

Dear Payor,

In August 2016 Ipsen issued a communication to your plan notifying that the Food and Drug Administration (FDA) approved Dysport® (abobotulinumtoxinA) for injection for the treatment of lower limb spasticity in pediatric patients 2 years of age and older. As Dysport® is the only approved botulinum toxin for this indication in children, I intend to utilize Dysport® to treat lower limb spasticity in pediatric patients 2 years of age and older as indicated and request that your billing and claims departments are prepared to manage these claims.

Medicare updates the Part B Drug Average Sales Price (ASP) fee schedule every quarter. Please see below for correct product coding information.

National Drug Code (NDC)	Dysport® Dosage Strength	HCPCS Code	HCPCS Code Description	HCPCS Code Dosage
15054-0500-01	500 Units	J0586	Injection, abobotulinumtoxinA	5 Units
15054-0530-06	300 Units			

Please let me know if I can supply any additional information not included in this letter to help ensure that my impending claims for Dysport® are properly paid.

### 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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

### INDICATIONS

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Adults with upper limb spasticity, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors
- Adults with cervical dystonia
- Lower limb spasticity in pediatric patients 2 years of age and older.

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

The safety and effectiveness of Dysport® in the treatment of lower limb spasticity in adult patients has not been demonstrated.

### Contraindications

Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow's milk protein.

### 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 side effects occur, additional respiratory muscles may be involved (see Boxed

## Important Safety Information (continued)

Warning). 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. 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 (eg, 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®.

### Human Albumin

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. 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 reported for albumin.

### 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.

### Adverse reactions

Most common adverse reactions ( $\geq 2\%$  and greater than placebo in either Dysport® group) in **adults with upper limb spasticity** for Dysport® 500 Units, Dysport® 1000 Units, and Placebo, respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions ( $\geq 5\%$  and greater than placebo) in **adults with cervical dystonia** for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

Most common adverse reactions ( $\geq 10\%$  in any group and greater than placebo) in **pediatric patients with lower limb spasticity** for Dysport® 10 Units/kg, 15 Units/kg, 20 Units/kg, or 30 Units/kg; and Placebo, respectively, were: upper respiratory tract infection (9%, 20%, 5%, 10%, 13%), nasopharyngitis (9%, 12%, 16%, 10%, 5%), influenza (0%, 10%, 14%, 3%, 8%), pharyngitis (5%, 0%, 11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

### Drug interactions

Co-administration 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 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 or after administration of Dysport®.

### Use in Pregnancy

Based on animal data Dysport® may cause fetal harm. There are no adequate and well-controlled studies in pregnant women. Dysport® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### Pediatric Use

Based on animal data Dysport® may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

### Geriatric Use

In general, elderly patients should be observed to evaluate their tolerability of Dysport®, due to the greater frequency of concomitant disease and other drug therapy.

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](http://www.fda.gov/medwatch).

Please see accompanying Full Prescribing Information and Medication Guide, including **Boxed Warning** regarding distant spread of toxin effect.

Sincerely,

Dysport® (abobotulinumtoxinA) for injection, for intramuscular use, 300 Unit vial and 500 Unit vial  
Dysport® is a registered trademark of Ipsen Biopharm Ltd.  
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