RXADVANCE
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Clinical Policy Title:	incobotulinumtoxinA
Policy Number:	RxA.312
Drug(s) Applied:	Xeomin®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of Business

Background

IncobotulinumtoxinA (Xeomin®) is an acetylcholine release inhibitor and a neuromuscular blocking agent. It is indicated for the treatment or improvement of adult patients with:

- Chronic sialorrhea
- Upper limb spasticity
- Cervical dystonia (CD)
- Blepharospasm
- Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. [Cosmetic use is under benefit exclusion]

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
IncobotulinumtoxinA (Xeomin®)	Chronic sialorrhea	Xeomin is injected into the parotid and submandibular glands on both sides (i.e., 4 injection sites per treatment session). The recommended total dose per treatment session is 100 Units. The dose is divided with a ratio of 3:2 between the parotid and submandibular glands.	• One treatment period per weeks 16. • 100 units per treatment session consisting: - Parotid gland(s): 60 units (30 units per side) - Submandibular gland(s): 40 units (20 units per side)
IncobotulinumtoxinA (Xeomin®)	CD	The usual starting dose is 120 units per treatment session, doses up to 400 units may be used in treatment-experienced patients. Dose, number, and location of injection sites should be based on the number and location of muscles involved, severity of dystonia, and response to any previous botulinum toxin injections.	400 units per treatment session

IncobotulinumtoxinA (Xeomin®)	Blepharospasm	The recommended starting dose is 25 units per eye.	50 units per eye per treatment session
IncobotulinumtoxinA (Xeomin®)	Upper limb spasticity	Dosing varies based on location of muscles to be treated (*refer to dosing chart in the prescribing information*).	400 units per treatment session

Dosage Forms

- Single-dose vial: 50 units, 100 units, or 200 units lyophilized powder

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Chronic Sialorrhea (must meet all)**:**

1. Diagnosis of chronic sialorrhea for at least the last three months due to an underlying neurologic disorder or craniofacial abnormality *(see Appendix D);*
2. Prescribed by or in consultation with a neurologist, physiatrist, or physical medicine and rehabilitation specialist;
3. Age 18 years of age or older;
4. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each gland, anticipated frequency of injection(s), and total dose per visit;
5. Dose does not exceed 100 units per treatment session.

Approval duration
Commercial: 6 months
Medicaid: 112 days (single treatment session)
HIM: 112 days (single treatment session)

B. Cervical Dystonia (must meet all)**:**

1. Diagnosis of CD *(see Appendix E);*
2. Prescribed by or in consultation with a neurologist, orthopedist , physiatrist, or physical medicine and rehabilitation specialist;
3. Age 18 years of age or older;
4. Experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) 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, anticipated frequency of injection, and total dose per visit;
7. Dose does not exceed 120 units per treatment session.

Approval duration
Commercial: 6 months
Medicaid: 84 days (single treatment session)
HIM: 84 days (single treatment session)

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

1. Diagnosis of blepharospasm (i.e., abnormal contraction of eyelid muscles);
2. Prescribed by or in consultation with a neurologist or ophthalmologist;
3. Age 18 years of age or older;
4. Member has significant disability in daily functional activities due to interference with vision;
5. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
6. Dose does not exceed 50 units per eye per treatment session.

Approval duration
Commercial: 6 months
Medicaid: 84 days (single treatment session)
HIM: 84 days (single treatment session)

D. Upper Limb Spasticity (must meet all)**:**

1. Diagnosis of upper limb spasticity;
2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
3. Age 18 years of age or older;
4. Provider submits treatment plan detailing the quantity (in units) of Xeomin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
5. Dose does not exceed 400 units per treatment session.

Approval duration
Commercial: 6 months
Medicaid: 84 days (single treatment session)
HIM: 84 days (single treatment session)

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. It has been at least 12 weeks (16 weeks if sialorrhea) 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, anticipated frequency of injection, and total dose per visit;
5. If request is for a dose increase, new dose does not exceed the following indication specific maximums (a or b):
   a. Chronic sialorrhea: 100 units per treatment session;
   b. CD: 120 units per treatment session;
   c. Upper limb spasticity: 400 units per treatment session;
   d. Blepharospasm: 50 units per eye per treatment session.

Approval duration
Commercial: 12 months
Medicaid: 84 days, or 112 days if sialorrhea (single treatment session)
HIM: 84 days, or 112 days if sialorrhea (single treatment session)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CD: cervical dystonia
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

- Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to the active substance botulinum neurotoxin type A or to any of the excipients.
  - Infection at the proposed injection sites.
- Boxed warning(s):
  - Distant spread of toxin effect.

APPENDIX D: *Examples of Neurologic Disorders and Craniofacial Abnormalities*

- Neurologic Disorder:
  - Parkinson disease, atypical parkinsonism, stroke, traumatic brain injury, cerebral palsy, amyotrophic lateral sclerosis
- Craniofacial abnormalities:
  - Goldenhar syndrome

APPENDIX E: Definition and Classification of Dystonia

- 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.

References

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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial and Continued Therapy approval duration was updated to include HIM approval duration. 5. Initial Approval duration: Medicaid and HIM approval duration for 'Chronic Sialorrhea' is updated from '16 weeks to 112 days' and for all other indication from 12 weeks to 84 days. 6. References were updated	07/07/2020	09/14/2020