Reference number
2250-A

SPECIALTY GUIDELINE MANAGEMENT

XEOMIN (incobotulinumtoxinA)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Treatment of chronic sialorrhea in patients 2 years of age and older
B. Treatment of upper limb spasticity in adult patients
C. Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
D. Treatment of cervical dystonia in adult patients
E. Treatment of blepharospasm in adult patients

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. CRITERIA FOR INITIAL APPROVAL

A. Cervical dystonia
Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

B. Blepharospasm
Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

C. Upper limb spasticity
Authorization of 12 months may be granted for treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

D. Excessive salivation
Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g. anticholinergics).

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Xeomin [package insert]. Dessau-Rosslau, Germany: Merz Pharmaceuticals, LLC; August 2020.
2. Restivo D, Panebianco M, Casabona A et al. Botulinum Toxin A for Sialorrhea Associated with Neurological Disorders: Evaluation of the Relationship between Effect of Treatment and the Number of Glands Treated. *Toxins* 2018;55:1-10.
3. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. *Toxins* 2013, 5, 1010-1031
4. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. American Academy for Cerebral Palsy and Developmental Medicine Care Pathways. https://www.aacpdm.org/publications/care-pathways/sialorrhea. Accessed August 23, 2019.
5. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. *Degener Neurol Neuromuscul Dis*. 2019; 9: 19–26.