Policy:	**Botulinum Toxin – Dysport Utilization Management Medical Policy** • Dysport® (abobotulinumtoxinA injection – Ipsen/Galderma)
Date:	06/23/2026
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States/Territories:	Noridian JE: California, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada Noridian JF: Alaska, Idaho, Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah, Wyoming
Applicable NCDs, LCDs, and/or LCAs	L35172, A57186, L35170, A57185

SUMMARY OF EVIDENCE

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

- **Cervical dystonia** in adults.
- **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:

- **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]
- **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]
- **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]
- **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]

- **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]

Dosing Information

The general approach for first time botulinum toxin injections is to focus on using minimum effective starting doses and titrate based on patient response for further treatments.[14] Toxin distribution varies between the commercially available botulinum toxin products.[1,16,17] Labeling for the botulinum toxin products states 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; however, conversion ratios of 1:1 for Botox to Xeomin, 1:2-3 for Botox to Dysport have been suggested.[18]

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

- **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]
- **Blepharospasm:** A maximum dose of 120 units of Dysport, not more frequently than once every 12 weeks, has been suggested.[19]
- **Hemifacial Spasm**: A long-term study involving 175 consecutive cases treated with Dysport over a period of up to 7 years reported a treatment dose range of 28 to 220 units, with a mean dose of 92 units per session.[22]
- **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.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Dysport. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for 1 year in duration. In cases where the dosing interval is provided in months, 1 month is equal to 30 days.

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 Sources of Information 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 Sources of Information 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 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 with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Cervical Dystonia. ^

Note: Cervical dystonia is also referred to as spasmodic torticollis.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age. [IC-L]

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

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2. Spasticity, Limb(s). ^

Criteria. Approve for 1 year if the patient is ≥ 2 years of age. [IC-L]

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.

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. ^

Criteria. Approve for 1 year.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

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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.

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5. Sialorrhea, Chronic. ^

Criteria. Approve for 1 year.

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

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6. Oromandibular Dystonia. ^
Note: Oromandibular dystonia is also referred to as orofacial dystonia.

Criteria. Approve for 1 year.

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

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7. Hemifacial Spasm. ^

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** 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. Cosmetic use is not recommended for coverage as this indication is excluded from coverage under the Medicare benefit.[28, 30]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SOURCES OF INFORMATION

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5. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: management of benign anorectald. *Am J Gastroenterol* 2021;116(10):1987-2008.
6. Truong D, Comella C, Fernandez HH, et al.; Dysport Benign Essential Blepharospasm Study Group. Efficacy and safety of purified botulinum toxin type A (Dysport) for the treatment of benign essential blepharospasm: a randomized, placebo-controlled, phase II trial. *Parkinsonism Relat Disord*. 2008;14(5):407-414.
7. Kollewe K, Mohammadi B, Köhler S, et al. Blepharospasm: long-term treatment with either Botox®, Xeomin® or Dysport®. *J Neural Transm*. 2015;122(3):427-431.
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13. Van den Bergh P, Francart J, Mourin S, Kollmann P, Laterre EC. Five-year experience in the treatment of focal movement disorders with low-dose Dysport botulinum toxin. *Muscle Nerve*. 1995;18(7):720-729.
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17. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.
18. Scaglione F. Conversion ratio between Botox®, Dysport®, and Xeomin® in clinical practice. *Toxins (Basel)*. 2016;8(3):65.
19. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed on September 17, 2024. Search terms: Dysport.
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HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	04/15/2020
Policy revision	**FDA-Approved Indications:** • "Cervical Dystonia (torticollis)" updated to "Cervical Dystonia (spasmodic torticollis)". • Pediatric dosing added for "Spasticity, Upper Limb" in accordance with updated FDA labeling. • Clarified "adults" as ≥ 18 years of age and "pediatric patients" as < 18 years of age for lower and upper limb spasticity dosing.	06/08/2020
Policy revision	**Cervical Dystonia:** The phrase "spasmodic torticollis" was removed from the approval condition. **Spasticity, Limb:** The approval conditions of "Spasticity, Lower Limb" and "Spasticity, Upper Limb" were rolled together into this approval condition. **Hyperhidrosis, Gustatory, Spasticity, other than Limb and Sialorrhea, Chronic added as covered indications** **Hyperhidrosis, Primary Axillary:** Examples of topical agents were moved to a Note. **Cosmetic Uses:** Examples were removed from the Condition Not Recommended for Approval into a Note. **Dosing:** In "Spasticity, Lower Limb" pediatric dosing, clarification was added that this dosing also applies to combined lower and upper limb	08/02/2021

	spasticity. Reference to unilateral vs. bilateral lower limb injections was removed, and the maximum dose of 15 units/kg for unilateral lower limb injections was removed. In dosing for "Sialorrhea, Chronic", dosing was updated to reflect the maximum dose of 225 units (112.5 units per side) for a patient < 18 years of age (extrapolated from Xeomin labeling). In the following Other Uses with Supportive Evidence, the dosing was updated such that the maximum dose for patients < 18 years of age is the lesser of 30 units/kg or 1,000 units in 3 months (adult maximum dosing remains unchanged at 1,200 units in 3 months): Anal Fissure; Hyperhidrosis, Gustatory; and Spasticity, other than Limb. Under the condition of Spasticity, other than Limb, the dosing specific to hemifacial spasm was removed from the policy; the same dosing is now applied to hemifacial spasm as for other forms of Spasticity, other than Limb.	
Policy revision	**Hyperhidrosis, Gustatory:** This Other Use with Supportive Evidence was removed from the policy. **Hyperhidrosis, Primary Axillary:** This Other Use with Supportive Evidence was removed from the policy.	02/23/2023
Policy revision	**Cervical Dystonia**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. **Spasticity, Limb**: An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place. **Sialorrhea, Chronic**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed.	11/07/2023
Policy revision	**Oromandibular Dystonia:** This Other Use with Supportive Evidence was added to the Policy. A new dosing limitation was added.	11/01/2024
Policy revision	No criteria changes. Formatting and notation updates.	06/18/2025
Policy revision	**Spasticity other than limb:** The dosing limitation was decreased from 1200 units to 220 units.	10/09/2025
Policy revision	**Achalasia:** Removed this indication from policy. **Anal Fissure, Chronic:** Added this indication to the policy. **Oromandibular Dystonia and Sialorrhea, Chronic:** Removed age requirement, previously criteria required patient be greater than or equal to 18 years of age. **Hemifacial Spasm:** New indication in policy. **Spasticity, other than Limb:** Removed this indication from policy.	02/04/2026, effective 02/22/2026
Policy review	No criteria changes, CMS surveillance review	04/02/2026
Policy review	No criteria changes, CMS surveillance review	06/23/2026