Effective Date: 01/01/2024
Reviewed: 12/2023, 01/2024, 6/2024, 6/2025
Medical Scope: Medicaid, Commercial, Medicare

Daxxify® (daxibotulinumtoxinA) (Intramuscular)

Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

- Coverage will be provided for 6 months and may be renewed for 12 months.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Medical Benefit]:

- Daxxify 100-unit powder for injection in a SDV: 3 vials per 140 days
- **Max Units (per dose and over time) [HCPCS Unit]:**
    i. 250 Units every 140 days

B. Quantity Limit (max daily dose) [Medicaid Pharmacy Benefit]:

- Daxxify 1 fill per 140 days

III. Summary of Evidence

Daxxify (daxibotulinumtoxinA-lanm) is indicated for the treatment of cervical dystonia (CD) in adults. The ASPEN-1 randomized, double-blind, placebo-controlled, parallel-group, multicenter trial studied Daxxify 125 units, Daxxify 250 units, and placebo in 301 adult patients with CD. The primary endpoint of the study was a mean change in Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) score from baseline average over weeks 4 and 6. Both the 125 unit and 250 unit strengths of Daxxify demonstrated a greater mean change in TWSTRS score versus placebo (-12.7, $p<0.0001$ and -10.9, $p=0.0007$, respectively, versus -4.3 in the placebo arm). The median duration of effect was between 20 and 24 weeks for the high-dose and low-dose groups, respectively.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- 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; **Φ** Orphan Drug

V. 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 IV; **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

VI. 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 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.	

VII. Billing Code/Availability Information

HCPCS Code:

- J0589 – Injection, daxibotulinumtoxina-lanm, 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*

VIII. References

1. Daxxify [package insert]. Newark, CA; Revance, Inc; January 2024. Accessed June 2025.
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

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)
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

Policy Rationale:
Daxxify was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Daxxify according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.