



Dysport® (abobotulinumtoxinA) (Intramuscular/Intradetrusor/Intradermal)

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05/2020, 08/2020, 05/2021, 05/2022, 05/2023, 12/2024

I. Length of Authorization ³⁶

Coverage will be provided for 6 months and may be renewed annually thereafter (unless otherwise specified).

- Chronic Anal Fissures: Coverage will be provided for 6 months and may be renewed at 6month intervals.
- Ventral Hernia: Initial coverage will be provided for 6 months and may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Indication	Billable Units	Per # days
Cervical Dystonia	200	84
Chronic Migraine Prophylaxis	60	84
Sialorrhea	100	84
Chronic Anal Fissure	60	84
Blepharospasms	60	84
Upper Limb Spasticity	200	84
Lower Limb Spasticity	300	84
Neurogenic Detrusor Overactivity/OAB	160	84
Severe Primary Axillary Hyperhidrosis	100	84
Hemifacial Spasms	60	84
Ventral Hernia	100	N/A

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Patient is at least 18 years of age (unless otherwise specified); AND

Universal Criteria 1

- Patient does not have a hypersensitivity to any botulinum toxin product; AND
- Patient does not have a hypersensitivity to cow's milk protein; AND
- Patient does not have an active infection at the proposed injection site; 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, daxibotulinumtoxinA, rimabotulinumtoxinB, etc.);

Cervical Dystonia † 1,2

- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; AND
 - o Patient has sustained head tilt; OR
 - Patient has abnormal posturing with limited range of motion in the neck

Spastic Conditions † ‡ 1,2,12-14,20,21,39

- 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 † Φ
 - Spasticity of the lower limbs due to multiple sclerosis or Schilder's disease ‡
 - Hemifacial Spasm ‡

Blepharospasms ± 2,9-11

Prophylaxis for Chronic Migraines ‡ 3,22,38,40,41,43

- Patient is utilizing prophylactic intervention modalities (i.e. avoiding migraine triggers, pharmacotherapy, behavioral therapy, or physical therapy, etc.);
- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months;
 - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§;
 - On at least 8 days per month for > 3 months:
 - Headaches have characteristics and symptoms consistent with migraine§; OR
 - Patient suspected migraines are relieved by a triptan or ergot derivative medication;
 AND
- One of the following apply:
 - Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of migraine-prophylactic medications below for examples ±); OR
 - Patient had previous treatment with a CGRP antagonist used for prevention of migraines

Sialorrhea associated with Neurological Disorders ‡ 4,5

Patient has a history of troublesome sialorrhea for at least a 3-month period; AND



- o Patient has Parkinson's disease; OR
- o Patient has severe developmental delays; OR
- Patient has cerebral palsy

Chronic Anal Fissure ‡ 6-8

- Other causes of disease have been ruled out (i.e., Crohn's Disease, etc.);
- Patient has failed on non-pharmacologic supportive measures (i.e., sitz baths, psyllium fiber, bulking agents, etc.);
- 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 ‡ 15-17,23,35

- 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 (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or betaadrenergic (e.g., mirabegron, vibegron, etc.) classes

Overactive Bladder (OAB) ‡ 15-17,23,35,44

- 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 (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or betaadrenergic (e.g., mirabegron, vibegron, etc.) classes

Severe Primary Axillary Hyperhidrosis ‡ 18,19,42

- Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, 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.)

Ventral Hernia ‡ ^{36,37}

- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; AND
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)
- † FDA approved indication(s); ‡ Literature Supported Recommendation; Orphan Drug

± Migraine-Prophylaxis Oral Medications (list not all-inclusive) 25,26,29,43

• Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine, etc.)



- Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.)
- Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.)
- Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)

§ Migraine Features 29,38,40

Migraine without aura

- At least five attacks have the following:
 - Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
 - Headache has at least two of the following characteristics:
 - Unilateral location
 - Pulsating quality
 - Moderate or severe pain intensity
 - Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); AND
 - During headache at least one of the following:
 - Nausea and/or vomiting
 - Photophobia and phonophobia

Migraine with aura

- At least two attacks have the following:
 - One or more of the following fully reversible aura symptoms:
 - Visual
 - Sensory
 - Speech and/or language
 - Motor
 - Brainstem
 - Retinal; AND
 - At least three of the following characteristics:
 - At least one aura symptom spreads gradually over ≥5 minutes
 - Two or more symptoms occur in succession
 - Each individual aura symptom lasts 5 to 60 minutes
 - At least one aura symptom is unilateral
 - At least one aura symptom is positive (e.g., scintillations and pins and needles)
 - The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria 1-37

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III;
 AND
- Duration of authorization has not been exceeded (refer to Section I); AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reactions (e.g., anaphylaxis, serum sickness, urticaria, soft tissue edema, dyspnea, etc.); AND
- Disease response as evidenced by the following:

Blepharospasms 2,9-11

Improvement of severity and/or frequency of eyelid spasms

Cervical Dystonia 1



- Improvement in the severity and frequency of pain; AND
- Improvement of abnormal head positioning

Upper/Lower Limb Spasticity 1

• 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 18,19

- Significant reduction in spontaneous axillary sweat production; AND
- Patient has a significant improvement in activities of daily living

Prophylaxis for Chronic Migraines ^{24,29,38}

- Significant decrease in the number, frequency, and/or intensity of headaches; AND
- Improvement in function; AND
- Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.)

Sialorrhea associated with Neurological Disorders 4,5

Significant decrease in saliva production

Incontinence due to Detrusor Overactivity 15-17,23

- Significant improvements in weekly frequency of incontinence episodes; AND
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Overactive Bladder (OAB) 15-17.23

- 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 20,21

 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 6-8

- Complete healing of anal fissure; OR
- Symptomatic improvement of persistent fissures

V. Dosage/Administration 1-4,6-8,15-17,19,20,36

Indication Dose



Cervical Dystonia	Initial dose: 500 units divided among the affected muscles.
	Re-treatment: 250-1000 units every 12 weeks or longer as necessary
Upper Limb Spasticity	Adults 500-1000 units divided among the affected muscles every 12-16 weeks or longer, as necessary. Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.
	Pediatrics Up to 8-16 units/kg divided among the affected muscles every 16 weeks, or longer, as necessary. Maximum dose per treatment session for upper limb spasticity is 16 units/kg or 640 units, whichever is lower. Maximum recommended total dose per treatment session for spasticity in
	pediatric patients is 30 units/kg or 1000 units in a 3-month interval, whichever is lower.
Chronic Migraine Prophylaxis	Up to 240 units divided among the affected muscles every 12 weeks
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	Adults 1000-1500 units divided among the affected muscles every 12-16 weeks. Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.
	Pediatrics Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks, or longer, as necessary. 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 in a 3-month interval, whichever is lower.
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.







Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. <i>May not be renewed.</i>	
Note: Units of Disport are specific to the preparation and assay method utilized and are not interchangeable with		

Note: Units of Dysport are specific to the preparation and assay method utilized and are not interchangeable with other preparations of botulinum toxin products and cannot be compared to or converted into units of any other botulinum toxin products.

VI. Billing Code/Availability Information

HCPCS Code:

J0586 – Injection, abobotulinumtoxinA, 5 units; 1 billable unit = 5 units

NDC(s):

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

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G11.4	Hereditary spastic paraplegia
G24.3	Spasmodic torticollis
G24.5	Blepharospasm
G35	Multiple sclerosis
G37.0	Diffuse sclerosis of central nervous system
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G51.3	Clonic hemifacial spasm
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
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 nondominant side
G81.14	Spastic hemiplegia affecting left nondominant 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

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G83.13	Monoplegia of lower limb affecting right nondominant side
G83.14	Monoplegia of lower limb affecting left nondominant 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 nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
169.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
169.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
169.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non- dominant side
169.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
169.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
169.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
169.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
169.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
169.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
169.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
169.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
169.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
l69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non- dominant side
l69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site
169.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
169.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
169.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non- dominant side
l69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non- dominant side
169.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
169.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
169.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side







169.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non- dominant side
169.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non- dominant side
169.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site
169.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
169.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
169.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
169.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
169.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
169.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
169.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
169.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
169.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
169.339	Monoplegia of upper limb following cerebral infarction affecting unspecified site
169.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
169.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
169.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
169.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
169.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
169.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
169.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
169.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
169.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
169.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site
169.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
169.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
169.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
169.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
169.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
169.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
169.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
169.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non- dominant side
169.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side







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169.849	Monoplegia of lower limb following other cerebrovascular disease affecting unspecified site
169.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
169.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
169.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
169.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
169.949	Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
K11.7	Disturbances of salivary secretions
K43.6	Other and unspecified ventral hernia with obstruction, without gangrene
K43.7	Other and unspecified ventral hernia with gangrene
K43.9	Ventral hernia without obstruction or gangrene
K60.1	Chronic anal fissure
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
L74.510	Primary focal hyperhidrosis, axilla
M43.6	Torticollis

Dual coding requirements:

• Primary G and M codes require a secondary G or I code in order to be payable

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor
5 & 8	A57474	Wisconsin Physicians Service Insurance Corp (WPS)
N	A57715	First Coast Service Options, Inc.
6 & K	A52848	National Government Services, Inc. (NGS)



	Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor	
15	A56472	CGS Administrators, LLC	
F	A57186	Noridian Healthcare Solutions, LLC	
Е	A57185	Noridian Healthcare Solutions, LLC	
J & M	A56646	Palmetto GBA	
H&L	A58423	Novitas Solutions, Inc.	

	Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdiction	Applicable State/US Territory	Contractor		
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC		
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC		
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)		
6	MN, WI, IL	National Government Services, Inc. (NGS)		
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.		
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)		
N (9)	FL, PR, VI	First Coast Service Options, Inc.		
J (10)	TN, GA, AL	Palmetto GBA		
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA		
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.		
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)		
15	KY, OH	CGS Administrators, LLC		

