Set your patients’ treatment in motion with Dysport

REIMBURSEMENT GUIDE*

Indication

Dysport® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients.

Warning

Distant Spread of Toxin Effect: Postmarketing reports indicate that the effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, 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 of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Please see additional Important Safety Information throughout this brochure and accompanying Prescribing Information, including Boxed Warning regarding distant spread of toxin effect.

*Does not apply to Dysport for cosmetic use.
Important Notice

The Dysport Reimbursement Guide is strictly related to Dysport for the use of its therapeutic indication

This guide was developed to assist physician practices and hospital outpatient office staff in understanding third-party reimbursement for Dysport and not intended to provide recommendations on clinical practice or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Although we have made an effort to be current as of the issue date of this document, the information may not be correct or comprehensive when you view it. This document represents no statement, promise, or guarantee concerning coverage or levels of reimbursement. Similarly, all International Classification of Diseases, 9th edition, Clinical Modification (ICD-9-CM); Current Procedural Terminology (CPT); and Health Care Procedure Coding System (HCPCS) codes for Dysport are supplied for informational purposes. It is always the physician's or facility's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. It is recommended that you contact your local payers with regard to local reimbursement policies and practices. Please consult your counsel or reimbursement specialist on reimbursement or billing questions specific to your practice.

Select Important Safety Information (cont.)

Contraindications
Dysport is contraindicated in patients with hypersensitivity to any botulinum toxin product or its excipients, including human albumin, lactose, and cow's milk protein, or who have an infection at the proposed injection site.

Lack of interchangeability between botulinum toxin products
The potency Units of Dysport are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of Dysport cannot be compared to or converted into Units of any other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded.

Dysphagia and breathing difficulties
Immediate medical attention may be required in cases of respiratory, speech, or swallowing difficulties. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.

Pre-existing neuromuscular disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects, including severe dysphagia and respiratory compromise from typical doses of Dysport.

Human albumin
Dysport contains human albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Immune reaction
The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport for the treatment of hyperhidrosis has not been established.

Drug interactions
Patients receiving concomitant treatment of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxins during the course of treatment with Dysport is unknown.

Please see additional Important Safety Information throughout this brochure and accompanying Prescribing Information, including Boxed Warning regarding distant spread of toxin effect.

Billing and coding basics

Payers require providers to include standard CPT, HCPCS, and ICD-9-CM codes on claims for Dysport treatments.

Common codes for cervical dystonia

<table>
<thead>
<tr>
<th>Code</th>
<th>Code type</th>
<th>Description</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0586</td>
<td>HCPCS</td>
<td>Injection, abobotulinumtoxin A, 5 units</td>
<td>To bill the amount of Dysport administered</td>
</tr>
<tr>
<td>333.83</td>
<td>ICD-9-CM</td>
<td>Spasmodic torticollis</td>
<td>To denote the diagnosis of cervical dystonia</td>
</tr>
<tr>
<td>64613</td>
<td>CPT</td>
<td>Chemodenervation of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)</td>
<td>To describe the injection procedure</td>
</tr>
<tr>
<td>95873</td>
<td>CPT</td>
<td>Electrical stimulation for guidance in conjunction with chemodenervation (list separately in addition to code for primary procedure)</td>
<td>To account for guidance using electrical stimulation, use CPT code 95873 in addition to the CPT code for the injection</td>
</tr>
<tr>
<td>95874</td>
<td>CPT</td>
<td>Needle electromyography for guidance in conjunction with chemodenervation (list separately in addition to code for primary procedure)</td>
<td>To account for the EMG guidance, use CPT code 95874 in addition to the CPT code for the injection. Do not report 95874 in conjunction with 95873.1</td>
</tr>
</tbody>
</table>

Additional information: Consult with individual payers as appropriate

- Evaluation and Management (E&M) Services: E&M or office visit services in addition to injection may be appropriate. Most payers require documentation of a separate and identifiable procedure.
- Use of Modifiers: Document procedure modifier codes on the claim form. Coding advice from the American Academy of Neurology may differ from the payer’s requirements.
- Average Sales Price (ASP): Reported by the manufacturer quarterly. Current Medicare payment rates for Dysport: physician's office ASP + 6%; hospital outpatient ASP + 4%
- Drug Wastage: Some, but not all, payers allow payment for discarded drug from single-use vials. Contact your Ipsen Payer Relations Manager for information on local policies.

For additional medical information about Dysport, please call 1-877-397-7671.

Select Important Safety Information (cont.)

Patient counseling information
The physician should provide a copy of the FDA-approved Patient Medication Guide and review the contents with the patient. Patients should be advised to inform their doctor or pharmacist if they develop any unusual symptoms (including difficulty with swallowing, speaking, or breathing), or if any known symptom persists or worsens.

Always verify the patient’s health insurance benefits prior to injecting neurotoxin. Medicare contractor coverage policies for neurotoxins vary and are publicly available on the Centers for Medicare and Medicaid Services (CMS) Web site at http://www.cms.gov/

CPT is ©2009 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein.

Sample CMS-1500 claim form for Dysport (abobotulinumtoxinA) — physician office setting

Enter the appropriate ICD-9-CM diagnosis code, e.g., 333.83 for spasmodic torticollis (cervical dystonia). Enter the appropriate primary ICD-9-CM diagnosis code, e.g., 333.83 for spasmodic torticollis (cervical dystonia).

Enter the appropriate CPT code to report the administration procedure and the unique HCPCS code for Dysport (J0586). Note: For Dysport obtained through a specialty pharmacy, no charges for the drug should be billed by the provider. However, inclusion of the HCPCS code (J0586) is recommended to designate the drug administered and number of units administered. Consult with the individual payer to determine the appropriate method of documenting and billing for drugs obtained through a specialty pharmacy.

Include the appropriate revenue codes.

Include the appropriate CPT codes to report administration procedures, e.g., 64613 (chemodenervation of muscles); cervical spinal muscles). For Dysport, use the unique HCPCS code required by payer. Also, include appropriate modifiers as instructed by payer.

NOTE: For Dysport obtained through a specialty pharmacy, no charges for the drug should be billed by the provider. However, inclusion of the HCPCS code (J0586) is recommended to designate the drug administered and number of units administered. Consult with the individual payer to determine the appropriate method of documenting and billing for drugs obtained through a specialty pharmacy.

Report the appropriate number of units for the procedure and the appropriate number of HCPCS Units for Dysport, J0586 (500 Unit vial = 100 billing units, and 300 Unit vial = 60 billing units).

Please see additional Important Safety Information throughout this brochure and accompanying Prescribing Information, including Boxed Warning regarding distant spread of toxin effect.

Sample CMS-1450 claim form for Dysport (abobotulinumtoxinA) — hospital outpatient setting

The healthcare provider is responsible for determining appropriate codes and is directed to consult with the payer for acceptable codes.

The diagnosis and procedure codes listed on these sample claim forms are provided as examples only. Current Procedural Terminology (CPT) codes ©2009 American Medical Association (AMA). All rights reserved.
Coding information for Dysport

Vial sizes and strengths:

- **300 Unit vial NDC 15054-0530-6**
  - Box containing 1 sterile, single-use vial. Each single-use vial contains 300 Units of freeze-dried abobotulinumtoxinA, 125 μg human serum albumin, and 2.5 mg lactose.
  - HCPCS: J0586
  - Billing units: 60

- **500 Unit vial NDC 15054-0500-1**
  - Box containing 1 sterile, single-use vial. Each single-use vial contains 500 Units of freeze-dried abobotulinumtoxinA, 125 μg human serum albumin, and 2.5 mg lactose.
  - HCPCS: J0586
  - Billing units: 100

ICD-9-CM diagnosis code¹:
333.83 – Spasmodic Torticollis (cervical dystonia).

HCPCS coding for Dysport:
J0586 (injection, abobotulinumtoxinA, 5 units).

- **Dysport ordering options:**
  - Purchase directly by calling PACE at 1-888-525-2423
  - Acquisition through a specialty pharmacy
  - Acquisition through a wholesaler

Indication
Dysport is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients.

Select Important Safety Information (cont.)

Adverse events
The most commonly reported adverse events (>5% of patients) with Dysport for the treatment of cervical dystonia are muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, neck pain, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

¹Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (e.g., “15054-0500-0”). This is consistent with the Red Book and First Databank listings.

²ICD-9-CM codes are based on the World Health Organization (WHO) International Classification of Diseases, 9th edition. ICD-9-CM codes are provided for reference only. The responsibility of determining the appropriate ICD-9-CM code lies solely with the provider.

³J0586 effective as of January 1, 2010.

Please see additional Important Safety Information throughout this brochure and accompanying Prescribing Information, including Boxed Warning regarding distant spread of toxin effect.

PACE services—helping your patients and staff every step of the way

For assistance with coverage and coding, please contact the Dysport Patient Access, Care, and Education (PACE™) Program at 1-888-525-2423 or contact your Ipsen Payer Relations Manager at reimbursementservice@ipsen.com

Benefits Verification
Verify coverage, determine Medical and Pharmacy benefits
- >90% of investigations result in coverage for cervical dystonia
- Two benefits verifications conducted per patient

Prior Authorization & Recertification
Contact payers to identify requirements; support your staff with their preparation of paperwork and follow until decision is made
Track expiration dates; help obtain recertifications if needed

Appeal & Claim Support
Support your staff with appeals and reconciliations of denied, underpaid or overpaid claims
- Contact insurers to research appeals process
- Track appeal status

Specialty Pharmacy Navigation
Research and communicate any specialty pharmacy requirements

Dysport NOW Sample Program
See if samples could be an option for you—talk to your Dysport sales representative

Account Setup
Simplified account initiation and product ordering

Make a move to Dysport® (abobotulinumtoxinA)

Phone: 1-888-525-2423

For eligible commercially insured cervical dystonia patients

The Dysport Co-Pay Assistance Program can offer substantial savings on out-of-pocket costs

Savings up to $2000 annually

Eligible patients can save up to $500 per injection on Dysport, the injection procedure, and injection guidance

For use only in office, or at a specialty pharmacy, for savings of up to $500/injection.* Dysport co-pay program covers the following:

- Patient cost-share of drug cost (HCPCS J0586)
- Injection procedure (CPT 64613)
- EMG guidance coverage (CPT 95873 and 95874)

*Must be for cervical dystonia (ICD 9-CM 333.83).

To enroll your patient in the Dysport co-pay program or for answers to any reimbursement questions, contact PACE:

Phone: 1-888-525-2423 Fax: 1-888-525-2417 8:00 AM to 8:00 PM Eastern Time, Monday through Friday

Program eligibility:

Must be for cervical dystonia. Patients cannot be reimbursed under Medicaid or Medicare drug benefit plans or other federal or state programs (such as medical assistance programs). Patients living in Massachusetts, Michigan, Minnesota, and Rhode Island can only receive assistance with the cost of Dysport but not the cost of related medical services (injection and injection guidance). The Co-Pay Assistance Program can reimburse patients for up to 4 Dysport treatments per year. The program covers costs associated with Dysport injection fees, the injection procedure, and injection guidance.

Select Important Safety Information (cont.)

Contraindications

Dysport is contraindicated in patients with hypersensitivity to any botulinum toxin product or its excipients, including human albumin, lactose, and cow’s milk protein, or who have an infection at the proposed injection site.

Please see additional Important Safety Information throughout this brochure and accompanying Prescribing Information, including Boxed Warning regarding distant spread of toxin effect.