PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Daxxify (DaxibotulinumtoxinA-lanm)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Daxxify is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adult patients. It was designed to have a longer duration of effect than other botulinum neurotoxin products and may also have a lower incidence of dysphagia side effects.
Cervical dystonia, also known as spasmodic torticollis, is a painful, chronic neurological condition characterized by involuntary contractions of neck muscles, leading to abnormal movements and awkward postures of the head, neck, and shoulders. Botulinum toxin products are first line treatment.
The Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-total score is used to assess the severity and treatment success of cervical dystonia, and its change from baseline was the primary outcome in the Phase 3 ASPEN-1 clinical trial, in which Daxxify was superior to placebo.

Daxxify (DaxibotulinumtoxinA-lanm) will be considered for coverage when the following criteria are met:

Cervical Dystonia

For **initial** authorization:
1. Member has a documented diagnosis of moderate to severe cervical dystonia.
2. **Dosage allowed/Quantity limit:** 125 Units to 250 Units given intramuscularly as a divided dose among affected muscles no more frequently than every three months.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improved severity, disability, or pain compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Daxxify (DaxibotulinumtoxinA-lanm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/20/2023	New policy for Daxxify created.
10/02/2024	Removed age limit and specialist.

References:

1. Daxxify [prescribing information]. Revance Therapeutics, Inc.; 2023.
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3. 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
4. Dressler D, Altenmueller E, Bhidayasiri R, et al. Strategies for treatment of dystonia [published correction appears in J Neural Transm (Vienna). 2016 Mar;123(3):259]. *J Neural Transm (Vienna)*. 2016;123(3):251-258. doi:10.1007/s00702-015-1453-x
5. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. *J Neural Transm (Vienna*). 2021;128(4):531-537. doi:10.1007/s00702-020-02266-z
6. Rodrigues FB, Duarte GS, Marques RE, et al. Botulinum toxin type A therapy for cervical dystonia. *Cochrane Database Syst Rev.* 2020;11(11):CD003633. Published 2020 Nov 12. doi:10.1002/14651858.CD003633.pub4
7. Solish N, Carruthers J, Kaufman J, Rubio RG, Gross TM, Gallagher CJ. Overview of DaxibotulinumtoxinA for Injection: A Novel Formulation of Botulinum Toxin Type A. *Drugs*. 2021;81(18):2091-2101. doi:10.1007/s40265-021-01631-w

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Revised date: 10/02/2024