URO

BOTOX® Billing and Coding for Urology

NOTE: The billing and coding information in this guide is gathered from third-party publicly available sources and is intended for reference only. Decisions regarding coding, medical necessity, and any documentation to support coverage are the responsibility of the healthcare provider and must be made considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. Nothing in this document is intended to serve as reimbursement guidance or treatment advice, a guarantee of coverage, or a guarantee of partial or full payment. Plans, coding, and coverage parameters issued by payers, including formularies, are subject to change without notice. Actual benefits are determined by the respective plan administrators. Check each patient's coverage with the applicable insurer. AbbVie does not endorse any individual plans. Coverage does not imply safety or efficacy.

INDICATIONS

Adult Bladder Dysfunction

Overactive Bladder

BOTOX® (onabotulinumtoxinA) 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 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 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 Important Safety Information about BOTOX® on the following pages.

Please see accompanying full Prescribing Information, including Boxed Warning, or visit https://www.rxabbvie.com/pdf/botox_pi.pdf

BOTOX® onabotulinumtoxinA injection

Within this guide are codes you may find helpful when billing payers. All coding decisions should be made by the healthcare provider based on an independent review of the patient's condition. Please note that payer policies regarding coverage vary. Check each patient's coverage with the applicable insurer.

Common codes for BOTOX® urology indications

PRODUCT CODES		
CODE TYPE	**CODE**	**CODE DEFINITION**
HCPCS II	J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-1145-01	BOTOX® 100 Unit vial
	00023-3921-02	BOTOX® 200 Unit vial

MODIFIER INFORMATION*,**	
JW Modifier	**Effective January 1, 2017**, Medicare requires providers to use the JW modifier (drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single-use vials that are appropriately discarded, and to document the discarded drug or biological in the patient's medical record.
JZ Modifier	**Effective July 1, 2023**, Medicare requires the JZ modifier on all claims for single-use vials where there are no discarded amounts.

CPT® CODE***,****		
CODE TYPE	**CODE**	**CODE DEFINITION**
CPT®	52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder

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).

*Modifier requirements for payers other than Medicare may vary—providers should check with their specific plans about policies.

**For more information on the JW and JZ modifiers, visit CMS.gov.

***CPT® codes submitted to the payer must describe the service(s) performed. Please check with your specific payer to determine the use of modifiers.

****CPT® codes and descriptors are derived from the American Medical Association (AMA) 2016 CPT® manual. These may include uses that are outside labeled indications.

[a]Some Medicare plans may require an approved secondary diagnosis from their policy. Reference your individual policy for guidance.

The information in this guide is for reference only, subject to change, and not intended to serve as reimbursement guidance or treatment advice, a guarantee of coverage, or a guarantee of partial or full payment. Check each patient's coverage with the applicable insurer.

INDICATIONS (continued)

Pediatric Detrusor Overactivity Associated With a Neurologic Condition

BOTOX 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.

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.

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Common codes for BOTOX® urology indications (continued)

DIAGNOSIS CODES		
	CODE	**CODE DEFINITION**
Diagnosis *ICD-10-CM* for Neurogenic Detrusor Overactivity (NDO)	N31.9[a]	Neuromuscular dysfunction of bladder, unspecified
Diagnosis *ICD-10-CM* for Overactive Bladder (OAB)	N32.81	Overactive bladder
	N39.41[a]	Urge incontinence
	N39.46[a]	Mixed incontinence

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® 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)

The information in this guide is for reference only, subject to change, and not intended to serve as reimbursement guidance or treatment advice, a guarantee of coverage, or a guarantee of partial or full payment. Check each patient's coverage with the applicable insurer.

For additional support, please contact your local Field Reimbursement Manager or visit BOTOXOneGo.com

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS (continued)
BOTOX is contraindicated for intradetrusor injection in patients with a urinary tract infection (UTI), 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 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.

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 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. The safety and effectiveness of BOTOX for unapproved uses have not been established.

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BOTOX® onabotulinumtoxinA injection

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 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 (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 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 in Patients With Compromised Respiratory Status Treated for Detrusor Overactivity Associated With a Neurologic Condition

Patients with compromised respiratory status treated with BOTOX 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 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 200 Units compared with placebo (1.5% vs 0.4%, respectively).

Urinary Tract Infections in Patients With Overactive Bladder

BOTOX increases the incidence of UTI. 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 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 posttreatment, if required, for urinary retention.

In patients who are not catheterizing, PVR urine volume should be assessed within 2 weeks posttreatment 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 CIC for urinary retention following treatment with BOTOX 100 Units, as compared to 0.4% of patients (2/542) treated with placebo. The median duration of catheterization for patients treated with BOTOX 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 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 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 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 CIC prior to injection required catheterization for urinary retention following treatment with BOTOX 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 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 postinjection 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 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 UTI (BOTOX 18%, placebo 6%); dysuria (BOTOX 9%, placebo 7%); urinary retention (BOTOX 6%, placebo 0%); bacteriuria (BOTOX 4%, placebo 2%); and residual urine volume (BOTOX 3%, placebo 0%).

A higher incidence of UTI was observed in patients with diabetes mellitus treated with BOTOX 100 Units and placebo than nondiabetics.

The incidence of UTI increased in patients who experienced a maximum PVR urine volume ≥200 mL following BOTOX injection compared to those with a maximum PVR <200 mL following BOTOX injection, 44% vs 23%, respectively.

Adult Detrusor Overactivity Associated With a Neurologic Condition

The most frequently reported adverse reactions within 12 weeks of BOTOX injection for detrusor overactivity associated with a neurologic condition include UTI (BOTOX 24%, placebo 17%); urinary retention (BOTOX 17%, placebo 3%); and hematuria (BOTOX 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): UTIs (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 injection of 200 Units for pediatric detrusor overactivity associated with a neurologic condition include bacteriuria (20%), UTI (7%), leukocyturia (7%), and hematuria (3%).

The most common adverse reactions in patients who received BOTOX 6 Units/kg and less than a total dose of 200 Units were UTI, bacteriuria, and hematuria.

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

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BOTOX® onabotulinumtoxinA injection

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS (continued)

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.

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US-BUO-250087 07/2025 031784