Clinical Policy: IncobotulinumtoxinA (Xeomin)

Reference Number: CP.PHAR.231
Effective Date: 07/16
Last Review Date: 07/17

Coding Implications
Revision Log

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

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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 and 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. Intent of treatment is to decrease severity of increased muscle tone in elbow flexors (i.e., biceps brachii, brachialis, pronator teres, brachioradialis), wrist flexors (i.e., flexor carpi radialis, flexor carpi ulnaris), finger flexors (i.e., flexor digitorum profundus, flexor digitorum sublimis [superficialis]), or thumb flexors (i.e., adductor pollicis, flexor pollicis longus);
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 400 units per treatment session.

Approval duration: 12 weeks (single treatment session)

D. Other diagnoses/indications:
1. Refer to 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 Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. It has been at least 12 weeks since the last injection of Xeomin;
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 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 Centene benefit and documentation supports positive response to therapy;
   Approval duration: 12 weeks (single treatment session); or
2. Refer to 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.

FDA Approved Indications (non-cosmetic):
Xeomin is an acetylcholine release inhibitor/neuromuscular blocking agent formulated for intramuscular injection and indicated for:

- Treatment of adults with cervical dystonia in both botulinum toxin-naïve and previously treated patients.
- Treatment of adults with blepharospasm who were previously treated with onabotulinumtoxinA (Botox).
- Treatment of adults with upper limb spasticity.

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
Policy split from CP.PHAR.09. Created criteria for new indication of upper limb spasticity per FDA labeling. Added max dosing per FDA labeling.	05/16	07/16

Reviews, Revisions, and Approvals	Date	Approval Date
Added prescriber requirement. Removed reauthorization criteria requiring attestation of significant improvement in symptoms and/or health-related quality of life.		
CD and upper limb spasticity are split into separate criteria sets. Added to CD a definition and requirement of pain and functional impairment. CD dose reduced from 400 to 120 units per treatment session per PI. Blepharospasm definition is added; "focal dystonia" parenthetical is added clarifying it as a dystonia. Added examples of muscle groups and an informational footnote to upper limb spasticity. Efficacy statement added under continuation criteria. Removed safety information. Dystonia information is added at Appendix B. "Non-cosmetic" parenthetical added to the background FDA indication section; cosmetic coverage restriction reworded under the "Other Diagnoses/Indications" section to include notation of glabellar lines.	06/17	07/17

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 June 13, 2017.
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.

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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