Botulinum Toxin Policy Update

We've updated our *Botulinum Toxin* policy to allow substitution of Xeomin for Botox. Clinical criteria did not change. For prior authorization requirements, please log in at **hap.org**. Select *Procedure Reference Lists* under *Quick Links*, then *Services that require Prior Authorization List*.

A copy of the updated policy is attached for your convenience.

Botulinum Toxin

DESCRIPTION

Botulinum toxins work in the peripheral and autonomic nervous systems by preventing the release of acetylcholine. This effect results in disrupted neurotransmission and muscle paralysis. Clostridium botulinum (C. botulinum), C. baratii, and C. butyricum all produce the neurotoxin, botulinum. The available formulations of botulinum therapy are derived from Clostridium botulinum.

There are currently four botulinum toxin products commercially available in the United States: onabotulinumtoxinA, rimabotulinumtoxinB, abobotulinumtoxinA, and incobotulinumtoxinA.

Each preparation has distinct pharmacological and clinical profiles specified on the product insert. Dosing patterns are also specific to the preparation of neurotoxin and are very different between different serotypes. Failure to recognize the unique characteristics of each formulation of botulinum toxin can lead to undesired patient outcomes. It is expected that physicians will be familiar with and experienced in the use of these agents and utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient condition. Although botulinum toxins have only been FDA-approved for limited uses, they are frequently used off-label as well. A Member who is not responsive or who ceases to respond to one serotype may respond to the other.

FDA approved indications:
Botox®: onabotulinumtoxinA (Botox®) FDA package insert @
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
Dysport®: abobotulinumtoxinA(Dysport®) FDA package insert @
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125274s107lbl.pdf
Myobloc®: rimabotulinumtoxinB (Myobloc®) FDA package insert @
https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/103846s5190lbl.pdf
Xeomin®: incobotulinumtoxinA (Xeomin®) FDA package insert @
https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125360s073lbl.pdf

Please Note: *The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.*

RELEVANT HCPCS CODES

J0585	Onabotulinum Toxin A, 1 Unit
J0586	Abobotulinum Toxin A, 5 units
J0587	Rimabotulinum Toxin type B, 100 units
J0588	Incobotulinum Toxin A, 1 unit
S2340	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation of adductor muscle(s) of vocal cord

RELEVANT CPT® CODES

31513	Laryngoscopy, Indirect; W/Vocal Cord Injection
31570	Laryngoscopy, Direct, W/Injection Into Vocal Cord(S), Therapeutic;
31571	Laryngoscopy, Direct, W/Injection Into Vocal Cord, Therapeutic; W/Microscope
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
43201	Esophagoscopy, Rigid/Flexible; W/Directed Submucosal Injection(S), Any Substance
46505	Chemodenervation of internal anal sphincter
52287	Cystourethroscopy, With Injection(s) For Chemodenervation Of The Bladder
64611	Chemodenervation Of Parotid And Submandibular Salivary Glands, Bilateral
64612	Chemodenervation, Muscle(S); Innervated, Facial Nerve
64615	Chemodenervation Of Muscle(s); Muscle(s) Innervated By Facial, Trigeminal, Cervical Spinal And Accessory Nerves, Bilat

64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscle(s)
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscle(s) (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscle(s)
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
67345	Chemodenervation, Extraocular Muscle

REVENUE CODES

0636	Drugs Requiring Specific Ident - Drugs Requiring Detailed Coding

ICD-10 CODES requiring pre-authorization for treatment.

G43.001 - G43.919	Migraine Headaches
G44.001 - G44.89	Other headache syndromes
R51	Headache

COVERAGE CRITERIA

NEUROLOGICAL CONDITIONS:

1. Blepharospasm:
    a. Medications:
        i. **abobotulinumtoxinA (Dysport®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. **onabotulinumtoxinA (Botox®)**
        iv. Covered for HAP/AHL Members when used for:
            A. Treatment for blepharospasm characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle.
2. Cervical dystonia (including spasmodic torticollis):
    a. Medications:
        i. **abobotulinumtoxinA(Dysport®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. **onabotulinumtoxinA (Botox®)**
        iv. **rimabotulinumtoxinB (Myobloc®)**
        v. Covered for HAP/AHL Members when used for treatment and BOTH of the following are present:
            A. Involuntary, simultaneous activation of agonist and antagonist muscles of the neck and shoulder (e.g., sternocleidomastoid, splenius, levator scapulae, trapezius, semispinalis, scalene)
            B. Sustained head torsion and/or tilt with limited range of motion in the neck
3. Chronic Migraine Headache, Prevention:
    a. Medication:
        i. **onabotulinumtoxinA (Botox®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. NITIAL Authorization criteria: Covered for HAP/AHL Members when BOTH of the following are present:
            A. Diagnosis of Chronic Migraine headache as defined by 15 days or more migraine headache days monthly for 3 months, with headaches lasting 4 hours or more in an adult.
            B. Failure or inadequate response, contraindication per FDA label, or documented intolerance to at least two different prescription migraine prevention therapies medications. The two medications need to be from different classes of chronic migraine prophylaxis therapies as listed below:
                I. Anticonvulsant medications, FDA approved for migraine prevention:
                    1. Topiramate (Topamax)

2. Valproate (Depakote) * contraindicated during pregnancy

II. Beta-blockers, examples include (list may not be all inclusive):
1. Acebutolol (Sectral)
2. Atenolol (Tenormin)
3. Bisoprolol (Zebeta)
4. Metoprolol (Lopressor, Toprol Xl)
5. Nadolol (Corgard)
6. Nebivolol (Bystolic)
7. Propranolol (Inderal La, Innopran Xl)

III. Antidepressants, examples include (list may not be all inclusive):
1. Amitriptyline (Elavil)
2. Desipramine (Norpramin)
3. Doxepin (Sinequan)
4. Imipramine (Tofranil)
5. Nortriptyline (Pamelor)
6. Protriptyline (Vivactil)

iv. REAUTHORIZATION Criteria: Subsequent therapy is covered when BOTH of the following are met:
A. Previously met clinical criteria (see above)
B. **ONE** of the following:
I. Documentation of a decrease in the number of monthly migraine headache days or hours.
II. Documentation of a decrease in the number of days requiring acute migraine headache-specific treatment.

v. New therapeutic interventions and botulinum toxin use for Migraine Headaches:
A. Calcitonin-gene-related peptide (CGRP) blocker medications (such as Aimovig, Ajovy, Emgality) are self-injectable drugs and are considered a pharmacy benefit.
I. Please refer to the provider portal for specific information about coverage criteria for CGRP blocker medications (see prescriptions)
II. At the time of this policy, coverage for HAP/AHL Members other than Medicare Advantage Plan Members is as follows:
1. CGRP blocker medications are not approved for use in conjunction with botulinum toxin for headache prophylaxis.
2. If the Member has not received botulinum toxin for a period of 4 months, a request for Aimovig (the plan's preferred CGRP blocker medication) can be submitted for coverage determination to the pharmacy benefit.
3. If a CGRP blocker medication is approved, any active authorizations for botulinum toxin will be closed.

vi. Therapy is authorized by a HAP Medical director or designee.

4. Essential tremor:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for:
A. Treatment of disabling condition (including head, neck, hand, and voice tremor)

5. Focal dystonias:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for treatment and ANY of the following are present:
A. Focal hand dystonia (e.g., writer's cramp) causing persistent pain or interfering with the ability to perform age-related activities of daily living
B. Adductor spasmodic dysphonia/laryngeal dystonia
C. Jaw-closing oromandibular dystonia
D. Meige's syndrome/cranial dystonia (i.e., blepharospasm)

6. Spasms/palsies:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for treatment and ANY of the following are present:
A. Hemifacial spasms
B. Seventh cranial nerve palsy (Bell's Palsy)
C. Gaze palsies causing persistent pain or vision impairment

7. Spastic conditions:
a. Medication #1:
i. **onabotulinumtoxinA (Botox®)**

ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for treatment of a spastic condition related to ANY of the following:
A. Cerebral palsy (including spastic equinus foot deformities)
B. Spinal cord injury
C. Traumatic brain injury
D. Hereditary spastic paraplegia
E. Localized adductor muscle spasticity in multiple sclerosis
F. Pediatric or adult Members with lower limb spasticity with documentation of significant decrease of function or Activities of Daily Living (for example, walking)
G. Pediatric or adult Members with upper limb spasticity with documented significant decrease of function or Activities of Daily Living (for example, washing, eating) in either pediatric or adult Members.

b. Medication #2:
i. **abobotulinumtoxinA (Dysport®)**
ii. Covered for HAP/AHL Members when used for treatment of a spastic condition related to ANY of the following:
A. Cerebral palsy (including spastic equinus foot deformities)
B. Spasticity in multiple sclerosis.
C. Pediatric or adult Members with lower limb spasticity with documentation of significant decrease of function or Activities of Daily Living (for example, walking).
D. Pediatric or adult Members with upper limb spasticity with documented significant decrease of function or Activities of Daily Living (for example, washing, eating) in either pediatric or adult Members.

c. Medication #3:
i. **rimabotulinumtoxinB (Myobloc®)**
ii. Covered for HAP/AHL Members when used for:
A. Pediatric or adult Members with Lower limb spasticity with documentation of significant decrease of function or Activities of Daily Living (for example, walking).
B. Pediatric or adult Members with Upper limb spasticity with documented significant decrease of function or Activities of Daily Living (for example, washing, eating).

8. Strabisumus: Please see Opthalmologic Conditions.

GASTROINTESTINAL:

1. Chronic anal fissure:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for:
A. Treatment following failure of conventional non-surgical treatment (e.g., nitrate preparations, sitz baths, stool softeners, bulk agents, diet modifications)
2. Hirschsprung disease:
a. Medication:
i. **abobotulinumtoxinA(Dysport®)**
ii. **onabotulinumtoxinA (Botox®)**
iii. **incobotulinumtoxinA (Xeomin®)**
iv. overed for HAP/AHL Members when used for:
A. Treatment of obstructive symptoms due to a non-relaxing internal anal sphincter following surgery for Hirschsprung disease
3. Primary esophageal achalasia:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for treatment of ANY of the following:
A. Concomitant illness and/or high risk for complications from myotomy or dilation
B. Poor response to prior myotomy or dilation
C. History of perforation caused by previous pneumatic dilation
D. Epiphrenic diverticulum

EXOCRINE:

1. Glandular secretion:
a. Medication:
i. **onabotulinumtoxinA (Botox®)**
ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members when used for:

A. Treatment of cholinergic-mediated secretions associated with a fistula (e.g. parotid gland, pharyngocutaneous) refractory to pharmacotherapy (including anticholinergics).

2. Ptyalism/sialorrhea:
    a. Medication:
        i. **onabotulinumtoxinA (Botox®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. **rimabotulinumtoxinB (Myobloc®)**
        iv. Covered for HAP/AHL Members when used for the treatment of:
            A. Ptyalism/sialorrhea (excessive salivation) associated with Parkinsonism with Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following:
                I. Glycopyrolate
                II. Scopolamine
            B. Ptyalism/sialorrhea (excessive salivation) associated with cerebral palsy with documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following:
                I. Atropine
                II. Glycopyrolate
3. Hyperhidrosis:
    a. Medication:
        i. **onabotulinumtoxinA (Botox®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. Covered for HAP/AHL Members when used for:
            A. Treatment for ANY of the following when the associated criteria are met:
                I. Primary axillary hyperhidrosis inadequately managed with a prescription topical antiperspirant agent AND EITHER of the following:
                    1. The condition is significantly interfering with the ability to perform age-appropriate activities of daily living.
                    2. The condition is causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections and secondary microbial conditions.
                II. Palmar hyperhidrosis refractory to conventional medical treatment (unless clinically contraindicated) including both a prescription topical antiperspirant agent and Iontophoresis treatment AND EITHER of the following:
                    1. The condition is significantly interfering with the ability to perform age-appropriate activities of daily living.
                    2. The condition is causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections and secondary microbial conditions.
                III. Gustatory sweating (Frey's syndrome, diabetic gustatory sweating).

OPHTHALMOLOGIC:

1. Strabismus disorders in adults:
    a. medication:
        i. **onabotulinumtoxinA (Botox®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. Covered for HAP/AHL Members when used for strabismus treatment when BOTH of the following are met:
            A. ONE of the following is present:
                I. Horizontal strabismus up to 50 prism diopters
                II. Vertical strabismus
                III. Persistent sixth nerve palsy of one month or longer duration, accompanied by ONE of the following:
                    1. Diplopia
                    2. Impaired depth perception
                    3. Impaired peripheral vision
                    4. Impaired ability to maintain fusion
2. Strabismus disorders in children:
    a. medication:
        i. **onabotulinumtoxinA (Botox®)**
        ii. **incobotulinumtoxinA (Xeomin®)**
        iii. Covered for HAP/AHL Members for when used to:
            A. Achieve normal binocular motor alignment.

UROLOGIC

1. Bladder dysfunction:
    a. medication:
        i. **onabotulinumtoxinA (Botox®)**

ii. **incobotulinumtoxinA (Xeomin®)**
iii. Covered for HAP/AHL Members for the treatment of:
A. Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of a trial of TWO antimuscarinic medications for OAB:
I. Darifenacin (Brand name: Enablex)
II. Fesoterodine (Brand name: Toviaz)
III. Flavoxate (Brand name: Urispas)
IV. Oxybutynin (Brand names: Ditropan XL; Gelnique; Oxytrol; Oxytrol For Women [OTC])
V. Solifenacin (Brand name: VESIcare)
VI. Tolterodine (Brand names: Detrol; Detrol LA)
VII. Trospium (Brand names: Sanctura XR [DSC]; Sanctura [DSC])
A. Urinary incontinence due to detrusor overactivity in adults who have an inadequate response to or are intolerant of an anticholinergic medication (antimuscarinic medication, see above list) when associated with ANY of the following:
I. Multiple sclerosis (MS)
II. Spinal cord injury (SCI)
III. An intracranial lesion or cerebrovascular accident (CVA)
B. Interstitial cystitis/bladder pain syndrome when there is an inadequate response to other second- and third-line treatment options (e.g., oral or intravesical treatments and cystoscopy).

For all indications:

1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
2. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.
3. Medicaid Providers should refer to the Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**

LIMITATIONS

1. When criteria are met for coverage of Botulinum Therapy, approval consists of a maximum quantity of four (4) treatments in a 12 month period (one (1) treatment every 90 days.
    a. If the initial approval criteria (listed above) are met AND clinical improvement with previous Botulinum Therapy is documented but duration of benefit is < 90 days/treatment, then up to six treatments in a 12 month period (one treatment per 60 days) may be considered on a case-by-case basis.
2. Coverage of treatments provided may be continued if the criteria (above) for response to therapy are met; unless any two treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin, failed to produce satisfactory clinical response.

EXCLUSIONS

1. All other uses of specific botulinum toxin products for conditions other than those as listed above are considered investigational and therefore, not covered for HAP/AHL Members.
2. The use of botulinum toxin for cosmetic reasons (i.e., wrinkle removal, treatment of glabellar lines) is not covered under a Member's HAP/AHL Subscriber Contract.
    a. Jeuveau™ (prabotulinumtoxinA-xvfs) is approved by the FDA only for cosmetic use; it has no other indications; therefore, it is considered cosmetic and not eligible for reimbursement under the medical or pharmacy benefit.
3. None of the four (4) botulinum therapy products are covered for HAP/AHL Members for ANY of the following because it is considered experimental, investigational, or unproven (this list may not be all-inclusive):
    a. Chronic low back pain
    b. Headache including:
        i. Cervicogenic headache
        ii. Chronic daily headache
        iii. Episodic migraine headache (i.e., 14 headache days or fewer per month)
        iv. Menstrual headache (e.g., 90% of attacks generally occur between two days before menses and the last day of menses)
        v. Tension-type headache
        vi. Chronic migraine headache, when used concurrently with a calcitonin gene-related peptide receptor antagonist (such as: Aimovig, Ajovy, Emgality)
    c. Hemorrhoid pain
    d. Myofascial pain
    e. Sphincter of Oddi dysfunction
    f. Temporomandibular joint (TMJ) syndrome

g. Tics
h. Voiding dysfunction associated with benign prostatic hyperplasia
i. Lateral epicondylitis
j. Bruxism
k. Gastroparesis
l. Nausea and vomiting, post sleeve gastrectomy
m. Spastic pelvic floor syndrome
n. Plantar Hyperhidrosis
o. Trigeminal neuralgia

RELATED BENEFIT ADMINISTRATION MANUAL POLICIES:

1. Intravenous (IV) Calcitonin Gene-Related Peptide (CGRP) Antagonist

MEDICARE REFERENCE:

1. Local Coverage Determination (LCD): Botulinum Toxin Type A & Type B (L34635) **https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34635&ver=29&Date=&DocID=L34635&bc=iAAAABAAoAAA&**
    a. Policy Article: Billing and Coding Guidelines for LCD Titled: Botulinum Toxin Type A & Type B **https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57474&ver=9&LCDId=34635&Date=&DocID=L34635&bc=iAAAABAAoAAA&**

This Benefit policy discusses the medical criteria for covered services. Coverage of services for Members is based on the Member's subscriber documents and are subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).
HAP HMO/POS and AHL EPO/PPO Members:
If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.
ASO Members:
Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.
Medicare Advantage Plan Members:
Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.
Medicaid Plan Members:
For Medicaid/Healthy Michigan Plan members coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html**, the Michigan Medicaid Provider Manual will apply.

EFFECTIVE DATE

09/01/2002

REVISED DATE

01/13/2021

REVIEWED DATE

01/13/2021