PART B DRUG MEDICAL/PHARMACY	ASPIRE HEALTH	Effective Date August 15, 2024	
	Botulinum Toxin **Botox, Daxxify, Dysport, Myobloc, Xeomin**	**Policy#** Botulinum Toxin	
		Review Date 05/28/2024	**Applicable to:** ☑ Medicare Advantage ☐ Commercial ☐ Elevance Health HMO ☐ Blue Shield Trio
	Approver's Name &Title QI & UM Drug Subcommittee		

Aspire Health Plan applies medical drug clinical criteria as a reference for medical policy information only. Federal and state laws or requirements, contract language, and Plan benefit may take precedence over the application of these clinical criteria. Please consult the applicable certificate or contract for benefit details. This policy is subject to revision at the discretion of the Plan and is therefore subject to change. Refer to the 'Disclaimer' section below for more information.

OVERVIEW

This policy addresses the coverage of Botulinum Toxin Types A and B and provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate.

Medicare allows coverage and payment for only those services that are considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Aspire Health Plan may request additional documentation to determine coverage, ensure quality enhancement, and prevent fraud, waste, and abuse. The documentation that may be necessary consists of patient records, test results, and the credentials of the provider who prescribed or rendered the service or drug. If the documentation fails to substantiate the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits provided to the member, or if the documentation presents an inappropriate or excessive billing or practice pattern, Aspire Health Plan reserves the right to deny reimbursement or pursue further appropriate action as appropriate to CMS regulations.

Botulinum toxin injections are notcovered for cosmetic purposes.

Aspire Health Plan (AHP) adheres to Medicare guidelines and coverage determinations will be in compliance with the Local Coverage Determination (LCD) Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction]: Active LCDs - JE Part B – Noridian (noridianmedicare.com) Revised 10/01/2019.

APPLICABLE HCPCS

Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA), Daxxify (daxibotulinumtoxinA-lanm)

J Code	Description	Available As
J0585	Injection, onabotulinumtoxinA, 1 unit (Botox)	100-unitvial (10mL = 1 unit) 200-unitvial (10mL= 2 unit)
J0586	Injection, abobotulinumtoxinA, 5 units (Dysport)	300-unitvial (3mL = 10 units) 500-unitvial (5mL = 10 units)
J0587	Injection, rimabotulinumtoxinB, 100 units (Myobloc)	2500-units / 0.5mL 5000-units / 1mL 10000-units / 2mL
J0588	Injection, incobotulinumtoxinA, 1 unit (Xeomin)	50-units vial (5mL = 1 unit) 100-units vial (5mL = 2 units) 200-units vial (5mL = 4 units)
J0589	Injection, daxibotulinumtoxinA-lanm, 1 unit (Daxxify)	100 units/single-dose vial *Daxxify 50 Unit vials is indicated for cosmetic use only

Administration Code	Description
64612	Chemodenervation of muscles; muscles innervated by facial nerve, unilateral (e.g., for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscles; muscles innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)

PA REQUIRED: One of the J-codes above **(J0585, J0586, J0587, J0588, J0589)** is usedin conjunction with one of the required Administration Codes:

- **64612**: Chemodenervation of muscles; muscles innervated by facial nerve, unilateral (e.g., for blepharospasm, hemifacial spasm)
- **64615**: Chemodenervation of muscles; muscles innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)

NO PA REQUIRED: If one of these J codes **(J0585, J0586, J0587, J0588, J0589)** are paired with any other administration code not listed here, no prior authorization is required.

EXCLUSIONS

1) Jeuveau (prabotulinumtoxinA-xvfs) or Botox Cosmetic (onabotulinumtoxinA [Cosmetic])
   - Jeuveau (prabotulinumtoxinA-xvfs) is indicated for the temporary improvement in the appearance of moderate to severe glabellar (frown) lines between the eyebrows in adults.
   - Botox Cosmetic (onabotulinumtoxinA [Cosmetic]) is indicated for the temporary improvement in the appearance of glabellar lines, lateral canthal lines (crow's feet), and forehead lines.

   Currently, Jeuveau and Botox Cosmetic are FDA approved only for cosmetic use. Cosmetic use is excluded from coverage and therefore Jeuveau™ (prabotulinumtoxinA-xvfs) and Botox Cosmetic (onabotulinumtoxinA [Cosmetic]) are excluded from coverage.

2) Daxxify (daxibotulinumtoxinA-lanm), Dysport (abobotulinumtoxinA), Xeomin (incobotulinumtoxinA) for glabellar lines
   - Daxxify (daxibotulinumtoxinA-lanm) is also indicated for the temporary improvement in the appearance of moderate to severe glabellar (frown) lines.
   - Dysport (abobotulinumtoxinA) is also indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age.
   - Xeomin (incobotulinumtoxinA) is also indicated for the temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity in adults.

   Cosmetic use is excluded from coverage and therefore Daxxify (daxibotulinumtoxinA-lanm), Dysport (abobotulinumtoxinA), Xeomin (incobotulinumtoxinA) for glabellar lines is excluded from coverage.

CLINICAL CRITERIA

This policy aligns with the Medicare Part B Administrative Contractor (MAC) for CA **BotulinumToxin Injections - JE Part B - Noridian (noridianmedicare.com)**.

Policy References

Noridian Botulinum Toxin (Botox) Injections Documentation Requirements
Local Coverage Determination: Botulinum Toxin Types A and B (L35170)
Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57185)

NOTE: PA is only required when one of the required Botulinum Toxin codes **(J0585, J0586, J0587, J0588, J0589)** is used in conjunction with one of the required CPT injection codes **(64612,** injection of chemical destruction of nerve muscles on one side of face, or **64615,** injection of chemical for destruction of facial and neck nerve muscles on both sides of face). **Use of these Botulinum Toxin codes in conjunction/paired with procedure codes other than 64612 or 64615 will not require PA.**

I. INITIAL CRITERIA

Botulinum Toxin Types A and B may be authorized when **ALL** of the following criteria are met:

A. Prescriber attests to, or the clinical reviewer has confirmed, BOTH of the following:

1. Requested botulinum toxin is not prescribed concurrently with other botulinum toxin products; **and**

2. Member has not received botulinum toxin therapy for cosmetic or medical conditions within the last 12 weeks to the site intended for administration.

AND

B. Requested product has an FDA-labeled or compendia-supported indication for member's confirmed diagnosis. Refer to 'Appendix' section of this policy for FDA-label/compendia and dosage.

NOTE: If the botulinum toxin product requested to treat a diagnosis is not an indication listed in the FDA label or CMS-supported compendia, the clinical rationale for the non-compendial use is required.

AND

C. **Documentation Required for Review**

1. Requested botulinum toxin:
   a. Type of botulinum toxin: Botox (onabotulinumtoxinA), Daxxify (daxibotulinumtoxinA-lanm) Dysport (abotulinumtoxinA), Xeomin (incobotulinumtoxinA), Myobloc (rimabotulinumtoxinB); and
   b. Strength of toxin; and
   c. Dosage of toxin used (including dosage in units per site); and
   d. Frequency of injections requested.

and

2. Support of medical necessity of the botulinum toxin (type A or type B) injection requested.

   **Documentation supporting the medical necessity of this service as outlined in the LCD: Botulinum Toxin Types A and B Policy (L35170) (Billing and Coding: Botulinum Toxin Types A and B Policy)*

and

3. Prescribed for **ONE** of the following condition-specific criteria for member's confirmed diagnosis (LCD L35170):

   a. Spasticity or excessive muscular contractions: Botulinum toxin can be used to reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and walking, to allow better range of motion, to permit better physical therapy, and to reduce severe spasm to provide adequate perineal and palmar hygiene.

   b. Overactive bladder: Documentation of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

c. Severe primary axillary hyperhidrosis:
   i. Documented diagnosis of primary axillary hyperhidrosis (excessive underarm sweating); and
   ii. Documentation of an adequate trial of a topical 20% aluminum chloride agent OR oral glycopyrrolate, unless contraindicated or clinically significant adverse reactions were experienced.

d. Certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis): Coverage is limited to those conditions listed in the Covered ICD-10-CM section of the billing and coding article (A57185). This group of codes shall be used only when accompanied by spasticity of central nervous system origin. Recently, there has been approval by the FDA for use in upper limb spasticity.

   All other uses in the treatment of other types of spasm, including smooth muscle types, will be considered as investigational (not proven effective) and, therefore, noncovered by Medicare.

e. For treatment of achalasia of cardia (cardiospasm) (LCD: L35170)
   Documentation of ONE or more of the following conditions:
   i. Memberhas failed conventional therapy; or
   ii. Member is at high risk of complications from pneumatic dilation or surgical myotomy; or
   iii. Member who refuses surgical myotomy or balloon dilation, in preference to a less invasive risky procedure; or
   iv. A priormyotomy or dilatation has failed; or
   v. A prior dilatation caused an esophageal perforation; or
   vi. Member has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilatation-induced perforation.

f. Prophylaxis of headaches in adult patients with chronic migraine:
   i. Documented diagnosis of chronic migraines (i.e., ≥ 15 headache days per month for at least 3 months with headache lasting 4 hours a day or longer); **and**
   ii. Documentation of a compliant trial and ineffectiveness / failure, or adverse effects. or contraindication to conventional treatment with ANY of the following therapeutic classes: beta blockers (propranolol, timolol, atenolol, metoprolol, nadolol), antiepileptics (divalproex sodium, topiramate), antidepressants (amitriptyline, nortriptyline, venlafaxine, duloxetine), antihypertensive (verapamil, lisinopril, candesartan).

and

4. If diagnosis is not addressed in #3: A statement that conventional treatment that is accepted standard of care (e.g. medication, physical therapy, etc.) have been tried and proven unsuccessful. **EXCEPTION** for confirmed diagnosis of focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, or dysphonia [LCD: Botulinum Toxin Types A and B (L35170)]; **and**

5. For members who require electromyography (EMG) to determine the proper injection site(s): Documentation supporting the medical necessity of EMG procedures performed in conjunction with botulinum toxin type A injections. NOTE: The EMG procedure codes specified in the HCPCS section of the LCD: Botulinum Toxin Types A and B (L35170) may be covered if criteria is met.

and

6. Dosage and frequency of the injections AND total requested units required for therapy duration. **NOTE:** If dosage, frequency, and total requested units required for therapy duration is not provided, FDA limit per indication will be approved.

   *In all cases, the documentation must show the exact dosage of the drug administered, the reason for unavoidable wastage, and the amount of the discarded portion of the drug.

7. Specific site(s) injected.

AND

D. **Coverage Exclusions**

1. Treatment of skin wrinkles using botulinum toxin is cosmetic and is not covered by Medicare.
2. Deviations over 50 prism diopters
3. Restrictive strabismus
4. Chronic paralytic strabismus except to reduce antagonist contracture in conjunction with surgical repair
5. Duane's syndrome with lateral rectus muscle weakness
6. Recurrent temporomandibular joint (TMJ) disorder
7. Anal spasm, irritable colon, biliary dyskinesia, or any treatment of spastic conditions not listed as covered in this policy are considered to be cosmetic, investigational, or not safe and effective.
8. Treatment of muscle tension.
9. Tension headaches, myofascial pain, irritable colon, biliary dyskinesia, other forms of smooth muscle spasm *not* specifically addressed in the LCD (L35170), and any other spastic conditions not listed in the 'ICD-10 CM Codes That Support Medical Necessity' section of the Billing and Coding article (A57185) will be considered investigational, not safe and effective, or not accepted as the standard of practice within the medical community and, therefore, not medically reasonable and necessary.

NOTE: Diagnosis that is not covered as outlined in LCD: Botulinum Toxin Types A and B (L35170), and any other spastic conditions not listed in the 'ICD-10 CM Codes That Support Medical Necessity' section of the Billing and Coding article (A57185) OR submitted documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary. Reference: Billing and Coding: Botulinum Toxin Types A and B Policy

II. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

The requested botulinum toxin may be authorized for continuation of therapy when initial criteria have been met **AND** there is documentation of beneficial response from previous course(s) of treatment:

1. Clinical benefit to treatment as evidenced by documentation to member's diagnosis.
   NOTE: Coverage of treatments provided may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of a botulinum toxin, fail to produce a satisfactory clinical response. In such situations it may be appropriate to use an alternative botulinum toxin once to determine if a more satisfactory response can be obtained. Providers must also document the results of and response to these injections.

AND

2. Absence of unacceptable toxicity from the drug [e.g., symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, swallowing/breathing difficulties, etc.), severe hypersensitivity reactions, severe pulmonary effects (e.g., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, and urinary retention, etc.]

AND

3. Documentation of previous injections, as well as the future treatment plan, of total units administered in each site and discarded units.

STEPTHERAPY

Step therapy is not applicable at this time.

AHP may recommend the most cost-effective formulary product in accordance with the FDA approved indication for the member.

DOSAGE, ADMINISTRATION, AND AUTHORIZATION

1. Recommended Dose: Neurotoxin products should be dosed according to their FDA-approved indications, accepted compendia, and/or evidence-based practice guidelines. The unit dose of one form must not be equated with the unit dose of any of the others, i.e., one unit of Botox does not equal one unit of Dysport, Xeomin or Myobloc. Refer to FDA-label for Botulinum Toxin product requested.

2. Maximum Quantity*
   a) Botox (J0585: Injection, onabotulinumtoxinA,1 unit): up to 400 units every 3 months
   b) Dysport (J0586: Injection, abobotulinumtoxinA, 5 units): up to 1500 units every 3 months for adults
   c) Myobloc (J0587: Injection, rimabotulinumtoxinB, 100 units): up to 10,000 units every 3 months
   d) Xeomin (J0588: Injection, incobotulinumtoxinA, 1 unit): up to 400 units every 3 months
   e) Daxxify (J0589: daxibotulinumtoxinA-lanm, 1 unit): up to 250 units every 3 months

   NOTE: Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as a single limb, single eyelid, side of the face, side of the neck, both vocal cords, etc.

   *Refer to 'Appendix' section for additional information for quantity limits by specific botulinum toxin product and indication. If there is any discrepancy, the FDA-labeling, CMS compendia, and Medicare source materials will take precedence.

3. Authorization Period (initial authorization and re-authorization)

   a) Chronic Anal Fissure, Adjunct to surgical larynx closure procedure:
      Initial authorization: 1 treatment
      Continuation of Therapy: N/A

   b) All other indications:
      Initial authorization: 12 months
      Continuation of Therapy: 12 months

4. Dosage and Frequency: Authorization is subject to dosing limits in accordance with FDA-approved labeling, CMS-accepted compendia and/or evidence-based practice guidelines.

5. Botulinum toxin products are not interchangeable, and dosing units of one product cannot be converted or compared with dosing units of another botulinum toxin product. When treating one or more indications, the maximum cumulative dose of onabotulinumtoxinA should generally not exceed 400 units in a 3- month interval. Refer to 'Appendix' section of policy for dosage labeled limits.

6. Place of Service: The injectable products in this policy should be administered in a place of service that is a non-hospital facility-based location. Exceptions to the site of service recommended must be submitted for review and authorization.

DRUG INFORMATION

PHARMACOLOGIC CATEGORY: Neuromuscular Blocking Agent

ROUTE OF ADMINISTRATION: Intramuscular

FDA-APPROVED INDICATIONS
Botox (onabotulinumtoxinA) is indicated for:

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic

condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain.
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.
- Treatment of blepharospasm associated with dystonia in patients 12 years of age and older.
- Treatment of strabismus in patients 12 years of age and older
- Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.

Limitations of Use: Safety and effectiveness of BOTOX have not been established for:
- Prophylaxis of episodic migraine (14 headache days or fewer per month)
- Treatment of hyperhidrosis in body areas other than axillary

Daxxify (daxibotulinumtoxinA-lanm) is indicated for:
- Treatment of cervical dystonia adult patients

Dysport (abobotulinumtoxinA) is indicated for:
a) Treatment of cervical dystonia in adults
b) Treatment of spasticity in patients 2 years of age and older

Xeomin (incobotulinumtoxinA) is indicated for the treatment or improvement of:
- Chronic sialorrhea in patients 2 years of age and older
- Upper limb spasticity in adults
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
- Cervical dystonia in adults
- Blepharospasm in adults

Myobloc (rimabotulinumtoxinB) is indicated for:
- Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.
- Treatment of chronic sialorrhea in adults

COMPENDIAL APPROVED (OFF-LABEL) USES
Botox (onabotulinumtoxinA): Esophageal Achalasia, Adjunct to surgical larynx closure procedure for chronic aspiration, Organic voice tremor, Spasm of pharyngoesophageal segment following total laryngectomy, Spastic dysphonia.
Dysport (abobotulinumtoxinA): Blepharospasm, Hemifacial spasm
Xeomin (incobotulinumtoxinA): None
Myobloc (rimabotulinumtoxinB): None

CONTRAINDICATIONS: Contraindications to botulinum toxins include hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation, infection at the proposed injection site. For intradetrusor injections only: current urinary tract infection or urinary retention. For Dysport only: hypersensitivity to cow's milk protein.

OTHER CONSIDERATIONS: Botulinum toxin agents have black box warnings regarding the potential for distant spread of toxin effect. This can produce symptoms including asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk is likely greatest in children treated for spasticity but can also occur in adults.

CLINICAL SUMMARY / APPENDIX

Botulinum is a family of toxins produced by the anaerobic organism Clostridium botulinum. There are seven known serotypes of botulinum toxin: types A, B, C-1, D, E, F, and G. Of the seven immunologically distinct botulinum toxins, only serotypes A and B are available for clinical use. There are currently four neurotoxin type A products on the market, OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify), and 1 neurotoxin type B, RimabotulinumtoxinB (Myobloc).

Botulinum Toxin Quantity Limits

Botox (onabotulinumtoxinA) 100-unit, 200-unit vial	
Quantity Limit Per Indication	**Maximum Units by Indication***
Follow indication-specific dosage and administration recommendations; in a 3-month interval do not exceed a total dose [cumulative for all indications treated] of: **Adults: 400 units**	
Neurogenic Overactive Bladder: 200 units as frequently as every 12 weeks	200 units
Chronic Migraine: 155 units as frequently as every 12 weeks	200 units
Cervical Dystonia: 400 units as frequently as every 12 weeks	400 units
Axillary hyperhidrosis: 50 units per axilla as frequently as every 8 weeks	100 units
Blepharospasm: 200 units as frequently as every 12 weeks	200 units
Dystonia-associated strabismus: 25 units per muscle; as frequently as every 12 weeks	100 units
Upper limb spasticity in adults: Dose selected based on muscles affected, severity of muscle activity, prior response to treatment and adverse event history (maximum dose 400 units) as frequently as every 12 weeks	400 units
Lower limb spasticity in adults: 300 units to 400 units divided across lower limb muscles as frequently as every 12 weeks	400 units
Achalasia: 100 units as frequently as every 12 weeks (Off-label use/dosing)	100 units
Hemifacial spasm: 25 units as frequently as every 12 weeks (Off-label use/dosing)	100 units
Spasmodic Dysphonia: 25 units as frequently as every 12 weeks (Off-label use/dosing)	100 units
Other indications: Up to 400 units as frequently as every 12 weeks	400 units
Accepted Off-label Indications **Bladder muscle dysfunction:** overactive, Refractory to or intolerant of anticholinergic medication Men with no prior prostate surgery: 100 to 300 units intra-detrusor injection (off- label dosage), Men with previous prostate surgery: 100 to 200 units intra-detrusor injection (off-label dosage) **Chronic anal fissure:** 25 Units per treatment session (off-label dosage) **Adjunct to surgical larynx closure procedure:** 200 to 280 units IM into the laryngeal musculature prior to surgery for larynx closure was used in a clinical trial (n=6) (Pototshnig et al, 1996) **Organic voice tremor:** 0.6 to 5 units IM bilaterally OR 15 units IM unilaterally into affected muscles (Off- label dosage) **Spasm of pharyngoesophageal segment following total laryngectomy:** 30 to 100 units IM (Off-label dosage) Initial, 2.5 to 5 units IM and additional injections up to 30 units (Off-label dosage)	
Daxxify (daxibotulinumtoxinA- lanm) 50-unit, 100-unit vial	
Cervical Dystonia: 125 to 250 units as a divided dose among affected muscles as frequently as every 3 months	250 units
Accepted Off-label Indications: None	N/A
Dysport (abobotulinumtoxinA) 300-unit, 500-unit vial	
Upper and lower limb spasticity in adults: 1500 units (cumulative for all treated muscles) as frequently as every 12 weeks	1500 units

Cervical Dystonia: 1000 units as frequently as every 12 weeks	1000 units
Other indications: Up to 1500 units as frequently as every 12 weeks	1500 units
Blepharospasm: 120 units per eye as frequently as every 12 weeks (Off-label use/dosing)	300 units
Hemifacial spasm: 220 units as frequently as every 12 weeks (Off-label use/dosing)	300 units
Myobloc (rimabotulinumtoxinB) 2500-unit, 5000-unit,10000-unit vial	
Cervical dystonia: Initial dose of 2,500 – 5,000 units divided among effected muscles as frequently as every 12 weeks; subsequent doses should be based on individual response to treatment, up to 10,000 units as frequently as every 12 weeks	10,000 units
Chronic sialorrhea in adults: 1,500 – 3.500 units (500 units – 1,500 units per parotid gland and 250 units per submandibular gland) as frequently as every 12 weeks	5000 units
All other Indications: 10,000 units as frequently as every 12 weeks	10,000 units
Xeomin (incobotulinumtoxinA) 200-unit, 100-unit, 50-unit vial	
Cervical dystonia: Initial dose of 120 units as frequently as every 12 weeks; subsequent doses should be based on past dose, response to treatment, duration of effect and adverse event history; up to 400 units as frequently as every 12 weeks	400 units
Chronic sialorrhea: 100 units as frequently as every 16 weeks	100 units
Blepharospasm: Initial dose 50 units (25 units per eye) as frequently as every 12 weeks; subsequent doses based on past dose, response to treatment, duration of effect and adverse event history; dose should not exceed 100 units per treatment session (50 units per eye) as frequently as every 12 weeks	100 units
Upper limb spasticity: 400 units as frequently as every 12 weeks	400 units
Other indications: Up to 400 units as frequently as every 12 weeks	400 units

**Based on maximum dose for condition and vial size available*

REFERENCES

Government Agency

Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: No NCD identified (search terms: Botulinum Toxin; Botox, Dysport, Myobloc, Xeomin).

Local Coverage Determination: Botulinum Toxin Types A and B (L35170) Available: Nordian Jurisdiction E - Medicare Part B. Botulinum Toxin Injections. Available at: https://med.noridianmedicare.com/web/jeb/cert-reviews/pre-claim/opd/botulinum-toxin-injections Baltimore, MD. CMS. Accessed April 2024.

Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57185). Baltimore, MD. CMS. Accessed April 2024.

Prescribing Information

1. Botox [prescribing information]. Irvine, CA: Allergan Pharmaceuticals, Inc., November 2023.
2. Daxxify [package insert]. Newark, CA: Revance Therapeutics Inc.; August 2023.
3. Dysport [prescribing information]. Wrexham, UK: Ipsen Biopharm Ltd., January 2023.
4. Myobloc [prescribing information]. Rockville, MD: Solstice Neurosciences, Inc., March 2021
5. Xeomin [prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC, September 2023.
6. Jeuveau (prabotulinumtoxinA-xvfs) [prescribing information]. Newport Beach, CA: Evolus Inc; April 2021.

Drug Compendia

DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

IMPORTANT REMINDER

This Medicare Part B Step Therapy Medical Necessity Guideline is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers is solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

Aspire Health Plan (AHP) adheres to Medicare guidelines, including National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare manuals established by CMS. Compliance with these guidelines is required when applicable. Refer to the CMS website at http://www.cms.hhs.gov. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. All LCDS are the same for each state within a Jurisdiction. Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction E (1)]: Active LCDs - JE Part B – Noridian (noridianmedicare.com). In the event of a discrepancy between this policy and the Medicare NCD or LCD, the Medicare NCD/LCD will govern.

This policy is utilized by AHP to determine coverage in the absence of applicable CMS Medicare guidelines. Please refer to the links provided in the References section below to access the Medicare source materials that were used for developing this resource document. This document does not serve as a substitute for the official Medicare source materials that provide detailed information on Medicare coverage requirements. In the event of a conflict between this document and Medicare source materials, the Medicare source materials will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested to support coverage.

POLICY HISTORY

Version	Approval Date	Summary of Changes
1	05/28/2024	New Policy