Policy Name	Clinical Policy - Botulinum Toxin
Policy Number	1325.00
Department	Clinical Product & Development
Subcategory	Medical Management
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Current Effective Date	07/01/2024

Company Entities Supported (Select All that Apply)
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company'

ACRONYMS or DEFINITIONS	
n/a	

PURPOSE

To provide the medical criteria to support the indication(s) for botulinum toxin therapy. Applicable procedure codes are also defined.

POLICY

A. BACKGROUND

Botulinum toxin is used for strabismus and chemodenervation of facial muscles for blepharospasm and hemifacial spasm. Botulinum toxins produce presynaptic neuromuscular blockade by preventing release of acetylcholine from nerve endings and is used to treat overactive skeletal muscles.

There are several botulinum toxin products in the US market – Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Xeomin® (incobotulinumtoxinA), and Myobloc® (rimabotulinumtoxinB). Each product has unique characteristics, dosing, and preparation specific to individual neurotoxin.

Blepharospasm, also known as benign essential blepharospasm, is a progressive neurologic disorder characterized by involuntary eyelid muscle contractions. In some patients the eyelid muscle spasms are associated with other facial muscle spasms. It is usually bilateral but may initially be unilateral. It is distinguished from temporary eyelid twitching due to other factors such as stress, caffeine, fatigue, dry eyes, and other unrelated eyelid muscle spasms such as that associated with spastic entropion.

Hemifacial spasm is a nervous system disorder in which the muscles on one side of the face twitch involuntarily. Strabismus is a condition where the two eyes do not align causing double vision. In some cases of hemifacial spasm or strabismus, botulinum toxin is an effective treatment.

B. Medically Necessary

1. The use of botulinum toxin A drugs may be medically necessary for strabismus, blepharospasm, hemifacial spasm and related seventh nerve disease.

2. All botulinum toxin A and B products are not equivalent or interchangeable. At present, only Botox® (onabotulinumtoxinA) and Xeomin® (incobotulinumtoxinA) are FDA-approved for blepharospasm. Xeomin use is only FDA-approved in patients previously treated with Botox®. Botox® is currently the only FDA-approved botulinum toxin product for use on hemifacial spams.

C. Not Medically Necessary

1. Injections of botulinum toxin for spastic conditions more frequently than every 90 days [1] may not be medically necessary except in extraordinary circumstances.
2. Ongoing treatment with botulinum toxin may be medically necessary if there is documentation of treatment success. Failure to produce a satisfactory response to two consecutive treatments at the appropriate or maximum dose is considered treatment failure and further treatments may not be considered medically necessary.
3. Myobloc® (RimabotulinumtoxinB) is not currently approved for either blepharospasm or hemifacial spasm. Medical necessity for Myobloc® is determined on an individual case-by-case basis. There must be documentation of prior treatment failure with one of the other commercially available botulinum toxin A drugs.
4. Use of botulinum toxin for cosmetic purposes may not be a medically necessary service.
5. Multiple injections on the same side are classified as a single procedure.

D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale as in the requirements above. For any retrospective review, a full operative report and/or the clinical care plan is needed.

All items must be available upon request to initiate or sustain previous payments. Every page of the record must be legible and include appropriate patient identification information

[1] FDA Prescribing Information 4086832; update 4/2017.

(e.g., complete name, date(s) of service). Services provided or ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

Documentation for botulinum toxin therapeutics includes all of the following:

1. Eye exam with description of medical justification for injection of botulinum toxin and absence of contraindications for the procedure.

2. For repeat injections, description of effectiveness of prior injection(s).

3. Allied diagnostic testing with physician's order, medical rational, findings, interpretation and report.

4. Detailed operative report that incorporates:
   a. Indication(s)
   b. Product name, dosage, site(s), and frequency of injections
   c. Total amount of botulinum toxin used, and the amount discarded.

E. Procedural Detail

CPT/HCPCS CODES	
64612	Chemodenervation of muscles innervated by facial nerve e.g., blepharospasm, hemifacial spasm
67345	Chemodenervation of extraocular muscle
J0585	injection onabotulinumtoxinA 1 unit
J0586	injection abobotulinumtoxinA 5 units
J0587	injection rimabotulinumtoxinB 100 units
J0588	injection incobotulinumtoxinA 1 unit
Required Modifiers	
RT	Right side
LT	Left side
50	Bilateral procedure
Case Specific Modifier	
JW or JZ	Discarded drug or no discarded drug
Invalid Modifiers	
24	EM visit during post-op
25	EM visit same day as minor procedure
57	EM Visit same day as major procedure

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DOCUMENT HISTORY

Approval Date	***Revision History***	***Effective Date***
05/01/2018	Initial Policy	05/01/2018
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