



Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Dysport®	Drug Generic Name:	AbobotulinumtoxinA
J Code:	J0586	1 billable unit =	5 units
Original Date of Review:	12/7/2022	Last Reviewed:	6/11/2025
Revision Date History	12/7/2022, 8/30/2023, 6/12/2024, 6/11/2025		

AbobotulinumtoxinA is a neuromuscular blocking agent.

Criteria:

- **Length of authorization: 6 months** (initial and renewal)
- **Age:** see below for product specific requirements
- **Diagnoses [including ICD-10 codes]:** see below
- **Quantity Limit:**
 - Dysport® 300-unit Injection: 1 vial per 84-day supply
 - Dysport® 500-unit Injection: 3 vials per 84-day supply
- **Maximum Units:**

Indication	Billable Units	Per Number of Days
Cervical Dystonia	200	84
Sialorrhea	100	84
Chronic Anal Fissure	60	84
Blepharospasms	60	84
Upper Limb Spasticity	200	84
Upper Limb Spasticity (Pediatric)	160	84
Lower Limb Spasticity	300	84
Lower Limb Spasticity (Pediatric)	200	84
Neurogenic detrusor overactivity/OAB	160	84
Severe Primary Axillary Hyperhidrosis	100	84
Hemifacial Spasms	60	84

- **Initial Approval Criteria**
 - **Universal Criteria [if applicable]**
 - Patient is at least 18 years of age (unless otherwise noted); **AND**
 - Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
 - Patient does not have a hypersensitivity to cow’s milk protein; **AND**
 - Provider attests that the patient will be screened for active infection at the injection site prior to each administration of this medication ; **AND**

- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., incobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB, etc.); **AND**
- **Indication Specific Criteria [if applicable]**
 - **Cervical Dystonia**
 - Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
 - Patient has sustained head tilt; **OR**
 - Patient has abnormal posturing with limited range of motion in the neck
 - **Spastic Conditions**
 - Patient has one of the following:
 - Upper/Lower Limb Spasticity in adults (i.e., spasticity post-stroke, traumatic brain or spinal cord injuries)
 - Upper/Lower Limb Spasticity in pediatric patients at least 2 years of age
 - Spasticity of the lower limbs due to multiple sclerosis or Schilder's disease
 - **Blepharospasms**
 - Patient has a history of recurrent involuntary contraction of one or more muscles of the eye including orbicularis oculi, procerus, corrugator, or other periocular muscles; **AND**
 - Patient has moderate to severe symptoms; **OR**
 - Symptoms interfere with activities such as reading or driving
 - **Sialorrhea associated with neurological disorders**
 - Patient has a history of troublesome sialorrhea for at least a 3-month period; **AND**
 - Patient has Parkinson's disease; **OR**
 - Patient has severe developmental delays; **OR**
 - Patient has cerebral palsy
 - **Chronic Anal Fissure**
 - Other causes of disease have been ruled out (i.e., Crohn's Disease, etc.); **AND**
 - Patient has failed on non-pharmacologic supportive measures (i.e., sitz baths, psyllium fiber, bulking agents, etc.); **AND**
 - Patient has tried and failed a ≥ 1 month trial of conventional pharmacologic therapy (e.g. oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)
 - **Incontinence due to neurogenic detrusor overactivity**
 - Patient has detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing; **AND**
 - Patient has failed a 1 month or longer trial of two medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.
 - **Overactive Bladder (OAB)**
 - Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
 - Patient has failed a 1 month or longer trial of two medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.
 - **Severe Primary Axillary Hyperhidrosis**
 - Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., aluminum chloride, glycopyrronium, etc.); **AND**

- Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
 - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)
 - **Hemifacial Spasms**
 - Patient has a history of recurrent involuntary contraction of one or more muscles of the face; **AND**
 - Patient has moderate to severe symptoms affecting quality of life
- **Renewal Criteria**
 - Coverage can be renewed based upon the following criteria:
 - Patient continues to meet universal and indication specific criteria as identified in section III; **AND**
 - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., asthenia, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties, etc.); **AND**
 - Disease response as evidenced by the following:
 - **Blepharospasms**
 - Improvement of severity and/or frequency of eyelid spasms
 - **Cervical Dystonia**
 - Improvement in the severity and frequency of pain; **AND**
 - Improvement of abnormal head positioning
 - **Upper/Lower Limb Spasticity**
 - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)
 - **Severe Primary Axillary Hyperhidrosis**
 - Significant reduction in spontaneous axillary sweat production; **AND**
 - Patient has a significant improvement in activities of daily living
 - **Sialorrhea associated with neurological disorders**
 - Significant decrease in saliva production
 - **Incontinence due to detrusor overactivity**
 - Significant improvements in weekly frequency of incontinence episodes; **AND**
 - Patient's post-void residual (PVR) periodically assessed as medically appropriate
 - **Overactive Bladder (OAB)**
 - Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
 - Patient's post-void residual (PVR) periodically assessed as medically appropriate
 - **Hemifacial Spasms**
 - Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face
 - **Chronic Anal Fissure**
 - Complete healing of anal fissure; **OR**
 - Symptomatic improvement of persistent fissures
 - **Dosage/Administration**

Dysport®	
Indication	Dose
Cervical Dystonia	Initial dose: 500 units divided among the affected muscles. Re-treatment: 250-1000 units every 12-16 weeks or longer as necessary

Upper Limb Spasticity	<p><u>Adults</u> 500-1000 units divided among the affected muscles every 12-16 weeks or longer, as necessary. <i>Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.</i></p> <p><u>Pediatrics</u> Up to 8-16 units/kg per limb every 12 weeks. Maximum dose per treatment session for upper limb spasticity is 16 units/kg or 640 units, whichever is lower. <i>Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower.</i></p>
Sialorrhea	Up to 450 units divided among the affected muscles every 12 weeks
Chronic Anal Fissure	Up to 150 units divided among the affected muscles every 12 weeks
Lower Limb Spasticity	<p><u>Adults</u> Up to 1500 units divided among the affected muscles every 12 weeks. Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.</p> <p><u>Pediatrics</u> Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks. Maximum dose per treatment session for lower limb spasticity is 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1000 units, whichever is lower. Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower.</p>
Blepharospasms	Up to 120 units per affected eye every 12 weeks
Neurogenic Detrusor Overactivity/ Overactive Bladder (OAB)	Up to 750 units divided among the affected muscles every 12 weeks
Severe Primary Axillary Hyperhidrosis	Up to 200 units per axilla not more often than every 12 weeks
Hemifacial Spasms	Up to 220 units per treatment session based on sites and severity of the spasm. Subsequent injections administered upon recurrence of spasm, every 12 weeks, if needed.

NDC:

- Dysport® 300-unit powder for injection; single-dose vial: 15054-0530-06
- Dysport® 500-unit powder for injection; single-dose vial: 15054-0500-01

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Covered Diagnosis Codes

ICD-10	ICD-10 Description
G11.4	Hereditary spastic paraplegia
G24.01	Drug induced subacute dyskinesia
G24.3	Spasmodic torticollis
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.8	Other cerebral palsy

ICD-10	ICD-10 Description
G80.9	Cerebral Palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right non-dominant side
G81.14	Spastic hemiplegia affecting left non-dominant side
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7, complete
G82.54	Quadriplegia, C5-C7, incomplete
G83.0	Diplegia of upper limbs, Diplegia (Upper), Paralysis of both upper limbs
G83.10	Monoplegia of lower limb affecting unspecified side
G83.11	Monoplegia of lower limb affecting right dominant side
G83.12	Monoplegia of lower limb affecting left dominant side
G83.13	Monoplegia of lower limb affecting right non-dominant side
G83.14	Monoplegia of lower limb affecting left non-dominant side
G83.20	Monoplegia of upper limb affecting unspecified side
G83.21	Monoplegia of upper limb affecting right dominant side
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right non-dominant side
G83.24	Monoplegia of upper limb affecting left non-dominant side
G83.30	Monoplegia, unspecified affecting unspecified side
G83.31	Monoplegia, unspecified affecting right dominant side
G83.32	Monoplegia, unspecified affecting left dominant side
G83.33	Monoplegia, unspecified affecting right non-dominant side
G83.34	Monoplegia, unspecified affecting left non-dominant side
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side

ICD-10	ICD-10 Description
I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.041	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.042	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.043	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.044	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side

ICD-10	ICD-10 Description
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified site
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side

ICD-10	ICD-10 Description
I69.349	Monoplegia of lower limb following cerebral infarction affection unspecified side
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site
I69.841	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side
I69.842	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side
I69.843	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side
I69.844	Monoplegia of lower limb following other cerebrovascular disease affecting left non-dominant side
I69.849	Monoplegia of lower limb following other cerebrovascular disease affecting unspecified side
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side

ICD-10	ICD-10 Description
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
I69.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
I69.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
I69.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side
K11.7	Disturbances of salivary secretions
K60.0	Acute anal fissure
K60.1	Chronic anal fissure
K60.2	Anal fissure, unspecified
K62.6	Ulcer of anus and rectum
L74.510	Primary focal hyperhidrosis, axilla
L98.8	Other specified disorders of the skin and subcutaneous tissue
M62.40	Contracture of muscle, unspecified site
M62.411	Contracture of muscle, right shoulder
M62.412	Contracture of muscle, left shoulder
M62.419	Contracture of muscle, unspecified shoulder
M62.421	Contracture of muscle, right upper arm
M62.422	Contracture of muscle, left upper arm
M62.429	Contracture of muscle, unspecified upper arm
M62.431	Contracture of muscle, right forearm
M62.432	Contracture of muscle, left forearm
M62.439	Contracture of muscle, unspecified forearm
M62.441	Contracture of muscle, right hand
M62.442	Contracture of muscle, left hand
M62.449	Contracture of muscle, unspecified hand

ICD-10	ICD-10 Description
M62.451	Contracture of muscle, right thigh
M62.452	Contracture of muscle, left thigh
M62.459	Contracture of muscle, unspecified thigh
M62.461	Contracture of muscle, right lower leg
M62.462	Contracture of muscle, left lower leg
M62.469	Contracture of muscle, unspecified lower leg
M62.471	Contracture of muscle, right ankle and foot
M62.472	Contracture of muscle, left ankle and foot
M62.479	Contracture of muscle, unspecified ankle and foot
M62.48	Contracture of muscle, other site
M62.49	Contracture of muscle, multiple sites
M62.831	Muscle spasm of calf
M62.838	Other muscle spasm
R25.2	Cramp and spasm