curative

Botulinum Toxin Medical Policy

Drug(s) Applied:	**Botox** (onabotulinum toxin A), **Dysport** (abobotulinum toxin A), **Xeomin** (incobotulinum toxin A)

Criteria:
Curative considers Botox, Dysport, and Xeomin to be preferred botulinum toxins. All other botulinum toxins are considered non-preferred including Myobloc and Daxxify.

Coverage will not be provided for cosmetic use including but not limited to reduce skin lines or wrinkling.

Drug(s) Applied will be approved when the requested medication meets ALL the criteria below:

I. Initial Therapy Criteria

A. Achalasia documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox **and**
b. Patient has tried and failed or is a poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy **and**
c. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., gastroenterology, proctology, or colorectal surgery)

Approval Duration: Up to 100 units per 6 months (1 treatment session)

B. Blepharospasm documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox or Xeomin **and**
b. Confirmed diagnosis of blepharospasm including blepharospasm associated with dystonia, benign essential blepharospasm, or VII nerve disorder **and**
c. Patient has disability in daily functional activities due to interference with vision **and**
d. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication with ONE of the following:
    i. If for Botox, patient must be at least 12 years of age **or**
    ii. If for Xeomin, patient must be at least 18 years of age **and**
e. At least ONE of the following:
    i. If for Xeomin, total prescribed dose does not exceed 100 units (50 units per eye) **or**

ii. If for Botox, total prescribed dose does not exceed 5 units per treatment site (cumulatively, 200 units in a 30-day period) **and**

f. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., neurology, ophthalmology)

Approval Duration: 3 months (1 treatment session)

C. Cervical dystonia/torticollis documented by chart notes within past 180 days and ALL of the following:

a. Patient is at least 18 years of age **and**
b. Documented involuntary contractions of the neck and shoulder muscles (e.g., trapezius, sternocleidomastoid, etc.) with limited range of motion in the neck **and**
c. Contractions are causing pain or functional impairment **and**
d. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., neurology, orthopedics)

Approval Duration: 3 months (1 treatment session)

D. Chronic anal fissures documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox or Dysport **and**
b. Patient has had a chronic anal fissure present for at least 6 weeks **and**
c. Patient has not responded to conservative management with sitz baths and fiber supplementation/bulking agents (e.g., psyllium fiber) after a trial of at least 6 weeks **and**
d. Patient has not responded to at least one first-line therapy (e.g., topical nitrates) after an adequate trial (e.g., ≥8 weeks), or the patient has a contraindication or severe intolerance to topical nitrates **and**
e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., gastroenterology, proctology, colorectal surgery)

Approval Duration: 3 months (1 treatment session)

E. Chronic migraine prophylaxis documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox **and**
b. Patient is 18 years of age or older **and**
c. Diagnosis of chronic migraines by ALL of the following:
    i. 15 or more headache days per month for >3 months **and**
    ii. Headaches last 4 hours or longer on at least 8 days per month **and**
d. Patient has failed an adequate trial (minimum 60 days) of migraine preventative

therapies from at least 2 different classes, or patient has an intolerance or FDA-labeled contraindication to ALL migraine prophylaxis agents listed:
    i. Antidepressants (e.g., amitriptyline, venlafaxine ER) **or**
    ii. Antiepileptic drugs (e.g., divalproex sodium, topiramate, valproate sodium) **or**
    iii. Beta-blockers (e.g., metoprolol, propranolol, timolol, atenolol, nadolol) **and**
e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, pain management)

Approval Duration: 9 months (3 treatments separated by at least 12 weeks)

F. Essential hand tremor documented by chart notes within past 180 days and ALL of the following:
a. Request is for Botox **and**
b. Patient has a documented hand tremor that causes significant disruptions to activities of daily living **and**
c. Patient has not responded to at least one first-line therapy (e.g., propranolol or primidone) after an adequate trial (e.g., ≥6 weeks), unless the patient has contraindications or a severe intolerance (e.g.,bradycardia, acute neurotoxicity, etc.) to either therapy, not including the "first-dose" effects of primidone (e.g., sedation, nystagmus, etc.) **and**
d. Patient has not responded to combined propranolol/primidone therapy after an adequate trial (e.g., ≥6 weeks), unless the patient has contraindications or a severe intolerance (e.g.,bradycardia, acute neurotoxicity, etc.) to either therapy, not including the "first-dose" effects of primidone (e.g., sedation, nystagmus, etc.) **and**
e. Patient has not responded to at least one second-line therapy (e.g., gabapentin, topiramate, atenolol, sotalol, etc.) after an adequate trial (e.g., ≥6 weeks) **and**
f. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., neurology, physiatry)

Approval Duration: 3 months (1 treatment session)

G. Excessive salivation (chronic sialorrhea/ptyalism) documented by chart notes within past 180 days and ALL of the following:
a. Request is for Xeomin **and**
b. Patient has had an inadequate response to at least one anticholinergic therapy (e.g., glycopyrrolate, scopolamine, etc.) after an adequate trial (e.g., ≥4 weeks) **and**
c. Prescriber is a specialist or has consulted with a specialist in the area of the

patient's diagnosis (e.g., neurology, otolaryngology)

Approval Duration: Up to 100 units per 4 months (1 treatment session)

H. **First bite syndrome** documented by chart notes within past 180 days and ALL of the following:
   a. Request is for Botox **and**
   b. Patient experiences sharp, severe pain in the parotid region occurring with the first bite of food that decreases with subsequent bites **and**
   c. Patient has had an inadequate response to at least ONE agent from TWO different classes after an adequate trial at a therapeutic dose (e.g., ≥4 weeks for scheduled analgesics; ≥6 weeks for tricyclic antidepressants and anticonvulsants), or patient has contraindications or severe intolerances to each of these:
      i. Scheduled analgesics (e.g., acetaminophen, ibuprofen, etc.) **or**
      ii. Tricyclic antidepressants (e.g., amitriptyline) **or**
      iii. Anticonvulsants (e.g., carbamazepine, gabapentin, pregabalin, etc.) **and**
   d. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., neurology, oncology)

Approval Duration: 3 months (1 treatment session)

I. **Hirschsprung disease** documented by chart notes within past 180 days and ALL of the following:
   a. Request is for Botox **and**
   b. Confirmed diagnosis of Hirschsprung disease with internal sphincter achalasia following endorectal pull-through **and**
   c. Patient has tried and failed laxative therapy (e.g., polyethylene glycol, lactulose, senna, etc.) after an adequate trial (e.g., ≥4 weeks) **and**
   d. Patient has had an inadequate response (e.g., no meaningful improvement in stooling pattern or obstruction symptoms) to rectal irrigations after an adequate trial (e.g., ≥2 weeks) **and**
   e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., gastroenterology, proctology, colorectal surgery)

Approval Duration: 6 months (1 treatment session)

J. **Hyperhydrosis** documented by chart notes within past 180 days and ALL of the following:
   a. Request is for Botox or Dysport **and**
   b. Confirmed diagnosis of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis **and**

c. Documented significant disruption to daily life has occurred because of excessive sweating **and**
d. Patient has tried and failed topical aluminum chloride or other extra-strength antiperspirants after an adequate trial (e.g., 4 weeks), or they have resulted in a severe rash **and**
e. If for primary axillary or palmar hyperhydrosis, patient has had an inadequate response to at least one anticholinergic agent (e.g., glycopyrrolate, oxybutynin) after an adequate trial (e.g., ≥4 weeks) **and**
f. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, dermatology)

Approval Duration: 6 months (1 treatment session)

K. Orofacial tardive dyskinesia documented by chart notes within past 180 days and ALL of the following:
a. Request is for Botox **and**
b. Documentation of dystonia involving the orofacial region **and**
c. Symptoms noted to cause major impairment to activities of daily living (e.g., difficulty speaking, difficulty chewing, tongue or cheek biting, etc.) **and**
d. At least ONE of the following:
i. Prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents, anticholinergics) **or**
ii. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **and**
e. Patient has had an inadequate response, significant intolerance, or contraindication to a VMAT2 inhibitor (e.g., tetrabenazine) after an adequate trial (e.g., ≥6 weeks) **and**
f. Prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **and**
g. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, pain management)

Approval Duration: 3 months (1 treatment session)

L. Palatal myoclonus documented by chart notes within past 180 days and ALL of the following:
a. Request is for Botox **and**
b. Documented disabling symptoms (e.g., intrusive clicking tinnitus, palatal contractions) **and**

c. Patient has had an inadequate response to at least one conservative therapy (e.g., clonazepam, lamotrigine, carbamazepine, gabapentin, or valproate) after an adequate trial (e.g., ≥6 weeks), or patient has a contraindication or severe intolerance to all conservative therapies **and**
d. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology,otolaryngology)

Approval Duration: 3 months (1 treatment session)

M. Spasticity, hemifacial spasm, focal hand dystonia, facial myokymia documented by chart notes within past 180 days and ALL of the following:
a. Request is for Botox or Dysport **and**
b. Patient has significant functional impairment causing disruption to activities of daily living **and**
c. If requested agent is to treat focal hand dystonia, then patient has had an inadequate response to conservative measures (e.g., occupational therapy) **and**
d. If requested agent is to treat facial myokymia, the underlying condition has been appropriately treated or is being managed **and**
e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, otolaryngology, physiatry)

Approval Duration: 3 months (1 treatment session)

N. Spasticity, upper or lower limb documented by chart notes within past 180 days and ALL of the following:
a. At least ONE of the following:
i. If for Botox or Dysport, patient is at least 2 years of age **or**
ii. If for Xeomin, patient is at least 2 years of age, unless spasticity is due to cerebral palsy, then patient must be at least 18 years of age **and**
b. Confirmed primary diagnosis of upper or lower limb spasticity or as a symptom of a condition causing limb spasticity (including focal spasticity or equinus gait due to cerebral palsy) that causes significant interference with activities of daily living **and**
c. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, orthopedic surgery, physiatry)

Approval Duration:
If for Botox, up to 400 units (400 billed units) per 3 months (1 treatment session);
If for Dysport, up to 1,500 units (300 billed units) per 3 months (1 treatment session);
If for Xeomin, up to 600 units (600 billed units) per 3 months (1 treatment session)

O. Spasmodic dysphonia (laryngeal dystonia), oromandibular dystonia documented by

chart notes within past 180 days and ALL of the following:

a. Request is for Botox **and**
b. At least ONE of the following:
    i. Functional impairment involving chewing, swallowing, or pain associated with these **or**
    ii. Symptoms cause significant speech or voice impairment **and**
c. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, otolaryngology)

Approval Duration: 3 months (1 treatment session)

P. Strabismus documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox **and**
b. Patient is 12 years of age or older **and**
c. Documentation that strabismus interference with normal visual system development is likely to occur without spontaneous recovery **and**
d. Strabismus repair is not considered cosmetic (strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion) **and**
e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, ophthalmology)

Approval Duration: Up to 25 units per muscle per 3 months (1 treatment session)

Q. Urinary incontinence associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis), urinary incontinence due to overactive bladder documented by chart notes within past 180 days and ALL of the following:

a. Request is for Botox **and**
b. Patient is 5 years of age or older **and**
c. Patient has tried and failed behavioral therapy when feasible (e.g., fluid management, bladder training, pelvic floor training) for ≥8 weeks **and**
d. Patient has tried and failed at least 1 agent from each of the following classes for ≥6 weeks, or patient has a contraindication or severe intolerance to ALL agents:
    i. Anticholinergics (e.g., solifenacin, tolterodine, trospium, oxybutynin) **and**
    ii. Beta-3 adrenergic agonists (e.g., mirabegron) **and**
e. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, urology, gynecology)

Approval Duration:
If for urinary incontinence associated with a neurological condition, up to 200 units per 3 months (1 treatment session);
If for urinary incontinence due to overactive bladder, up to 100 units per 3 months (1

treatment session)

I. **Continued Therapy Criteria** - Drug(s) Applied will be approved when the requested medication meets the criteria below as indicated by chart notes within the past 12 months:

A. Chronic migraine prophylaxis

1. Request is for Botox **and**
2. Patient meets initial criteria above **and**
3. Documented clinical benefit since starting the requested agent (i.e., reduced migraine headache days, reduced migraine severity or duration, reduced use of acute abortive migraine medication) **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g.,neurology, pain management)

Approval Duration: 12 months

B. All other indications listed above

1. Meet initial therapy criteria above **and**
2. Documented continuous clinical benefit or symptom stabilization from botulinum toxin therapy

Approval Duration: 12 months

Curative considers all other indications as experimental and investigational.

EMG Guidance

Curative considers the use of electromyographic (EMG) guidance of botulinum toxin injections medically necessary for any of the following indications:

- Cervical dystonia
- Hand dystonia
- Limb spasticity
- Strabismus

Curative considers the use of EMG guidance of botulinum toxin injections experimental and investigational for all other indications.

If submitting for medical billing:

J0585, onabotulinumtoxinA (Botox), 1 unit = 1 dosing unit
J0586, abobotulinumtoxinA (Dysport), 1 unit = 5 dosing units
J0588, incobotulinumtoxinA (Xeomin), 1 unit = 1 dosing unit