BOTOX® onabotulinumtoxinA injection

BOTOX® Billing and Coding for Pediatric Spasticity

Indication

Spasticity

BOTOX® 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.

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 on following pages.

Important Codes

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).

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 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.

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 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.

Please see additional Important Safety Information on following pages.

Important Codes (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)

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.

PEDIATRIC UPPER LIMB SPASTICITY CODES

TYPE	CODE	CODE DESCRIPTOR
For Pediatric Upper Limb Spasticity Caused by Cerebral Palsy	G80.2	Spastic hemiplegic cerebral palsy
For Pediatric Upper Limb Spasticity Following Stroke	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
	I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
	I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
	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
	I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
	I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side

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.

Please see additional Important Safety Information on following pages.

Important Codes (continued)

PEDIATRIC UPPER LIMB SPASTICITY CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
For Pediatric Upper Limb Spasticity Following Stroke	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
	I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
	I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-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
	I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
	I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-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
	I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
	I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side

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 (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*).

Please see additional Important Safety Information on following pages.

Important Codes (continued)

PEDIATRIC UPPER LIMB SPASTICITY CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
For Pediatric Upper Limb Spasticity Following Stroke	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
	I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
	I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-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
	I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
	I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-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
	I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
	I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side

*Contact payers to confirm their reporting preferences. Check payer guidelines regarding the definition of site, coding, and use of modifiers. *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 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)
WARNINGS AND PRECAUTIONS (continued)

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.

Upper Respiratory Tract Infections in Patients Treated for Spasticity
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.

Please see additional Important Safety Information on following pages.

Important Codes (continued)

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

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- 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)

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PEDIATRIC LOWER LIMB SPASTICITY CODES

TYPE	CODE	CODE DESCRIPTOR
For Pediatric Lower Limb Spasticity Caused by Cerebral Palsy	G80.0	Spastic quadriplegic cerebral palsy
	G80.1	Spastic diplegic cerebral palsy
	G80.2	Spastic hemiplegic cerebral palsy
For Pediatric Lower Limb Spasticity Following Stroke	I69.041	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
	I69.042	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
	I69.043	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
	I69.044	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
	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
	I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side

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

Please see additional Important Safety Information on following pages.

Important Codes (continued)

PEDIATRIC LOWER LIMB SPASTICITY CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
For Pediatric Lower Limb Spasticity Following Stroke	I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
	I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
	I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side
	I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
	I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-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
	I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
	I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
	I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
	I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
	I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
	I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

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

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).

Please see additional Important Safety Information on following pages.

Important Codes (continued)

PEDIATRIC LOWER LIMB SPASTICITY CODES		
TYPE	**CODE**	**CODE DESCRIPTOR**
For Pediatric Lower Limb Spasticity Following Stroke	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
	I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
	I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
	I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
	I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
	I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
	I69.344	Monoplegia of upper limb following cerebral infarction affecting left non-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
	I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
	I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side

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IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

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.

Please see additional Important Safety Information on following pages.

Important Codes (continued)

PEDIATRIC SPASTICITY CODES		
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
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)
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.

Please see additional Important Safety Information on following page.

BOTOX®
onabotulinumtoxinA injection

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

IMPORTANT SAFETY INFORMATION (continued)

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.

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