Pharmacy Drug Policy Checklist

POLICY NAME	Botox (onabotulinumtoxin A)	POLICY #	2373P

Criteria

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

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

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 Criteria
- ☐ **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

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

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

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

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

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

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

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

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 References
  - 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

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

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]