

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxin – Daxxify Utilization Management Medical Policy

- Daxxify® (daxibotulinumtoxinA-lanm injection – Revance)

REVIEW DATE: 08/30/2023

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.

Dosing Considerations

After reconstitution, 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.¹ 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 Daxxify dose. If dose modification is necessary, dose adjustments can be made in 50 to 75 unit increments according to individual patient response. Daxxify should be administered no more frequently than once every 3 months for any indication.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Daxxify. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for 1 year in duration.

Medical benefit coverage is not recommended for cosmetic conditions.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Daxxify is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cervical Dystonia.** Approve for 1 year if the patient is ≥ 18 years of age.

Note: Cervical dystonia is also known as spasmodic or cervical torticollis.

Dosing. Approve up to a maximum dose of 300 units, administered not more frequently than once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Daxxify is not recommended in the following situations:

- 1. Cosmetic Uses.** Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, or rejuvenation of the periorbital region. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/30/2023