

Daxxify® (daxibotulinumtoxinA) (Intramuscular)

Document Number: IC-0728

Last Review Date: 12/03/2024

Date of Origin: 09/05/2023

Dates Reviewed: 09/2023, 12/2024

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

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

- 300 billable units every 84 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

Universal Criteria ¹

- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, etc.); **AND**

Cervical Dystonia † ¹⁻⁴

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

† FDA Approved Indication; ‡ Literature Supported Indication; Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient 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 (i.e., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, swallowing/breathing difficulties, etc.), severe hypersensitivity reactions (i.e., anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea, etc.), severe pulmonary effects (i.e., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, and 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.
<ul style="list-style-type: none"> – 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 patients 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 November 2024.
2. Albanese A, Barnes MP, Bhatia KP, et al. A systematic review on the diagnosis and treatment of primary (idiopathic) dystonia and dystonia plus syndromes: report of an EFNS/MDS-ES Task Force. *Eur J Neurol.* 2006;13(5):433-444
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. National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848). Centers for Medicare & Medicaid Services, Inc. Updated on 09/25/2024 with effective date 07/01/2024. Accessed November 2024.
6. Noridian Administrative Services, LLC Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186). Centers for Medicare & Medicaid Services, Inc. Updated on 03/25/2024 with effective date 04/01/2024. Accessed November 2024.
7. Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B Policy (A57185). Centers for Medicare & Medicaid Services, Inc. Updated on 03/25/2024 with effective date 04/01/2024. Accessed November 2024.
8. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 03/27/2024 with effective date 04/01/2024. Accessed November 2024.
9. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A58423). Centers for Medicare & Medicaid Services, Inc. Updated on 03/27/2024 with effective date 04/01/2024. Accessed November 2024.

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
N	A57715	First Coast Service Options, Inc.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor
6 & K	A52848	National Government Services, Inc. (NGS)
F	A57186	Noridian Healthcare Solutions, LLC
E	A57185	Noridian Healthcare Solutions, LLC
H & L	A58423	Novitas Solutions, Inc.

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
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