

## Dysport™ (abobotulinumtoxinA)

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### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

– N/A

#### B. Max Units (per dose and over time) [Medical Benefit]:

##### Dysport (J0586)

**Male:** 200 billable units per 12 weeks (84 days)

**Female:** 200 billable units per 12 weeks (84 days)

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

**Dysport** is considered medically necessary in the following:

Patient age 18 or greater; **AND**

#### Cervical dystonia †

- Patient has sustained head tilt; **OR**
- Abdominal posturing with limited range of motion in neck; **AND**
- History of recurrent involuntary contraction of one or more muscles in the neck

#### Upper Limb Spasticity †

- Patient has increased muscle tone in elbow flexors, wrist flexors, and finger flexors

†FDA approved indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug

#### V. Dosage/Administration

| Indication            | Dose   |
|-----------------------|--|
| Cervical Dystonia     | Initial dose: 500 units divided among the affected muscles.<br>Re-treatment: 250-1000 units every 12 -16 weeks or longer as necessary  |
| Upper Limb Spasticity | Initial dose: 500 – 1000 units based on muscles affected, severity of muscle spasticity, prior response and adverse reaction history<br>Re-treatment: 500 – 1000 units every 12 – 16 weeks or longer, as necessary |

#### VI. Billing Code/Availability Information

Jcode:

- J0586 – Dysport (Ipsen) 300 units, 500 units, Injection: 1 billable unit = 5 units

NDC:

N/A

#### VII. References

1. Dysport [package insert]. Wrexham, UK; Ipsen Biopharm Ltd; July 2015. Accessed January 2016.
2. Simpson DM, Blitzer A, Brashear A, Comella C, Dubinsky R, Hallett M, Jankovic J, Karp B, Ludlow CL, Miyasaki JM, Naumann M, So Y, Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008 May 6;70(19):1699-706.
3. Cahaba Government Benefit Administrators, LLC. Local Coverage Determination (LCD): Botulinum Toxins (L34253). Centers for Medicare & Medicaid Services, Inc. Updated on 12/16/2015 with effective date 10/1/2015. Accessed January 2016.

4. CGS, Administrators, LLC. Local Coverage Determination (LCD): Botulinum Toxins (L33949). Centers for Medicare & Medicaid Services, Inc. Updated on 11/23/2015 with effective date 10/1/2015. Accessed January 2016.
5. First Coast Service Options, Inc. Local Coverage Determination (LCD): Botulinum Toxins (L33274). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 10/1/2015. Accessed January 2016.
6. National Government Services, Inc. Local Coverage Determination (LCD): Botulinum Toxins (L33646). Centers for Medicare & Medicaid Services, Inc. Updated on 10/30/2015 with effective date 10/1/2015. Accessed January 2016.
7. Noridian Administrative Services, LLC. Local Coverage Determination (LCD): Botulinum Toxin Types A and B (L35172). Centers for Medicare & Medicaid Services, Inc. Updated on 11/20/2015 with effective date 10/1/2015. Accessed January 2016.
8. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD): Botulinum Toxin Types A and B (L35170). Centers for Medicare & Medicaid Services, Inc. Updated on 11/20/2015 with effective date 10/1/2015. Accessed January 2016.
9. Palmetto GBA. Local Coverage Determination (LCD): Chemodenervation (L33458). Centers for Medicare & Medicaid Services, Inc. Updated on 11/20/2015 with effective date 12/16/2015. Accessed January 2016.
10. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Botulinum Toxin Type A & Type B (L34635). Centers for Medicare & Medicaid Services, Inc. Updated on 11/16/2015 with effective date 12/1/2015. Accessed January 2016.

## Appendix 1 – Covered Diagnosis Codes

| ICD-9 Codes | Diagnosis   |
|-------------|---|
| 333.83      | Spasmodic torticollis   |
| 342.10      | Spastic hemiplegia and hemiparesis affecting unspecified side |
| 342.11      | Spastic hemiplegia and hemiparesis affecting dominant side    |
| 342.12      | Spastic hemiplegia and hemiparesis affecting nondominant side |
| 343.0       | Diplegic; Congenital diplegia; Congenital paraplegia          |
| 343.1       | Hemiplegic; Congenital hemiplegia                             |
| 343.2       | Quadriplegic; Tetraplegic                                     |
| 344.03      | Quadriplegia, C5-C7, complete                                 |
| 344.04      | Quadriplegia, C5-C7, incomplete                               |
| 344.2       | Diplegia of upper limbs                                       |
| 344.40      | Monoplegia of upper limb affecting unspecified side           |
| 344.41      | Monoplegia of upper limb affecting dominant side              |
| 344.42      | Monoplegia of upper limb affecting nondominant side           |

|        |  |
|--------|--|
| 438.20 | Late effects of cerebrovascular disease, hemiplegia affecting unspecified side               |
| 438.21 | Late effects of cerebrovascular disease, hemiplegia affecting dominant side                  |
| 438.22 | Late effects of cerebrovascular disease, hemiplegia affecting non-dominant side              |
| 438.30 | Late effects of cerebrovascular disease; monoplegia of upper limb affecting unspecified side |
| 438.31 | Late effects of cerebrovascular disease; monoplegia of upper limb affecting dominant side    |
| 438.32 | Late effects of cerebrovascular disease; monoplegia of upper limb affecting nondominant side |
| 723.5  | Torticollis, unspecified   |

| ICD-10  | ICD-10 Description  |
|---------|---|
| G24.3   | Spasmodic torticollis   |
| G80.1   | Spastic diplegic cerebral palsy   |
| G80.2   | Spastic hemiplegic cerebral palsy   |
| G80.3   | Spastic quadriplegic 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  |
| G82.53  | Quadriplegia, C5-C7, complete   |
| G82.54  | Quadriplegia, C5-C7, incomplete   |
| G83.0   | Diplegia of upper limbs, Diplegia (Upper), Paralysis of both upper limbs                                  |
| G83.20  | 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     |
| 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  |
| I69.039 | Monoplegia of upper 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          |
| I69.151 | 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 |
| 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          |
| I69.251 | 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                                 |
| I69.351 | 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                       |

|         |  |
|---------|--|
| I69.851 | 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    |
| I69.939 | Monoplegia of upper 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        |
| M43.6   | Torticollis  |

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare>

[coverage-database/search/advanced-search.aspx](https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

|   |                                     |
|---|-------------------------------------|
| <b>Jurisdiction(s):</b> 10 (J)  | <b>NCD/LCD Document (s):</b> L34253 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34253&amp;ver=12&amp;Date=02%2f01%2f2016&amp;DocID=L34253&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34253&amp;ver=12&amp;Date=02%2f01%2f2016&amp;DocID=L34253&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> 15  | <b>NCD/LCD Document (s):</b> L33949 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33949&amp;ver=7&amp;Date=02%2f01%2f2016&amp;DocID=L33949&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33949&amp;ver=7&amp;Date=02%2f01%2f2016&amp;DocID=L33949&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a>   |                                     |
| <b>Jurisdiction(s):</b> 9 (N)   | <b>NCD/LCD Document (s):</b> L33274 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33274&amp;ver=3&amp;Date=02%2f01%2f2016&amp;DocID=L33274&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33274&amp;ver=3&amp;Date=02%2f01%2f2016&amp;DocID=L33274&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a>   |                                     |
| <b>Jurisdiction(s):</b> 11 (M)  | <b>NCD/LCD Document (s):</b> L33458 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33458&amp;ver=20&amp;Date=02%2f01%2f2016&amp;DocID=L33458&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33458&amp;ver=20&amp;Date=02%2f01%2f2016&amp;DocID=L33458&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> 6,K   | <b>NCD/LCD Document (s):</b> L33646 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33646&amp;ver=11&amp;Date=02%2f01%2f2016&amp;DocID=L33646&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33646&amp;ver=11&amp;Date=02%2f01%2f2016&amp;DocID=L33646&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> F   | <b>NCD/LCD Document (s):</b> L35172 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35172&amp;ver=19&amp;Date=02%2f01%2f2016&amp;DocID=L35172&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35172&amp;ver=19&amp;Date=02%2f01%2f2016&amp;DocID=L35172&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> (J-E)   | <b>NCD/LCD Document (s):</b> L35170 |
| <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35170&amp;ver=11&amp;Date=02%2f01%2f2016&amp;DocID=L35170&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35170&amp;ver=11&amp;Date=02%2f01%2f2016&amp;DocID=L35170&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAAA%3d%3d&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> 5, 8  | <b>NCD/LCD Document (s):</b> L34635 |



<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34635&ver=12&Date=02%2f01%2f2016&DocID=L34635&SearchType=Advanced&bc=KAAAAAgAAAAAA%3d%3d&>

| <b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b> |  |  |
|--|--|--|
| <b>Jurisdiction</b>  | <b>Applicable State/US Territory</b>   | <b>Contractor</b>                        |
| E  | CA, HI, NV, AS, GU, CNMI               | Noridian Administrative Services (NAS)   |
| F  | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Administrative Services (NAS)   |
| 5  | KS, NE, IA, MO                         | Wisconsin Physicians Service (WPS)       |
| 6  | MN, WI, IL                             | National Government Services (NGS)       |
| H  | LA, AR, MS, TX, OK, CO, NM             | Novitas Solutions                        |
| 8  | MI, IN                                 | Wisconsin Physicians Service (WPS)       |
| 9 (N)  | FL, PR, VI                             | First Coast Service Options              |
| 10 (J)   | TN, GA, AL                             | Cahaba Government Benefit Administrators |
| 11 (M)   | NC, SC, VA, WV                         | Palmetto GBA                             |
| 12 (L)   | DE, MD, PA, NJ, DC                     | Novitas Solutions                        |
| K  | NY, CT, MA, RI, VT, ME, NH             | National Government Services (NGS)       |
| 15   | KY, OH                                 | CGS Administrators, LLC                  |