Clinical Policy: DaxibotulinumtoxinA-lanm (Daxxify)

Reference Number: LA.PHAR.651
Effective Date:
Last Review Date: 01.04.24
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

DaxibotulinumtoxinA-lanm (Daxxify®) is an acetylcholine release inhibitor and neuromuscular blocking agent.

FDA Approved Indication(s)

Daxxify is indicated for:

- **Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator**
- **The treatment of cervical dystonia (CD) in adult patients**

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Daxxify is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Cervical Dystonia (must meet all):

1. **Diagnosis of CD;**
2. **Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;**
3. **Age ≥ 18 years;**
4. **Member is experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius capitis, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulders or head;**
5. **Contractions are causing pain and functional impairment;**
6. **Failure of Botox® and Dysport®, unless clinically significant adverse effects are experienced, or both are contraindicated;**
7. **Daxxify is not prescribed concurrently with other botulinum toxin products;**
8. **Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;**
9. **Treatment plan provided detailing number of Units per indication and treatment session;**

10. Dose does not exceed 250 Units per treatment session.
Approval duration:12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. **If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;**
2. **If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.PMN.53.**

II. Continued Therapy

A. Cervical Dystonia (must meet all):
1. **Member is currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy;**
3. **Daxxify is not prescribed concurrently with other botulinum toxin products;**
4. **Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 week;**
5. **Treatment plan provided detailing number of Units per indication and treatment session;**
6. **If request is for a dose increase, new dose does not exceed 250 Units per treatment session.**

Approval duration:12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. **If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;**
2. **If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.PMN.53.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –LA.PMN.53 for Medicaid or evidence of coverage documents;

B. Cosmetic treatment of hyperfunctional wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CD: cervical dystonia
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Dysport® (AbobotulinumtoxinA)	Cervical Dystonia: Divided among affected muscles every 12 weeks: Up to 1,000 Units IM	See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks
Botox® (OnabotulinumtoxinA)	Cervical Dystonia: Up to 50 Units IM per injection, 100 Units total in the sternocleidomastoid, and 300 Units per treatment session	See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to any botulinum toxin preparation or any of the components in the formulation
  - Infection at the proposed injection sites
- Boxed warning(s): distant spread of toxin effect

Appendix D: Botulinum Toxin Product Interchangeability

- Potency Units of Daxxify are not interchangeable with other botulinum toxin product preparations (e.g., Dysport®, Botox®, Myobloc®, Xeomin®)

Appendix E: Guideline Support for Botulinum Toxin Use

Indication	Guideline
Cervical dystonia	Academy of Neurology (2016)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	125 Units to 250 Units IM divided among affected muscles every 12 weeks	250 Units IM Frequency: One treatment session every 12 weeks

VI. Product Availability

Vials: 50 Units, 100 Units

VII. References

1. **Daxxify Prescribing Information. Newark, CA: Revance Therapeutics, Inc; August 2023. Available at https://www.revance.com/wp-content/uploads/2023/08/daxi-pi-and-med-guide.pdf. Accessed August 27, 2023.**
2. **Albanese A, Bhatia K, Bressman SB, et al. Phenomenology and classification of dystonia: a consensus update. Mov Disord. June 15, 2013; 28(7): 863-873. doi:10.1002/mds.25475.**
3. **Cloud LJ, Jinnah HA. Treatment strategies for dystonia. Expert Opin Pharmacother 2010; 11(1):5-15.**
4. **Position statement: botulinum toxin treatment. American Academy of Otolaryngology-Head and Neck Surgery. April 21, 2021. Available at: https://www.entnet.org/resource/position-statement-botulinum-toxin-treatment/. Accessed August 27, 2023.**
5. **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(19):1818-1826. doi:10.1212/WNL.0000000000002560**

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	01.04.24	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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