IPSENCARES®
Coverage, Access, Reimbursement & Education Support

Dysport®
(abobotulinumtoxinA)

Guide to Writing a Letter of Medical Necessity

A **Letter of Medical Necessity** (LMN) explains the prescriber's rationale and clinical decision-making for choosing a specific treatment option.

Health plans often require LMNs as part of a prior authorization or when appealing a coverage determination.

Use of this information **does not guarantee** that a health plan will provide reimbursement 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 LMN and a template you can use to write your LMN 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**

Tips for Writing an Effective Letter of Medical Necessity

Dysport® (abobotulinumtoxinA)

Before you begin a LMN, have the following information ready:

- **Patient's full name and date of birth**
- **Patient's insurance policy/ID number**
- **Case ID number (for appeals)**
- **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 health plan's coverage criteria** for Dysport and provide details for the criteria that your patient meets. If applicable, provide your rationale for excluding your patient from criteria they do not meet.
- **Clearly state** why Dysport is the appropriate choice for the patient.
- **Provide clinical justification** to support your decision to prescribe Dysport and attach relevant clinical data, such as chart notes and relevant 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.

Be mindful of following preferred health plan processes

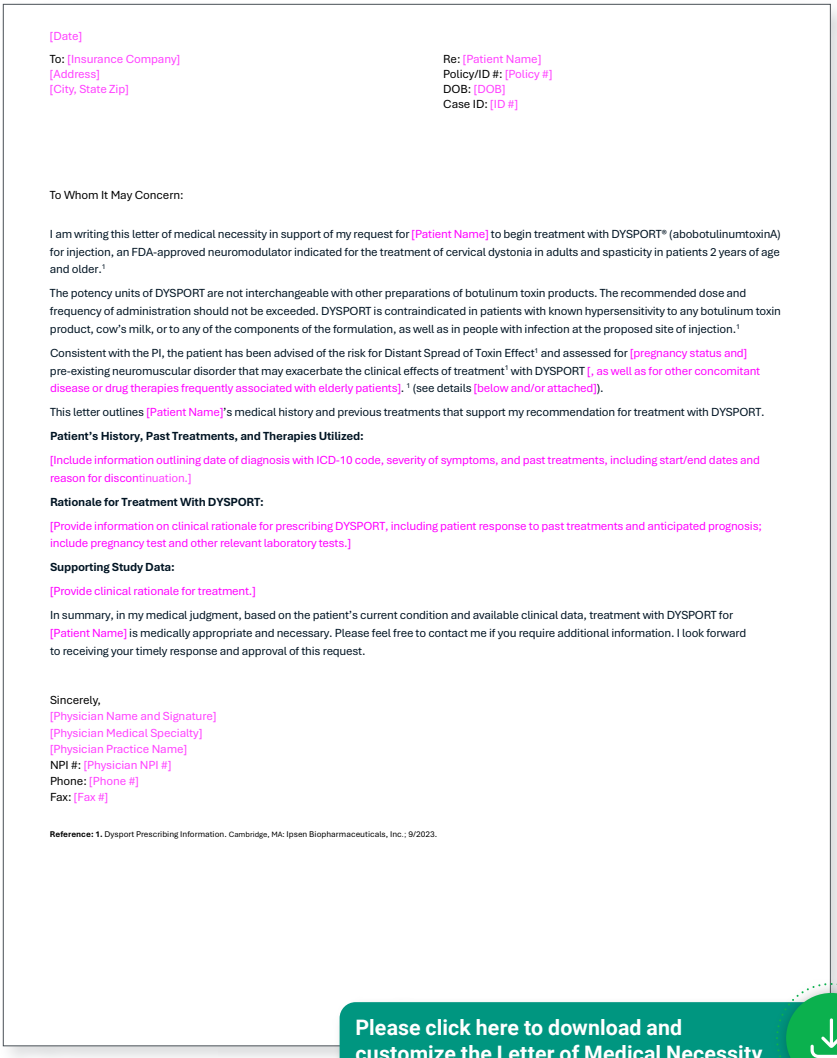
- **Read the process** for submitting the letter to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (e.g., fax, phone, email, health plan website).
- **Track the status** of your request and follow up with the health plan if needed.

Reference: Dysport (abobotulinumtoxinA) Prescribing Information. Ipsen Biopharmaceuticals, Inc.; September 2023.

Sample Letter of Medical Necessity for Dysport

Dysport® (abobotulinumtoxinA)

Below is a sample LMN for Dysport that uses the editable template provided as the last page of this document. Read through to get a better idea of what a LMN looks like, and then use the template to customize based on your medical opinion and your individual patients' 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 of medical necessity in support of my request for [Patient Name] to begin treatment with DYSPORT® (abobotulinumtoxinA) for injection, an FDA-approved neuromodulator indicated for the treatment of cervical dystonia in adults and spasticity in patients 2 years of age and older.[1]

The potency units of DYSPORT are not interchangeable with other preparations of botulinum toxin products. The recommended dose and frequency of administration should not be exceeded. DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin product, cow's milk, or to any of the components of the formulation, as well as in people with infection at the proposed site of injection.[1]

Consistent with the PI, the patient has been advised of the risk for Distant Spread of Toxin Effect[1] and assessed for [pregnancy status and] pre-existing neuromuscular disorder that may exacerbate the clinical effects of treatment[1] with DYSPORT [, as well as for other concomitant disease or drug therapies frequently associated with elderly patients]. [1] (see details [below and/or attached]).

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 Therapies Utilized:

[Include information outlining date of diagnosis with 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 clinical rationale for prescribing DYSPORT, including patient response to past treatments and anticipated prognosis; include pregnancy test and other relevant laboratory tests.]

Supporting Study Data:

[Provide clinical rationale for treatment.]

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.; 9/2023.

Please click here to download and customize the Letter of Medical Necessity

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.

[Date]

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

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

To Whom It May Concern:

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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.; 9/2023.