Pharmacy Drug Policy & Procedure

Policy Name:	Botox (onabotulinumtoxin A)	Policy #:	2373P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Botox.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Botox (onabotulinumtoxinA) under the general medical benefit when the following criteria have been met.

Criteria

1. Criteria for Coverage for Chronic Migraine Headaches

1.1 Documented diagnosis of chronic migraine.

1.2 Documented headache diary or chart notes describing the patient's migraine history.

1.3 Documented failure, intolerance, or contraindication to at least 2 American Headache Society Level A or B migraine prophylactic therapies with claims history to support member compliance with filling at least a 90 day supply within a 120 day time frame

- Beta Blockers
  - Level A: metoprolol, propranolol, timolol
  - Level B: atenolol, nadolol
- Antidepressants
  - Level B: amitriptyline, nortriptyline, duloxetine, venlafaxine
- Anticonvulsants
  - Level A: divalproex, valproic acid, topiramate

1.4 Reauthorization requires a documented reduction in “migraine days” by 7 days per month

1.5 Prescribed by a neurologist (central nervous system doctor), physical medicine rehabilitation specialist, or pain management specialist

1.6 Approval Time

- Initial approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Subsequent approvals: 4 procedures, spaced apart by 12 weeks with documentation that patient has experienced a positive response to therapy
  - Reduction in headache frequency and/or intensity
  - Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs (NSAIDs), triptans) has decreased since the start of Botox therapy
  - Documentation that patient continues to be monitored for medication overuse headache

2. Coverage Criteria for Concurrent use of a Prophylactic C-GRP and Botulinum toxin

2.1 Documentation showing that member has had at least a 6 month trial of botulinum toxin without adequate improvement in migraine, OR

2.2 Documentation showing that member has had at least a 3 month trial of Aimovig, Ajovy, Emgality, Nurtec, Qulipta, or Vyepti as prophylactic treatment without adequate improvement in migraine

- Coverage of Emgality 120mg requires trial and failure of Aimovig and Ajovy

3. Criteria for Coverage for Cervical Dystonia

3.1 Alternative diagnoses ruled out including adverse effects of medications or other injuries or disorders of the muscles, nerves, tendons, joints, cartilage, or spinal discs

3.2 Involuntary contractions of the neck muscles
3.3 Chronic head torsion (twisting) or tilt
3.4 Symptoms present for at least 6 months
3.5 Approval Time
- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

4. Criteria for Coverage for Overactive Bladder Syndrome

4.1 Documented urinary urgency and frequency, urge incontinence and/or waking up in the night to urinate;
4.2 Documented limited ability to participate in daily activities
4.3 Documented failure of conservative therapies
- Pelvic floor exercises
- Biofeedback
- Times voids
- Dietary/fluid management under the direction of a qualified therapist

4.4 Prescribed by a urologist (urinary tract doctor)
4.5 Documented failure, intolerance, or contraindication to at least 2 anticholinergics, OR
- Some examples are oxybutynin, tolterodine, Enablex, Toviaz

4.6 Documented failure, intolerance, or contraindication to 1 anticholinergic and 1 other class of medication for overactive bladder syndrome
- Some examples are amitriptyline, desipramine, clonidine, Myrbetriq, duloxetine

4.7 Approval Time
- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

5. Criteria for Coverage for Dynamic Contracture in Cerebral Palsy

5.1 Documented hygienic problems or significant functional limitations
5.2 Approval Time
- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart

6. Criteria for Coverage for Axillary Hyperhidrosis (excessive perspiration of the underarms)

6.1 Uncontrolled perspiration present for more than 1 year
6.2 Perspiration severely impacts the member's occupational and social activities
6.3 Documented failure, intolerance, or contraindication to an adequate trial of topical aluminum chloride solution
6.4 Documented failure, intolerance, or contraindication to local and systemic drug therapy
- Anticholinergics
- Beta blockers
- Benzodiazepines

6.5 Botox is not covered for hyperhidrosis (excessive perspiration) in other body areas because safety and efficacy has not been established
6.6 Approval Time
- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy's

7. Criteria for Coverage for Chronic Anal Fissures

7.1 Documented trial and failure of conservative therapy
- Nitroglycerin ointment

- Diltiazem
- Bethanechol

7.2 Prescribed by a gastroenterologist (stomach doctor) or colorectal (colon and anus) surgeon;

7.3 Approval Time

- Initial Approval: 2 procedures spaced 12 weeks apart within a 12 month approval duration
- Max 2 procedures per lifetime

8. Criteria for Coverage for Upper Limb Spasticity

8.1 Documented focal wrist, elbow, or finger spasticity which originated at least 6 weeks post- cerebrovascular event (CVE) or progression of multiple sclerosis

8.2 Difficulty maintaining hygiene, dressing or pain

8.3 Documented failure, intolerance, or contraindication to oral antispasmodics and muscle relaxants

- Baclofen
- Tizanidine
- Cyclobenzaprine
- Methocarbamol
- Carisoprodol

8.4 Sufficient motivation and cognitive function to actively participate in physical therapy post injection

8.5 No documented fixed contractures (tightening of muscle tendons, ligaments or skin which prevents normal movement of the body part) or profound muscle wasting; AND

8.6 Member will not receive treatment with phenol, alcohol, or surgery

8.7 Approval Time

- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

9. Criteria for Coverage of Upper or Lower Limb Spasticity for Pediatric Patients

9.1 Age 2 to 17 years

9.2 Documented upper limb spasticity due to cerebral palsy, traumatic brain injury, multiple sclerosis, spinal cord injury, and stroke

9.3 Approval time

- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

10. Criteria for Coverage for Lower Limb Spasticity

10.1 Documented severe spastic equinovarus foot (overactivity of lower leg muscles) as a result of stroke

10.2 Failure to respond to oral antispasmodics, physical therapy, orthotics or other non-operative modalities

- Some examples of antispasmodics are baclofen, tizanidine, cyclobenzaprine

10.3 Sufficient motivation and cognitive function to actively participate in physical therapy post injection

10.4 No documented fixed contractures or profound muscle atrophy

10.5 Member will not receive treatment with phenol, alcohol, or surgery

10.6 Approval Time

10.7 Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration

- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

11. Criteria for Coverage for Writer's Cramp (abnormal movement of the hand and/or forearm during tasks requiring skilled hand use, such as writing)

11.1 Documented significant functional limitations that interfere with daily activities

11.2 Documented failure of conservative treatments;

- Transcutaneous electrical nerve stimulation
- Biofeedback

- Hypnotherapy
- Relaxation therapy

11.3 Approval Time

- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

12. Criteria for Coverage of Pediatric Detrusor Overactivity associated with a Neurologic Condition

12.1 Age 5 and older

12.2 Documented inadequate response to or intolerance of anticholinergic medications

- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced at least 12 weeks apart with documentation of positive response to therapy

13. Criteria for Coverage for Other Indications

13.1 Diagnosis of Achalasia

- muscle disorder which prevents lower esophagus to open up during swallowing

13.2 Diagnosis of Adductor laryngeal dystonia

- abnormal involuntary excessive contraction of the muscles that bring the vocal cords together

13.3 Diagnosis of Blepharospasm

- abnormal contraction of the eyelid muscles

13.4 Diagnosis of Focal dystonia

- Neuromuscular disorder with involuntary muscle contractions in one body part such as neck, face, jaw, feet or hands

13.5 Diagnosis of Hemifacial spasm

- neuromuscular disorder causing frequent involuntary contractions of the muscles on one side of the face

13.6 Diagnosis of Jaw closing dystonia

- involuntary and forceful muscle contractions of the face, jaw, and/or tongue

13.7 Diagnosis of Strabismus

- condition in which the eyes do not properly align with each other when looking at an object

13.8 Approval Time

- Initial Approval: 4 procedures each spaced 12 weeks apart within a 12 month approval duration
- Reapproval: 4 procedures each spaced 12 weeks apart with documentation that patient experienced a positive response to therapy

CPT Codes

HCPCS Codes

J0585	Injection, onabotulinumtoxinA [Botox]

References

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