CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.02**
POLICY TITLE	**BOTOX® (botulinum toxin) INJECTION**				
POLICY DATE	**01/01/2020**	**REVISION DATE**	**08/08/2022**	**APPROVAL DATE**	**08/10/2022**
DISCLAIMER LANGUAGE	- **Policy content and application may have state specific variance and considerations** - **Health Plan specific 'Indications and Limitations of Coverage' may apply as specified** - **Line of Business considerations (i.e., Medicaid, Medicare, Commercial) may apply as specified**				
EXCLUSIONS	- **This policy is not applicable to Medicaid in the state(s) of North Carolina, as BOTOX® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Coverage of BOTOX® (botulinum toxin) injection will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity for this service, Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO). The AAO incorporates evidence based best practice and FDA approval and/or recommendations[1]. Avēsis Medical Directors and clinical staff are licensed medical professionals and review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Coverage is limited to membership eligible at the time of the date of service and in accordance with continuity requirements, as applicable.

2.0 Coverage may be indicated for treatment when enrollees have the following ocular conditions:

- 2.1 Blepharospasm
- 2.2 Chronic Migraine
- 2.3 Orofacial Dyskinesia

3.0 BOTOX® (botulinum toxin) injections will not be covered at a frequency that exceeds what is medically reasonable and necessary.

4.0 It is usually considered not medically necessary to give botulinum toxin injections for spastic conditions more frequently than every 90 days.

- 4.1 There may be slight variation based on FDA indications for a particular product.

5.0 Authorizations will cover up to 600 units per treatment.

- 5.1 Additional injections requested will be considered a new request for service, requiring prior authorization review and determinations made on a case-by-case basis and subject to medical necessity.

6.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for BOTOX® (botulinum toxin) injections.

- 6.1 Requests are monitored, and when services are requested/performed in excess of established parameters, the provider may be subject to retrospective quality review.

[1]American Academy of Ophthalmology https://www.aao.org

III. TREATMENT RECOMMENDATIONS AND PARAMETERS

1.0 Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonia, spasms, and twitches.
- 1.1 These agents produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings.
  - 1.1.1 Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated.
  - 1.1.2 The agents are used in the treatment of overactive skeletal muscles (e.g., hemifacial spasm, dystonia and spasticity).

2.0 The patient who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin.
- 2.1 Other spastic or muscular contraction conditions, such as eye muscle disorders, (e.g., blepharospasm) may require lesser amounts of botulinum toxin.

3.0 For larger muscle groups, it is generally agreed that once a maximum dose per site has been reached and there is no response, the treatment is discontinued.
- 3.1 The treatments may be resumed at a later date.

4.0 With response, the effect of the injections generally lasts for three months at which time the patient may require repeat injections to control the spastic or excessive muscular condition.

5.0 Migraine headaches are described as an intense pulsing or throbbing pain in one area of the head.
- 5.1 The headaches are often accompanied by nausea, vomiting, and sensitivity to light and sound.
- 5.2 Migraines usually begin with intermittent headache attacks 14 days or fewer each month (episodic migraine), but some patients go on to develop the more disabling chronic migraine.
- 5.3 To treat chronic migraines, botulinum toxin is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future headache symptoms.
- 5.4 Botulinum toxin has not been shown to work for the treatment of migraine headaches that occur 14 days or less per month, or for other forms of headache.

IV. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J0585

1.0 To establish medical necessity all criterion points referenced below must be clearly & legibly documented in the medical record and made available to Avēsis upon submission of request.
- 1.1 Areas where ‘white out’ is used are not accepted.
- 1.2 Areas with ‘black out’ or ‘scribble’ will not be accepted.
  - 1.2.1 A single line through text where the text will remain readable is acceptable with provider initials and date.

2.0 Physician signature must be present on chart and procedural notes, orders, and testing interpretations.

3.0 A baseline visual status (visual acuity) must be provided.

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the BOTOX® (botulinum toxin) injection and the frequency of its usage.

5.0 Specific to Migraine Protocol, the following must be documented:
- 5.1 Headache frequency clearly noting headaches on most days of the month
- 5.2 Chronic presence of migraines, clearly noted by history
- 5.3 Anticipated frequency must clearly be noted
- 5.4 Subsequent evaluation & support of the clinical effectiveness of BOTOX® (botulinum toxin)

6.0 Procedure note must include:
- 6.1 Dosage (number of units) of BOTOX® (botulinum toxin) given
- 6.2 Site of injection
- 6.3 Route of administration
- 6.4 Injection Lot Number

6.5 Injection expiration date
6.6 Physician Signature

7.0 Medical documentation must evidence full informed consent, outlining all pertinent risks, inclusive of the following:

7.1 Date
7.2 Consent to perform
7.3 Consent to waive
7.4 Patient or Representative Signature
7.5 Surgeon/Physician Signature
7.6 Witness Signature

V. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G43.701 - G43.709	Chronic migraine without aura, not intractable
G43.711 – G43.719	Chronic migraine without aura, intractable
G51.2	Melkersson's syndrome
G51.31 – G51.39	Clonic hemifacial spasm
G51.4	Facial myokymia
G81.10 – G81.14	Spastic hemiplegia
H02.041 – H02.046	Spastic entropion of eyelid
H02.141 – H02.146	Spastic ectropion of eyelid
H49.00 – H49.03	Third [oculomotor] nerve palsy
H49.10 – H49.13	Fourth [trochlear] nerve palsy
H49.20 – H49.23	Sixth [abducent] nerve palsy
H49.30 – H49.33	Total (external) ophthalmoplegia
H49.40 – H49.43	Progressive external ophthalmoplegia
H49.811 – H49.819	Kearns-Sayre syndrome
H49.9	Unspecified paralytic strabismus
H51.20 – H51.23	Internuclear ophthalmoplegia