MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy
Botulinum Toxin Injections

Table of Contents

Policy Number: 006

BCBSA Reference Number: 5.01.05 & 8.01.19

Related Policies

- Formulary Exception Form #434

Prior Authorization Information

Policy	☒ **Prior Authorization** ☐ Step Therapy ☐ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**4/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ **Rx (Specialty Network Access)** ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

Botulinum is a family of toxins produced by the anaerobic organism *Clostridia botulinum.* Multiple formulations of botulinum toxin have been approved by the U.S. Food and Drug Administration (FDA). Labeled indications of these agents differ. Botulinum toxin products are also used for a range of off-label indications. This is a comprehensive policy covering the preferred covered formulary agents as well as covered label and off-label indications.

BCBSMA formulary status of botulinum toxin agents is as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	FDA-approved Covered Indication
Preferred Toxins		
Botox™ (onabotulinumtoxin a)	Preferred; PA required	Overactive bladder, Urinary incontinence, Limb spasticity, Chronic migraine, Cervical dystonia, Severe axillary hyperhidrosis, Blepharospasm, Strabismus, Chronic sialorrhea
Dysport™ (botulinum toxin a)	Preferred; PA required	Limb spasticity, Cervical dystonia
Non-Preferred Toxins		
Myobloc™ (rimabotulinumtoxin b)	Non-Preferred; PA required	Cervical dystonia, Chronic sialorrhea
Xeomin® **(**incobotulinumtoxin a)	Non-Preferred; PA required	Limb spasticity, Cervical dystonia, Blepharospasm, Chronic sialorrhea
Daxxify	Non-Preferred; PA required	Cervical Dystonia

PA – Prior Authorization; NFNC – Non-formulary Non-covered

Policy

Length of Approval	12 months
Formulary status	Trial and failure of a preferred toxin (Botox, or Dysport) is required before coverage of a non-Preferred toxin (Daxxify, Myobloc or Xeomin). for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Criteria for On-label/FDA-approved indications

On-label/FDA-approved indications implies at least 1 of the 4 FDA approved botulinum toxin agents are approved for the indications below.

Please Note: Trial and failure of a preferred toxin like Botox, or Dysport is required before coverage of a non-preferred toxin like Daxxify, Myobloc or Xeomin. For requests that do not meet this criteria and the following clinical criteria of this policy and an exception is required, please see section labeled Individual Consideration for additional information on next steps.

Botulinum toxin may be considered **MEDICALLY NECESSARY** for the following indications when the corresponding criteria are met:

1. **Treatment of cervical dystonia** (spasmodic torticollis; applicable whether congenital, due to childbirth injury, or traumatic injury) when **ALL** of the following criteria are met:
    a. Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; **AND**
    b. A history of recurrent involuntary contraction of 1 or more of the muscles of the neck, e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles.

2. **Treatment of dystonia resulting in functional impairment** (interference with joint function, mobility, communication, nutritional intake) and/or pain in individuals with **ANY** of the following:
    a. Focal upper-limb dystonia (eg, organic writer's cramp); **OR**
    b. Oromandibular dystonia (orofacial dyskinesia, Meige syndrome); **OR**
    c. Laryngeal dystonia (adductor spasmodic dysphonia); **OR**
    d. Idiopathic (primary or genetic) torsion dystonia; **OR**
    e. Symptomatic (acquired) torsion dystonia.
3. **Treatment of upper and lower limb spasticity as well spastic conditions related to:**
    a. Cerebral palsy
    b. Stroke
    c. Acquired spinal cord or brain injury
    d. Hereditary spastic paraparesis
    e. Spastic hemiplegia
    f. Neuromyelitis optica.
4. **Multiple sclerosis or Schilder disease**

    (For additional details on dystonia and spastic condition, see "A" in the Policy Guidelines section).
5. **Treatment of overactive bladder** with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
6. **Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition** (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
7. **Prophylaxis of chronic migraine headache in the following situations:**

    Initial approval duration – 6 months
    a. Initial 6-month trial when the following criteria is met:
        i. Age 18 years and older; **AND**
        ii. Prescribed by a neurologist, ophthalmologist, or board-certified headache medicine specialist; **AND**
        iii. Meet International Classification of Headache Disorders diagnostic criteria for chronic migraine headache (i.e., ≥ 15 days/month with duration ≥ 4 hours/day); **AND**
        iv. At least 3-month trial with an inadequate response; OR an adverse reaction; OR a contraindication to at **least TWO** different classes of medications recommended for preventive treatment of migraines (e.g., beta blocker, anti-depressants, antihypertensives, calcium channel blockers, anticonvulsants)
    b. Continuing treatment beyond 6 months - may be re-authorized when the following criteria is met:
        i. Migraine headache frequency reduced by at least 7 days per month compared with pretreatment level; **OR**
        ii. Migraine headache duration reduced at least 100 hours per month compared with pretreatment level

(For additional details on chronic migraine headache, see "B" in the Policy Guidelines section).

8. **Treatment of axillary hyperhidrosis and palmar hyperhidrosis when the following criteria are met:**

    a. Patient is 18 years of age or older

    b. Diagnosis of severe primary axillary or palmar hyperhidrosis that is inadequately managed with topical agents (e.g., aluminum chloride)

9. **Treatment of blepharospasm associated with dystonia** or facial nerve (VII) disorders (including hemifacial spasm).
10. **Treatment of strabismus** or misalignment of the eyes (e.g., esotropia, exotropia, hypertropia, hypotropia, etc.)
11. **Treatment of chronic sialorrhea**

    a. Chronic sialorrhea associated with amyotrophic lateral sclerosis or atypical parkinsonian disorders or cerebral palsy or Parkinson disease or stroke or traumatic brain injury; **AND**

    b. has experienced excessive salivation for 3 or more months; **AND**

    c. Refractory to at least 2 months of continuous treatment with at least 1 oral pharmacotherapy (e.g., anticholinergics).

Criteria for Off-label Indications

Off-label use implies none of the 4 FDA approved botulinum toxin agents are approved or preferred for the indications.

Botulinum toxin may be considered **MEDICALLY NECESSARY** for:

1. **Treatment of esophageal achalasia** in individuals who have not responded to dilation therapy or who are considered poor surgical candidates.
2. **Treatment of chronic anal fissure** in individuals with a history of failure, contraindication, or intolerance to 1 of the following conventional therapies: a. topical nitrates b. topical calcium channel blockers (e.g., diltiazem, nifedipine).
3. **Treatment of individuals with Hirschsprung disease** who develop obstructive symptoms after a pull-through operation.

Use of botulinum toxin is considered **INVESTIGATIONAL** for all other indications not specifically mentioned above, including, but not limited to:

1. Neurological indications such as

    a. Headaches, except as noted above for prevention of chronic migraine headache including maintenance therapy

    b. Essential tremor

    c. Tinnitus

    d. Chronic motor tic disorder and tics associated with Tourette syndrome (motor tics).

2. Urological indications such as

a. Benign prostatic hyperplasia
b. Interstitial cystitis
c. Detrusor sphincteric dyssynergia (after spinal cord injury).

3. Pain due to multiple etiologies such as

a. Chronic low back pain
b. Joint pain
c. Mechanical neck disorders
d. Neuropathic pain after neck dissection
e. Myofascial pain syndrome
f. Temporomandibular joint disorders
g. Trigeminal neuralgia
h. Pain after hemorrhoidectomy or lumpectomy
i. Lateral epicondylitis
j. Prevention of pain associated with breast reconstruction after mastectomy.

4. Ano-rectal conditions such as

a. Internal anal sphincter achalasia
b. Animus

5. Other miscellaneous conditions such as

a. Gastroparesis
b. Facial wound healing
c. Depression.

6. Treatment of wrinkles or other cosmetic indications.
7. Treatment for severe gustatory hyperhidrosis

Use in specific populations

For patient safety, we do not cover any type of botulinum injections for:

- Patients who are on aminoglycoside therapy, as it may increase the risk of problems between the muscles and the nerves.
- Patients with retrobulbar hemorrhages sufficient to compromise retinal circulation.
- Patients with severe laryngeal or respiratory weakness
- Patients with sensitivity or allergy to any type of botulinum injections or known high antibody titers to any type of botulinum injections.

Policy Guidelines

A. Dystonia is a general term describing a state of abnormal or disordered tonicity of muscle. As an example, achalasia is a dystonia of the lower esophageal sphincter, while cervical dystonia is also known as torticollis. Spasticity is a subset of dystonia, describing a velocity-dependent increase in

tonic-stretch reflexes with exaggerated tendon jerks. Spasticity typically is associated with injuries to the central nervous system. Spasticity is a common feature of cerebral palsy.

B. International Classification of Headache Disorders (ICHD-3) diagnostic criteria for chronic migraine headache include the following:

Headaches at least 15 days per month for more than 3 months; have features of migraine headache on at least 8 days.

Features of migraine headache:

- Lasts 4 to 72 hours.
- Has at least 2 of the following 4 characteristics:
  - Unilateral
  - Pulsating
  - Moderate or severe pain intensity
  - Aggravates or causes avoidance of routine physical activity.
- Associated with:
  - Nausea and/or vomiting
  - Photophobia and phonophobia.

(In ICHD-2, absence of medication overuse was 1 of the diagnostic criteria for chronic migraine. In the ICHD-3, this criterion was removed from the chronic migraine diagnosis and "medication overuse headache" is now a separate diagnostic category.)

Continuing treatment with botulinum toxin beyond 6 months for chronic migraine includes the following:

The policy includes the requirement that migraine headache frequency be reduced by at least 7 days per month compared with pretreatment level, or that migraine headache duration be reduced by at least 100 hours per month compared with pretreatment level in order to continue treatment beyond 6 months. The 7 days per month represents a 50% reduction in migraine days for individuals who have the lowest possible number of migraine days (ie, 15) that would allow them to meet the ICHD-3 diagnostic criteria fewest chronic migraine. A 50% reduction in frequency is a common outcome measure for assessing the efficacy of headache treatments.

Individual Consideration (Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital

Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

CPT Codes / HCPCs Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
C9160	Injection, daxibotulinumtoxina-lanm, 1 unit (DAXI)
J0585	Injection, onabotulinumtoxin A, 1 unit (Botox)
J0587	Injection, rimabotulinumtoxin B, 100 units (Myobloc)
J0586	Injection, abobotulinumtoxin A, 5 units (Dysport)
J0588	Injection, incobotulinumtoxin A, 1 unit (Xeomin)

Background

Botulinum Toxins

This policy refers to the following botulinum toxin types A and B drug products: abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), onabotulinumtoxinA (Botox), and rimabotulinumtoxinB (Myobloc). PrabotulinumtoxinA-xvfs (Jeuveau®) was approved by the U.S. Food and Drug Administration (FDA) on February 1, 2019 for cosmetic use and is considered out of scope of the review.

Regulatory Status

On December 9, 1989, onabotulinumtoxinA (Botox) was approved by the FDA for treatment of ocular dystonias. Since then, its use has been expanded for multiple indications.

On December 8, 2000, rimabotulinumtoxinB (Myobloc) was approved by the FDA for treatment of cervical dystonias. Since then, its use has also been expanded for multiple indications.

On April 29, 2009, abobotulinumtoxinA (Dysport) was approved by the FDA for treatment of cervical dystonias. Since then, its use has been expanded for multiple indications.

On July 30, 2010, incobotulinumtoxinA (Xeomin) was approved by the FDA for treatment of cervical dystonias and blepharospasm. Since then, its use has been expanded for multiple indications.

Summary of Evidence

For individuals who have esophageal achalasia who fail initial treatment with medications who receive botulinum toxin injections, the evidence includes 2 meta-analyses that included RCTs comparing endoscopic PD or laparoscopic myotomy with botulinum toxin. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The systematic review reported that PD, as well as laparoscopic myotomy, afforded a higher and statistically significant greater symptom remission rates. OnabotulinumtoxinA was not associated with any serious adverse events while PD resulted in perforation in a few cases. While the evidence was suggestive that PD and surgical myotomy are definitive therapies for esophageal achalasia and are associated with superior long-term outcomes compared with botulinum toxin A, in patients who are not good candidates for PD and/or surgical myotomy, botulinum toxin A may be a reasonable option. Further, botulinum toxin injection has the advantage of being less invasive as compared with surgery and can be easily performed during routine endoscopy. Initial success rates with botulinum toxin are comparable to PD and surgical myotomy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic anal fissure who fail medical treatment who receive botulinum toxin injections, the evidence includes 2 meta-analyses. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The results of 2 meta-analyses suggest that sphincterotomy is a more effective treatment option for chronic anal fissure compared with botulinum toxin A and is associated with a significantly higher healing rate as well as a lower recurrence rate. However, these meta-analyses report

higher fecal incontinence rates with surgical procedures. Since botulinum toxin A injections are less invasive and do not require the internal sphincter muscle to be divided and, thereby, reduce the risk of fecal incontinence, the injections are preferred for patients who are not good surgical candidates or who want to minimize the likelihood of incontinence. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Hirschsprung disease who develop obstructive symptoms after a pull-through operation who receive botulinum toxin injections, the evidence includes 5 case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The 5-case series included a total of 135 patients with a median follow-up of more than 7 years. In 2 out of the 5 published case series, consistent short-term responses were reported in more than 75% of patients. Long-term follow-up is suggestive of durability of response. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other indications such as neurological indications (non-migraine headaches, essential tremor, tinnitus), urological indications (benign prostatic hyperplasia, interstitial cystitis), pain due to multiple etiologies, other ano-rectal conditions (internal anal sphincter achalasia, anismus) and miscellaneous other conditions (gastroparesis, depression, facial wound healing) who receive botulinum toxin injections, the evidence includes case series and RCTs. Relevant outcomes are symptoms, functional outcomes, medication use, and treatment-related morbidity. Generally, botulinum toxin has been evaluated in clinical settings where patients have failed the standard of care or in whom standard of care interventions are contraindicated. However, in multiple indications with high prevalence rates (e.g., benign prostatic hyperplasia, low back pain, depression, tinnitus, etc.), where multiple effective treatments supported by an adequate quality evidence base are available, studies using a placebo comparator that lack scientific rigor do not permit conclusions about the net health benefit of botulinum toxin. Future studies in these clinical indications should use appropriate comparators in adequately powered prospective studies using a standardized treatment dose and adequate follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary axillary hyperhidrosis who receive botulinum toxin type A or B, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebo-controlled randomized trials have generally found better outcomes in the botulinum toxin groups. Meta-analyses have showed that botulinum toxin injections significantly decreased sweating in the short (2 to 4 weeks) and long term (16 weeks), and significantly improved Hyperhidrosis Disease Severity Scale scores. Several RCTs have compared different botulinum toxin type A formulations with botulinum toxin type A and B formulations in patients with axillary hyperhidrosis. Although these studies had small sample sizes, their findings suggested that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
4/2024	Updated to remove Pregnancy as a reason for denial.
1/2024	Clarified coding information.
11/2023	Reformatted policy.
9/2023	Reformatted policy. Updated IC to align with 118E MGL § 51A. Updated criteria for treatment of severe hyperhidrosis for clarity. Updated to include new FDA-approved toxin - Daxxify
6/2023	Updated template. Updated approved indications to include blepharospasms and examples of strabismus. Removed age criteria of 5 years and older for treatment of urinary incontinence
7/2021	Updated to include Botox & Dysport preferred.
4/2021	Updated detrusor overactivity criteria with age and clarified coding in strabismus and blepharospasm.

12/2020	BCBSA National medical policy review. No changes to policy statements. New references added.
10/2020	Clarified coding information
4/2020	Updated Chronic Migraine preventative medication list and definition.
11/2019	Updated to include new indications and criteria for Dysport.
8/2019	Updated to include new FDA indication - the treatment of upper limb spasticity in pediatric patients 2 to 17 years of age.
11/2018	BCBSA National medical policy review. No changes to policy statements. New references added.
11/2018	Updated new FDA indication for chronic sialorrhea.
6/2018	Updated to clarify coverage and to add Specialty Pharmacy link.
1/2018	Updated to add Dysport's updated spasticity FDA indication.
07/2017	Updated to Prefer Dysport & Botox and to include hyperhidrosis to this policy and retired policy 405. Clarified coding information.
11/2015	Clarified coding information.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
3/2014	Updated to include adding the sub specialty of board certified headache medicine.
1/2014	Updated to remove Blue Value.
12/2012	Updated to add new CPT code 64615 effective 1/1/2013.
10/2012	Updated to reclassify as a pharmacy medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
7/2012	Updated to clarify coverage criteria and coding for Dysport™ (abobotulinumtoxin A), add diagnosis codes for cervical dystonia, clarify the patient safety section, and add ophthalmologist under migraine criteria.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
5/2011	Updated to include coverage criteria for new FDA approved indication of migraine for Botox
2/2011	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2010	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
12/2010	Updated to include coverage criteria for new FDA-approved product Xeomin® (incobotulinumtoxin A).
6/2010	Updated to include coverage criteria for new FDA-approved product Dysport™ (abobotulinumtoxin A).
6/2010	BCBSA National medical policy review. Changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2010	Updated to include 10/1 UM requirements.
12/2009	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
12/2009	Updated to remove coverage of Botulinum Type B, Myobloc™ for all types of hyperhidrosis.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.

1/2009	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2008	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2007	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2007	BCBSA National medical policy review. Changes to policy statements.
1/1/2001	New policy, effective 1/1/2001, describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use ref
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

Endnotes

1. FDA-approved indications
2. From National Blue Cross Blue Shield Association policy 5.01.05
3. Local Medicare policy http://www.medicarenhic.com/ and CMS guidelines http://www.hcfa.gov/pubforms/14%5Fcar/3b2049.htm#_1_7.

References

#5.01.05

1. Leyden JE, Moss AC, MacMathuna P. Endoscopic pneumatic dilation versus botulinum toxin injection in the management of primary achalasia. Cochrane Database Syst Rev. 2014; (12): CD005046. PMID 25485740
2. Wang L, Li YM, Li L. Meta-analysis of randomized and controlled treatment trials for achalasia. Dig Dis Sci. Nov 2009; 54(11): 2303-11. PMID 19107596
3. Smith CD, Stival A, Howell DL, et al. Endoscopic therapy for achalasia before Heller myotomy results in worse outcomes than heller myotomy alone. Ann Surg. May 2006; 243(5): 579-84; discussion 584-6. PMID 16632991

4. Chen HL, Woo XB, Wang HS, et al. Botulinum toxin injection versus lateral internal sphincterotomy for chronic anal fissure: a meta-analysis of randomized control trials. Tech Coloproctol. Aug 2014; 18(8): 693-8. PMID 24500725
5. Nelson RL, Thomas K, Morgan J, et al. Non surgical therapy for anal fissure. Cochrane Database Syst Rev. Feb 15 2012; (2): CD003431. PMID 22336789
6. Koivusalo AI, Pakarinen MP, Rintala RJ. Botox injection treatment for anal outlet obstruction in patients with internal anal sphincter achalasia and Hirschsprung's disease. Pediatr Surg Int. Oct 2009; 25(10): 873-6. PMID 19662428
7. Minkes RK, Langer JC. A prospective study of botulinum toxin for internal anal sphincter hypertonicity in children with Hirschsprung's disease. J Pediatr Surg. Dec 2000; 35(12): 1733-6. PMID 11101725
8. Patrus B, Nasr A, Langer JC, et al. Intrasphincteric botulinum toxin decreases the rate of hospitalization for postoperative obstructive symptoms in children with Hirschsprung disease. J Pediatr Surg. Jan 2011; 46(1): 184-7. PMID 21238663
9. Svetanoff WJ, Lopez J, Aguayo P, et al. The impact of botulinum injection for hospitalized children with Hirschsprung-associated enterocolitis. Pediatr Surg Int. Oct 2021; 37(10): 1467-1472. PMID 34309717
10. Roorda D, Oosterlaan J, van Heurn E, et al. Intrasphincteric botulinum toxin injections for post-operative obstructive defecation problems in Hirschsprung disease: A retrospective observational study. J Pediatr Surg. Aug 2021; 56(8): 1342-1348. PMID 33288128
11. Han-Geurts IJ, Hendrix VC, de Blaauw I, et al. Outcome after anal intrasphincteric Botox injection in children with surgically treated Hirschsprung disease. J Pediatr Gastroenterol Nutr. Nov 2014; 59(5): 604-7. PMID 25000353
12. Bendtsen L, Evers S, Linde M, et al. EFNS guideline on the treatment of tension-type headache - report of an EFNS task force. Eur J Neurol. Nov 2010; 17(11): 1318-25. PMID 20482606
13. Wieckiewicz M, Grychowska N, Zietek M, et al. Evidence to Use Botulinum Toxin Injections in Tension-Type Headache Management: A Systematic Review. Toxins (Basel). Nov 15 2017; 9(11). PMID 29140286
14. Bogduk N, Govind J. Cervicogenic headache: an assessment of the evidence on clinical diagnosis, invasive tests, and treatment. Lancet Neurol. Oct 2009; 8(10): 959-68. PMID 19747657
15. Hanno PM, Erickson D, Moldwin R, et al. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. J Urol. May 2015; 193(5): 1545-53. PMID 25623737
16. Jackson JL, Kuriyama A, Hayashino Y. Botulinum toxin A for prophylactic treatment of migraine and tension headaches in adults: a meta-analysis. JAMA. Apr 25 2012; 307(16): 1736-45. PMID 22535858
17. Silberstein SD, Gobel H, Jensen R, et al. Botulinum toxin type A in the prophylactic treatment of chronic tension-type headache: a multicentre, double-blind, randomized, placebo-controlled, parallel-group study. Cephalalgia. Jul 2006; 26(7): 790-800. PMID 16776693
18. Linde M, Hagen K, Salvesen O, et al. Onabotulinum toxin A treatment of cervicogenic headache: a randomised, double-blind, placebo-controlled crossover study. Cephalalgia. May 2011; 31(7): 797-807. PMID 21300635
19. Braker C, Yariv S, Adler R, et al. The analgesic effect of botulinum-toxin A on postwhiplash neck pain. Clin J Pain. Jan 2008; 24(1): 5-10. PMID 18180629
20. Freund BJ, Schwartz M. Treatment of chronic cervical-associated headache with botulinum toxin A: a pilot study. Headache. Mar 2000; 40(3): 231-6. PMID 10759926
21. Padberg M, de Bruijn SF, Tavy DL. Neck pain in chronic whiplash syndrome treated with botulinum toxin. A double-blind, placebo-controlled clinical trial. J Neurol. Mar 2007; 254(3): 290-5. PMID 17345052
22. Deuschl G, Raethjen J, Hellriegel H, et al. Treatment of patients with essential tremor. Lancet Neurol. Feb 2011; 10(2): 148-61. PMID 21256454
23. Jankovic J, Schwartz K, Clemence W, et al. A randomized, double-blind, placebo-controlled study to evaluate botulinum toxin type A in essential hand tremor. Mov Disord. May 1996; 11(3): 250-6. PMID 8723140
24. Brin MF, Lyons KE, Doucette J, et al. A randomized, double masked, controlled trial of botulinum toxin type A in essential hand tremor. Neurology. Jun 12 2001; 56(11): 1523-8. PMID 11402109

25. Mittal SO, Machado D, Richardson D, et al. Botulinum Toxin in Parkinson Disease Tremor: A Randomized, Double-Blind, Placebo-Controlled Study With a Customized Injection Approach. Mayo Clin Proc. Sep 2017; 92(9): 1359-1367. PMID 28789780
26. Slengerik-Hansen J, Ovesen T. Botulinum Toxin Treatment of Objective Tinnitus Because of Essential Palatal Tremor: A Systematic Review. Otol Neurotol. Aug 2016; 37(7): 820-8. PMID 27273401
27. Stidham KR, Solomon PH, Roberson JB. Evaluation of botulinum toxin A in treatment of tinnitus. Otolaryngol Head Neck Surg. Jun 2005; 132(6): 883-9. PMID 15944559
28. Morra ME, Elgebaly A, Elmaraezy A, et al. Therapeutic efficacy and safety of Botulinum Toxin A Therapy in Trigeminal Neuralgia: a systematic review and meta-analysis of randomized controlled trials. J Headache Pain. Dec 2016; 17(1): 63. PMID 27377706
29. Marchal C, Perez JE, Herrera B, et al. The use of botulinum toxin in benign prostatic hyperplasia. Neurourol Urodyn. Jan 2012; 31(1): 86-92. PMID 21905088
30. Akiyama Y, Nomiya A, Niimi A, et al. Botulinum toxin type A injection for refractory interstitial cystitis: A randomized comparative study and predictors of treatment response. Int J Urol. Sep 2015; 22(9): 835-41. PMID 26041274
31. Kuo HC, Jiang YH, Tsai YC, et al. Intravesical botulinum toxin-A injections reduce bladder pain of interstitial cystitis/bladder pain syndrome refractory to conventional treatment - A prospective, multicenter, randomized, double-blind, placebo-controlled clinical trial. Neurourol Urodyn. Jun 2016; 35(5): 609-14. PMID 25914337
32. Manning J, Dwyer P, Rosamilia A, et al. A multicentre, prospective, randomised, double-blind study to measure the treatment effectiveness of abobotulinum A (AboBTXA) among women with refractory interstitial cystitis/bladder pain syndrome. Int Urogynecol J. May 2014; 25(5): 593-9. PMID 24276074
33. Zhang W, Deng X, Liu C, et al. Intravesical treatment for interstitial cystitis/painful bladder syndrome: a network meta-analysis. Int Urogynecol J. Apr 2017; 28(4): 515-525. PMID 27614759
34. Wang J, Wang Q, Wu Q, et al. Intravesical Botulinum Toxin A Injections for Bladder Pain Syndrome/Interstitial Cystitis: A Systematic Review and Meta-Analysis of Controlled Studies. Med Sci Monit. Sep 14 2016; 22: 3257-67. PMID 27624897
35. Lin YC, Wu WT, Hsu YC, et al. Comparative effectiveness of botulinum toxin versus non-surgical treatments for treating lateral epicondylitis: a systematic review and meta-analysis. Clin Rehabil. Feb 2018; 32(2): 131-145. PMID 28349703
36. Krogh TP, Bartels EM, Ellingsen T, et al. Comparative effectiveness of injection therapies in lateral epicondylitis: a systematic review and network meta-analysis of randomized controlled trials. Am J Sports Med. Jun 2013; 41(6): 1435-46. PMID 22972856
37. Sims SE, Miller K, Elfar JC, et al. Non-surgical treatment of lateral epicondylitis: a systematic review of randomized controlled trials. Hand (N Y). Dec 2014; 9(4): 419-46. PMID 25414603
38. Soares A, Andriolo RB, Atallah AN, et al. Botulinum toxin for myofascial pain syndromes in adults. Cochrane Database Syst Rev. Jul 25 2014; (7): CD007533. PMID 25062018
39. Desai MJ, Shkolnikova T, Nava A, et al. A critical appraisal of the evidence for botulinum toxin type A in the treatment for cervico-thoracic myofascial pain syndrome. Pain Pract. Feb 2014; 14(2): 185-95. PMID 23692187
40. Foster L, Clapp L, Erickson M, et al. Botulinum toxin A and chronic low back pain: a randomized, double-blind study. Neurology. May 22 2001; 56(10): 1290-3. PMID 11376175
41. Chen YW, Chiu YW, Chen CY, et al. Botulinum toxin therapy for temporomandibular joint disorders: a systematic review of randomized controlled trials. Int J Oral Maxillofac Surg. Aug 2015; 44(8): 1018-26. PMID 25920597
42. Patti R, Almasio PL, Muggeo VM, et al. Improvement of wound healing after hemorrhoidectomy: a double-blind, randomized study of botulinum toxin injection. Dis Colon Rectum. Dec 2005; 48(12): 2173-9. PMID 16400513
43. Patti R, Almasio PL, Luigi AP, et al. Botulinum toxin vs. topical glyceryl trinitrate ointment for pain control in patients undergoing hemorrhoidectomy: a randomized trial. Dis Colon Rectum. Nov 2006; 49(11): 1741-8. PMID 16990976
44. Abbott JA, Jarvis SK, Lyons SD, et al. Botulinum toxin type A for chronic pain and pelvic floor spasm in women: a randomized controlled trial. Obstet Gynecol. Oct 2006; 108(4): 915-23. PMID 17012454

45. Friedmacher F, Puri P. Comparison of posterior internal anal sphincter myectomy and intrasphincteric botulinum toxin injection for treatment of internal anal sphincter achalasia: a meta-analysis. Pediatr Surg Int. Aug 2012; 28(8): 765-71. PMID 22806601
46. Emile SH, Elfeki HA, Elbanna HG, et al. Efficacy and safety of botulinum toxin in treatment of anismus: A systematic review. World J Gastrointest Pharmacol Ther. Aug 06 2016; 7(3): 453-62. PMID 27602248
47. Farid M, El Monem HA, Omar W, et al. Comparative study between biofeedback retraining and botulinum neurotoxin in the treatment of anismus patients. Int J Colorectal Dis. Jan 2009; 24(1): 115-20. PMID 18719924
48. Farid M, Youssef T, Mahdy T, et al. Comparative study between botulinum toxin injection and partial division of puborectalis for treating anismus. Int J Colorectal Dis. Mar 2009; 24(3): 327-34. PMID 19039596
49. Bai Y, Xu MJ, Yang X, et al. A systematic review on intrapyloric botulinum toxin injection for gastroparesis. Digestion. 2010; 81(1): 27-34. PMID 20029206
50. Arts J, Holvoet L, Caenepeel P, et al. Clinical trial: a randomized-controlled crossover study of intrapyloric injection of botulinum toxin in gastroparesis. Aliment Pharmacol Ther. Nov 01 2007; 26(9): 1251-8. PMID 17944739
51. Friedenberg FK, Palit A, Parkman HP, et al. Botulinum toxin A for the treatment of delayed gastric emptying. Am J Gastroenterol. Feb 2008; 103(2): 416-23. PMID 18070232
52. Magid M, Finzi E, Kruger TH, et al. Treating depression with botulinum toxin: a pooled analysis of randomized controlled trials. Pharmacopsychiatry. Sep 2015; 48(6): 205-10. PMID 26252721
53. Wollmer MA, de Boer C, Kalak N, et al. Facing depression with botulinum toxin: a randomized controlled trial. J Psychiatr Res. May 2012; 46(5): 574-81. PMID 22364892
54. Finzi E, Rosenthal NE. Treatment of depression with onabotulinumtoxinA: a randomized, double-blind, placebo controlled trial. J Psychiatr Res. May 2014; 52: 1-6. PMID 24345483
55. Magid M, Reichenberg JS, Poth PE, et al. Treatment of major depressive disorder using botulinum toxin A: a 24-week randomized, double-blind, placebo-controlled study. J Clin Psychiatry. Aug 2014; 75(8): 837-44. PMID 24910934
56. Ziade M, Domergue S, Batifol D, et al. Use of botulinum toxin type A to improve treatment of facial wounds: a prospective randomised study. J Plast Reconstr Aesthet Surg. Feb 2013; 66(2): 209-14. PMID 23102873
57. Gassner HG, Brissett AE, Otley CC, et al. Botulinum toxin to improve facial wound healing: A prospective, blinded, placebo-controlled study. Mayo Clin Proc. Aug 2006; 81(8): 1023-8. PMID 16901024
58. Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. Sep 2019; 202(3): 558-563. PMID 31039103
59. Clemens JQ, Erickson DR, Varela NP, et al. Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome. J Urol. Jul 2022; 208(1): 34-42. PMID 35536143
60. Simpson DM, Hallett M, Ashman EJ, et al. 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. Neurology. May 10 2016; 86(19): 1818-26. PMID 27164716
61. Zesiewicz TA, Elble RJ, Louis ED, et al. Evidence-based guideline update: treatment of essential tremor: report of the Quality Standards subcommittee of the American Academy of Neurology. Neurology. Nov 08 2011; 77(19): 1752-5. PMID 22013182
62. Stewart DB, Gaertner W, Glasgow S, et al. Clinical Practice Guideline for the Management of Anal Fissures. Dis Colon Rectum. Jan 2017; 60(1): 7-14. PMID 27926552
63. Langer JC, Rollins MD, Levitt M, et al. Guidelines for the management of postoperative obstructive symptoms in children with Hirschsprung disease. Pediatr Surg Int. May 2017; 33(5): 523-526. PMID 28180937

#8.01.19

64. Food and Drug Administration. Approved risk evaluation and mitigation strategies. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. Accessed April 28, 2022.
65. Wade R, Rice S, Llewellyn A, et al. Interventions for hyperhidrosis in secondary care: a systematic review and value-of-information analysis. Health Technol Assess. Dec 2017; 21(80): 1-280. PMID 29271741
66. Rajagopal R, Mallya NB. Comparative evaluation of botulinum toxin versus iontophoresis with topical aluminium chloride hexahydrate in treatment of palmar hyperhidrosis. Med J Armed Forces India. Jul 2014; 70(3): 247-52. PMID 25378778
67. Solish N, Bertucci V, Dansereau A, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatol Surg. Aug 2007; 33(8): 908-23. PMID 17661933
68. Dogruk Kacar S, Ozuguz P, Eroglu S, et al. Treatment of primary hyperhidrosis with tap water iontophoresis in paediatric patients: a retrospective analysis. Cutan Ocul Toxicol. Dec 2014; 33(4): 313-6. PMID 24405389
69. McAleer MA, Collins P. A study investigating patients' experience of hospital and home iontophoresis for hyperhidrosis. J Dermatolog Treat. Aug 2014; 25(4): 342-4. PMID 23356798
70. Obed D, Salim M, Bingoel AS, et al. Botulinum Toxin Versus Placebo: A Meta-Analysis of Treatment and Quality-of-life Outcomes for Hyperhidrosis. Aesthetic Plast Surg. Aug 2021; 45(4): 1783-1791. PMID 33619611
71. Lowe NJ, Glaser DA, Eadie N, et al. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. Apr 2007; 56(4): 604-11. PMID 17306417
72. Baumann L, Slezinger A, Halem M, et al. Pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for treatment of axillary hyperhidrosis. Int J Dermatol. May 2005; 44(5): 418-24. PMID 15869543
73. Dressler D. Comparing Botox and Xeomin for axillar hyperhidrosis. J Neural Transm (Vienna). Mar 2010; 117(3): 317-9. PMID 20143241
74. Talarico-Filho S, Mendonca DO Nascimento M, Sperandeo DE Macedo F, et al. A double-blind, randomized, comparative study of two type A botulinum toxins in the treatment of primary axillary hyperhidrosis. Dermatol Surg. Jan 2007; 33(1 Spec No.): S44-50. PMID 17241414
75. Frasson E, Brigo F, Acler M, et al. Botulinum toxin type A vs type B for axillary hyperhidrosis in a case series of patients observed for 6 months. Arch Dermatol. Jan 2011; 147(1): 122-3. PMID 21242408
76. An JS, Hyun Won C, Si Han J, et al. Comparison of onabotulinumtoxinA and rimabotulinumtoxinB for the treatment of axillary hyperhidrosis. Dermatol Surg. Aug 2015; 41(8): 960-7. PMID 26218729
77. Mirkovic SE, Rystedt A, Balling M, et al. Hyperhidrosis Substantially Reduces Quality of Life in Children: A Retrospective Study Describing Symptoms, Consequences and Treatment with Botulinum Toxin. Acta Derm Venereol. Jan 12 2018; 98(1): 103-107. PMID 28761964
78. Lowe NJ, Yamauchi PS, Lask GP, et al. Efficacy and safety of botulinum toxin type a in the treatment of palmar hyperhidrosis: a double-blind, randomized, placebo-controlled study. Dermatol Surg. Sep 2002; 28(9): 822-7. PMID 12269876
79. Saadia D, Voustianiouk A, Wang AK, et al. Botulinum toxin type A in primary palmar hyperhidrosis: randomized, single-blind, two-dose study. Neurology. Dec 11 2001; 57(11): 2095-9. PMID 11739832
80. Campanati A, Giuliodori K, Martina E, et al. Onabotulinumtoxin type A (Botox((R))) versus Incobotulinumtoxin type A (Xeomin((R))) in the treatment of focal idiopathic palmar hyperhidrosis: results of a comparative double-blind clinical trial. J Neural Transm (Vienna). Jan 2014; 121(1): 21-6. PMID 24052109
81. Baumann L, Slezinger A, Halem M, et al. Double-blind, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for the treatment of palmar hyperhidrosis. Dermatol Surg. Mar 2005; 31(3): 263-70. PMID 15841624
82. Hsu TH, Chen YT, Tu YK, et al. A systematic review of microwave-based therapy for axillary hyperhidrosis. J Cosmet Laser Ther. Oct 2017; 19(5): 275-282. PMID 28281850
83. Glaser DA, Coleman WP, Fan LK, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the dermatologic reduction in underarm perspiration study. Dermatol Surg. Feb 2012; 38(2): 185-91. PMID 22289389

84. Hong HC, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg. May 2012; 38(5): 728-35. PMID 22452511
85. Mostafa TAH, Hamed AA, Mohammed BM, et al. C-Arm Guided Percutaneous Radiofrequency Thoracic Sympathectomy for Treatment of Primary Palmar Hyperhidrosis in Comparison with Local Botulinum Toxin Type A Injection, Randomized Trial. Pain Physician. Nov 2019; 22(6): 591-599. PMID 31775406
86. Rummaneethorn P, Chalermchai T. A comparative study between intradermal botulinum toxin A and fractional microneedle radiofrequency (FMR) for the treatment of primary axillary hyperhidrosis. Lasers Med Sci. Jul 2020; 35(5): 1179-1184. PMID 31939036
87. Purtuloglu T, Atim A, Deniz S, et al. Effect of radiofrequency ablation and comparison with surgical sympathectomy in palmar hyperhidrosis. Eur J Cardiothorac Surg. Jun 2013; 43(6): e151-4. PMID 23428574
88. Hafner J, Beer GM. Axillary sweat gland excision. Curr Probl Dermatol. 2002; 30: 57-63. PMID 12471699
89. Deng B, Tan QY, Jiang YG, et al. Optimization of sympathectomy to treat palmar hyperhidrosis: the systematic review and meta-analysis of studies published during the past decade. Surg Endosc. Jun 2011; 25(6): 1893-901. PMID 21136103
90. Baumgartner FJ, Reyes M, Sarkisyan GG, et al. Thoracoscopic sympathicotomy for disabling palmar hyperhidrosis: a prospective randomized comparison between two levels. Ann Thorac Surg. Dec 2011; 92(6): 2015-9. PMID 22115211
91. Yuncu G, Turk F, Ozturk G, et al. Comparison of only T3 and T3-T4 sympathectomy for axillary hyperhidrosis regarding treatment effect and compensatory sweating. Interact Cardiovasc Thorac Surg. Aug 2013; 17(2): 263-7. PMID 23644731
92. de Andrade Filho LO, Kuzniec S, Wolosker N, et al. Technical difficulties and complications of sympathectomy in the treatment of hyperhidrosis: an analysis of 1731 cases. Ann Vasc Surg. May 2013; 27(4): 447-53. PMID 23406790
93. Karamustafaoglu YA, Kuzucuoglu M, Yanik F, et al. 3-year follow-up after uniportal thoracoscopic sympathicotomy for hyperhidrosis: undesirable side effects. J Laparoendosc Adv Surg Tech A. Nov 2014; 24(11): 782-5. PMID 25376004
94. Smidfelt K, Drott C. Late results of endoscopic thoracic sympathectomy for hyperhidrosis and facial blushing. Br J Surg. Dec 2011; 98(12): 1719-24. PMID 21928403
95. Wait SD, Killory BD, Lekovic GP, et al. Thoracoscopic sympathectomy for hyperhidrosis: analysis of 642 procedures with special attention to Horner's syndrome and compensatory hyperhidrosis. Neurosurgery. Sep 2010; 67(3): 652-6; discussion 656-7. PMID 20647968
96. Lembranca L, Wolosker N, de Campos JRM, et al. Videothoracoscopic Sympathectomy Results after Oxybutynin Chloride Treatment Failure. Ann Vasc Surg. Aug 2017; 43: 283-287. PMID 28478174
97. de Campos JRM, Lembranca L, Fukuda JM, et al. Evaluation of patients who underwent resympathectomy for treatment of primary hyperhidrosis. Interact Cardiovasc Thorac Surg. Nov 01 2017; 25(5): 716-719. PMID 29049566
98. Fukuda JM, Varella AYM, Teivelis MP, et al. Video-Assisted Thoracoscopic Sympathectomy for Facial Hyperhidrosis: The Influence of the Main Site of Complaint. Ann Vasc Surg. Jan 2018; 46: 337-344. PMID 28689957
99. Vasconcelos-Castro S, Soares-Oliveira M, Tuna T, et al. Thoracoscopic sympathotomy for palmar hyperhidrosis: How young is too young?. J Pediatr Surg. Nov 2020; 55(11): 2362-2365. PMID 31870560
100. Lima SO, Santos RS, Moura AMM, et al. A systematic review and meta-analysis to evaluate the efficacy of lumbar sympathectomy for plantar hyperhidrosis. Int J Dermatol. Aug 2019; 58(8): 982-986. PMID 31099425
101. Loureiro Mde P, de Campos JR, Kauffman P, et al. Endoscopic lumbar sympathectomy for women: effect on compensatory sweat. Clinics (Sao Paulo). Apr 2008; 63(2): 189-96. PMID 18438572
102. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol. Aug 2004; 51(2): 274-86. PMID 15280848
103. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Iontophoresis for Medical Indications. TEC Assessments 2003;Volume 18, Tab 3.

104. Li C, Wu F, Zhang Q, et al. Interventions for the treatment of Frey's syndrome. Cochrane Database Syst Rev. Mar 17 2015; (3): CD009959. PMID 25781421
105. Clayman MA, Clayman SM, Seagle MB. A review of the surgical and medical treatment of Frey syndrome. Ann Plast Surg. Nov 2006; 57(5): 581-4. PMID 17060744
106. de Bree R, van der Waal I, Leemans CR. Management of Frey syndrome. Head Neck. Aug 2007; 29(8): 773-8. PMID 17230557
107. Cerfolio RJ, De Campos JR, Bryant AS, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis. Ann Thorac Surg. May 2011; 91(5): 1642-8. PMID 21524489
108. Naumann M, So Y, Argoff CE, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. May 06 2008; 70(19): 1707-14. PMID 18458231
109. Naumann M, Dressler D, Hallett M, et al. Evidence-based review and assessment of botulinum neurotoxin for the treatment of secretory disorders. Toxicon. Jun 01 2013; 67: 141-52. PMID 23178324
110. National Institute of Health and Care Excellence (NICE). Endoscopic thoracic sympathectomy for primary facial blushing [IPG480]. 2014; https://www.nice.org.uk/guidance/ipg480. Accessed April 29, 2022.
111. National Institute of Health and Care Excellence (NICE). Endoscopic throacic sympathectomy for primary hyperhidrosis of the upper limb [IPG487]. 2014; https://www.nice.org.uk/guidance/ipg487. Accessed April 29, 2022.