

# BOTOX<sup>®</sup> Billing and Coding for Urology



## Indications

### Adult Bladder Dysfunction:

#### *Overactive Bladder*

BOTOX<sup>®</sup> for injection is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

#### *Detrusor Overactivity Associated With a Neurologic Condition*

BOTOX<sup>®</sup> is indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (eg, SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

## 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 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 Indication and Important Safety Information about BOTOX<sup>®</sup> on following pages.

## Common codes for BOTOX<sup>®</sup> urology indications

PRODUCT CODES		
CODE TYPE	CODE	CODE DEFINITION
HCPCS II	J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-1145-01	BOTOX <sup>®</sup> 100 Unit vial
	00023-3921-02	BOTOX <sup>®</sup> 200 Unit vial
CPT <sup>®</sup> CODE		
CODE TYPE	CODE	CODE DEFINITION
CPT <sup>®*</sup>	52287	Cystourethroscopy, with injection(s) for chemodeneration of the bladder
DIAGNOSIS CODES		
	CODE	CODE DEFINITION
Diagnosis ICD-10-CM for Neurogenic Detrusor Overactivity (NDO)	N31.9 <sup>a</sup>	Neuromuscular dysfunction of bladder, unspecified
Diagnosis ICD-10-CM for Overactive Bladder (OAB)	N32.81	Other specified disorders of bladder; overactive bladder
	N39.41 <sup>b</sup>	Other specified urinary incontinence; urge incontinence
	N39.46 <sup>b</sup>	Other specified urinary incontinence; mixed incontinence

<sup>a</sup>Use additional code to identify any associated urinary incontinence.

<sup>b</sup>Code also any associated overactive bladder (N32.81).

**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).

\*CPT<sup>®</sup> codes and descriptors are derived from the American Medical Association (AMA) 2016 CPT<sup>®</sup> manual. These may 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.**

ICD-10-CM codes submitted to the payer must:

- Accurately describe the diagnosis for which the patient receives BOTOX<sup>®</sup> 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 and be included in a Letter of Medical Necessity (LOMN) or prior authorization (PA)

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<sup>®</sup>. 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.

### Indications (continued)

#### Pediatric Detrusor Overactivity Associated With a Neurologic Condition

BOTOX<sup>®</sup> is indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.

Please see additional Important Safety Information about BOTOX<sup>®</sup> on following pages.

## IMPORTANT SAFETY INFORMATION (continued)

### CONTRAINDICATIONS

BOTOX<sup>®</sup> 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.

BOTOX<sup>®</sup> is contraindicated for intradetrusor injection in patients with a urinary tract infection, or in patients with urinary retention, or post-void residual (PVR) urine volume > 200 mL who are not routinely performing clean intermittent self-catheterization (CIC).

### WARNINGS AND PRECAUTIONS

#### Spread of Toxin Effect

See Boxed Warning.

#### Lack of Interchangeability Between Botulinum Toxin Products

**The potency Units of BOTOX<sup>®</sup> 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<sup>®</sup> cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.**

#### 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<sup>®</sup> 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<sup>®</sup> to the site of injection and/or adjacent structures. In several of the cases, patients had preexisting 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<sup>®</sup>. The safety and effectiveness of BOTOX<sup>®</sup> 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<sup>®</sup> 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 Preexisting 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<sup>®</sup> (see *Warnings and Precautions*).

#### Dysphagia and Breathing Difficulties

Treatment with BOTOX<sup>®</sup> and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with preexisting 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<sup>®</sup> in Patients With Compromised Respiratory Status Treated for Detrusor Overactivity Associated With a Neurologic Condition

Patients with compromised respiratory status treated with BOTOX<sup>®</sup> for detrusor overactivity associated with a neurologic condition should be monitored closely.

#### Autonomic Dysreflexia in Patients Treated for Detrusor Overactivity Associated With a Neurologic Condition

Autonomic dysreflexia associated with intradetrusor injections of BOTOX<sup>®</sup> could occur in patients treated for detrusor overactivity associated with a neurologic condition and may require prompt medical therapy. In clinical trials, the incidence of autonomic

dysreflexia was greater in adult patients treated with BOTOX<sup>®</sup> 200 Units compared with placebo (1.5% vs 0.4%, respectively).

#### Urinary Tract Infections in Patients With Overactive Bladder

BOTOX<sup>®</sup> increases the incidence of urinary tract infection. Clinical trials for overactive bladder excluded patients with more than 2 UTIs in the past 6 months and those taking antibiotics chronically due to recurrent UTIs. Use of BOTOX<sup>®</sup> for the treatment of overactive bladder in such patients and in patients with multiple recurrent UTIs during treatment should only be considered when the benefit is likely to outweigh the potential risk.

#### Urinary Retention in Adults Treated for Bladder Dysfunction

Due to the risk of urinary retention, treat only patients who are willing and able to initiate catheterization post treatment, if required, for urinary retention.

In patients who are not catheterizing, post-void residual (PVR) urine volume should be assessed within 2 weeks post treatment and periodically as medically appropriate up to 12 weeks, particularly in patients with multiple sclerosis or diabetes mellitus. Depending on patient symptoms, institute catheterization if PVR urine volume exceeds 200 mL and continue until PVR falls below 200 mL. Instruct patients to contact their physician if they experience difficulty in voiding as catheterization may be required.

#### Overactive Bladder

In clinical trials, 6.5% of patients (36/552) initiated clean intermittent catheterization for urinary retention following treatment with BOTOX<sup>®</sup> 100 Units, as compared to 0.4% of patients (2/542) treated with placebo. The median duration of catheterization for patients treated with BOTOX<sup>®</sup> 100 Units was 63 days (minimum 1 day to maximum 214 days), as compared to a median duration of 11 days (minimum 3 days to maximum 18 days) for patients receiving placebo.

Patients with diabetes mellitus treated with BOTOX<sup>®</sup> were more likely to develop urinary retention than nondiabetics. In clinical trials, 12.3% of patients (10/81) with diabetes developed urinary retention following treatment with BOTOX<sup>®</sup> 100 Units vs 0% of patients (0/69) treated with placebo. In patients without diabetes, 6.3% of patients (33/526) developed urinary retention following treatment with BOTOX<sup>®</sup> 100 Units vs 0.6% of patients (3/516) treated with placebo.

#### Adult Detrusor Overactivity Associated With a Neurologic Condition

In clinical trials, 30.6% of adult patients (33/108) who were not using clean intermittent catheterization (CIC) prior to injection required catheterization for urinary retention following treatment with BOTOX<sup>®</sup> 200 Units, as compared to 6.7% of patients (7/104) treated with placebo. The median duration of postinjection catheterization for these patients treated with BOTOX<sup>®</sup> 200 Units (n = 33) was 289 days (minimum 1 day to maximum 530 days), as compared to a median duration of 358 days (minimum 2 days to maximum 379 days) for patients receiving placebo (n = 7).

Among adult patients not using CIC at baseline, those with multiple sclerosis were more likely to require CIC post injection than those with spinal cord injury.

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

#### Overactive Bladder

The most frequently reported adverse reactions for overactive bladder occurring within 12 weeks of injection include urinary tract infection (BOTOX<sup>®</sup> 18%, placebo 6%); dysuria (BOTOX<sup>®</sup> 9%, placebo 7%); urinary retention (BOTOX<sup>®</sup> 6%, placebo 0%); bacteriuria (BOTOX<sup>®</sup> 4%, placebo 2%); and residual urine volume (BOTOX<sup>®</sup> 3%, placebo 0%).

A higher incidence of urinary tract infection was observed in patients with diabetes mellitus treated with BOTOX<sup>®</sup> 100 Units and placebo than nondiabetics.

**IMPORTANT SAFETY INFORMATION (continued)**
**ADVERSE REACTIONS (continued)**
**Overactive Bladder (continued)**

The incidence of UTI increased in patients who experienced a maximum post-void residual (PVR) urine volume  $\geq$  200 mL following BOTOX<sup>®</sup> injection compared to those with a maximum PVR  $<$  200 mL following BOTOX<sup>®</sup> injection, 44% vs 23%, respectively.

**Adult Detrusor Overactivity Associated With a Neurologic Condition**

The most frequently reported adverse reactions within 12 weeks of BOTOX<sup>®</sup> injection for detrusor overactivity associated with a neurologic condition include urinary tract infection (BOTOX<sup>®</sup> 24%, placebo 17%); urinary retention (BOTOX<sup>®</sup> 17%, placebo 3%); and hematuria (BOTOX<sup>®</sup> 4%, placebo 3%).

The following adverse event rates were reported at any time following initial injection and prior to reinjection or study exit (median duration of 44 weeks of exposure): urinary tract infections (49%), urinary retention (17%), constipation (4%), muscular weakness (4%), dysuria (4%), fall (3%), gait disturbance (3%), and muscle spasm (2%).

**Pediatric Detrusor Overactivity Associated With a Neurologic Condition**

The most frequently reported adverse reactions during the 12 weeks following BOTOX<sup>®</sup> injection of 200 Units for pediatric detrusor overactivity associated with a neurologic condition include bacteriuria (20%), urinary tract infection (7%), leukocyturia (7%), and hematuria (3%).

The most common adverse reactions in patients who received BOTOX<sup>®</sup> 6 Units/kg and less than a total dose of 200 Units were urinary tract infection (UTI), bacteriuria, and hematuria.

These patients were not adequately managed with at least one anticholinergic agent and were using clean intermittent catheterization at baseline.

**Postmarketing Experience**

Adverse reactions that have been identified during postapproval use of BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.

**For more information on BOTOX<sup>®</sup>, please see the accompanying full [Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).**