response to inquiries relative to the identification of drug codes, diagnosis codes, and procedure codes.

ICD-10-CM codes submitted to the payer must accurately describe the diagnosis for which the patient receives BOTOX® treatment, represent codes at the highest level of specificity (up to 3-7 character codes) and reflect the contents of any clinical notes and/or chart documentation and be included in a Letter of Medical Necessity (LOMN) or prior authorization (PA). CPT® codes submitted to the payer must describe the service(s) performed. The coding information contained herein is gathered from various resources and is subject to change. This document is intended for reference only. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for BOTOX®. Third-party payment for medical products and services is affected by numerous factors. The decision about which code to report must be made by the provider/physician considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. Please refer to your Medicare policy/other payer policies for specific guidance.

## 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.

### WARNINGS AND PRECAUTIONS

#### 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 dose have been reported.

#### 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 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® for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

### **Chronic Migraine**

The most frequently reported adverse reactions following injection of BOTOX® for Chronic Migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

### **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. 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](#).**