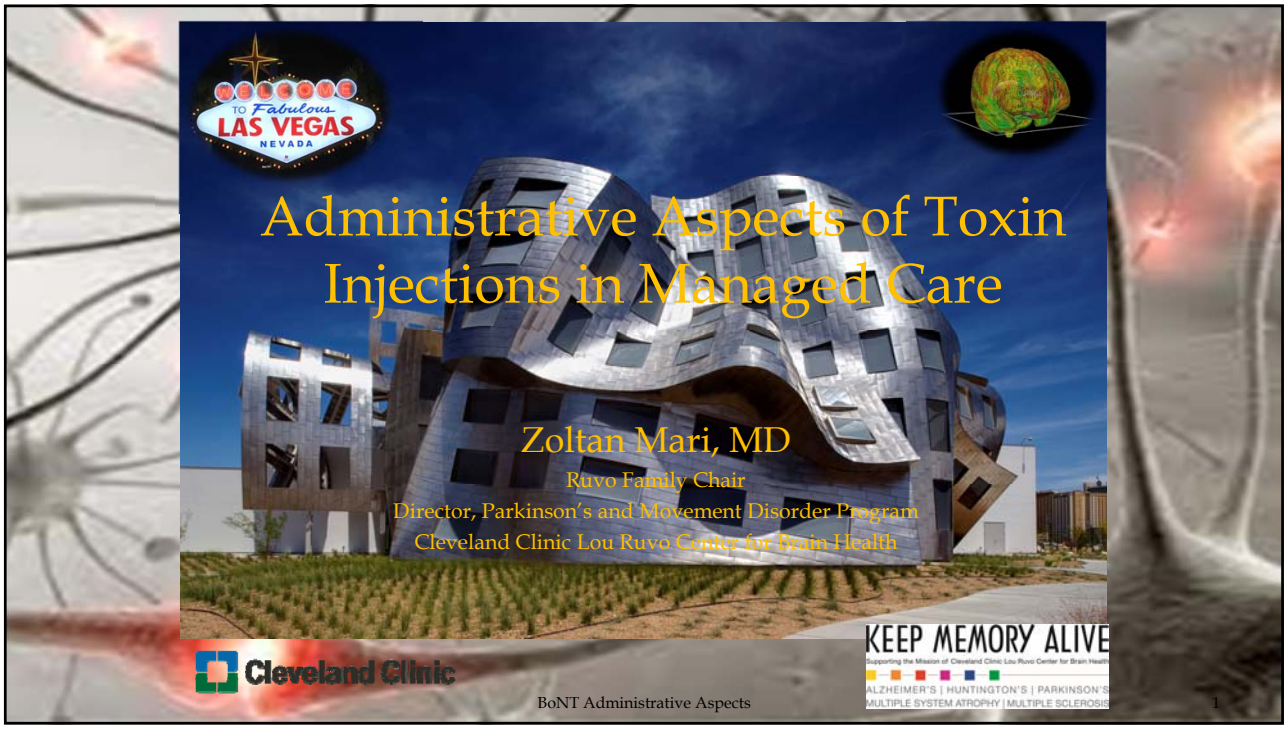

Administrative Aspects of Toxin Injections in Managed Care

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Cleveland Clinic

KEEP MEMORY ALIVE
ALZHEIMER'S | HUNTINGTON'S | PARKINSON'S
MULTIPLE SYSTEM ATROPHY | MULTIPLE SCLEROSIS

Overview

- Introduction
  - Therapeutic uses
  - Toxin brands
- Consenting
  - Proper consenting
  - Sample consents
- Coding and Billing
  - Proper coding practices
  - Updates
- Documentation

Botulinum Toxins: Perspective on Development

- Availability of new brands and serotypes
  - OnabotulinumtoxinA
  - RimabotulinumtoxinB
  - AbobotulinumtoxinA
  - IncobotulinumtoxinA
  - Several other brands are available outside the US and/or currently in the process of being developed for the US market – in various stages of clinical trial testing
- Expanding list of possible uses
  - Close to 100 uses described in all areas of medicine
  - Only a few receiving approval of government agencies
  - Introduction of ICD-10 codes increased specificity

Approved indications in US

OnabotulinumtoxinA
Blepharospasm, CD, UE & LE spasticity in adults and children >2y, chronic migraine, overactive bladder, detrusor overactivity, axillary hyperhidrosis, strabismus, wrinkles

AbobotulinumtoxinA
CD, UE & LE spasticity in adults and children >2y, wrinkles

IncobotulinumtoxinA
Blepharospasm, CD, wrinkles

RimabotulinumtoxinB
CD, sialorrhea

There are many CPT codes associated with these many different indications/uses of botulinum toxins

Know Your Botulinum Toxin!

Be familiar with the brand of BoNT

Storage, vial size, dosing, serotype

(also be familiar with coding)

LABEL SYRINGE WITH TYPE AND CONCENTRATION


SPECIAL ARTICLE

Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review)

Report of the Therapeutics and Technology Assessment Subcomm

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ABSTRACT

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Review

Evidence-based review and assessment of botulinum neurotoxin for the treatment of movement disorders

Mark Hallett, Alberto Albanese, Dirk Dressler, Karen R. Segal, David M. Simpson, Daniel Truong

Neurology

The Official Journal of the American Academy of Neurology

Home | Current Issue | All Issues | Ahead of Print | Special Interest

Special Article

Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache

Report of the Guideline Development Subcommittee of the American Academy of Neurology

Evidence-Based Reviews

Evidence-Based Review: Focal Dystonia

Disorder	Conclusions	Recommend	Limitations
Cervical dystonia	Established safe and effective	A	No effective alternative
Blepharospasm	Probably effective	A	No effective alternative
Arm/hand dystonia	Probably effective	B	No effective alternative
Leg/foot dystonia	Data inadequate	None	No effective alternative
Spasmodic dysphonia (adductor)	Probably effective	B	No effective alternative

Simpson et al. *Neurology.* 2016:86:18181-1826.

Evidence-Based Review: Spasticity and Headache

Disorder	Conclusions	Recommend	Limitations
Upper-limb spasticity	Established safe and effective	A	
Lower-limb spasticity	Established safe and effective	A	
Chronic migraine	Established safe and effective	A	Decreases number of headache days, but magnitude of difference is small
Episodic migraine	Ineffective	A	

Simpson et al. *Neurology.* 2016:86:18181-1826.

BoNT Clinical Uses: Approved and Proposed

- Ophthalmologic
  - Strabismus
  - Nystagmus
  - Apraxia of eyelid opening
- Dystonia
  - Blepharospasm
  - Cervical dystonia
  - Spasmodic dysphonia
  - Oromandibular dystonia
  - Limb dystonia
- Spasticity
  - Arm/hand
  - Leg
    - Post-stroke
    - Multiple sclerosis
    - Cerebral palsy (CP)
  - Spinal cord injury
  - Other neurological disorders
- Hemifacial spasm
- Palatal myoclonus
- Tremor
- Tics
- Parkinson's disease/CBD
  - Freezing gait
  - Clenched fist
- Pain/Headache
  - Chronic migraine
  - Tension headache
  - Episodic Migraine
  - Fibromyalgia
  - Low-back pain
  - Radiculopathy
  - Neuropathies
  - Neuralgias
- Gastrointestinal disorders
  - Achalasia
  - Anal sphincter spasm
- Gyn/Urological
  - Vaginismus
  - Urinary sphincter spasm
  - Chronic pelvic pain
  - Spastic bladder
  - OAB
- Sialorrhea
- Stuttering
- Glabellar lines
- Hyperhidrosis

Legend
Blue = Probably ineffective
Yellow = Approved for at least 1 brand
Green = Not established but used clinically

Price Comparisons

Brand	Vial Size	Price/Vial	Code
onabotulinumtoxinA	100 U 200 U	$601.00 $1,202.00	J0585 (per 1 U)
abobotulinumtoxinA	300 U 500 U	$515.00 $859.00	J0586 (per 5 U)
incobotulinumtoxinA	50 U 100 U 200 U	$253.00 $482.00 $964.00	J0588 (per 1 U)
rimabotulinumtoxinB	2,500 U 5,000 U 10,000 U	$290.50 $581.00 $1,162.00	J0587 (per 100 U)

Please note that "billing unit" is not the same as "drug unit", except for onabotulinumtoxinA and incobotulinumtoxinA – for the other 2 it is different!!!

Informed Consent #1

Although the specific definition of informed consent may vary from state to state, it basically means that a physician (or other medical provider) must tell a patient all of the potential benefits, risks, and alternatives involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient's written consent to proceed. The concept is based on the principle that a physician has a duty to disclose information to the patient so he or she can make a reasonable decision regarding treatment.

http://healthcare.findlaw.com/patient-rights/understanding-informed-consent-a-primer.html

Informed Consent #2

QuickSafety

An advisory on safety & quality issues

Issue 21 February 2016

Informed consent: More than getting a signature

Issue:

There are numerous challenges to implementing an effective informed consent process – that is, one in which the patient fully understands the health care treatment or surgical procedure they are agreeing to undergo. Even after signing a consent form, patients frequently do not understand the risks, benefits and alternatives involved in their course of treatment or surgical procedure – all of which are imperative for a patient to provide valid authorization.[1,2]

Stated simply, informed consent in medical care is a *process of communication* between a clinician and a patient that results in the patient's authorization or agreement to undergo a specific medical intervention (see sidebar box for The Joint Commission's glossary definition). In addition to the process of communicating to their patients, clinicians are concerned with obtaining the evidence of consent that serves to document their legal and ethical responsibility.

Informed consent: *Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.*

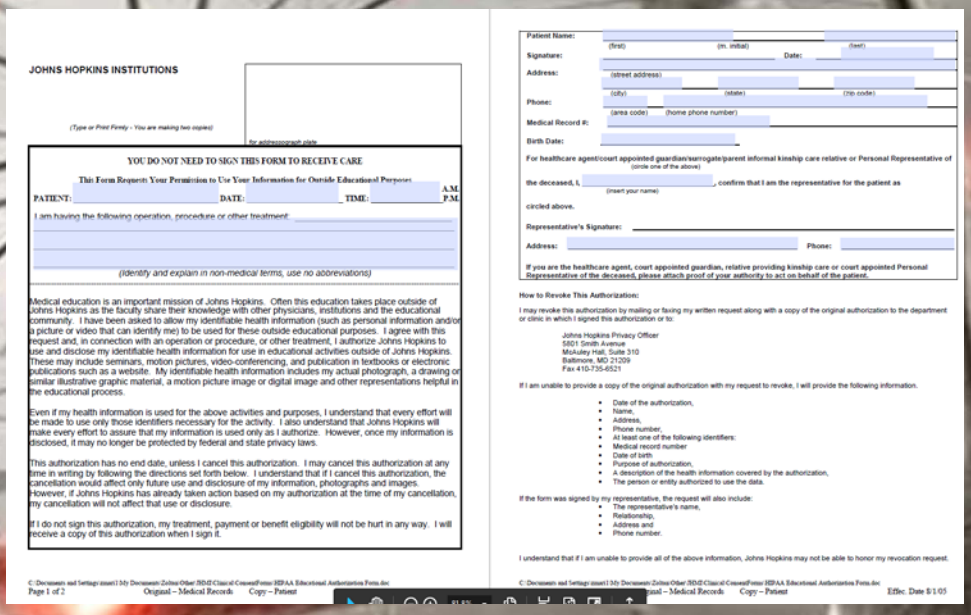
Source: The Joint Commission. 2016. Comprehensive Accreditation Manual glossary.

Unfortunately, the emphasis on obtaining a patient's signature as documentation of informed consent results in varying effectiveness of the communication between a clinician and a patient.[1,2,3] Communication issues are the most frequent root cause of serious adverse events reported to The Joint Commission's sentinel event database. The process of obtaining informed consent is an essential aspect of patient-centered care and remains central to patient safety. The Joint Commission's Sentinel Event database includes 44 reports since 2010 of informed consent-related sentinel events; 32 of the reports were specifically related to wrong site surgery, and five were related to operative or post-operative complication. Other reports were related to elopement, falls, medication errors and suicide.

Informed Consent #3

- Strongly recommended, but per informal survey in 2012 only ~50% of injectors used it
- May be a consent for each injection session or can be a "serial" consent, usually covering 1 yr
- Can be a generic consent with effectively no specific information documented in the ICF text, can be highly individualized to the specific procedure (risks vary), or anything in between, including fill-in fields
- Should be part of the medical record – not required to give a copy to patient (as in research)

Sample Consent: Generic



JOHNS HOPKINS INSTITUTIONS

(Type or Print Firmly - You are making two copies)

for addressograph plate

YOU DO NOT NEED TO SIGN THIS FORM TO RECEIVE CARE

This Form Requests Your Permission to Use Your Information for Outside Educational Purposes

PATIENT: _____ DATE: _____ TIME: _____ A.M. P.M.

I am having the following operation, procedure or other treatment:

(Identify and explain in non-medical terms, use no abbreviations)

Medical education is an important mission of Johns Hopkins. Often this education takes place outside of Johns Hopkins as the faculty share their knowledge with other physicians, institutions and the educational community. I have been asked to allow my identifiable health information (such as personal information and/or a picture or video that can identify me) to be used for these outside educational purposes. I agree with this request and, in connection with an operation or procedure, or other treatment, I authorize Johns Hopkins to use and disclose my identifiable health information for use in educational activities outside of Johns Hopkins. These may include seminars, motion pictures, video-conferencing, and publication in textbooks or electronic publications such as a website. My identifiable health information includes my actual photograph, a drawing or similar illustrative graphic material, a motion picture image or digital image and other representations helpful in the educational process.

Even if my health information is used for the above activities and purposes, I understand that every effort will be made to use only those identifiers necessary for the activity. I also understand that Johns Hopkins will make every effort to assure that my information is used only as I authorize. However, once my information is disclosed, it may no longer be protected by federal and state privacy laws.

This authorization has no end date, unless I cancel this authorization. I may cancel this authorization at any time in writing by following the directions set forth below. I understand that if I cancel this authorization, the cancellation would affect only future use and disclosure of my information, photographs and images. However, if Johns Hopkins has already taken action based on my authorization at the time of my cancellation, my cancellation will not affect that use or disclosure.

If I do not sign this authorization, my treatment, payment or benefit eligibility will not be hurt in any way. I will receive a copy of this authorization when I sign it.

C:\Documents and Settings\user1\My Documents\Zebra\Other JSM\Clinical Consent\Forms\ HIPAA Educational Authorization Form.doc

Page 1 of 2 Original – Medical Records Copy – Patient

Patient Name: (first) (m. initial) (last)

Signature: Date:

Address: (street address) (city) (state) (zip code)

Phone: (area code) (home phone number)

Medical Record #:

Birth Date:

For healthcare agent/court appointed guardian/surrogate/parent informal kinship care relative or Personal Representative of (circle one of the above)

the deceased, I _____ (insert your name), confirm that I am the representative for the patient as circled above.

Representative's Signature: _____

Address: Phone:

If you are the healthcare agent, court appointed guardian, relative providing kinship care or court appointed Personal Representative of the deceased, please attach proof of your authority to act on behalf of the patient.

How to Revoke This Authorization:

I may revoke this authorization by mailing or faxing my written request along with a copy of the original authorization to the department or clinic in which I signed this authorization or to:

Johns Hopkins Privacy Officer
5801 Smith Avenue
McAuley Hall, Suite 310
Baltimore, MD 21209
Fax 410-735-6521

If I am unable to provide a copy of the original authorization with my request to revoke, I will provide the following information.

- Date of the authorization,
- Name,
- Address,
- Phone number,
- At least one of the following identifiers:
- Medical record number
- Date of birth
- Purpose of authorization,
- A description of the health information covered by the authorization,
- The person or entity authorized to use the data.

If the form was signed by my representative, the request will also include:

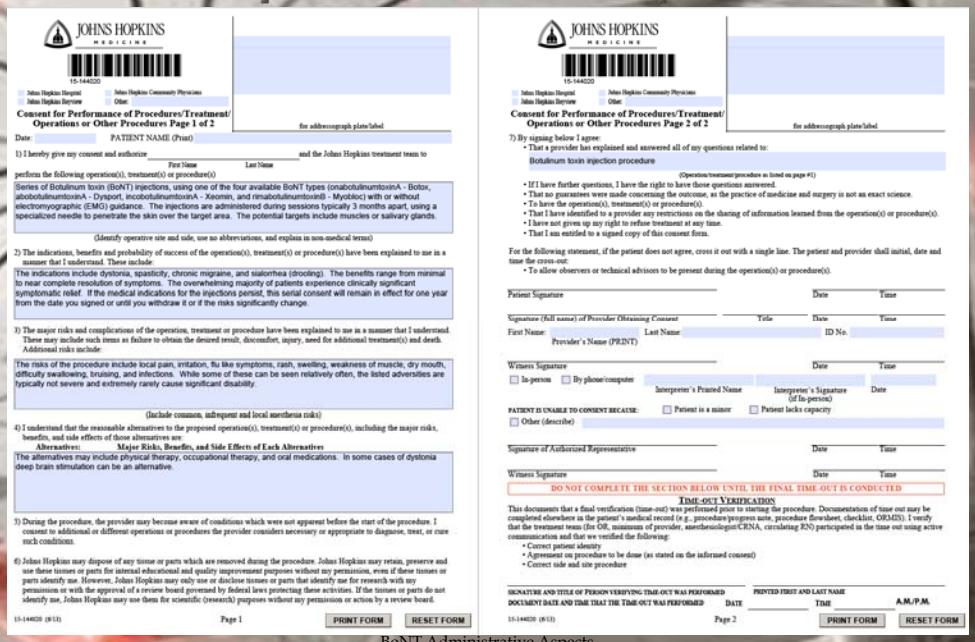
- The representative's name,
- Relationship,
- Address and
- Phone number.

I understand that if I am unable to provide all of the above information, Johns Hopkins may not be able to honor my revocation request.

C:\Documents and Settings\user1\My Documents\Zebra\Other JSM\Clinical Consent\Forms\ HIPAA Educational Authorization Form.doc

Original – Medical Records Copy – Patient Effec. Date 8/1/05

Sample Consent: Specific



JOHNS HOPKINS MEDICINE

15-144020

Consent for Performance of Procedures/Treatment/ Operations or Other Procedures Page 1 of 2

for addressograph plate/label

Date: PATIENT NAME (Print)

1) I hereby give my consent and authorize _____ and the Johns Hopkins treatment team to
First Name Last Name
perform the following operation(s), treatment(s) or procedure(s)

Series of Botulinum toxin (BoNT) injections, using one of the four available BoNT types (onabotulinumtoxinA - Botox, abobotulinumtoxinA - Dysport, incobotulinumtoxinA - Xeomin, and rimabotulinumtoxinB - Myobloc) with or without electromyographic (EMG) guidance. The injections are administered during sessions typically 3 months apart, using a specialized needle to penetrate the skin over the target area. The potential targets include muscles or salivary glands.

(Identify operative site and side, use no abbreviations, and explain in non-medical terms)

2) The indications, benefits and probability of success of the operation(s), treatment(s) or procedure(s) have been explained to me in a manner that I understand. These include:

The indications include dystonia, spasticity, chronic migraine, and sialorrhea (drooling). The benefits range from minimal to near complete resolution of symptoms. The overwhelming majority of patients experience clinically significant symptomatic relief. If the medical indications for the injections persist, this serial consent will remain in effect for one year from the date you signed or until you withdraw it or if the risks significantly change.

3) The major risks and complications of the operation, treatment or procedure have been explained to me in a manner that I understand. These may include such items as failure to obtain the desired result, discomfort, injury, need for additional treatment(s) and death. Additional risks include:

The risks of the procedure include local pain, irritation, flu like symptoms, rash, swelling, weakness of muscle, dry mouth, difficulty swallowing, bruising, and infections. While some of these can be seen relatively often, the listed adversities are typically not severe and extremely rarely cause significant disability.

(Include common, infrequent and local anesthesia risks)

4) I understand that the reasonable alternatives to the proposed operation(s), treatment(s) or procedure(s), including the major risks, benefits, and side effects of those alternatives are:

Alternatives: **Major Risks, Benefits, and Side Effects of Each Alternatives**

The alternatives may include physical therapy, occupational therapy, and oral medications. In some cases of dystonia deep brain stimulation can be an alternative.

5) During the procedure, the provider may become aware of conditions which were not apparent before the start of the procedure. I consent to additional or different operations or procedures the provider considers necessary or appropriate to diagnose, treat, or cure such conditions.

6) Johns Hopkins may dispose of any tissue or parts which are removed during the procedure. Johns Hopkins may retain, preserve and use these tissues or parts for internal educational and quality improvement purposes without my permission, even if these tissues or parts identify me. However, Johns Hopkins may only use or disclose tissues or parts that identify me for research with my permission or with the approval of a review board governed by federal laws protecting these activities. If the tissues or parts do not identify me, Johns Hopkins may use them for scientific (research) purposes without my permission or action by a review board.

15-144020 (8/13) Page 1 PRINT FORM RESET FORM

JOHNS HOPKINS MEDICINE

15-144020

Consent for Performance of Procedures/Treatment/ Operations or Other Procedures Page 2 of 2

for addressograph plate/label

7) By signing below I agree:

- That a provider has explained and answered all of my questions related to:

Botulinum toxin injection procedure

(Operation/treatment/procedure as listed on page #1)

- If I have further questions, I have the right to have those questions answered.
- That no guarantees were made concerning the outcome, as the practice of medicine and surgery is not an exact science.
- To have the operation(s), treatment(s) or procedure(s).
- That I have identified to a provider any restrictions on the sharing of information learned from the operation(s) or procedure(s).
- I have not given up my right to refuse treatment at any time.
- That I am entitled to a signed copy of this consent form.

For the following statement, if the patient does not agree, cross it out with a single line. The patient and provider shall initial, date and time the cross-out:

- To allow observers or technical advisors to be present during the operation(s) or procedure(s).

Patient Signature Date Time

Signature (full name) of Provider Obtaining Consent Title Date Time

First Name: Last Name: ID No.
Provider's Name (PRINT)

Witness Signature Date Time

☐ In-person ☐ By phone/computer Interpreter's Printed Name Interpreter's Signature (If In-person) Date

PATIENT IS UNABLE TO CONSENT BECAUSE: ☐ Patient is a minor ☐ Patient lacks capacity

☐ Other (describe)

Signature of Authorized Representative Date Time

Witness Signature Date Time

DO NOT COMPLETE THE SECTION BELOW UNTIL THE FINAL TIME-OUT IS CONDUCTED

TIME-OUT VERIFICATION

This documents that a final verification (time-out) was performed prior to starting the procedure. Documentation of time out may be completed elsewhere in the patient's medical record (e.g., procedure/progress note, procedure flowsheet, checklist, ORMIS). I verify that the treatment team (for OR, minimum of provider, anesthesiologist/CRNA, circulating RN) participated in the time out using active communication and that we verified the following:

- Correct patient identity
- Agreement on procedure to be done (as stated on the informed consent)
- Correct side and site procedure

SIGNATURE AND TITLE OF PERSON VERIFYING TIME-OUT WAS PERFORMED PRINTED FIRST AND LAST NAME

DOCUMENT DATE AND TIME THAT THE TIME-OUT WAS PERFORMED DATE TIME A.M./P.M.

15-144020 (8/13) Page 2 PRINT FORM RESET FORM

Consent Form Summary

- There are no universal guidelines
- Please consult your institution's risk management team or medico-legal officer or in practice your medico-legal adviser regarding the specifics and if available, conform to the practice's or institution's generic format
- While written and signed ICFs are highly encouraged, if your institution/practice does not do it, make sure your documentation clearly states that you obtained verbal consent

Which of the following statements about a procedure consent for BoNT injections is correct?

a. Signed informed consent is required for dystonia, but not spasticity injections, as consenting is only necessary for on-label diagnoses.
b. Only the patient herself or himself may sign the consent for BoNT injections, even if they lack capacity.
c. The text of the BoNT procedural informed consent is included in the label and should not be modified by the injector's institution
d. Signed informed consent for each BoNT injection session is highly recommended, but not universally required or practiced.
e. Signed informed consent is only recommended when EMG guidance is part of the BoNT injection procedure.

Which of the following statements about the purpose of the signed informed consent is correct?

a. The primary purpose of BoNT informed consents is to provide the patient with post-procedure instructions.
b. One of the purposes of the BoNT informed consent is to keep the IRB informed about the number of procedures performed at the institution.
c. The signed informed consent aims to document permission from the patient or their authorized representative for the procedure.
d. The signed paper consent has no purpose anymore as the details of the procedure are otherwise documented in the electronic chart.
e. The sole purpose of informed consenting is legal, to minimize liability to the manufacturer.

Coding and Billing: Procedure Codes #1

CPT 64611	Submandibular/Parotid
CPT 64612	Head/Face
CPT 64613	Neck (Deleted after 1/1/14)
CPT 64614	Limb/Trunk (Deleted after 1/1/14)
CPT 64615	Chronic migraine
CPT 64650	Axillary (hyperhidrosis)
CPT 64653	Other area (hyperhidrosis)

…"new" (2014) codes…

Coding and Billing: Procedure Codes #2: "New" Codes for the Muscles of the Neck

64616:

Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis)

(To report a bilateral procedure, use modifier 50*)

64617:

Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed.

(To report a bilateral procedure, use modifier 50*)

*Please consult your billing team – modifier 51 could also be used in a multi-line way for bilateral procedures and proper/recommended use of these modifiers could vary

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*	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-1145-01[b]	BOTOX® 100 Unit vial
	00023-3921-02[b]	BOTOX® 200 Unit vial

*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.

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

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

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
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

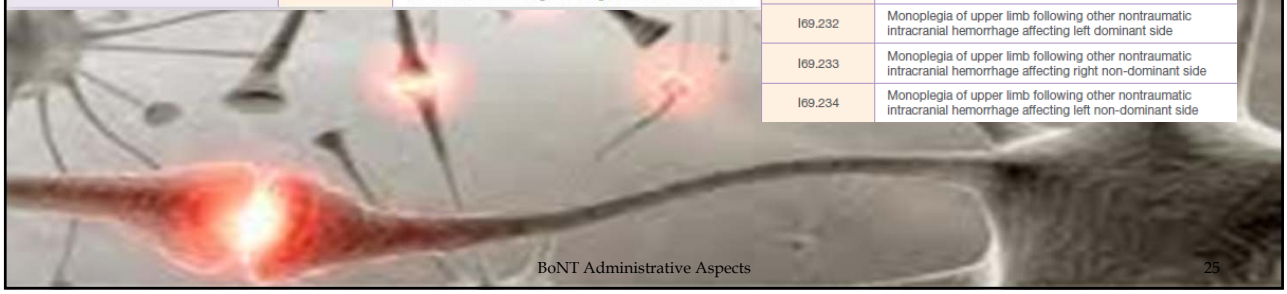
ADULT SPASTICITY CODES (continued)

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
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
For Adult Upper Limb Spasticity and 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
	I69.861 – I69.865, I69.869	Other paralytic syndrome following other cerebrovascular disease

PEDIATRIC UPPER LIMB SPASTICITY CODES

TYPE	CODE	CODE DESCRIPTOR
For Pediatric Upper Limb Spasticity Due to 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

CODE	CODE DESCRIPTOR
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



PEDIATRIC LOWER LIMB SPASTICITY CODES

TYPE	CODE	CODE DESCRIPTOR
For Pediatric Lower Limb Spasticity Following Stroke	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

CODE	CODE DESCRIPTOR
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

CPT 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

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)

Migraine Codes

CODE TYPE	CODE	CODE DEFINITION
HCPCS II	J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
NDC	00023-3921-02	BOTOX® 200 Unit vial
PROCEDURE CODE		
*CPT®**	64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
DIAGNOSIS CODES **Please see full Indications and Important Limitations on following pages.**		
Diagnosis *ICD-10-CM*	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

Note: For electronic billing, payers require an 11-digit NDC number [5-4-2 configuration] 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].

Contact payers to confirm their reporting preferences and determine which procedure code to use. Check payer guidelines regarding the definition of site, coding, and use of modifiers.

CPT® codes and descriptors are copyrighted by the AMA. These 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.

This piece is being provided in response to inquiries relative to the identification of drug codes, diagnosis codes, and procedure codes.

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) and 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). *CPT®* codes submitted to the payer must describe the service(s) preformed. 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.

Chemodenervation of Muscles of the Trunk

Trunk muscles include the erector spinae and paraspinal muscles, rectus abdominus and obliques.

All other somatic muscles are extremity muscles, head muscles, or neck muscles.

- 64646 Chemodenervation of trunk muscle(s); 1-5 muscle(s)
- 64647 Chemodenervation of trunk muscle(s); 6 or more muscle(s)

(Report either 64646 or 64647 only once per session)

Chemodenervation of Muscles of One or More Extremity(ies)

64642 Chemodenervation of one extremity; 1-4 muscle(s)
+64643 Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s)
(Use 64643 in conjunction with 64642, 64644)

64644 Chemodenervation of one extremity; 5 or more muscle(s)
+64645 Chemodenervation of one extremity; each additional extremity, 5+ muscle(s)
(Use 64645 in conjunction with 64644)

Note: 64642-64645 can be reported together up to a combined total of four units of service per patient when all four extremities are injected.

(Do not report modifier 50 in conjunction with 64642-64645)

Definition of a Site

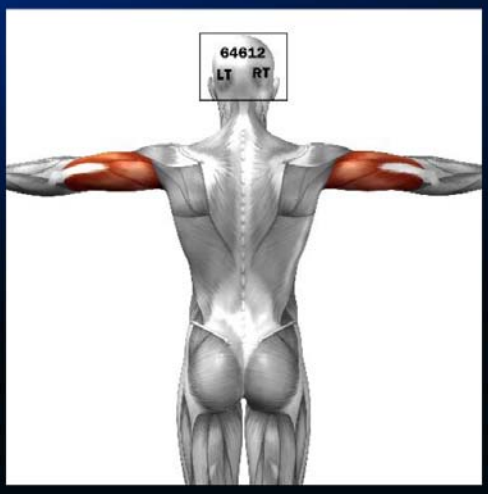
Medicare will allow payment for one injection per site regardless of the number of injections made into the site.

Examples:

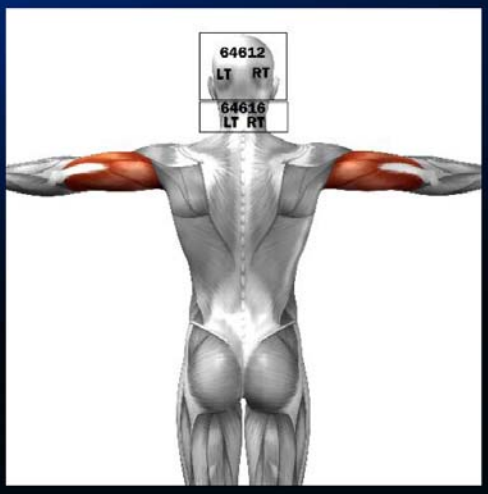
Face right or left; defined as one eye (including all muscles surrounding the eye including both upper and lower lids) one side of the face.

Limb; defined as all muscles of one limb and their associated girdle muscles.

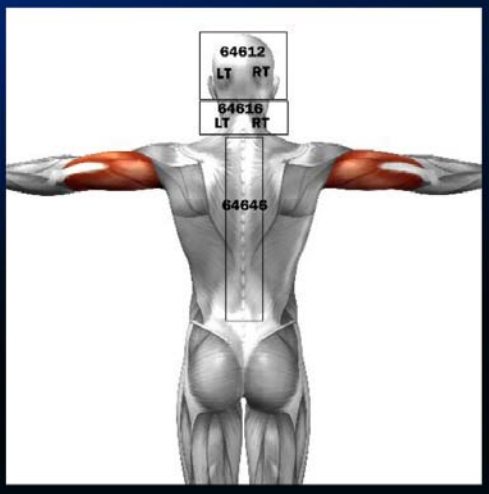
Head/Face



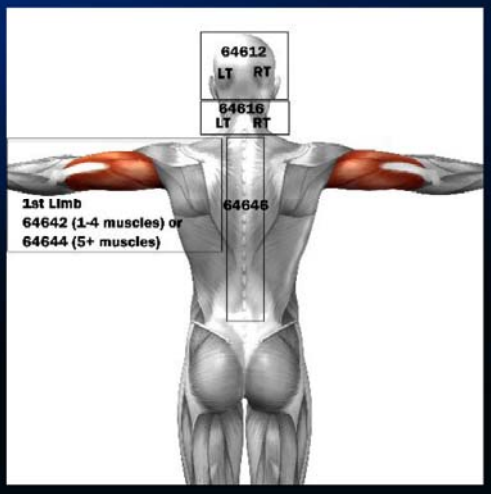
Neck



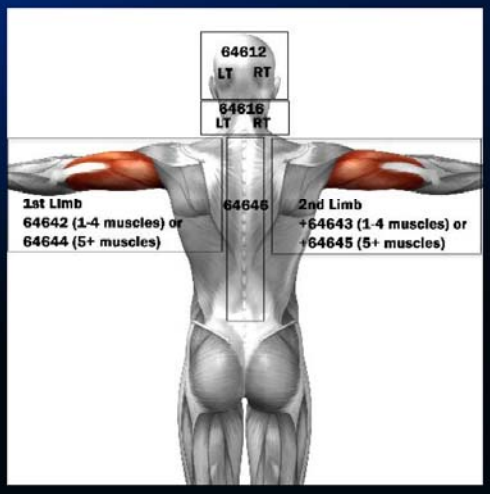
Trunk



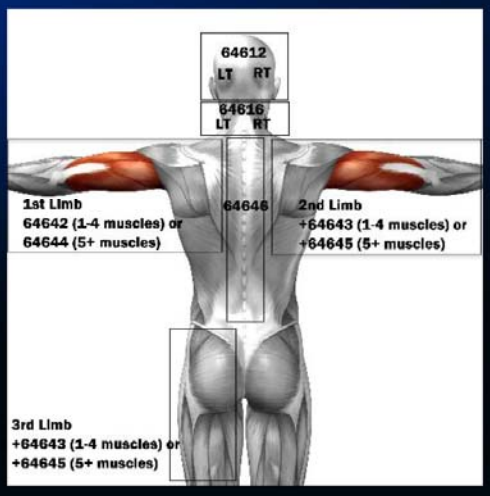
1st Limb



2nd Limb

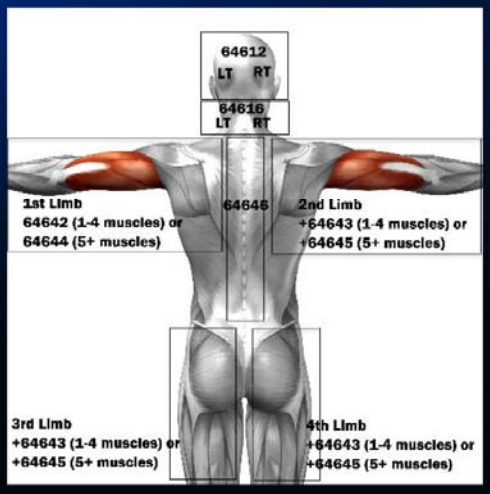


3rd Limb



In case of multiple limb injections with limbs on both sides, modifier -50 (bilateral injections) may be used (recognition of modifiers varies).

4th Limb



In case of multiple limb injections with injected muscle numbers varying between 1-4 and 5+, there is one instance of "1st limb" code (either 64642 or 64644) and all subsequent limbs are billed using secondary codes (64643 or 64645, depending on the # of muscles injected).

Anatomic Guidance CPT Codes

- 95874 EMG Guidance for BTX
- 95873 Muscle Stimulation
- 76942 Ultrasound guided injection

*Each code should be used once per session.

*Private insurances will typically cover any combination of guidance used. Medicare will pay for either EMG or muscle stimulation but not both.

The Use of Modifiers

- Right -RT
- Left -LT
- Bilateral -50
- Multiple sites -51
- Same side, different site -57
- Other procedure -59
- Procedure with E/M -25
- Wastage (as of 1/1/17) -JW

Simultaneous use of -50 and -51 is possible! Recognition of modifiers may vary, but is a way to increase the level of your billing specificity.

Which of the following statements about BoNT billing practices is correct?

a. It is acceptable practice to select a number of 64*** codes even if some are not technically applicable, because the insurance company will pay for whatever they like to pay for anyway.
b. Salivary gland injections (for sialorrhea) are billed using a single-line 64611 code without a modifier for laterality (LT or RT).
c. The migraine injection protocol strictly includes 31 injection sites and is billed using the 64615 code for each side separately (64615,LT and 64615,RT).
d. It any E&M component occurred simultaneously with the BoNT injection procedure, it is acceptable to bill for it additionally to the procedure code, time-based, with a -25 modifier, using the total face-to-face time of the entire visit.
e. It is not allowed to use multiple different 64*** codes for the same injection session, even if muscles in multiple different body parts were part of the regimen.

Chronic Migraine

ICD10:	G43.719
Jcode:	J0585/Ona (200 u)
Muscles	Paradigm
CPT	64615

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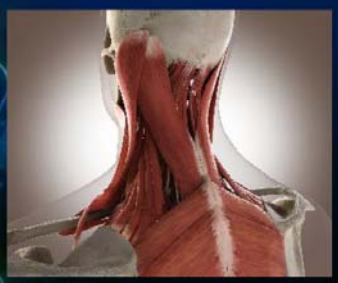
Cervical Dystonia



ICD10:	G24.3, G24.1
Jcode:	J0588/Inco (400 u)
EMG:	95874

Muscles injected	CPT
Left splenius	64616-LT
Right SCM	64616-RT
Levator Scapulae (below C7)	64642

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Spasticity

ICD10:	G81.11, G81.14
Jcode:	J0586/Abo (1,000 u)
EMG/E-stim:	95874/95873

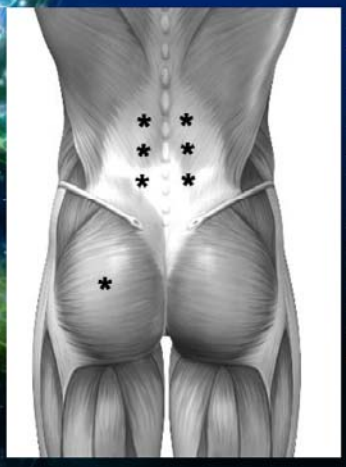
Muscles injected	CPT
Right FF, FCR, FCU, biceps, pect	64644
Left FCR, biceps	+64643
Right gastroc, post tib	+64643

Cervicothoracic Myofascial Pain/Spasm

ICD10	M63.838, M54.6
Jcode:	J0585 (100 u)
EMG:	95874

Muscles injected	CPT
RT Cervical Paraspinal	64616
RT Thoracic Paraspinal	64646
Levator Scapulae (below C7)	64642

Piriformis/Low Back



ICD10:	G57.0/M62.838
Jcode:	J0587/Rima (20,000 u)
EMG:	95874
Ultrasound:	76942

Muscles injected	**CPT**
Left lumbar	64646
Right lumbar	no charge
Left piriformis	64642

Botulinum Toxin Billing and Coding Pearls

- Always perform prior-authorization
- Don't forget to link your ICD9 and CPT codes
- Avoid charging an E/M with an injection
- Some insurances **require** specialty pharmacy
- Be aware of which insurance carriers in your area allow for injections to be performed every twelve weeks (84 days) vs every 90 days or 13 weeks (such as Medicare) to ensure payment
- Don't forget to bill for wastage
- Perform regular chart reviews

Documentation #1

- Critically important – must match coded procedure
- Consider developing templates (see a few examples after this slide)
- If your EMR allows copy-forward make sure you update the note accordingly!
- Document wastage
- Document use of guidance techniques
- Some E&M is meant to be included in procedures! – if you are to bill an E&M code with procedure, justify it plentifully

Documentation #2

- Review medical necessity requirements for key payers
- Include such medical necessity language/payer guidelines in your template
- Ensure your ICD-10 diagnostic codes are on label for the toxin you use (of note, Medicare treats all 'A' toxin brands as equal)
- Include details on how non-injection treatments were exhausted
- Details, details, details – the more details you include (anatomical descriptions, drawings, added clinical rationale – including rationale for change from previous injections, guidance details – such as EMG description, time, time-out, who was present, etc)

Which of the following statements about documentation of BoNT injections is correct?

a. It is sufficient to provide minimal documentation in the procedure note, because the CPT code informs about what was performed anyway.
b. The documentation in the procedure note must include the rationale explaining why the patient is an injection candidate, the toxin brand used, a detailed summary of the injected muscle selection, and whether EMG or US guidance was used.
c. It is not necessary to document the rationale, as that should be obvious from the referral record.
d. It is acceptable and common practice to inject patients on first visit, if they have not been previously injected elsewhere, as long as the insurance company is informed afterwards.
e. Pre-certification of coverage for BoNT injections is not required for any of the private insurances and is discouraged because they might deny payment as the procedure documentation is not yet available.

Conclusions

- Observe the appropriate on-label indications and carefully consider off-label but otherwise standard practice use of botulinum toxins
- Informed consenting is optional, but strongly recommended
- Documentation of the procedure is critically important, including indications and rationale for candidacy, precise description of what was done, the patient's consent, and complications
- Proper billing should include the most recent ICD-10 and CPT codes and must be in line with documentation