Clinical Policy: IncobotulinumtoxinA (Xeomin)
Reference Number: ERX.SPMN.218
Effective Date: 01/17
Last Review Date:

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

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that incobotulinumtoxinA (Xeomin®) is medically necessary when one of the following criteria are met:

I. Initial Approval Criteria
   A. Cervical Dystonia or Upper Limb Spasticity (must meet all):
      1. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
      2. Age ≥ 18 years;
      3. Diagnosis of one of the following:
         a. Cervical dystonia;
         b. Upper limb spasticity;
      4. Prescribed dose of Xeomin does not exceed 400 units per single treatment session.

   Approval duration: 12 weeks (single treatment session)

   B. Blepharospasm (must meet all):
      1. Prescribed by or in consultation with a neurologist or ophthalmologist;
      2. Age ≥ 18 years;
      3. Diagnosis of blepharospasm;
      4. Member previously received treatment with onabotulinumtoxinA (Botox);
      5. Prescribed dose of Xeomin does not exceed 35 units per eye.

   Approval duration: 12 weeks (single treatment session)

   C. Other diagnoses/indications:
      1. Refer to ERX.SPMN.16 - Global Biopharm Policy if requested indication is non-cosmetic.

II. Continued Approval
   A. Cervical Dystonia, Upper Limb Spasticity, or Blepharospasm (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Prescribed dose of Xeomin does not exceed indication-specific maximum:
         a. 400 units per single treatment session for cervical dystonia or upper limb spasticity;
         b. 35 units per eye for treatment of blepharospasm;
      3. It has been at least 12 weeks since the last injection of Xeomin.

   Approval duration: 12 weeks (single treatment session)
**Clinical Policy**

IncobotulinumtoxinA

**B. Other diagnoses/indications** (must meet either 1 or 2):
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to ERX.SPMN.16 - Global Biopharm Policy if requested indication is non-cosmetic.

**Background**

*Description/Mechanism of Action:*
IncobotulinumtoxinA is a botulinum toxin type A produced from fermentation of Clostridium botulinum. It blocks cholinergic transmission at the neuromuscular junction by inhibiting the release of acetylcholine from peripheral cholinergic nerve endings. Impulse transmission is eventually re-established by the formation of new nerve endings.

*FDA Approved Indication(s):*
Xeomin is an acetylcholine release inhibitor and neuromuscular blocking agent/intramuscular injection indicated for:
- Treatment of adults with cervical dystonia in both botulinum toxin-naïve and previously treated patients
- Treatment of adults with upper limb spasticity
- Treatment of adults with blepharospasm who were previously treated with onabotulinumtoxinA (Botox)
- Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients

**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.

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, 1 unit</td>
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**Reviews, Revisions, and Approvals**

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**References**

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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