Botulinum Toxins A and B (for Indiana Only)

Policy Number: CSIND0017.07
Effective Date: March 1, 2025

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Related Policy

- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Indiana Only)

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

This policy refers to the following Botulinum toxin type A and B drug products:

- Botox® (onabotulinumtoxinA)
- Daxxify® (daxibotulinumtoxinA-lanm)
- Dysport® (abobotulinumtoxinA)
- Myobloc® (rimabotulinumtoxinB)
- Xeomin® (incobotulinumtoxinA)

Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), and Xeomin® (incobotulinumtoxinA) are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline:

- **Botox**: CP: Specialty Rx Non-Oncology, OnabotulinumtoxinA (Botox)
- **Dysport**: CP: Specialty Rx Non-Oncology, AbobotulinumtoxinA (Dysport)
- **Myobloc**: CP: Specialty Rx Non-Oncology, RimabotulinumtoxinB (Myobloc)
- **Xeomin**: CP: Specialty Rx Non-Oncology, IncobotulinumtoxinA (Xeomin)

Click here to view the InterQual® criteria.

Daxxify (daxibotulinumtoxinA-lanm) is medically necessary in the treatment of the following condition:

- Cervical dystonia (also known as spasmodic torticollis)
  Daxxify is medically necessary for the treatment of cervical dystonia when both of the following criteria are met:
  - Diagnosis of cervical dystonia; **and**
  - Symptoms including **both** of the following:
    - Sustained head tilt or abnormal posturing resulting in pain and/or functional impairment
    - Recurrent involuntary contraction of one or more muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

Diagnosis Code	Description
G24.09	Other drug induced dystonia
G24.1	Genetic torsion dystonia
G24.2	Idiopathic nonfamilial dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G24.9	Dystonia, unspecified

Clinical Evidence

Proven

Cervical Dystonia

The efficacy of Daxxify was evaluated in a randomized, double-blind, placebo-controlled, multicenter trial in a total of 301 patients (NCT03608397). At study baseline, 84% of patients had previously received a botulinum toxin as treatment for cervical dystonia. Patients had a clinical diagnosis of cervical dystonia with baseline Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score ≥ 20, TWSTRS severity score ≥ 15, TWSTRS disability score ≥ 3, and TWSTRS pain score ≥ 1. For patients who had previously received a botulinum toxin treatment for cervical dystonia, the trial required that ≥ 14 weeks had passed since the most recent botulinum toxin administration. Patients were randomized (3:3:1) to receive a single administration of 2.5 mL of either Daxxify 125 Units (n = 125), Daxxify 250 Units (n = 130), or placebo (n = 46), divided amongst the affected muscles as selected by the investigator. The primary efficacy endpoint was the mean change in the TWSTRS total score from baseline averaged over weeks 4 and 6. TWSTRS evaluates the severity of dystonia, patient-perceived disability from dystonia, and pain, with a range of possible scores from 0 to 85. The mean change from baseline in the total TWSTRS score was significantly greater for both dosage groups of Daxxify than for placebo.

U.S. Food and Drug Administration (FDA)

For non-cosmetic use, daxibotulinumtoxinA-lanm (Daxxify) is FDA approved for the treatment of cervical dystonia in adult patients.

References

1. Daxxify [prescribing information]. Newark, CA: Revance Therapeutics, Inc., November 2023.

Policy History/Revision Information

Date	Summary of Changes
03/01/2025	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CSIND0017.06

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.