IPSENCARES®
Coverage, Access, Reimbursement & Education Support

Dysport® (abobotulinumtoxinA)

Guide to Writing a Letter of Appeal

If a health insurer refuses to pay a claim, the patient, an advocate, or a healthcare provider has the right to appeal the company's decision.

There are 2 types of appeals[1]:

Internal appeal

A request for an insurance company to conduct a full and fair review of its decision. If the case is urgent, the insurance company must speed up this process.

External review

A request for a review by an independent third party. External review means the insurance company no longer gets the final say over whether to pay a claim.

The process and requirements are different for each type of appeal.
Visit Healthcare.gov/appeal-insurance-company-decision/appeals to learn more.

Use of this information does not guarantee that a health plan will provide coverage for DYSPORT and is not intended to be a substitute for, or an influence, on your independent medical judgment.

The following pages share tips for writing an effective Letter of Appeal and a template you can use to write your Letter of Appeal for individual patients.

**Call 1-866-435-5677 Monday – Friday,
8:00 AM – 8:00 PM ET
for additional information or visit us online at IPSENCARES.com**

Reference: 1. Appealing a health plan decision. Healthcare.gov. Accessed June 18, 2025. https://www.healthcare.gov/appeal-insurance-company-decision/

Tips for Writing an Effective Letter of Appeal

Dysport® (abobotulinumtoxinA)

Before you begin a Letter of Appeal, have the following information ready:

- **Patient's full name and date of birth**
- **Patient's insurance policy/ID number**
- **The Explanation of Benefits (EOB) forms or letters showing what was denied**
- **Case ID number**
- **Brief medical history, including diagnosis, ICD-10 code, comorbidities, and allergies**
- **Patient's current and prior therapeutic regimens (include start/stop dates and the reason[s] for discontinuation)**
- **Background on the patient's current condition and symptoms**
- **Clinical support for your recommendation**

Consider these additional points when writing your letter for DYSPORT:

- **Review the EOB** and provide details for the criteria your patient meets or the rationale for excluding your patient from criteria they do not meet
- **Clearly state** why DYSPORT is the medically necessary choice for the patient
- **Provide clinical justification** to support your decision to prescribe DYSPORT and attach relevant clinical data, such as chart notes, laboratory test results, and pregnancy status[1]
- **Describe** any other patient characteristics and/or clinical considerations relevant to DYSPORT therapy
  - Attach clinical documentation that supports your recommendation[1]

Be mindful of following preferred health plan processes and timing:

- Read the process for submitting the letter to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (eg, fax, phone, email, health plan website)
  - **Internal appeals** must be submitted within **180 days (6 months)** of receiving the denial notice from the health plan[2]
  - **External reviews** must be submitted within **4 months** of receiving the denial notice from the health plan[3]
- Track the status of your request and follow up with the health plan if needed

IPSEN CARES can provide logistical information about submitting letters

Call 1-866-435-5677 Monday – Friday, 8:00 AM – 8:00 PM ET, for additional information, or visit us online at IPSENCARES.com

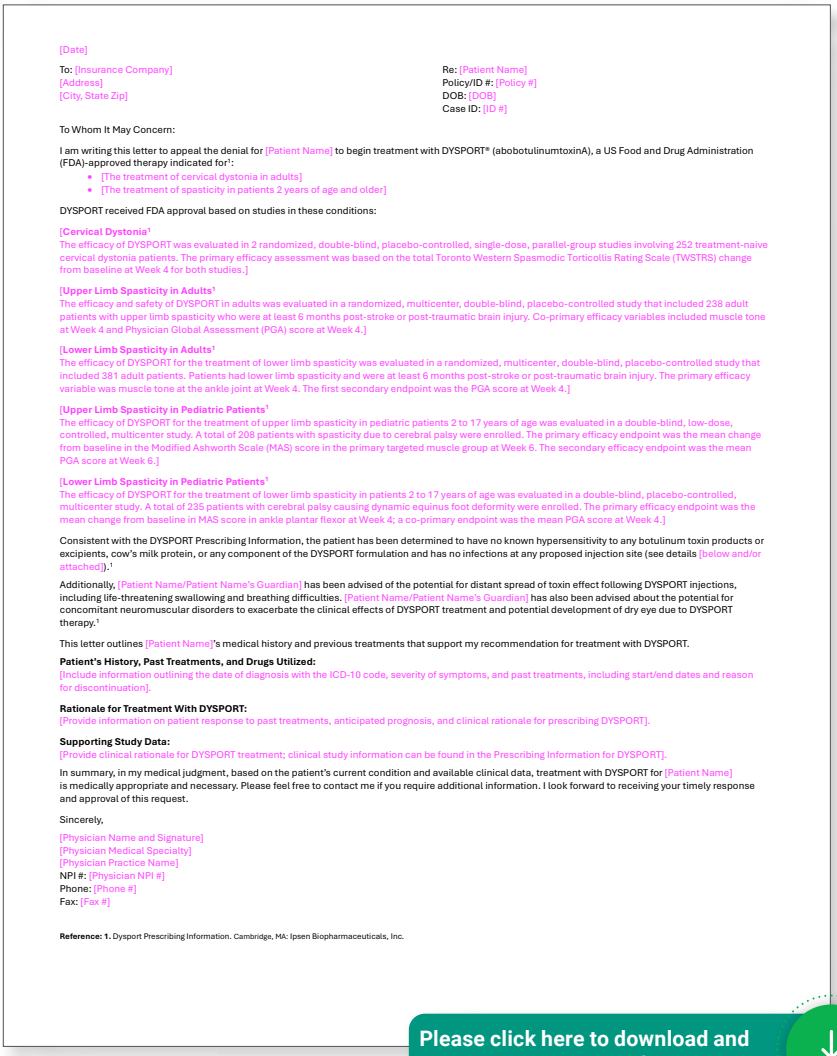
ICD-10, International Classification of Diseases, 10th Revision.

References: 1. Dysport Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc. **2.** Internal appeals. Healthcare.gov. Accessed July 24, 2025. https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/758def52-8632-4c00-9564-2ddd2b77e6ec/758def52-8632-4c00-9564-2ddd2b77e6ec_source__v.pdf **3.** External review. Healthcare.gov. Accessed June 19, 2025. https://www.healthcare.gov/appeal-insurance-company-decision/external-review

Sample Letter of Appeal for DYSPORT

Dysport® (abobotulinumtoxinA)

The image below shows the format for a sample Letter of Appeal for DYSPORT that uses a downloadable template. Take a look to get a sense of what a letter format may look like, and then you may download the template to customize it based on your medical opinion and your individual patient's needs.



[Date]

To: [Insurance Company]
[Address]
[City, State Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
Case ID: [ID #]

To Whom It May Concern:

I am writing this letter to appeal the denial for [Patient Name] to begin treatment with DYSPORT® (abobotulinumtoxinA), a US Food and Drug Administration (FDA)-approved therapy indicated for[1]:

- [The treatment of cervical dystonia in adults]
- [The treatment of spasticity in patients 2 years of age and older]

DYSPORT received FDA approval based on studies in these conditions:

[Cervical Dystonia[1]
The efficacy of DYSPORT was evaluated in 2 randomized, double-blind, placebo-controlled, single-dose, parallel-group studies involving 252 treatment-naive cervical dystonia patients. The primary efficacy assessment was based on the total Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) change from baseline at Week 4 for both studies.]

[Upper Limb Spasticity in Adults[1]
The efficacy and safety of DYSPORT in adults was evaluated in a randomized, multicenter, double-blind, placebo-controlled study that included 238 adult patients with upper limb spasticity who were at least 6 months post-stroke or post-traumatic brain injury. Co-primary efficacy variables included muscle tone at Week 4 and Physician Global Assessment (PGA) score at Week 4.]

[Lower Limb Spasticity in Adults[1]
The efficacy of DYSPORT for the treatment of lower limb spasticity was evaluated in a randomized, multicenter, double-blind, placebo-controlled study that included 381 adult patients. Patients had lower limb spasticity and were at least 6 months post-stroke or post-traumatic brain injury. The primary efficacy variable was muscle tone at the ankle joint at Week 4. The first secondary endpoint was the PGA score at Week 4.]

[Upper Limb Spasticity in Pediatric Patients[1]
The efficacy of DYSPORT for the treatment of upper limb spasticity in pediatric patients 2 to 17 years of age was evaluated in a double-blind, low-dose, controlled, multicenter study. A total of 208 patients with spasticity due to cerebral palsy were enrolled. The primary efficacy endpoint was the mean change from baseline in the Modified Ashworth Scale (MAS) score in the primary targeted muscle group at Week 6. The secondary efficacy endpoint was the mean PGA score at Week 6.]

[Lower Limb Spasticity in Pediatric Patients[1]
The efficacy of DYSPORT for the treatment of lower limb spasticity in patients 2 to 17 years of age was evaluated in a double-blind, placebo-controlled, multicenter study. A total of 235 patients with cerebral palsy causing dynamic equinus foot deformity were enrolled. The primary efficacy endpoint was the mean change from baseline in MAS score in ankle plantar flexor at Week 4; a co-primary endpoint was the mean PGA score at Week 4.]

Consistent with the DYSPORT Prescribing Information, the patient has been determined to have no known hypersensitivity to any botulinum toxin products or excipients, cow's milk protein, or any component of the DYSPORT formulation and has no infections at any proposed injection site (see details [below and/or attached]).[1]

Additionally, [Patient Name/Patient Name's Guardian] has been advised of the potential for distant spread of toxin effect following DYSPORT injections, including life-threatening swallowing and breathing difficulties. [Patient Name/Patient Name's Guardian] has also been advised about the potential for concomitant neuromuscular disorders to exacerbate the clinical effects of DYSPORT treatment and potential development of dry eye due to DYSPORT therapy.[1]

This letter outlines [Patient Name]'s medical history and previous treatments that support my recommendation for treatment with DYSPORT.

Patient's History, Past Treatments, and Drugs Utilized:
[Include information outlining the date of diagnosis with the ICD-10 code, severity of symptoms, and past treatments, including start/end dates and reason for discontinuation].

Rationale for Treatment With DYSPORT:
[Provide information on patient response to past treatments, anticipated prognosis, and clinical rationale for prescribing DYSPORT].

Supporting Study Data:
[Provide clinical rationale for DYSPORT treatment; clinical study information can be found in the Prescribing Information for DYSPORT].

In summary, in my medical judgment, based on the patient's current condition and available clinical data, treatment with DYSPORT for [Patient Name] is medically appropriate and necessary. Please feel free to contact me if you require additional information. I look forward to receiving your timely response and approval of this request.

Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: [Physician NPI #]
Phone: [Phone #]
Fax: [Fax #]

Reference: 1. Dysport Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

Please click here to download and customize the Letter of Appeal

This template is for informational purposes only, providing an outline of the types of information that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. IPSEN makes no representations or warranties about the template or its fitness for any specific use. IPSEN is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR DYSPORT

Dysport® (abobotulinumtoxinA)

INDICATION

DYSPORT (abobotulinumtoxinA) for injection is indicated for the treatment of:

- spasticity in patients 2 years of age and older
- cervical dystonia in adults

IMPORTANT SAFETY INFORMATION

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 and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

Contraindications

DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, or to any of the components in the formulation, or infection at the proposed injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a serious reaction occurs, discontinue DYSPORT and institute appropriate medical therapy immediately.

Warnings and Precautions

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of DYSPORT are specific to the preparation and assay method utilized. They 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 assessed with any other specific assay method.

Dysphagia and Breathing Difficulties

Treatment with DYSPORT and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. 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. Treatment of cervical dystonia with botulinum toxins may weaken accessory muscles of ventilation, which may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these muscles. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) 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.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR DYSPORT

Dysport® (abobotulinumtoxinA)

IMPORTANT SAFETY INFORMATION (continued)

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, vCJD, or CJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Intradermal 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. DYSPORT is approved only for intramuscular injection.

Pre-existing Conditions at the Injection Site

Caution should be exercised when DYSPORT is used where the targeted muscle shows excessive weakness or atrophy.

Adverse Reactions

- The most common adverse reactions (≥4%) in adults with upper limb spasticity include muscular weakness; in adults with lower limb spasticity (≥5%) include falls, muscular weakness, and pain in extremity
- The most common adverse reactions (≥10%) in pediatric patients with upper limb spasticity include upper respiratory tract infection and pharyngitis; in pediatric patients with lower limb spasticity include nasopharyngitis, cough, and pyrexia
- The most common adverse reactions (≥5%) in adults with cervical dystonia include muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders

Drug Interactions

Co-administration of DYSPORT and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents) should only be performed with caution because the effect of the botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of DYSPORT may potentiate systemic anticholinergic effects such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before and after administration of DYSPORT.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.