

PRIOR AUTHORIZATION POLICY

POLICY: Botulinum Toxins – Xeomin® (incobotulinumtoxinA for injection – Merz)

APPROVAL DATE: 05/08/2019; selected revision 05/22/2019

OVERVIEW

Xeomin® (incobotulinumtoxinA) is indicated in adult patients for the following:

- blepharospasm;
- cervical dystonia;
- chronic sialorrhea; AND
- upper limb spasticity.¹

Xeomin is also indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugators and/or procerus muscle activity in adult patients.

The labels for the botulinum toxin type A products (Botox® [onabotulinumtoxinA], Dysport® [abobotulinumtoxinA], and Xeomin) state that there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity.¹⁻³ However, studies have demonstrated that identical units of Xeomin and Botox were equally effective.⁴⁻⁷ Based on published literature, it has been established that Xeomin and Botox have identical therapeutic effects and adverse event (AE) profiles with a 1:1 conversion ratio.⁷

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Xeomin. Use should be limited to the treatment of medical conditions. Prescription benefit coverage of this product is not recommended for cosmetic conditions. All approvals are provided for 1 year.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. **Blepharospasm.** Approve for 1 year.
2. **Cervical Dystonia (torticollis).** Approve for 1 year.
Note: Cervical dystonia is also known as spasmodic or cervical torticollis.)
3. **Sialorrhea (Salivary Hypersecretion), Chronic.** Approve for 1 year.
4. **Spasticity, Upper Limb.** Approve for 1 year.
Note: For other forms of spasticity that do not fit this condition of approval, see Other Uses with Supportive Evidence, Spasticity.)

Other Uses with Supportive Evidence

5.—Hyperhidrosis – Primary Axillary, Palmar/Plantar, and Facial. Approve for 1 year if the patient has tried at least one topical agent (e.g., aluminum chloride, Qbrexza™ [glycopyrronium cloth 2.4% for topical use]).

Overall, topical antiperspirants (e.g., aluminum chloride) are the recommended first-line therapy for the treatment of primary axillary hyperhidrosis and focal hyperhidrosis.⁸⁻¹¹ In the setting of primary axillary hyperhidrosis, Qbrexza, a topical anticholinergic, may also be used first-line.²⁰ Other conventional treatments include oral anticholinergics; topical treatment is more effective in mild cases compared with more severe cases.^{8-11,14} The efficacy of Xeomin in the treatment of palmar/plantar hyperhidrosis and cranial hyperhidrosis was demonstrated in patients (n = 20) previously treated with onabotulinumtoxinA for at least 1 year under stable conditions and crossed over in a blinded fashion to Xeomin for 3 years.¹³ In a double-blind clinical trial, patients (n = 25) with moderate or severe palmar hyperhidrosis received in the same session intradermal injections of Botox on one hand and Xeomin on the other. The two products appeared to be comparable in terms of anhidrotic effect, duration of benefits, muscle strength reduction, pain related to injections, and treatment satisfaction expressed by patients.¹⁹ The efficacy of Xeomin for axillary hyperhidrosis was demonstrated in a prospective, double-blind, head-to-head intra-individual comparison trial vs. onabotulinumtoxinA (Botox).¹² A total of 46 patients received 50 units of botulinum toxin type A treatment (Xeomin in one axilla, and onabotulinumtoxinA in the other axilla). Efficacy and tolerability were similar between Botox and Xeomin. In addition, the efficacy of Xeomin in the treatment of axillary hyperhidrosis was demonstrated in patients (n = 41) previously treated with onabotulinumtoxinA for at least 1 year under stable conditions and crossed over in a blinded fashion to Xeomin for 3 years.¹³ The AAN notes that botulinum toxin therapy is established safe and effective in axillary hyperhidrosis (Level A).²¹ AAN guidelines state that botulinum toxins are probably safe and effective and should be considered for palmar hyperhidrosis (plantar and facial hyperhidrosis are not addressed in the AAN guideline).²¹

6.—Spasticity, Other Than Upper Limb (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm). Approve for 1 year.
(Note: For upper limb spasticity, see FDA-Approved Indication criterion #4 [above].)

Oral medications have a long history in spasticity treatment (e.g., baclofen, benzodiazepines, phenytoin, or gabapentin) yet they have dose-limiting side effects and limited diffusion across the blood brain barrier.¹⁶ In a prospective, randomized study in patients (n = 192) with upper limb spasticity due to stroke, brain injury, multiple sclerosis, or cerebral palsy, the majority of Xeomin-treated patients had improvement in functional disability and in muscle tone.¹⁷ In a Phase III randomized study in patients (n = 148) with post-stroke upper limb spasticity, Xeomin was significantly more effective than placebo at Week 4 and at Week 12.¹⁸ In addition, the efficacy of Xeomin in the treatment of hemispasticity, arm spasticity, generalized spasticity, paraspasticity, leg spasticity, and hemifacial spasm was demonstrated in patients (n = 95) previously treated with onabotulinumtoxinA for at least 1 year under stable conditions and crossed over in a blinded fashion to Xeomin for 3 years.¹³ Per the AAN, botulinum toxin is established effective in upper and lower limb spasticity and in cerebral palsy (Level A), and it may be considered in hemifacial spasm (Level C).^{22,23}

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xeomin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-

coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Cosmetic Uses** (e.g., facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the periorbital region). Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.
2. **Fibromyalgia.** Limited data are available with Botox. No data are available with Xeomin at this time.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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