Daxxify® (daxibotulinumtoxinA-lamn)
(Intramuscular)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 300 billable units every 84 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1]

- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., hypersensitivity to any botulinum toxin product or any of its components, active infection at the proposed injection site); **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**

Cervical Dystonia † Φ [1-5]

- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck

† FDA Approved Indication; ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet universal and indication specific criteria as identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect and clinically significant effects with pre-existing neuromuscular disorders (e.g., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, swallowing/breathing difficulties, etc.), severe hypersensitivity reactions (e.g., anaphylaxis, serum sickness, urticaria, soft tissue edema, dyspnea, etc.), severe pulmonary effects (e.g., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, urinary retention, etc.; **AND**
- Disease response as evidenced by the following:

Cervical Dystonia [1]

- Improvement in the severity and frequency of pain; **AND**
- Improvement of abnormal head positioning

V. Dosage/Administration [1]

Indication	Dose
Cervical Dystonia	The recommended dose of Daxxify for the treatment of cervical dystonia ranges from 125 Units to 250 Units given intramuscularly as a divided dose among affected muscles.
– When initiating treatment, the lowest recommended dose should be used. – Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection, frequencies used in pivotal trials ranged from every 5 to 6 months re-treatment. – In members previously treated with another botulinum toxin, their past dose, response to treatment, duration of effect, and adverse event history should be taken into consideration when determining the initial Daxxify dose.	

VI. Billing Code/Availability Information

HCPCS Code:

- J0589 – Injection, daxibotulinumtoxina-lanm, 1 unit; 1 billable unit = 1 unit

NDC:

- Daxxify 100 unit powder for injection; single-dose vial: 72960-0112-xx
  **Note: Daxxify 50 Unit vials is indicated for cosmetic use only*

VII. References

1. Daxxify [package insert]. Newark, CA; Revance Therapeutics, Inc; November 2023. Accessed May 2026.
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3. 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. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2016: 86:1-9.

4. Solish N, Carruthers J, Kaufaman J, et al. Overview of DaxibotulinumtoxinA for Injection: A Novel Formulation of Botulinum Toxin Type A. Drugs 81, 2091–2101 (2021). https://doi.org/10.1007/s40265-021-01631-w
5. Albanese A, Bhatia KP, Cardoso F, et al. Isolated Cervical Dystonia: Diagnosis and Classification. Mov Disord. 2023 Mar 29;38(8):1367-1378.
6. National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxin Injections (A59707). Centers for Medicare & Medicaid Services, Inc. Updated on 04/03/2026 with effective date 04/09/2026. Accessed May 2026.
7. Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Injections (A57186). Centers for Medicare & Medicaid Services, Inc. Updated on 04/03/2026 with effective date 04/09/2026. Accessed May 2026.
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9. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 12/05/2025 with effective date 11/09/2025. Accessed May 2026.
10. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A58423). Centers for Medicare & Medicaid Services, Inc. Updated on 12/05/2025 with effective date 11/09/2025. Accessed May 2026.
11. Palmetto GBA. Local Coverage Article: Billing and Coding: Botulinum Toxin Injections (A59714). Centers for Medicare & Medicaid Services, Inc. Updated on 04/02/2026 with effective date 04/09/2026. Accessed May 2026.
12. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article: Billing and Coding: Botulinum Toxin Injections (A59809). Centers for Medicare & Medicaid Services, Inc. Updated on 04/29/2026 with effective date 04/09/2026. Accessed May 2026.
13. CGS Administrators, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxins Injections (A59726). Centers for Medicare & Medicaid Services, Inc. Updated on 04/04/2026 with effective date 04/09/2026. Accessed May 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G24.3	Spasmodic torticollis
M43.6	Torticollis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
15	A59726	CGS Administrators, LLC
N	A57715	First Coast Service Options, Inc.
6 & K	A59707	National Government Services, Inc. (NGS)
F	A57186	Noridian Healthcare Solutions, LLC
E	A57185	Noridian Healthcare Solutions, LLC
H & L	A58423	Novitas Solutions, Inc.
J & M	A59714	Palmetto GBA
5 & 8	A59809	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC