Clinical Policy: IncobotulinumtoxinA (Xeomin)

Reference Number: PA.CP.PHAR.231
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for incobotulinumtoxinA (Xeomin®).

FDA Approved Indication(s)
Xeomin is indicated for the treatment or improvement of adult patients with:

- Upper limb spasticity
- Cervical dystonia (CD) in both botulinum toxin-naïve and previously treated patients
- Blepharospasm in adults 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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Xeomin is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Cervical Dystonia (must meet all):

1. Prescribed by or in consultation with a neurologist, orthopedist or physiatrist;
2. Age ≥ 18 years;
3. Diagnosis of cervical dystonia (CD) (see definition in Appendix B);
4. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, posterior cervical) resulting in abnormal postures or movements of the neck, shoulder or head;
5. Contractions are causing pain or functional impairment;
6. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site;
7. Prescribed dose of Xeomin does not exceed 120 units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Blepharospasm *(a focal dystonia)* (must meet all):

1. Prescribed by or in consultation with a neurologist or ophthalmologist;
2. Age ≥ 18 years;
3. Diagnosis of blepharospasm (i.e., abnormal contraction of eyelid muscles);
4. Member previously received treatment with onabotulinumtoxinA (Botox);
5. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site;
6. Prescribed dose of Xeomin does not exceed 35 units per eye per treatment session.

Approval duration: 12 weeks (single treatment session)

C. 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 upper limb spasticity;
4. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site;
5. Prescribed dose of Xeomin does not exceed 400 units per treatment session.

Approval duration: 12 weeks (single treatment session)

D. Other diagnoses/indications:
1. Refer to PA.CP.PHAR.57 - Global Biopharm Policy if requested indication is non-cosmetic.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site;
4. Prescribed dose of Xeomin does not exceed the following indication-specific maximums (a or b):
   a. CD: 120 units per treatment session;
   b. Upper limb spasticity: 400 units per treatment session;
   c. Blepharospasm: 35 units per eye per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: 12 weeks (single treatment session); or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy; coverage is not approved for cosmetic use, including for treatment of glabellar lines.

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.

Formulations:
Xeomin: Lyophilized powder for reconstitution in single-dose glass vials: 50 units, 100 units or 200 units of incobotulinumtoxinA.

Appendices
Appendix A: Abbreviation Key
CD: cervical dystonia
CNS: central nervous system

Appendix B: Definition and Classification of Dystonia [3]
Dystonia is defined as a movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements, postures, or both.

- Dystonic movements are typically patterned and twisting, and may be tremulous.
- Dystonia is often initiated or worsened by voluntary action and associated with overflow muscle activation.

Dystonia is classified along two axes:

- Clinical characteristics: Age at onset, body distribution, temporal pattern, associated features (additional movement disorders or neurological features) - *the clinical characteristics fall into several specific dystonia syndromes that help to guide diagnosis and treatment*;
- Etiology: Nervous system pathology, inheritance.

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.

HCPCS Codes	Description
J0588	Injection, incobotulinumtoxinA, 1 unit

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: intent of therapy language removed from upper limb spasticity indication; removed requirement of at least 12 weeks have passed since last treatment; references reviewed and updated.	2.9.18	

References
1. Xeomin Prescribing Information. Frankfurt, Germany: Merz Pharmaceuticals, LLC; December 2015. Available at http://xeomin.com/wp-content/uploads/xeomin-full-prescribing-information.pdf. Accessed February 16, 2018..
2. 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.

3. Albanese A, Bhatia K, Bressman SB, et al. Phenomenology and classification of dystonia: a consensus update. *Mov Disord.* June 15, 2013; 28(7): 863-873. doi:10.1002/mds.25475.