BOTOX® onabotulinumtoxinA injection

BOTOX® Billing and Coding
for Neurosciences

Cervical Dystonia, Blepharospasm, and Adult Spasticity

Indications

Spasticity

BOTOX® (onabotulinumtoxinA) for injection is indicated for the treatment of spasticity in patients 2 years of age and older.

Limitations of Use

BOTOX has not been shown to improve upper extremity functional abilities or range of motion at a joint affected by a fixed contracture.

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 older.

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

The information contained herein is gathered from third-party sources and is subject to change. This information is intended for reference only. Nothing in this document is intended to serve as reimbursement or legal advice, a guarantee of coverage, or a guarantee of payment for BOTOX®. Coding is a clinical decision, and the provider should code to the highest level of specificity.

Important Code Considerations

It is essential to diagnose and code correctly for BOTOX® therapy service(s) to help ensure timely and adequate reimbursement.

DRUG BILLING CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
HCPCS II	J0585[a]	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-1145-01[b]	BOTOX® 100 Unit vial
	00023-3921-02[b]	BOTOX® 200 Unit vial

[a]The descriptor for J0585 requires that BOTOX® be billed by number of Units, not number of vials.

[b]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 listed on the box (eg, 00023-1145-01).

IMPORTANT MODIFIERS INFORMATION	
JW Modifier	**Effective January 1, 2017**, Medicare required 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	**Beginning July 1, 2023**, CMS requires the use of the JZ modifier to indicate there were no Units of a drug discarded.

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

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

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.

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).

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Important Code Considerations (continued)

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 to be included in a Letter of Medical Necessity (LOMN) or Prior Authorization (PA)

CERVICAL DYSTONIA CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
ICD-10-CM	G24.3	Spasmodic torticollis
CPT®*	64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for Cervical Dystonia, spasmodic torticollis)

ADDITIONAL CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
Guidance	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)
Modifier	50	Bilateral procedure

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

IMPORTANT SAFETY INFORMATION (continued)
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 blepharospasm at the recommended dose (30 Units and below), severe primary axillary hyperhidrosis at the recommended dose (100 Units), strabismus, or for chronic migraine at the labeled doses 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.

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Important Code Considerations (continued)

BLEPHAROSPASM CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
ICD-10-CM	G24.5	Blepharospasm
CPT®*	64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for Blepharospasm, hemifacial spasm)
	67345	Chemodenervation of extraocular muscle

ADDITIONAL CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
Guidance	92265	Needle oculoelectromyography, 1 or more extraocular muscles, 1 or both eyes, with interpretation and report
Modifier	50	Bilateral procedure

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

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 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.

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 Spasticity or for Detrusor Overactivity Associated With a Neurologic Condition
Patients with compromised respiratory status treated with BOTOX for spasticity or detrusor overactivity associated with a neurologic condition 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.

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Important Code Considerations (continued)

ADULT SPASTICITY CODES		
TYPE	***ICD-10-CM* CODE**	**CODE DESCRIPTOR**
For Adult Upper Limb Spasticity and Adult Lower Limb Spasticity	G81.11	Spastic hemiplegia affecting right dominant side
	G81.12	Spastic hemiplegia affecting left dominant side
	G81.13	Spastic hemiplegia affecting right nondominant side
	G81.14	Spastic hemiplegia affecting left nondominant side
	G82.51	Quadriplegia, C1-C4 complete
	G82.52	Quadriplegia, C1-C4 incomplete
	G82.53	Quadriplegia, C5-C7 complete
	G82.54	Quadriplegia, C5-C7 incomplete
For Adult Lower Limb Spasticity	G83.10 – G83.14	Monoplegia of lower limb
For Adult Upper Limb Spasticity and Adult Lower Limb Spasticity	I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
	I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
	I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
	I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
	I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
	I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
	I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
	I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
	I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
	I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
	I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

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.

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Important Code Considerations (continued)

ADULT SPASTICITY CODES (continued)		
TYPE	***ICD-10-CM* CODE**	**CODE DESCRIPTOR**
For Adult Upper Limb Spasticity and Adult Lower Limb Spasticity	I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
	I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right nondominant side
	I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left nondominant side
	I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right nondominant side
	I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left nondominant side
	I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right nondominant side
	I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left nondominant side
	I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right nondominant side
	I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left nondominant side
For Adult Upper Limb Spasticity	I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
	I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
	I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
	I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
	I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
	I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
	I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
	I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
	I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
	I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
	I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult 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%).

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Important Code Considerations (continued)

ADULT SPASTICITY CODES (continued)		
TYPE	***ICD-10-CM* CODE**	**CODE DESCRIPTOR**
For Adult Upper Limb Spasticity	I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
	I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right nondominant side
	I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left nondominant side
	I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right nondominant side
	I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left nondominant side
	I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right nondominant side
	I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left nondominant side
	I69.333	Monoplegia of upper limb following cerebral infarction affecting right nondominant side
	I69.334	Monoplegia of upper limb following cerebral infarction affecting left nondominant side
	I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right nondominant side
	I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left nondominant side
	I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right nondominant side
	I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left nondominant side
For Adult Lower Limb Spasticity	I69.041 – I69.044, I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
	I69.141 – I69.144, I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
	I69.341 – I69.344, I69.349	Monoplegia of lower limb following cerebral infarction

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity (continued)
In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX (2% at 300 Units to 400 Units total dose) compared to placebo (1%). In pediatric patients treated for upper limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX (17% at 6 Units/kg and 10% at 3 Units/kg) compared to placebo (9%). In pediatric patients treated for lower limb spasticity, upper respiratory tract infection was not reported with an incidence greater than placebo.

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Important Code Considerations (continued)

ADULT SPASTICITY CODES (continued)		
TYPE	***ICD-10-CM* CODE**	**CODE DESCRIPTOR**
For Adult Lower Limb Spasticity	I69.841 – I69.844, I69.849	Monoplegia of lower limb following other cerebrovascular disease
	I69.941 – I69.944, I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
	I69.041 – I69.044, I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
	I69.141 – I69.144, I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
	I69.341 – I69.344, I69.349	Monoplegia of lower limb following cerebral infarction
	I69.841 – I69.844, I69.849	Monoplegia of lower limb following other cerebrovascular disease
	I69.941 – I69.944, I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
	I69.041 – I69.044, I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
	I69.141 – I69.144, I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
	I69.341 – I69.344, I69.349	Monoplegia of lower limb following cerebral infarction
	I69.841 – I69.844, I69.849	Monoplegia of lower limb following other cerebrovascular disease
	I69.941 – I69.944, I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
For Adult Upper Limb Spasticity and Adult Lower Limb Spasticity	I69.861 – I69.865, I69.869	Other paralytic syndrome following other cerebrovascular disease

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

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).

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Important Code Considerations (continued)

ADULT SPASTICITY CODES (continued)		
TYPE	**CODE**	**CODE DESCRIPTOR**
CPT®	64642 + 64643	Chemodenervation of one extremity; 1-4 muscle(s) Each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)
	64644 + 64645	Chemodenervation of one extremity; 5 or more muscle(s) Each additional extremity, 5 or more muscle(s) (list separately in addition to code for primary procedure)

ADDITIONAL CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
Guidance	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)
Ultrasound Guidance	76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

For additional support, please contact your local Reimbursement Business Advisor or visit www.BOTOXONEGO.com

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

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).

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BOTOX® onabotulinumtoxinA injection

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Adult Detrusor Overactivity Associated With a Neurologic Condition (continued)
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.

Chronic Migraine
The most frequently reported adverse reactions following injection of BOTOX for chronic migraine vs placebo include, respectively, neck pain (9% vs 3%); headache (5% vs 3%); eyelid ptosis (4% vs <1%); migraine (4% vs 3%); muscular weakness (4% vs <1%); musculoskeletal stiffness (4% vs 1%); bronchitis (3% vs 2%); injection-site pain (3% vs 2%); musculoskeletal pain (3% vs 1%); myalgia (3% vs 1%); facial paresis (2% vs 0%); hypertension (2% vs 1%); and muscle spasms (2% vs 1%).

Adult Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Adult 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.

Pediatric Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX in pediatric upper limb spasticity include upper respiratory tract infection (includes upper respiratory tract infection and viral upper respiratory tract infection), injection-site pain, nausea, constipation, rhinorrhea, nasal congestion, and seizure (includes seizure and partial seizure).

Pediatric Lower Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX in pediatric lower limb spasticity include injection-site erythema, injection-site pain, oropharyngeal pain, ligament sprain, skin abrasion, and decreased appetite.

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 (1% after inferior rectus injections, 16% after horizontal rectus injections, and 38% after superior rectus injections) and vertical deviation (17%).

Primary Axillary Hyperhidrosis
The most frequently reported adverse events (3%-10% of adult patients) following injection of BOTOX for severe primary axillary hyperhidrosis in double-blind studies include injection-site pain and hemorrhage, nonaxillary sweating, infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety.

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.

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

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