Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0588**

DaxibotulinumtoxinA-lanm

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Related Coverage Resources

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 guidance 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. 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 guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for daxibotulinumtoxinA-lanm (**Daxxify**®).

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

Medical Necessity Criteria

DaxibotulinumtoxinA-lanm (Daxxify) is considered medically necessary when the following are met:

Cervical Dystonia. Individual meets **ALL** of the following criteria:
A. Documentation of **BOTH** of the following:
i. Involuntary, simultaneous activation of agonist and antagonist muscles of the neck and shoulder (for example, sternocleidomastoid, splenius, levator scapulae, trapezius, semispinalis, scalene)
ii. Sustained head torsion and/or tilt with limited range of motion in the neck

B. Medication is prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician

Dosing. Up to a maximum dose of 300 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.

Reauthorization Criteria

Continuation of daxibotulinumtoxinA-lanm (Daxxify) is considered medically necessary for cervical dystonia when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial authorization is up to four (4) treatments in a 12 month period (one [1] treatment every 90 days).

If the initial approval criteria (listed above) are met AND clinical improvement with previous daxibotulinumtoxinA-lanm (Daxxify) therapy is documented but duration of benefit is less than 90 days/treatment, then up to six treatments in a 12 month period (one treatment per 60 days) may be considered on a case-by-case basis.

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Cosmetic use is considered not medically necessary.

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. Bruxism
2. Chronic low back pain
3. Gastroparesis
4. Headache, including Cervicogenic headache
5. Chronic daily headache
6. Migraine
7. Menstrual headache (for example, 90% of attacks generally occur between two days before menses and the last day of menses)
8. Tension-type headache
9. Hemorrhoid pain
10. Lateral epicondylitis
11. Nausea and vomiting, post sleeve gastrectomy
12. Myofascial pain
13. Hyperhidrosis
14. Spastic pelvic floor syndrome
15. Sphincter of Oddi dysfunction
16. Temporomandibular joint (TMJ) syndrome
17. Tics
18. Trigeminal Neuralgia
19. Voiding dysfunction associated with benign prostatic hyperplasia

Coding Information

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:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Background

OVERVIEW
Daxxify (daxibotulinumtoxinA-lanm), is indicated for the following uses:[1]

- **Cervical dystonia** in adults.

The medication labeling, like all other botulinum toxin products, state the potency units of Daxxify are specific to the preparation and test method utilized and not interchangeable with other preparations of other botulinum toxin products [Botox® (onabotulinumtoxinA), Xeomin® (incobotulinumtoxinA), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinumtoxinB)]; therefore, units of biological activity of Daxxify cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific test method.[1] Daxxify does not contain any human serum albumin in its formulation. The labeling also indicates a warning for potential serious adverse reactions after administration of Daxxify for unapproved uses.

References

1. Daxxify® injection [prescribing information]. Newark, CA: Revance; August 2023.