



Daxxify® (daxibotulinumtoxinA) (Intramuscular)

Document Number: SHP-0728

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Daxxify 100-unit powder for injection in a SDV: 3 vials per 140 days

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

- 250 Units every 140 days

III. Initial Approval Criteria ¹

Xeomin is the preferred botulinum product for the overlapping indications which includes Cervical Dystonia. Patients must have failed, or have a contraindication, or intolerance to Xeomin prior to consideration of Daxxify.

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:

- J3590 – Unclassified biologic

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, Inc; August 2023. Accessed August 2023.
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. Xeomin [package insert]. Dessau-Rosslau, Germany; Merz Group Services GmbH; September 2023. Accessed September 2023.

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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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