IncobotulinumtoxinA (Xeomin®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of chronic sialorrhea in patients 2 years of age and older
- Treatment of upper limb spasticity in adult patients
- Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Treatment of cervical dystonia in adult patients
- Treatment of blepharospasm in adult patients

All other indications are considered experimental/investigational and not medically necessary.

EXCLUSIONS

Coverage will not be provided for cosmetic use.

COVERAGE CRITERIA

Chronic Sialorrhea (excessive salivation)
Authorization of 12 months may be granted for treatment of chronic sialorrhea (excessive salivation) when all of the following criteria are met:

- Member is 2 years of age or older
- Member has been refractory to pharmacotherapy (e.g., anticholinergics)

Cervical Dystonia
Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when all of the following criteria are met:

- Member is 18 years of age or older
- There is abnormal placement of the head with limited range of motion in the neck.

Blepharospasm
Authorization of 12 months may be granted for treatment blepharospasm when all of the following criteria are met:

- Member has a diagnosis of blepharospasm including benign essential blepharospasm or blepharospasm associated with dystonia
- Member is 18 years of age or older.

Upper limb spasticity
Authorization of 12 months may be granted for the treatment of upper limb spasticity when all of the following are met:

- Member has a diagnosis of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity
- Member meets one of the following criteria:
  - Member is 18 years of age or older
  - Member is 2 to 17 years of age and the spasticity is not caused by cerebral palsy.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria and be experiencing benefit from therapy.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Xeomin (IncobotulinumtoxinA)	Blepharospasm	Route of Administration: Intramuscular ≥18 year(s) 100Units (max 50 units per eye) per treatment, divided among the affected muscles. May re-treat no sooner than every 12 weeks.
Xeomin (IncobotulinumtoxinA)	Cervical Dystonia	Route of Administration: Intramuscular ≥18 year(s) 400Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.
Xeomin (IncobotulinumtoxinA)	Chronic Sialorrhea	Route of Administration: Injection ≥ 2 to <18 year(s) 12- < 15 kg 20Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. 15- < 19 kg 30Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. 19 - < 23 kg 40Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. 23 - < 27 kg 50Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. 27 - < 30 kg

		60Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. ≥30kg 75Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks. ≥18 year(s) 100Units divided among the parotid and submandibular glands. May re-treat no sooner than every 16 weeks.
Xeomin (IncobotulinumtoxinA)	Upper Limb Spasticity	Route of Administration: Intramuscular ≥2 to <18 year(s) <25kg 8Units/kg per affected limb (max 16 Units/kg for both limbs) per treatment. May re-treat no sooner than every 12 weeks. ≥25kg 200Units per affected limb (max 400 Units for both limbs) per treatment. May re-treat no sooner than every 12 weeks. ~~8Units/kg up to max 200 Units per affected limb (max 400 Units for both limbs) per treatment. May re-treat no sooner than every 12 weeks~~ ≥18 year(s) 400Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals LLC; July 2024.
2. Restivo D, Panebianco M, Casabona A et al. Botulinum Toxin A for Sialorrhea Associated with Neurological Disorders: Evaluation of the Relationship between Effect of Treatment and the Number of Glands Treated. Toxins 2018;55:1-10.

3. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. Toxins 2013, 5, 1010-1031
4. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. American Academy for Cerebral Palsy and Developmental Medicine Care Pathways. https://www.aacpdm.org/publications/care-pathways/sialorrhea. Accessed August 13, 2024.
5. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. Degener Neurol Neuromuscul Dis. 2019; 9: 19–26.
6. Simpson DM, Hallett, M, Ashman E, 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;86:1818-1816.

EFFECTIVE DATE

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