

**Neuromuscular Blockers**  
**Botox (onabotulinumtoxinA)**  
**Daxxify (daxibotulinumtoxinA-lanm)**  
**Dysport (abobotulinumtoxinA)**  
**Myobloc (rimabotulinumtoxinB)**  
**Xeomin (incobotulinumtoxinA)**  
**Effective 11/12/2024**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Contact Information</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Notes</b>	Botox, Daxxify, Dysport, Myobloc, Xeomin are also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.		

### Overview

Indication	Botox	Dysport	Myobloc	Xeomin	Daxxify
Blepharospasm	✓	-	-	✓	-
Cervical Dystonia	✓	✓	✓	✓	✓
Lower Limb Spasticity	✓	✓	-	-	-
Migraine Prophylaxis	✓	-	-	-	-
Neurogenic detrusor overactivity	✓	-	-	-	-
Overactive bladder	✓	-	-	-	-
Sialorrhea	-	-	✓	✓	-
Strabismus	✓	-	-	-	-
Severe axillary hyperhidrosis	✓	-	-	-	-
Upper Limb Spasticity	✓	✓	-	✓	-
Urinary incontinence associated with neurologic conditions	✓	-	-	-	-

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met:

<b><u>Botox® (onabotulinumtoxinA)</u></b>	
<b>All indications EXCEPT bladder dysfunction, migraine prophylaxis, hyperhidrosis</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. <b>ONE</b> of the following diagnoses:               <ol style="list-style-type: none"> <li>a. Strabismus and blepharospasms associated with dystonia (including essential blepharospasm, cranial nerve VII disorders/hemifacial spasm)</li> <li>b. Focal dystonias (including cervical dystonia/spasmodic torticollis in members &gt; 16 years of age; spasmodic dysphonia, oromandibular dystonia)</li> <li>c. Limb spasticity (due to cerebral palsy, multiple sclerosis, or other demyelinating CNS diseases, spinal cord injury)</li> <li>d. Focal spasticity related to cerebral vascular accident (including hemorrhagic stroke, anoxia, and traumatic brain injury)</li> </ol> </li> <li>2. Dose is appropriate for stated indication (prescriber must provide child's weight)</li> </ol>
<b>Migraine Prophylaxis</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of migraine prophylaxis</li> <li>2. Prescriber is a neurologist, pain medicine/anesthesiology physician or physical medicine/rehabilitation physician or consult notes from one are provided</li> <li>3. Documentation of migraine headache frequency <math>\geq</math> 15 days per month</li> <li>4. Physician attestation of inadequate response or adverse reaction to <b>ONE</b> or contraindication to <b>ALL</b> of the following (<i>e.g., concurrent diagnosis of depression, asthma, COPD, peripheral vascular disease, Raynaud's, baseline hypotension or bradycardia, and pheochromocytoma</i>):               <ol style="list-style-type: none"> <li>a. atenolol</li> <li>b. metoprolol</li> <li>c. nadolol</li> <li>d. propranolol</li> <li>e. timolol</li> </ol> </li> <li>5. Physician attestation of inadequate response or adverse reaction to <b>TWO</b> or contraindication to <b>ALL</b> of the following:               <ol style="list-style-type: none"> <li>a. amitriptyline, nortriptyline or protriptyline</li> <li>b. topiramate</li> <li>c. valproic acid</li> <li>d. venlafaxine</li> </ol> </li> <li>6. Dose is appropriate for stated indication (<i>See Appendix for 10-week dosing</i>)</li> </ol>
<b>Overactive bladder</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of overactive bladder (<i>"urinary urgency, with or without incontinence", "nocturia", or "urinary frequency" may be reviewed using criteria for overactive bladder</i>)</li> <li>2. Prescriber is a urologist or consult notes from a urologist are provided</li> <li>3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to BOTH of the following classes:               <ol style="list-style-type: none"> <li>a. <b>TWO</b> anticholinergic medications (<i>e.g., oxybutynin, tolterodine</i>)</li> </ol> </li> </ol>



	<ul style="list-style-type: none"> <li>b. <b>ONE</b> anticholinergic medication and <b>ONE</b> <math>\beta</math>-3 adrenergic receptor agonist (mirabegron)</li> <li>4. Dose is appropriate for stated indication</li> </ul>
<b>Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (adults)</b>	<p><b>ALL</b> of the following:</p> <ul style="list-style-type: none"> <li>1. Diagnosis of neurogenic bladder dysfunction</li> <li>2. Prescriber is a urologist or consult notes from a urologist are provided</li> <li>3. Paid claims or physician attestation of inadequate response or adverse reaction to <b>ONE</b> of the following or contraindication to <b>ALL</b> of the following classes: <ul style="list-style-type: none"> <li>a. <b>TWO</b> anticholinergic medications (e.g. oxybutynin, tolterodine)</li> <li>b. <b>ONE</b> anticholinergic medication and <b>ONE</b> alpha blocker (e.g. prazosin, terazosin)</li> <li>c. <b>ONE</b> anticholinergic medication and <b>ONE</b> cholinergic agent (e.g. bethanechol)</li> </ul> </li> <li>4. Dose is appropriate for stated indication</li> </ul>
<b>Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (pediatrics)</b>	<p><b>ALL</b> of the following:</p> <ul style="list-style-type: none"> <li>1. Diagnosis of neurogenic bladder dysfunction</li> <li>2. Prescriber is a urologist or consult notes from a urologist are provided</li> <li>3. Paid claims or physician attestation of inadequate response or adverse reaction to <b>ONE</b> of the following or contraindication to <b>BOTH</b> of the following classes: <ul style="list-style-type: none"> <li>a. <b>ONE</b> anticholinergic medication (e.g. oxybutynin, solifenacin)</li> <li>b. <b>ONE</b> <math>\beta</math>-3 adrenergic receptor agonist (mirabegron)</li> </ul> </li> <li>4. Dose is appropriate for stated indication (not more frequently than every 12 weeks)</li> </ul>
<b>Primary focal hyperhidrosis (Axillary, Palmar, or Plantar)</b>	<p><b>ALL</b> of the following:</p> <ul style="list-style-type: none"> <li>1. Diagnosis of <b>ONE</b> of the following: <ul style="list-style-type: none"> <li>a. Severe primary axillary hyperhidrosis <ul style="list-style-type: none"> <li>i. Member is <math>\geq</math> 18 years of age OR 12 to &lt;18 years of age</li> </ul> </li> <li>b. Severe palmar hyperhidrosis</li> <li>c. Severe plantar hyperhidrosis</li> </ul> </li> <li>2. Prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided</li> <li>3. Physician attestation of inadequate response, adverse reaction or contraindication to aluminum chloride solution</li> <li>4. Dose is appropriate for stated indication</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>Escalated dosing in axillary hyperhidrosis</b></p> <ul style="list-style-type: none"> <li>1. Diagnosis of severe axillary hyperhidrosis</li> <li>2. Prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided</li> <li>3. Inadequate response to FDA-approved dosing of 50 units per axilla</li> <li>4. Requested dose is <math>\leq</math> 200 units per axilla</li> </ul>
<b>Off-Label Indications</b>	
<b>Achalasia/esophageal dysphagia</b>	<p><b>ALL</b> of the following:</p> <ul style="list-style-type: none"> <li>1. Diagnosis of achalasia/esophageal dysphagia</li> </ul>



	<ol style="list-style-type: none"> <li>2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided</li> <li>3. ONE of the following: <ol style="list-style-type: none"> <li>a. The member has failed a surgical option (e.g., pneumatic dilation, laparoscopic Heller myotomy with a partial fundoplication and peroral endoscopic myotomy [POEM])</li> <li>b. The member is not a surgical candidate or is unwilling to undergo these procedures.</li> </ol> </li> <li>4. Initial requested dose is ≤ 100 units no more frequently than every six months</li> </ol>
<b>Anal stenosis, chronic constipation, encopresis</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of anal stenosis, chronic constipation, encopresis</li> <li>2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided</li> <li>3. Inadequate response or adverse reaction to TWO or contraindication to ALL laxatives</li> <li>4. Inadequate response to dietary changes (e.g., increased intake of fluids and fiber) and/or behavior modification (e.g., biofeedback training, toilet training)</li> <li>5. Initial requested dose is ≤ 100 units no more frequently than every three months</li> </ol>
<b>Sialorrhea</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of sialorrhea</li> <li>2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following: <ol style="list-style-type: none"> <li>a. atropine</li> <li>b. glycopyrrolate</li> <li>c. hyoscyamine</li> <li>d. scopolamine</li> <li>e. tricyclic antidepressant (e.g., amitriptyline, nortriptyline, etc.)</li> </ol> </li> <li>3. Appropriate dosing (40 to 100 units every 3 to 6 months)</li> <li>4. Inadequate response, adverse reaction, or contraindication to BOTH of the following agents: <ol style="list-style-type: none"> <li>a. Myobloc</li> <li>b. Xeomin</li> </ol> </li> </ol>
<b>Migraine prophylaxis, concomitant therapy with a CGRP inhibitor</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Individual drug PA criteria must be met first where applicable</li> <li>2. Diagnosis of migraine prophylaxis</li> <li>3. Partial, but incomplete, response to CGRP inhibitor</li> <li>4. Appropriate dosing</li> </ol>
<b>Migraine prophylaxis, dosing every 10 weeks</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Individual drug PA criteria must be met first where applicable</li> <li>2. Diagnosis of migraine prophylaxis</li> <li>3. Member received initial positive response to therapy</li> <li>4. Member is still experiencing a “wearing-off” of efficacy after a dose increase to 195 units</li> </ol>



<p><b>Myofascial pain syndrome</b></p>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of myofascial pain syndrome</li> <li>2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> <li>a. cyclobenzaprine</li> <li>b. gabapentin or pregabalin</li> <li>c. local anesthetic (e.g., lidocaine patch)</li> <li>d. SNRI (e.g., duloxetine)</li> <li>e. TCA agent (e.g., amitriptyline)</li> </ol> </li> <li>3. Appropriate dosing (up to a total dose of 200 units)</li> </ol>
<p><b>Myofascial pelvic pain syndrome</b></p>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of myofascial pelvic pain syndrome</li> <li>2. Inadequate response, adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> <li>a. gabapentin or pregabalin</li> <li>b. muscle relaxant (e.g., cyclobenzaprine)</li> <li>c. SNRI (e.g., duloxetine)</li> <li>d. TCA agent (e.g., amitriptyline)</li> <li>e. vaginal diazepam</li> </ol> </li> <li>3. Appropriate dosing (up to a total dose of 300 units)</li> </ol>
<p><b>Raynaud’s Phenomenon</b></p>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of Raynaud’s Phenomenon</li> <li>2. Inadequate response or adverse reaction to THREE or contraindication to ALL of the following: <ol style="list-style-type: none"> <li>a. Calcium channel blocker (amlodipine or nifedipine)</li> <li>b. fluoxetine</li> <li>c. losartan</li> <li>d. PDE type 5 inhibitor</li> <li>e. Topical nitrate</li> </ol> </li> <li>3. Requested dose is <math>\leq</math> 200 units/90 day</li> </ol>
<p><b>Trigeminal Neuralgia</b></p>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of trigeminal neuralgia</li> <li>2. Prescriber is a neurologist or physical medicine/rehabilitation physician or consult notes from a specialist are provided</li> <li>3. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following: <ol style="list-style-type: none"> <li>a. baclofen</li> <li>b. carbamazepine</li> <li>c. gabapentin</li> <li>d. lamotrigine</li> <li>e. oxcarbazepine</li> <li>f. tizanidine</li> <li>g. topiramate</li> </ol> </li> <li>4. Appropriate dosing (<i>Use FDA-approved dosing as reference</i>)</li> </ol>
<p><b>Severe Craniofacial Hyperhidrosis</b></p>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of severe craniofacial hyperhidrosis</li> <li>2. Prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided</li> </ol>



	<ol style="list-style-type: none"> <li>3. Inadequate response or adverse reaction to ONE or contraindication to ALL of the following: <ol style="list-style-type: none"> <li>a. Aluminum chloride solution</li> <li>b. Oral glycopyrrolate</li> <li>c. Oral oxybutynin</li> </ol> </li> <li>4. Appropriate dosing</li> </ol>
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<b>Daxxify® (daxibotulinumtoxinA-lanm)</b>	
<b>Cervical dystonia/spasmodic torticollis</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of cervical dystonia/spasmodic torticollis</li> <li>2. Member is ≥ 18 years of age</li> <li>3. Appropriate dosing</li> </ol>

<b>Dysport® (abobotulinumtoxinA)</b>	
<b>Cervical dystonia/spasmodic torticollis</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of cervical dystonia/spasmodic torticollis</li> <li>2. Member is ≥ 18 years of age</li> <li>3. Appropriate dosing</li> </ol>
<b>Limb Spasticity</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>a. Upper limb spasticity</li> <li>b. Lower limb spasticity</li> </ol> </li> <li>2. Member is ≥ 2 years of age</li> <li>3. Dose is appropriate for stated indication (prescriber must provide child's weight)</li> </ol>

<b>Off-Label Indications</b>	
<b>Achalasia/esophageal dysphagia</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of achalasia/esophageal dysphagia</li> <li>2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided</li> <li>3. ONE of the following: <ol style="list-style-type: none"> <li>a. The member has failed a surgical option (e.g., pneumatic dilation, laparoscopic Heller myotomy with a partial fundoplication and peroral endoscopic myotomy [POEM])</li> <li>b. The member is not a surgical candidate or is unwilling to undergo these procedures.</li> </ol> </li> <li>4. Initial requested dose is ≤ 250 units no more frequently than every six months</li> </ol>
<b>See Appendix for High Dose Requests</b>	

<b>Myobloc® (rimabotulinumtoxinB)</b>	
<b>Cervical dystonia (spasmodic torticollis)</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of cervical dystonia/spasmodic torticollis</li> </ol>



	<ol style="list-style-type: none"> <li>2. Member is ≥ 18 years of age</li> <li>3. Dose is appropriate for stated indication</li> </ol>
<b>Sialorrhea (salivary hypersecretion)</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of sialorrhea</li> <li>2. Member is ≥ 18 years of age</li> <li>3. Physician attestation of inadequate response or adverse reaction to <b>TWO</b> or contraindication to <b>ALL</b> of the following agents: <ol style="list-style-type: none"> <li>a. scopolamine</li> <li>b. glycopyrrolate</li> <li>c. atropine</li> <li>d. hyoscyamine</li> <li>e. TCA agent (e.g., amitriptyline, nortriptyline, etc)</li> </ol> </li> <li>4. Dose is appropriate for stated indication</li> </ol>
<b>See Appendix for High Dose Requests</b>	

<b><u>Xeomin® (incobotulinumtoxinA)</u></b>	
<b>Cervical dystonia/spasmodic torticollis or Blepharospasm</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. <b>ONE</b> of the following diagnoses: <ol style="list-style-type: none"> <li>a. Cervical dystonia/spasmodic torticollis</li> <li>b. Blepharospasm</li> </ol> </li> <li>2. Member is ≥ 18 years of age</li> <li>3. Dose is appropriate for stated indication</li> </ol>
<b>Upper limb spasticity</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of upper limb spasticity</li> <li>2. Member is ≥ 2 years of age</li> <li>3. If &lt; 18 of age, spasticity is not caused by cerebral palsy</li> <li>4. Appropriate dosing (For pediatric members, prescriber must provide child’s weight)</li> </ol>
<b>Sialorrhea</b>	<p><b>ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of sialorrhea</li> <li>2. Member is ≥ 2 years of age</li> <li>3. Physician attestation of inadequate response or adverse reaction to <b>TWO</b> or contraindication to <b>ALL</b> of the following agents: <ol style="list-style-type: none"> <li>a. scopolamine</li> <li>b. glycopyrrolate</li> <li>c. atropine</li> <li>d. hyoscyamine</li> <li>e. Tricyclic antidepressant agent (e.g. amitriptyline, nortriptyline, etc)</li> </ol> </li> <li>4. Dose is appropriate for stated indication (prescriber must provide child’s weight)</li> </ol>
<b>See Appendix for High Dose Requests</b>	

<b>Off Label Indications for ALL agents</b>	
<b>Anal Fissures</b>	<b>ALL</b> of the following:



	<ol style="list-style-type: none"> <li>1. Diagnosis of anal fissures</li> <li>2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided</li> <li>3. Inadequate response or adverse reaction to ONE or contraindication to BOTH of the following: <ol style="list-style-type: none"> <li>a. topical nifedipine product</li> <li>b. topical nitroglycerin</li> </ol> </li> </ol>
<b>Gastroparesis</b>	<b>ALL</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of gastroparesis</li> <li>2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided</li> <li>3. Inadequate response, adverse reaction, or contraindication to metoclopramide</li> <li>4. Inadequate response or adverse reaction to ONE or contraindication to ALL antiemetics</li> </ol>

All other conditions AND doses exceeding the limits set within the criteria will be reviewed on a case by case basis. Risk-benefit assessment should precede any decision for use in unlabeled indications as well as establishing that the patient is unresponsive to conventional treatment options.

**Continuation of Therapy**

Migraine Prophylaxis (in combination with CGRP inhibitor): Resubmission should document positive response to therapy and improvement of headache days per month.

All other indications: Reauthorizations require physician attestation of a positive response to therapy.

**Limitations**

1. Initial Authorizations will be granted for 3 months for the first course of therapy.
2. Reauthorizations will be granted for the following:
  - a. Migraine Prophylaxis (in combination with CGRP inhibitor): 6 months
  - b. All other indications: 12 months
3. Exclusions:
  - a. The Plan will not cover Botox, Dysport, Myobloc or Xeomin for the following conditions: facial rhytids, frown lines, glabellar wrinkling, horizontal neck rhytids, hyperfunctional facial lines, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the periorbital region, lateral canthal lines (crow’s feet)
  - b. Botox® Cosmetic
  - c. Dysport® 300 units (abobotulinumtoxinA) (glabellar lines)

**Appendix**

**High Dose of Botulinum Toxin Products**

	<b>Adults:</b> Requests for adults beyond the FDA-approved dose can be approved up to the following doses:	<b>Pediatrics:</b> Requests for members less than 18 years of age (or less than 60 kg) can be approved up to the following doses:
	<b>Maximum Approvable Dose</b>	<b>Maximum Approvable Dose</b>





Botox® (onabotulinumtoxinA)	Up to 840 units	Up to 25 units/kg or a max total dose of up to 600 units (this would be multiple administration sites; please follow max dose per treatment session in respective area per PI)
Dysport® (abobotulinumtoxinA)	Up to 1,500 units	Up to 25 units/kg or a max total dose of up to 1,000 units
Myobloc® (rimabotulinumtoxinB)	Up to 25,000 units	Up to 400 units/kg or a max total dose of 10,000 units
Xeomin® (incobotulinumtoxinA)	Up to 840 units	Requests for dosing outside of FDA-approved use in pediatric patients will be evaluated on a case-by-case basis

## References

1. Botox® [package insert]. Irvine (CA): Allergan, Inc; 2021 Jul.
2. Dysport® [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; 2020 Jul.
3. Myobloc® [package insert]. South San Francisco (CA): Solstice Neuroscience, Inc; 2021 Mar.
4. Xeomin® [package insert]. Raleigh (NC): Merz Pharmaceuticals, LLC; 2021 Aug.
5. Bajwa ZH. Botulinum toxin pharmacology. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2010 [cited 2010 Dec 09]. Available from: <http://www.utdol.com/utd/index.do>.
6. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2021 Dec 17]. Available from: <http://www.thomsonhc.com/>.
7. Naumann M, So Y, Argoff CE, Childers MK, Dykstra DD, Gronseth GS, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. *Neurology*. 2008;70:1707-14.
8. Zalvan C, Bentianov B, Gonzalez-Yanes O, Blitzer A. Noncosmetic uses of botulinum toxin. *Dermatol Clin*. 2004;22:187-95.
9. Bleday R. Anal fissures: Medical Management. In: Weiser M, Friedman LS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: <http://www.utdol.com/utd/index.do>.
10. Brin MF, Lew MF, Adler CH, Comella SA, Factor SA, Jakovic J, et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. *Neurology*. 1999; 53: 1431-38.
11. Deik A, Comella C. Etiology, clinical features, and diagnostic evaluation of dystonia. In: Hurtig HI (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: <http://www.utdol.com/utd/index.do>.
12. Dressler D. Routine use of Xeomin in patients previously treated with Botox: long term results. *European Journal of Neurology*. 2009;16(2):2-5.
13. Mohammadi B, Balouch SA, Dengler R, Kollwe K. Long-term treatment of spasticity with botulinum toxin type A: an analysis of 1221 treatment in 137 patients. *Neurological Research*. 2010;32(3):309-13.
14. Berman B, Seeberger L, Kumar R. Long-term Safety, Efficacy, Dosing, and Development of Resistance with Botulinum Toxin Type B in Cervical Dystonia. *Movement Disorders*. 2005; 20(2):233-37.
15. Factor SA, Molho ES, Evans S, Fuestel PJ. Efficacy and Safety of Repeated Doses of Botulinum Toxin Type B in Type A resistant and Responsive Cervical Dystonia. *Movement Disorders*. 2005;20(9):1152-60.
16. Heinen F, Desloovere K, Schroeder AS, Berweck S, Borggraefe I, Capenhout A, et al. The updated European Consensus 2009 on the use of Botulinum toxin for children with cerebral palsy. 2010; 14:45-66.



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54. Daxxify® [package insert]. Newark (CA): Revance Therapeutics, Inc.; 2023 Aug.

### Review History

12/01/2005 – Implemented  
09/25/2006 – Reviewed  
09/24/2007 – Reviewed  
09/22/2008 – Reviewed  
09/21/2009 – Reviewed  
09/27/2010 – Reviewed  
01/03/2011 – Exclusions section updated with new Dysport product  
05/17/2011 – Xeomin BART  
09/19/2011 – Reviewed  
09/24/2012 – Reviewed  
09/19/2013 – Dysport 300 units glabellar lines product  
04/08/2013 – Botox exclusion: crow’s feet  
11/25/2013 – Reviewed  
06/09/2014 – Added migraine trials to 3 based on specialist input  
11/24/2014 – Reviewed  
11/20/2017 – Updated  
02/26/2018 – Updated  
07/05/2018 – Added diagnosis of chronic sialorrhea to Xeomin  
11/26/2018 – Updated  
09/18/2019 – Added restriction of using concurrent CGRP with Botox for migraine and new indication of sialorrhea for Myobloc  
11/20/2019 – Added new indications for upper limb spasticity in pediatrics and increased max dose for this indication from 1000 units to 1500 units  
05/20/2020 – Reviewed and Updated May P&T Mtg; updated reauthorization for chronic migraines to decrease in frequency and/or severity of migraines. Effective 8/1/20.  
07/20/2022 – Reviewed and Updated for July P&T; removed the following statement “The member is not concurrently using a calcitonin-gene receptor antagonist (CGRP), including, but not limited to Ajovy, Aimovig, Emgality.”  
09/21/2022 – Separated Comm/Exch vs MH policy; no clinical updates. Effective 10/1/2022  
1/11/2023 – Reviewed and updated for Jan P&T. Matched MH UPPL criteria for all drugs. Added Appendix sections. Clarified approval durations. Updated references. Effective 2/1/23.  
04/12/23 – Reviewed and updated for Apr P&T. Diagnosis of primary axillary hyperhidrosis age criteria update. Added specific criteria points to Concomitant CGRP and Botox therapy and 10-week botox dosing for migraine prophylaxis. Effective 6/5/23.  
07/12/23 – Reviewed and updated for P&T. Off-label criteria were added for Botox for myofascial pain syndrome and for myofascial pelvic pain syndrome. Brand preferred and mandatory generic language was added under Limitations. Brand preferred and mandatory generic language was added under Limitations. Effective 07/31/2023  
10/9/24 – Reviewed and updated for P&T. Daxxify was added to criteria. Botox criteria for overactive bladder was updated to include “urinary urgency, with or without incontinence”, “nocturia”, and “urinary frequency” as diagnoses. Botox criteria for migraine prophylaxis was updated to require “migraine” headache frequency (not just headache frequency). Botox off-label criteria were added for trigeminal neuralgia, severe craniofacial hyperhidrosis, and escalated dosing in axillary hyperhidrosis. Botox criteria for migraine prophylaxis, concomitant therapy with a CGRP inhibitor were updated to require appropriate dosing and to clarify



requirement of partial, but incomplete, response to CGRP inhibitor. Dysport, Myobloc, and Xeomin criteria were updated to align age and indication requirements with package inserts. Effective 11/12/24

