

Drug Coverage Policy

Effective Date7/	15/2025
Coverage Policy Number	IP0588
Policy Title	. Daxxify

Botulinum Toxin - Daxxify

• Daxxify® (daxibotulinumtoxinA-lanm injection - Revance)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Daxxify (daxibotulinumtoxinA-lanm), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following use:¹

• Cervical dystonia in adults.

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Policy Statement

Prior Authorization is recommended for prescription benefit coverage of Daxxify. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Daxxify as well as the monitoring required for adverse events and long-term efficacy, approval requires Daxxify to be prescribed by a physician who has consulted with or who specializes in the condition.

<u>Documentation</u>: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

Daxxify is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. Cervical Dystonia. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Note: Cervical dystonia is also known as spasmodic torticollis.

- **A)** Patient is ≥ 18 years of age; AND
- B) Patient has a diagnosis of cervical dystonia [documentation required]; AND
- **C)** Patient has sustained head torsion and/ or tilt with limited range of motion in the neck **[documentation required]**; AND
- **D)** Prescribed by or in consultation with a pain medicine specialist, neurologist, or physical medicine and rehabilitation physician

Dosing. Approve up to a maximum dose of 250 units, administered not more frequently than once every 3 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Daxxify (daxibotulinumtoxinA) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Cosmetic Uses.** Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.

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.

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Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®*	Description	
Codes		
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)	

HCPCS Codes	Description
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

^{*}Current Procedural Terminology (CPT $^{\otimes}$) $^{\odot}$ 2024 American Medical Association: Chicago, IL.

References

1. Daxxify® injection [prescribing information]. Newark, CA: Revance; January 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Policy Title Updated from "DaxibotulinumtoxinA-lanm" to "Botulinum Toxins – Daxxify."	7/15/2025
	Cervical Dystonia Updated cervical dystonia criteria for approval to require a screen patient is at least 18 years of age, documentation for diagnosis, documentation of head torsion with limited range of motion, specialist requirement. Updated dosing for use of Daxxify to treat cervical dystonia from "Dosing. Up to a maximum dose of 300 units, administered not more frequently than once every 3 months" to "Dosing. Approve up to a maximum dose of 250 units, administered not more frequently than once every 3 months."	
	Conditions Not Covered Updated to only include cosmetic uses.	
	Coding Information: Added CPT code 64616	

The policy effective date is in force until updated or retired.

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