Botulinum Toxin – PA Criteria

HCPC: J0585 onabotulinumtoxinA (Botox), J0586 abobotulinumtoxinA (Dysport), J0587 rimabotulinumtoxinB (Myobloc), J0588 incobotulinumtoxinA (Xeomin), J0589 daxibotulinumtoxinA (Daxxify)

Botulinum is a family of toxins produced by the anaerobic organism clostridia botulinum. When given as an intramuscular injection, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings. Botulinum toxin administration is payable with regards to maximum limits on dosing and frequency of administration as indicated in the table following the listed criteria at the bottom of this document. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy**
  - All requests for initial therapy will be approved with a 6 month duration
  - Treatment is deemed medically necessary, not determined to be investigational, experimental, or cosmetic and meets the following criteria as specified per indication:
    - **Axillary Hyperhidrosis (must meet all):**
      - Therapy is for onabotulinumtoxinA (Botox)
      - Individual has a diagnosis of primary axillary hyperhidrosis
      - Therapy is prescribed by a specialist in dermatology or another appropriate specialist
      - Potential causes of secondary hyperhidrosis have been ruled out (ex. hyperthyroidism)
      - The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections, secondary microbial infections)
      - Documentation is provided indicating that the condition is causing significant functional impairment leading to disruption of daily activities
      - Documentation is provided indicating failure of (for ≥2 month trial), intolerance or contraindication to topical agents (ex. ≥20% aluminum chloride)
      - Individual is ≥18 years of age
    - **Blepharospasm (must meet all):**
      - Therapy is for onabotulinumtoxinA (Botox) or incobotulinumtoxinA (Xeomin)
      - Individual has a diagnosis of blepharospasm
      - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
      - Individual has symptoms consistent with **all** the following:
        - Bilateral involuntary intermittent or sustained eyelid closure
        - Symptoms are progressively worsening or persistent and cause disruption to daily tasks
        - Symptoms are not relieved by other measures such as stress reducing techniques, lifestyle changes such as good nutrition, exercise, adequate sleep and/or decreased caffeine intake
      - Individual is ≥12 years of age for Botox, ≥18 years of age for Xeomin
    - **Cervical Dystonia (must meet all):**
      - Therapy is for onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), rimabotulinumtoxinB (Myobloc) or daxibotulinumtoxinA (Daxxify)
      - Individual has a diagnosis of cervical dystonia
      - Therapy is prescribed by or in consultation with specialist in neurology, physical medicine rehab, pain management or another appropriate specialist
      - Documentation is provided indicating that the individual has one more involuntary muscle contractions in the neck (sternocleidomastoid, splenius capitis, splenius cervicis, scalene complex, semispinalis capitis, trapezius, longissimus, levator scapulae)

- Individual has sustained head torsion and/or tilt causing limited range of motion in the neck, pain in the neck, and/or functional impairment
- The product is administered via electromyography (EMG) guided injections
- Individual is ≥ 18 years of age for Dysport, Myobloc, Xeomin and Daxxify, ≥16 years of age for Botox

▪ **Migraine Headaches (must meet all):**
- Therapy is for onabotulinumtoxinA (Botox)
- Therapy is prescribed by (and administered) by a specialist in neurology, physical medicine rehab or pain specialist
- Individual has a diagnosis of chronic migraine meeting the following criteria as defined by the International Headache Society (IHS): 15 or more headache (migraine or tension type) days per month for at least 3 months, with headaches lasting ≥4 hours (with ≥8 consistent with migraine type)
- Documentation is provided indicating current headache days per month (with average duration of episode) as well as number of days per month requiring acute treatment
- Individual is ≥18 years of age
- Documented failure of inadequate response (with a trial duration of ≥3 months), published contraindication, or intolerance to **at least three** different prescription migraine prevention therapies listed below (for migraine indication) from **at least two** of the medication classes. If disqualifying agents due to contraindications alone (without history of previous failed therapy), contraindications to all 5 classes listed below is required. Documentation must be submitted indicating reasoning behind each contraindication.
  - Antidepressants: amitriptyline or nortriptyline
  - Antiepileptic drugs: divalproex, gabapentin, topiramate or valproic acid
  - Beta blockers: propranolol, atenolol, or nadalol
  - Calcium channel blockers: verapamil
  - Calcitonin Gene-Related peptide (CGRP) antagonist: Emgality, Ajovy, Aimovig, Nurtec, Qulipta, Vyepti
- Documentation is supported in medical records that provider had addressed medication overuse (ex. opioids, barbiturates, chronic tylenol/ibuprofen, etc) as potential underlying migraine etiology

▪ **Overactive Bladder (must meet all):**
- Therapy is for onabotulinumtoxinA (Botox)
- Therapy is prescribed by or in consultation with a specialist in neurology, urology, urogynecology or another appropriate specialist
- Individual has a diagnosis of **one** of the following:
  - Overactive bladder with symptoms of urinary incontinence, urgency or frequency
  - Urinary incontinence associated with a neurologic condition (ex. multiple sclerosis, spinal cord injury, CVA, etc.)
- Individual meets one of the following in regards to age and indication for requested therapy
  - Overactive bladder: individual is ≥18 years of age
  - Neurologic involvement: individual is ≥5 years of age
- Documentation is provided indicating a failure of (≥2 month therapy), intolerance or contraindication to one oral anticholinergic medication and one oral beta-3 agonist medication

▪ **Sialorrhea (must meet all):**
- Therapy is for rimabotulinumtoxinB (Myobloc) or incobotulinumtoxinA (Xeomin),

- Therapy is prescribed by a specialist in endocrinology, neurology, otolaryngology or another appropriate specialist
- Individual is ≥2 years of age for Xeomin, ≥18 years of age for Myobloc
- Sialorrhea has been present for 3+ months and has resulted from **one** of the following
  - Underlying neurologic disorder (Parkinson's disease, stroke, traumatic brain injury, intellectual disability, genetic/congenital disorder, cerebral palsy, etc.)
  - Craniofacial abnormality
- Documentation is provided indicating failure (≥3 months), intolerance or contraindication to **one** of the following: glycopyrrolate or scopolamine

▪ **Spasticity (must meet all):**

- Therapy is prescribed by or in consultation with a specialist in pain management, neurology, physical medicine/rehab or another appropriate specialist
- Treatment is utilizing the corresponding approved agents based on location of limb spasticity:
  - Upper extremity: onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), or incobotulinumtoxinA (Xeomin)
  - Lower extremity: onabotulinumtoxinA (Botox) or abobotulinumtoxinA (Dysport)
- Limb spasticity is related to **at least one** of the following:
  - Cerebral palsy (excluded by incobotulinumtoxinA)
  - Multiple sclerosis
  - Spinal cord injury
  - Traumatic brain injury
  - Stroke
  - Hereditary spastic paraplegia
- Documentation is submitted indicating the location of patient's spasticity (upper and/or lower extremity) and supporting evidence that symptoms are causing a significant decrease or alteration in function or activities of daily living
- Individual meets the following age requirements with corresponding drug agent:
  - Botox: age ≥2 years
  - Dysport: age ≥2 years
  - Xeomin: age ≥2 years (for upper limb only)

▪ **Strabismus and Other Cranial Nerve Gaze Palsies (must meet all):**

- Therapy is for onabotulinumtoxinA (Botox)
- Individual has a diagnosis of vertical strabismus, horizontal strabismus or persistent sixth cranial nerve palsy involving the lateral rectus muscle
- Therapy is prescribed by a specialist in neurology, ophthalmology or another appropriate specialist
- Individual is ≥12 years of age

- **Continuation of Therapy**
  - All requests for continuation of therapy will be approved with a 1 year duration
  - Treatment remains medically necessary, not determined to be investigational, experimental, or cosmetic and meets the following criteria as specified per indication:

▪ **Axillary Hyperhidrosis (must meet all):**

- Individual continues to meet initial criteria
- Documentation is submitted indicating a positive response to therapy

▪ **Blepharospasm (must meet all):**

- Individual continues to meet initial criteria
- Documentation is submitted indicating a positive response to therapy

- **Cervical Dystonia (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a positive response to therapy
- **Migraine Headaches (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a decrease in the number of monthly migraine headache days or hours (additionally must provide current headache/migraine frequency for progress monitoring)
  - Documentation is submitted indicating a decrease in the number of days requiring acute migraine treatment (additionally must provide current average use of acute treatment for progress monitoring)
- **Overactive Bladder (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a positive response to therapy
- **Sialorrhea (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a positive response to therapy
- **Spasticity (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a positive response to therapy
- **Strabismus (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating a positive response to therapy

Drug	Approved Age	Indication with *Maximum Allowed* Frequency & Dosing Limit
OnabotulinumtoxinA (Botox)	18+ years	*Axillary Hyperhidrosis:* 50 units per axilla as frequently as every 12 weeks
	12+ years	*Blepharospasm:* 2.5 units per muscle, 7.5 units per eye, 15 units per treatment session as frequently as every 12 weeks
	16+ years	*Cervical Dystonia: 3*00 units as frequently as every 12 weeks
	18+ years	*Migraine Headache:* 155 units as frequently as every 12 weeks
	Per indication	*Overactive Bladder (18+ years):* 100 units as frequently as every 12 weeks *Detrusor overactivity associated with neurologic condition (5+ years)* • *Adults:* 200 units as frequently as every 12 weeks • *Pediatrics:* ≤34kg – dose does not exceed 6 units/kg per treatment session (max 200 units) ≥34kg – dose does not exceed 200 units/treatment session
	2+ years	*Spasticity* • *Upper limb in adults:* 400 units as frequently as every 12 weeks • *Lower limb in adults:* 400 units as frequently as every 12 weeks • *Upper limb in pediatrics:* 6 units/kg (max 200 units) as frequently as every 12 weeks

OnabotulinumtoxinA (Botox)		• *Lower limb in pediatrics:* 8 units/kg (max 300 units) as frequently as every 12 weeks ** If treating both upper and lower limbs, maximum dose should not exceed the lesser of 340 units total or 10 units/kg**
	12+ years	*Strabismus* • *Vertical muscles and horizontal strabismus <20 prism diopters:* 2.5 units/muscle (5 units/treatment session) as frequently as every 12 weeks • *Horizontal strabismus 20-50 prism diopters:* 5 units/muscle (10 units/treatment session) as frequently as every 12 weeks • *Persistent VI nerve palsy:* 2.5 units/session (limited to treatment of one eye) as frequently as every 12 weeks
AbobotulinumtoxinA (Dysport)	18+ years	*Cervical Dystonia:* 1000 units as frequently as every 12 weeks
	2+ years	*Spasticity* • *Upper limb in adults:* 1000 units as frequently as every 12 weeks • *Lower limb in adults:* 1500 units as frequently as every 12 weeks **If treating upper and lower limbs, max dose of 1500 units per session every 12 weeks** • *Upper limb in pediatrics: 1*6 units/kg (max 640 units) as frequently as every **16 weeks** • *Lower limb in pediatrics:* 15 units/kg per limb (max 30 units/kg if treating bilateral limbs) or 1000 units per session as frequently as every 12 weeks
RimabotulinumtoxinB (Myobloc)	18+ years	*Cervical Dystonia:* 5000 units as frequently as every 12 weeks
	18+ years	*Sialorrhea:* 3,500 units divided among parotid (max 1500 units) and submandibular (max 250 units) gland as frequently as every 12 weeks
IncobotulinumtoxinA (Xeomin)	18+ years	*Blepharospasm:* 100 units (50 units per eye) as frequently as every 12 weeks
	18+ years	*Cervical Dystonia:* 400 units as frequently as every 12 weeks
	2+ years	*Sialorrhea:* 100 units divided between the parotid and submandibular gland as frequently as **every 16 weeks**
	2+ years (upper limb)	*Spasticity* • *Upper limb in adults:* 400 units as frequently as every 12 weeks • *Upper limb in pediatrics:* 8 units/kg (max 200 units) per upper limb or 16 units/kg (max 400 units) if treating bilateral limbs as frequently as every 12 weeks
DaxibotulinumtoxinA (Daxxify)	18+ years	*Cervical Dystonia: 250 units divided among affected muscles as frequently as every 12 weeks*