S T R E A M L I N E

BOTOX® onabotulinumtoxinA injection

Injection Charge Sheet

PATIENT INFORMATION

Patient name: _____ Patient date of birth: _____ Date of service: _____

Insurance: _____ Specialty Pharmacy Provider (SPP): _____

DIAGNOSIS CODES AND CORRESPONDING PROCEDURE CODES

64612*Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)

☐ G24.5 Blepharospasm ☐ _____ Modifier†: ☐ -50 ☐ -51 ☐ -59 ☐ -RT ☐ -LT ☐ ___

64615* Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)

☐ 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

☐ _____

*CPT® *codes and descriptors are derived from the American Medical Association (AMA) 2016* CPT® *manual.* ***The procedure codes and diagnosis codes are for illustrative purposes only, as the practitioner must determine the proper coding for the treatment provided.***

†Modifier: -50 = bilateral procedure; -51 = multiple procedures; -59 = distinct procedural service; -RT = right side; -LT = left side.

Please refer to the *CPT*® manual and/or individual payer policies for specific guidance on billing for procedure codes and appropriate modifier codes.

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 Indications and additional Important Safety Information about BOTOX® on following pages.

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DIAGNOSIS CODES AND CORRESPONDING PROCEDURE CODES (CONTINUED)

64616* Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)

☐ G24.3 Spasmodic Torticollis ☐ _____ Modifier†: ☐ -50 ☐ -51 ☐ -59 ☐ -RT ☐ -LT ☐ ___

☐ **64642* Chemodenervation of one extremity; 1-4 muscle(s)**

☐ **64644* Chemodenervation of one extremity; 5 or more muscle(s)**

- Report only one base code (64642 or 64644) per session

Report one Unit of additional extremity code(s) for each additional extremity injected:

_____ **+ 64643* Each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)** ➡ Use with 64642 or 64644

_____ **+ 64645* Each additional extremity, 5 or more muscle(s) (List separately in addition to code for primary procedure)** ➡ Use with 64644

Multiple *ICD-10-CM* codes are available for upper limb spasticity and lower limb spasticity in adult patients; providers should use the most appropriate code. Please check your current *ICD-10-CM* code book for a complete list of codes.

☐ _____ ☐ _____ ☐ _____

☐ _____ ☐ _____ ☐ _____

Check appropriate guidance code, if applicable:

☐ 95873 Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

☐ 95874 Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

☐ _____

Please be aware that *ICD-10-CM* codes submitted to the payer must:

- Accurately describe the diagnosis for which the patient receives BOTOX® (onabotulinumtoxinA) treatment
- Represent codes at the highest level of specificity (up to 3-7 character codes)
- Reflect the contents of any clinical notes and/or chart documentation

This 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.

This piece is to be used only in response to inquiries relative to the identification of procedure codes and diagnosis codes.

*CPT® *codes and descriptors are derived from the American Medical Association (AMA) 2016* CPT® *manual.*

†Modifier: -50 = bilateral procedure; -51 = multiple procedures; -59 = distinct procedural service; -RT = right side; -LT = left side.

Indications

Chronic Migraine

BOTOX® 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.

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

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PRODUCT CODES

J-code—J0585 INJECTION, ONABOTULINUMTOXINA, 1 UNIT

Number of Units injected _____ Units

Number of Units of unavoidable wastage* +_____ Units

Total number of Units to be billed =_____ Units

NDC No. 00023-1145-01; 1 vial = 100 Units
NDC No. 00023-3921-02; 1 vial = 200 Units

Note: For electronic billing, payers require an 11-digit NDC number (5-4-2 configuration) to be reported 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).

**If wastage is allowed by the carrier, follow carrier's instructions regarding reporting of unavoidable wastage.*

☐ **Please check box if an SPP is used.**

Note: Do not bill for BOTOX® (onabotulinumtoxinA) if an SPP is used. Some payers may require a -JW modifier to report unavoidable wastage.

Indications (continued)

Spasticity:

Upper Limb Spasticity

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

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).

Important Limitations

Safety and effectiveness of BOTOX® have not been established for the treatment of other upper or lower limb muscle groups. Safety and effectiveness of BOTOX® have not been established for the treatment of spasticity in pediatric patients under age 18 years. 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.

Cervical Dystonia

BOTOX® 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.

Blepharospasm and Strabismus

BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

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.

Spread of Toxin Effect

See Boxed Warning.

No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX® for blepharospasm at the recommended dose (30 Units and below), strabismus, or for chronic migraine at the labeled doses have been reported.

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® 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.

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

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular 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® (onabotulinumtoxinA) (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 of BOTOX® in Patients With Compromised Respiratory Status Treated for Spasticity

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

Corneal Exposure and Ulceration in Patients Treated With BOTOX® for Blepharospasm

Reduced blinking from BOTOX® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect, and corneal ulceration, especially in patients with VII nerve disorders.

Retrobulbar Hemorrhages in Patients Treated With BOTOX® for Strabismus

During the administration of BOTOX® for the treatment of strabismus, retrobulbar hemorrhages sufficient to compromise retinal circulation have occurred. It is recommended that appropriate instruments to decompress the orbit be accessible.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in patients treated for upper limb spasticity with BOTOX® (3% at 251-360 Units total dose) compared to placebo (1%). In 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 event 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. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

The following adverse reactions to BOTOX® for injection are discussed in greater detail in the following sections: Spread of Toxin Effect (see Boxed Warning); Serious Adverse Reactions with Unapproved Use (see *Warnings and Precautions*); Hypersensitivity Reactions (see *Contraindications* and *Warnings and Precautions*); Increased Risk of Clinically Significant Effects with Pre-Existing Neuromuscular Disorders (see *Warnings and Precautions*); Dysphagia and Breathing Difficulties (see *Warnings and Precautions*); Pulmonary Effects of BOTOX® in Patients with Compromised Respiratory Status Treated for Spasticity (see *Warnings and Precautions*); Corneal Exposure and Ulceration in Patients Treated with BOTOX® for Blepharospasm (see *Warnings and Precautions*); Retrobulbar Hemorrhages in Patients Treated with BOTOX® for Strabismus (see *Warnings and Precautions*); and Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity (see *Warnings and Precautions*).

Chronic Migraine

The most frequently reported adverse reactions following injection of BOTOX® (onabotulinumtoxinA) 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%).

Upper Limb Spasticity

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

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.

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%).

Blepharospasm

The most frequently reported adverse reactions following injection of BOTOX® for blepharospasm include ptosis (21%), superficial punctate keratitis (6%), and eye dryness (6%).

Strabismus

The most frequently reported adverse events following injection of BOTOX® for strabismus include ptosis (15.7%) and vertical deviation (16.9%).

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®.

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

ALLERGAN

www.BOTOXChronicMigraine.com/HCP www.BOTOXMedical.com/HCP www.BOTOXReimbursementSolutions.com 1-800-44-BOTOX APC24NR16

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