Department:	Pharmacy Management	**Original Approval:**	12/11/2024
Policy No:	PM192	**Last Approval:**	10/16/2026
Policy Title:	AbobotulinumtoxinA (Dysport) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for abobotulinumtoxinA (Dysport):

1. History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
2. Diagnosis
3. Labs/Diagnostics
4. Dosing and duration requested
5. Initial/Extended approval
6. Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
7. Prescribed by or in consultation with a specialist, when indicated.

Background

Dysport (abobotulinumtoxinA), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

1. **Cervical dystonia** in adults.
2. **Spasticity** in patients ≥ 2 years of age.

Other Uses with Supportive Evidence

Botulinum toxins have been studied in a variety of indications outside of FDA-approved uses.[2-4] Literature is available to support use of Dysport in the following conditions:

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1. **Anal Fissure:** The American College of Gastroenterology (ACG) clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections (formulation not specified) may be attempted for patients with chronic anal fissures in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).[5] Dysport was also found to be more effective than isosorbide dinitrate ointment as the primary treatment for chronic anal fissures in a randomized, multicenter 4 year clinical trial.[21]
2. **Blepharospasm:** Dysport has demonstrated efficacy in clinical trials in patients with blepharospasm.[6,7] American Academy of Neurology (AAN) guidelines (2016, reaffirmed 2022) support the use of Dysport for blepharospasm with a Level C recommendation ("possibly effective").[8] An evidenced-based review and assessment (2013) for the treatment of blepharospasm indicate Dysport should be considered (Level B recommendation).[20] Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.[14]
3. **Hemifacial Spasm:** Per historical AAN guidelines for the treatment of movement disorders, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C recommendation).[9] Data with Botox® (onabotulinumtoxinA injection) and Dysport are cited in the recommendations regarding hemifacial spasm. An evidenced-based review and assessment (2013) for the treatment of hemifacial spasm indicate Botox ® (onabotulinumtoxinA injection) should be considered (Level B recommendation) and Dysport may be considered (Level C recommendation).[20]
4. **Oromandibular Dystonia:** Small clinical trials have shown botulinum toxin A to be effective in treating oromandibular dystonia.[10,11] The American Academy of Oral Medicine clinical practice statement on oromandibular dystonia recommend the use of botulinum type A injections (Botox is mentioned).[12] A five year trial with Dysport for the treatment of focal movement disorders including oromandibular dystonia showed effectiveness and no new safety concerns.[13] An evidence-based review and assessment (2013) for the treatment of oromandibular dystonia indicate Botox and Dysport may be considered (level C recommendation).[20] Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.[14]
5. **Sialorrhea:** Botulinum toxin A has been studied in the treatment of sialorrhea associated with Parkinson's Disease, parkinsonian syndromes, cerebral palsy, head and neck carcinoma, neurodegenerative disease, stroke, and amyotrophic lateral sclerosis.[2,] A review of the literature on medical treatment of sialorrhea found that Dysport is probably effective for the treatment of this condition (Level B evidence).[15]

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Dosing Information

Toxin distribution varies between the commercially available botulinum toxin products.[1,16,17] The labels for the botulinum toxin products state that there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity. Studies have attempted to establish a conversion ratio between botulinum toxin products, with variable results.[18] In general, conversion ratios of 1:1 for Botox to Xeomin, 1:3 for Botox to Dysport, and 1:50 to 1:100 for Botox to Myobloc have been suggested.

Definitive dosing has not been established for off-label uses of botulinum toxins, including Dysport. Specific dosing considerations by indication are noted below. For other indications addressed in this policy, specific dosing guidance is not available. In these cases, dosing is based on the Botox prescribing information, which states that in a 3-month interval, adults should not exceed a total dose of 400 units, and pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval.[16] Recommendations for maximum dosing and frequency for Dysport are based on a suggested relative conversion of 3:1 between Dysport and Botox units.[1] Additionally, the maximum dose supported for a patient < 18 years of age in Dysport labeling is 30 units/kg (not to exceed 1,000 units).

1. **Anal Fissures:** The ACG guidelines (2021) suggest botulinum toxin A injections (formulation not specified) may be used at doses of 5-100 units in patients with refractory, chronic anal fissures.[5] This is also supported by positive outcomes in a 4 year randomized, multicenter study for the treatment of chronic anal fissures which utilized a standard dosing of 60 units of Dysport.[21]
2. **Blepharospasm:** A maximum dose of 120 units of Dysport, not more frequently than once every 12 weeks, has been suggested.[19]
3. **Sialorrhea, Chronic:** Xeomin is indicated for this use.[17] Per Xeomin labeling, the maximum recommended dose for adults is 100 units (50 units per side) and for pediatric patients is 75 units (37.5 units per side), administered not more frequently than once every 16 weeks.

For Medicare: This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient

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to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications/Criteria

Medicaid and Individual & Family (Cascade Select) Members	***Continue to criteria for approval below.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***
Medicare Members	***Step-utilization of Part D drugs not required.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***

Medicaid/Cascade Select Criteria

FDA-Approved Indications

1. **Cervical Dystonia**. Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Cervical dystonia is also referred to as spasmodic torticollis.

   Dosing. Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.

2. **Spasticity, Limb(s).** Approve for 1 year if the patient is ≥ 2 years of age.

   Dosing. Approve ONE of the following regimens (A or B):

   A) Lower limb spasticity (or if treating BOTH upper AND lower limb spasticity): Approve ONE of the following regimens (i or ii):
   - **i.** Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,500 units, administered not more frequently than once every 12 weeks.
   - **ii.** Patient is < 18 years of age: Approve up to a maximum dose of 30 units/kg (not to exceed 1,000 units), administered not more frequently than once every 12 weeks.

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B) Upper limb spasticity: Approve ONE of the following regimens (i or ii):
- **i.** Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.
- **ii.** Patient is < 18 years of age: Approve up to a maximum dose of 16 units/kg (not to exceed 640 units), administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

3. **Anal Fissure, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.
4. **Blepharospasm.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

   Dosing. Approve up to a maximum dose of 120 units per eye, administered not more frequently than once every 12 weeks.

5. **Hemifacial Spasm.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 220 units, administered not more frequently than once every 3 months.

6. **Oromandibular Dystonia.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Oromandibular dystonia is also referred to as orofacial dystonia.

   Dosing. Approve up to a maximum dose of 260 units, administered not more frequently than once every 3 months.

7. **Sialorrhea, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 450 units, administered not more frequently than once every 12 weeks.

Medicare Criteria
FDA-Approved Indications

1. **Cervical Dystonia.**
   Note: Cervical dystonia is also referred to as spasmodic or cervical torticollis.

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Criteria. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.

2. **Spasticity, Limb.**
Note: For other forms of spasticity that do not fit this condition of approval, see Other Uses with Supportive Evidence, Spasticity.
Criteria. Approve for 1 year if the patient is ≥ 2 years of age.

Dosing. Approve one of the following regimens (A or B):
   - **A)** Lower limb spasticity (or combined upper and lower limb spasticity): Approve one of the following regimens (i or ii):
     - **i.** Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,500 units, administered not more frequently than once every 12 weeks.
     - **ii.** Patient is < 18 years of age: Approve up to a maximum dose of 30 units/kg (not to exceed 1,000 units), administered not more frequently than once every 12 weeks.
   - **B)** Upper limb spasticity: Approve one of the following regimens (i or ii):
     - **i.** Patient is ≥ 18 years of age: Approve up to a maximum dose of 1,000 units, administered not more frequently than once every 12 weeks.
     - **ii.** Patient is < 18 years of age: Approve up to a maximum dose of 16 units/kg (not to exceed 640 units), administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

3. **Achalasia (i.e., cardiospasm).** [23,24]
Criteria. Approve for 1 year if the patient meets ONE of the following criteria (A, B, C, D, E, or F): [23,24]
   - **A)** Patient has failed at least one conventional therapy; OR
   - **B)** Patient is at high risk of complications from pneumatic dilation or surgical myotomy; OR
   - **C)** Patient refuses surgical myotomy or balloon dilation, in preference to a less invasive risky procedure; OR
   - **D)** Patient had treatment failure with prior myotomy or dilatation; OR
   - **E)** Patient experienced an esophageal perforation with prior dilatation; OR
   - **F)** Patient has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilatation-induced perforation.

Dosing.[22] Dosing is 50-unit (up to 400 units total dose) injections to each quadrant of the lower esophageal sphincter 1 month before pneumatic dilatation

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4. **Blepharospasm.**
   Criteria. Approve for 1 year.

   Dosing. Approve up to a maximum dose of 120 units, administered not more frequently than once every 12 weeks.

5. **Sialorrhea, Chronic.**
   Criteria. Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 300 units (150 units per side), administered not more frequently than once every 16 weeks.

6. **Oromandibular Dystonia.**
   Criteria. Approve for 1 year if the patient is ≥ 18 years of age
   Note: Oromandibular dystonia is also referred to as orofacial dystonia.

   Dosing. Approve up to a maximum dose of 1,200 units, administered not more frequently than once every 3 months.

7. **Spasticity, other than Limb (i.e., spasticity or hypertonia due to cerebral palsy, [23,24] stroke, [23,24] brain injury, [23,24] spinal cord injury, [23,24] multiple sclerosis, [23,24] hemifacial spasm).**
   Note: For limb spasticity, refer to FDA-Approved Indications above.
   Criteria. Approve for 1 year.

   Dosing. Approve up to a maximum dose of 220 units, administered not more frequently than once every 3 months.

Conditions Not Recommended for Approval
Coverage of Dysport is not recommended in the following situations:

1. **Cosmetic Uses**. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit ad under the Medicare benefit.
   Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, or rejuvenation of the periorbital region.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Special Considerations

None.

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Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Dysport® injection [prescribing information]. Cambridge, MA and Fort Worth, TX: Ipsen/Galderma; July 2020. 2. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci*. 2005;235(1-2):1-9. 3. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 1. *Am J Health Syst Pharm.* 2006;63(2): 145–152. 4. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 2. *Am J Health Syst Pharm*. 2006;63(3):225-232.	

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Revision History

Revision Date	Revision Description	Revision Made By
12/09/2024	New policy.	Alan Gabot, PharmD
12/11/2024	Approval	UM Criteria Subcommittee
02/11/2025	Early update. For Medicare, Oromandibular Dystonia was added to the policy.	Alan Gabot, PharmD
02/12/2025	Approval	UM Criteria Subcommittee
12/11/2025	Annual review. For Medicaid, dosing limitation for Hemifacial Spasm was decreased from 1200 units to 220 units. For Medicare, dosing limitation for Spasticity other than Limb was decreased from 1200 units to 220 units.	Alan Gabot, PharmD
12/12/2025	Approval	UM Criteria Subcommittee
10/15/2026	Annual review. For Medicaid/Cascade Select: **Blepharospasm:** The dosing limitation was clarified to add "per eye". **Oromandibular Dystonia**: The dosing limitation was decreased from 1200 units to 260 units. **Sialorrhea, Chronic:** The dosing limitation was clarified from a "maximum dose of 300 units (150 per side), administered not more frequently than once every 16 weeks" to "maximum dose of 450 units, administered not more frequently than once every 12 weeks".	Alan Gabot, PharmD
10/16/2026	Approval	UM Criteria Subcommittee

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