FDA Indications and Usage[1,2,3,4]

	Botox®	Xeomin®	Dysport®	Myobloc®
	onabotulinumtoxin A	*incbotulinumtoxin A*	*abobotulinumtoxin A*	*rimabotulinumtoxin B*
Cervical dystonia	≥18 years	≥18 years	≥18 years	≥18 years
Overactive bladder (non-neurogenic)	≥18 years	**N/A**	**N/A**	**N/A**
Urinary incontinence secondary to detrusor overactivity (neurogenic)	≥18 years	**N/A**	**N/A**	**N/A**
Neurogenic Detrusor Overactivity (NDO)	≥5 years	**N/A**	**N/A**	**N/A**
Chronic migraine prophylaxis	≥18 years	**N/A**	**N/A**	**N/A**
Blepharospasm	≥12 years	≥18 years	**N/A**	**N/A**
Strabismus	≥12 years	**N/A**	**N/A**	**N/A**
Spasticity	≥2 years	Upper limb: 2-17 years (excluding spasticity secondary to cerebral palsy) Upper limb: ≥18 years	≥2 years	**N/A**
Axillary hyperhidrosis, severe	≥18 years	**N/A**	**N/A**	**N/A**
Chronic sialorrhea	**N/A**	≥2 years	**N/A**	≥18 years

Approval Criteria:

Indication	Approval Criteria[1,2,3,4]	Denial Criteria	Maximum Quantity[1,2,3,4]
Overactive bladder (OAB)[1,5]	• Age ≥18 years old; **AND** • Documented moderate to severe symptoms of urge urinary incontinence, urgency, and frequency; **AND** • Documented behavioral therapy trials • Documented trial of at least 2 different pharmacologic treatments for at least 60 days with documentation of inadequate response **OR** a justifiable contraindication to oral anti-muscarinics or oral β_3-adrenergic receptor agonists (e.g. oxybutynin, tolterodine, or mirabegron) ; **AND** • Product requested is **Botox®**.	• Patients unable/unwilling to perform self-catheterization if necessary during treatment course • Dose exceeds FDA recommendations for indication • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures	**Botox®:** • No more than 100 Units per 12 weeks
Neurogenic bladder with detrusor muscle overactivity[1,6]	• Age ≥5 years old; **AND** • Documented symptoms of detrusor over- activity; **AND** • Documented trial of at least 2 different pharmacologic treatments for at least 60 days with documentation of inadequate response or a justifiable contraindication to oral anti-muscarinics or oral β_3- adrenergic receptor agonists (e.g. oxybutynin, tolterodine, or mirabegron) ; **AND** • Product requested is **Botox®**.	• Dose exceeds FDA recommendations for indication • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures	**Botox®:** • No more than 200 Units per 12 weeks

ALASKA MEDICAID
Prior Authorization Criteria

Indication	Approval Criteria[1,2,3,4]	Denial Criteria	Maximum Quantity[1,2,3,4]
Chronic Migraine, headache prophylaxis[1,7,8]	• ≥18 yrs of age; **AND** • Headache on ≥15 days per month with headache lasting 4 hours a day or longer (chronic/transformed migraine); **AND** • Patient has tried and had an inadequate response, intolerance, or contraindication to at least two migraine prophylaxis classes (ie. anticonvulsants, beta blockers) **AND** • Prescriber is a neurologist; **AND** • Product requested is Botox®. • *Renewal Authorization:* ▪ Headache frequency has decreased by at least 2 headache days from baseline in the previous month	• Episodic migraine (<15 days per month) • Headache attributable to another disorder, including medication overuse. • Dose exceeds FDA recommendations for indication. • Cumulative Botox dose exceeds 360 units within a 3 month period from all procedures. • For renewal authorizations beyond the second treatment, headache frequency has not decreased from baseline by at least 2 headache days per month.	**Botox®:** • No more than 155 units per 12 weeks
Spacticity[1,2,8]	• Age ≥2 years old; **AND** • Spasticity refractory to oral medication; **AND** • Product requested is **Botox®**, or **Dysport®.**	• Dose exceeds FDA recommendations for indication. • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures	**Botox®:** • No more than 360 units per 12 weeks **Dysport®** • Pediatric patients: No more than the lesser of 30 units/kg or 1000 units per 12 weeks • Adults: No more than 1500 units per 12 weeks
Spacticity: Upper limb (Xeomin®)[4,8]	• Age ≥18 yrs; **OR** • Age 2-17 yrs (excluding spasticity secondary to cerebral palsy) **AND** • Spasticity refractory to oral medication; • Product requested is Xeomin®	• Dose exceeds FDA recommendations for indication or maximum cumulative dose over a 12 week period.	**Xeomin®:** • No more than 400 units total divided among affected muscles; o Pediatric max: 200 units per upper limb

Botulinum Toxin criteria
Version: 5
Updated: 02/26/2024
Previous: 04/17/2015
Approved:04/19/2024

ALASKA MEDICAID
Prior Authorization Criteria

Indication	Approval Criteria[1,2,3,4]	Denial Criteria	Maximum Quantity[1,2,3,4]
Cervical dystonia [1,2,3,4,8]	• ≥18 yrs of age; **AND** • Diagnosis of cervical dystonia; **AND** • Purpose of treatment is to reduce the severity of abnormal head position and neck pain.	• Dose exceeds FDA recommendations for indication or maximum cumulative dose over a 12 week period.	**Botox®:** • Maximum cumulative dose of no more than 360 units within a 3 month (12 week) period **Dysport®:** • Maximum dose initial – No more than 500 units per 12 weeks • Subsequent maximum dose – no more than 250 units more than previous dose up to a maximum of 1000 units per 12 weeks **Myobloc®:** • No more than 5,000 units within a 12 week period • No more than 10,000 units within a 16 week period **Xeomin®:** • No more than 120 units per 12 weeks
Axillary hyperhidrosis, severe[1]	• Age ≥17 years old; **AND** • Patient is being treated for severe axillary hyperhidrosis that has been inadequately managed by topical agents; **AND** • HDSS (Hyperhidrosis Disease Severity Scale) score is ≥ 3; **AND** • Product requested is Botox®.	• Dose exceeds FDA recommendations for indication. • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures.	**Botox®:** • No more than 50 units per axilla per 12 weeks

ALASKA MEDICAID
Prior Authorization Criteria

Indication	Approval Criteria[1,2,3,4]	Denial Criteria	Maximum Quantity[1,2,3,4]
Strabismus[1,9]	• Patient is ≥12 years old; **AND** • Patient is being treated for strabismus; **AND** • Product requested is Botox®.	• Initial or subsequent dose exceeds FDA recommendations for indication. • Subsequent dose more than two times the previous dose or exceeds 25 units. • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures.	**Botox®:** • No more than 25 units for any one muscle per 12 weeks
Blepharospasm associated with dystonia[1,4]	• Age ≥12 years old (Botox®) or ≥18 years old (Xeomin®); **AND** • Patient is unable to open their eyelid(s) or is functionally blind due to dystonia; **AND** • Medication is ordered by a neurologist or ophthalmologist; **AND** • Product requested is Botox® or Xeomin®.	• Initial or subsequent dose exceeds FDA recommendations for indication • Cumulative Botox® dose exceeds 360 units within a 3 month period from all procedures.	**Botox®:** • No more than 200 cumulative units in 30 day period; no more than 360 units per 12 weeks **Xeomin®:** • No more than 35 units per eye per 12 weeks
Chronic sialorrhea[3,4]	• Age ≥2 years old (Xeomin®) or ≥18 years old (Myobloc®); **AND** • Product has tried and failed one first line agent (benztropine, oral hyoscyamine, glycopyrrolate) or has a contraindication to all; **AND** • Product requested is Myobloc® or Xeomin®.	• Initial or subsequent dose exceeds FDA recommendations for indication.	**Myobloc®:** • No more than 3500 units per 12 weeks **Xeomin®:** • Adults: No more than 100 units per 12 weeks • Pediatric patients: No more than 75 units per 16 weeks

Non-FDA Approved Indications[10]

- All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy in the representative population.
- A letter of medical necessity must be included with each request and shall include previous therapies trialed.
- ICD-9 (or ICD-10, when applicable) codes must be included in the request and coded to the highest level of specificity.
- Each request will be reviewed on a case-by-case basis.
- The current version of the *CMS Local coverage determination (LCD) for Botulinum Toxins (L38809)* document will be used in the evaluation of the request.

Black Box Warning[1,2,3,4]

WARNING: DISTANT SPREAD OF TOXIN EFFECT Postmarketing reports indicate that the effects of Botox®, Dysport®, Myobloc®, Xeomin® and "all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses."

Denial Criteria

- The medication is being used for cosmetic purposes, including treatment of glabellar lines.
- ICD-9 (or ICD-10, when applicable) code is absent from prior authorization request.

Length of Authorization

- Coverage may be approved for up to 6 months.
- Re-authorization requires documentation of clinical response and progress as well as absence of limiting adverse effects.

References

1. Botox® [package insert]. North Chicago, IL; AbbVie, Inc., November 2023.
2. Dysport® [package insert]. Wrexham, UK; Ipsen Biopharm Ltd, September 2023.
3. Myobloc® [package insert]. Rockville, MD; Solstice Neurosciences, Inc.; March 2021.
4. Xeomin® [package insert]. Raleigh, NC; Merz Pharmaceuticals, LLC., September 2023.
5. 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 2019; 202: 558 Available at: https://www.auanet.org/guidelines-and-quality/guidelines/overactive-bladder-(oab)-guideline
6. Cameron AP. Medical Management of Neurogenic Bladder with Oral Therapy. Transl Androl Urol. 2016 Feb;5(1):51-62. doi:10.3978/j.issn.2223-4683.2015.12.07.
7. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice (2019). Headache: The Journal of Head and Face Pain, 59: 1-18. Available at https://headachejournal.onlinelibrary.wiley.com/doi/10.1111/head.13456.
8. 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. Neurology. 2016 May;86(19):1818-1826.
9. American Academy of Ophthalmology. Preferred Practice Pattern. Esotropia and Exotropia. Available at: https://www.aaojournal.org/article/S0161-6420(17)33034-8/pdf.
10. CMS Local coverage Determination (LCD): Botulinum Toxins (L38809). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38809&name=331*1&UpdatePeriod=923.