CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **AbobotulinumtoxinA (Dysport®)**

Effective Date **5/15/2010**
Next Review Date **5/15/2011**
Coverage Policy Number **1015**

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Hyperlink to Related Coverage Policies

OnabotulinumtoxinA (Botox® A)
RimabotulinumtoxinB (Myobloc®)

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA*

Coverage Policy

CIGNA covers abobotulinumtoxinA (Dysport®) as medically necessary for the treatment of cervical dystonia, including spasmodic torticollis, causing persistent pain or interfering with the ability to perform age-related activities of daily living.

When criteria are met for coverage, approval consists of a quantity of four (4) treatments in a 12 month period (one (1) treatment every 90 days)

If the initial approval criteria (listed above) are met AND clinical improvement with previous botulinum toxin treatment is documented but duration of benefit is < 90 days/treatment, then up to six treatments in a 12 month period (one treatment per 60 days) may be considered on a case-by-case basis.

CIGNA does not cover abobotulinumtoxinA (Dysport®) for temporary improvement in the appearance of moderate to severe glabellar lines because such use is considered cosmetic and not medically necessary.

CIGNA does not cover abobotulinumtoxinA (Dysport®) for any other indication because it is considered experimental, investigational, and unproven.

FDA Approved Indications

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.

FDA Recommended Dosing

Cervical Dystonia

Initial dose of Dysport is 500 Units given intramuscularly as a divided dose among the affected muscles; re-treatment every 12 to 16 weeks or longer, as necessary, based on return of clinical symptoms with doses administered between 250 and 1000 Units to optimize clinical benefit - re-treatment should not occur in intervals of less than 12 weeks; titration should occur in 250 Unit steps according to the patient's response.

Black Box Warning

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 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, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

Drug Availability

Dysport for injection is supplied in a sterile, single-use, 3 mL glass vial. For cervical dystonia, each vial contains 500 Units of freeze-dried abobotulinumtoxinA and comes in a box containing 1 vial or 2 vials.

General Background

Pharmacology

AbobotulinumtoxinA (Dysport) is labeled for the treatment of cervical dystonia, and for the temporary improvement of moderate to severe glabellar lines in patients 65 years or younger. AbobotulinumtoxinA has been available in Europe since 1990. Other available botulinum neurotoxin products approved for the treatment of cervical dystonia include onabotulinumtoxinA (Botox) and rimabotulinumtoxinB (Myobloc). Botulinum neurotoxin is well-studied for the treatment of cervical dystonia and is recommended as a treatment option by the American Academy of Neurology. This review will be limited to the use of abobotulinumtoxinA for cervical dystonia.

AbobotulinumtoxinA works in the peripheral and autonomic nervous system by preventing the release of acetylcholine. This effect results in disrupted neurotransmission and muscle paralysis. AbobotulinumtoxinA cannot be detected in peripheral blood and pharmacokinetic information including absorption, distribution, metabolism, and elimination are not available. Each botulinum neurotoxin product is different and these agents are not interchangeable on a unit per unit basis.

Clinical Efficacy

Thirteen trials compare abobotulinumtoxinA to onabotulinumtoxinA for treatment of glabellar lines (n=3), cervical dystonia (n=3), blepharospasm (n=3), and hyperhidrosis (n=4). Based on these trials, superiority of one product over another cannot be determined. No trials compare abobotulinumtoxinA to rimabotulinumtoxinB.
Cervical dystonia: AbobotulinumtoxinA is more effective than placebo or trihexyphenidyl for the treatment of cervical dystonia. AbobotulinumtoxinA was more efficacious than onabotulinumtoxinA (based on mean change in Tsui score, $p<0.05$) in one trial, but also produced more adverse effects (eg, dysphagia). In another trial, the efficacy and adverse effect profiles were similar between products, p=NS. In a third trial, onabotulinumtoxinA was more efficacious and had fewer adverse effects than abobotulinumtoxinA. Overall, there are insufficient data showing one agent is superior to another.

Adverse Reactions/Contraindications

The most common adverse events with abobotulinumtoxinA are dose related and include muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, and injection site pain. Based on a systematic review, abobotulinumtoxinA has a higher frequency of dysphagia

compared to onabotulinumtoxinA. AbobotulinumtoxinA carries a black box warning regarding the distant spread of the medication resulting in swallowing and breathing difficulties, with respiratory failure and death reported. Botulism resulting in mild generalized weakness has occurred. AbobotulinumtoxinA is contraindicated in patients who are allergic to any of the ingredients in the formulation, including an allergy to cow's milk.

The neuromuscular effects of abobotulinumtoxinA may be increased if administered to a patient receiving aminoglycosides, neuromuscular blocking agents, or muscle relaxants. Increased anticholinergic effects may occur in patients receiving abobotulinumtoxinA concomitantly with anticholinergic medications.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
J0586	AbobotulinumtoxinA, 5 units

ICD-9-CM Diagnosis Codes	Description
333.83	Spasmodic torticollis

Cosmetic/Not Medically Necessary and Not Covered:

ICD-9-CM Diagnosis Codes	Description
V0586	Other plastic surgery for unacceptable cosmetic appearance

Experimental/Investigational/Unproven and Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

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