



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 RimabotulinumtoxinB (Myobloc®)

Effective Date..... 9/15/2010
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Coverage Policy Number 5107

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Hyperlink to Related Coverage Policies

OnabotulinumtoxinA (Botox®)
AbobotulinumtoxinA (Dysport®)

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 rimabotulinumtoxinB (Myobloc®) as medically necessary for treatment of EITHER of the following indications:

- cervical dystonia including spasmodic torticollis, causing persistent pain or interfering with the ability to perform age-related activities of daily living
- ptyalism/sialorrhea (excessive salivation) associated with parkinsonism and/or cerebral palsy that is refractory to pharmacotherapy (including anticholinergics)

When coverage is available and medically necessary, the dosage, frequency, site of administration, and duration of therapy should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to rimabotulinumtoxinB (Myobloc®) therapy for the condition being addressed.

CIGNA does not cover rimabotulinumtoxinB (Myobloc®) for ANY of the following because it is considered experimental, investigational, or unproven (this list may not be all-inclusive):

- chronic pain including:

- low back pain
- mastectomy reconstruction pain
- hemorrhoid pain
- myofascial pain
- chronic prostate pain
- tennis elbow
- chronic neck pain
- temporo-mandibular dysfunction or chronic orofacial pain
- headache (tension-type headache, chronic daily headache)
- migraine
- rhinitis
- tics
- paralytic scoliosis
- diabetic gastroparesis
- sphincter of Oddi dysfunction
- voiding dysfunction associated with **ANY** of the following:
 - benign prostatic hyperplasia
 - detrusor hyperreflexia due to myelomeningocele
 - urge incontinence refractory to anticholinergic therapy
 - intracranial lesions or cerebrovascular accident-induced voiding difficulty
 - detrusor sphincter dyssynergia due to spinal cord injury

FDA Approved Indications

Myobloc is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

FDA Recommended Dosing

The recommended initial dose of Myobloc for patients with a prior history of tolerating botulinum toxin injections is 2,500 to 5,000 Units divided among affected muscles. Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dose. Subsequent dosing should be optimized according to the patient's individual response.

Black Box Warning

Postmarketing reports indicate that the effects of Myobloc 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 occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

Drug Availability

Myobloc is provided as a clear and colorless to light-yellow sterile injectable solution in single use 3.5-mL glass vials. Each single-use vial contains 5,000 Units of botulinum toxin type B per milliliter in 0.05% human serum albumin, 0.01 M sodium succinate, 0.1 M sodium chloride at approximately pH 5.6. Myobloc is available in the following three presentations - 2,500 Units 0.5 mL; 5,000 Units 1 mL; 10,000 Units 2 mL.

General Background

Pharmacology

Botulinum toxins work in the peripheral and autonomic nervous systems by preventing the release of acetylcholine. This effect results in disrupted neurotransmission and muscle paralysis. *Clostridium botulinum* (*C. botulinum*), *C. baratii*, and *C. butyricum* all produce the neurotoxin, botulinum. The available formulation of rimabotulinumtoxinB is derived from *Clostridium botulinum*. It specifically has been demonstrated to cleave synaptic vesicle associated membrane protein (VAMP, i.e. synaptobrevin), which is a component of the protein complex responsible for docking and fusion of the synaptic vesicle to the pre-synaptic membrane, a necessary step to neurotransmitter release.

There are seven antigenically different types of botulinum toxin: A, B, C, D, E, F, and G. Antitoxin to a specific botulinum toxin such as anti-A botulinum does not neutralize the effects of other types of toxins such as types B through G. Botulinum toxin doses are expressed in units of biologic activity, with one unit corresponding to the lethal dose for female Swiss-Webster mice. However, the different botulinum formulations are not interchangeable because assays measuring the lethal dose differ. Pharmacokinetic data such as absorption, distribution, metabolism, and elimination are not available for rimabotulinumtoxinB. Systemic concentrations of botulinum toxin following intradermal or intramuscular injection are not expected.

The potency units of Myobloc 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 Myobloc cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

Clinical Efficacy

Two phase III, randomized, multi-center, double-blind, placebo-controlled studies were conducted in adults with cervical dystonia who had a history of receiving botulinum toxin type A in an open-label manner, with a perceived good response and tolerable adverse effects. Patients in one study were randomized to receive placebo, 5000 units (U) or 10,000 U of rimabotulinumtoxinB; in another study, patients were randomized to receive placebo or 10,000 U of rimabotulinumtoxinB. Patients selected for the phase III studies had cervical dystonia of at least moderate severity for at least one year. The primary efficacy measure in these studies was combined improvement in the severity, pain, and disability subscales of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Total Score (scale range of possible scores is 0–87) at four weeks after a single treatment session consisting of 1–5 injections divided among 2–4 muscles in each patient. The secondary endpoints were the Patient Global and Physician Global Assessments of change at week four. Both Global Assessments used a 100 point visual-analog scale (VAS). The Patient Global Assessment allows a patient to indicate how they feel at the time of the evaluation compared to the pre-injection baseline. Patients receiving rimabotulinumtoxinB doses of 5000 or 10,000 units had greater improvement in dystonic manifestations and associated pain and disability than those receiving placebo. In one of the studies in which both doses of rimabotulinumtoxinB were evaluated, there were no statistically significant differences in results between the 5000 U and 10,000 U doses. Exploratory analyses of these two studies suggested that the majority of patients who showed a beneficial response by week four had returned to their baseline status between weeks 12–16 post-injection. Although there was a decrease in pain with the use of rimabotulinumtoxinB, there remained many patients who experienced an increase in dystonia-related neck pain irrespective of treatment group. TWSTRS Total Score at week four and Patient Global Assessment among subgroups by gender or age showed consistent treatment-associated effects across these subgroups.

Clinical Efficacy for Off-Label Uses

In a double-blind, placebo-controlled study, the safety and efficacy of botulinum toxin B was evaluated for the treatment of sialorrhea in patients with Parkinson's disease (PD). Patients were randomized to receive either 1000 units of botulinum toxin B into each parotid gland and 250 units into each submandibular gland or a pH-matched placebo, using only anatomic landmarks. Patients returned after one month to undergo an identical assessment. Compared with placebo, those randomized to drug reported improvement on the Visual Analogue Scale ($p < 0.001$), global impressions of change ($p < 0.005$), Drooling

Rating Scale ($p < 0.05$), and Drooling Severity and Frequency Scale ($p < 0.001$). Adverse events were mild and included dry mouth, worsened gait, diarrhea, and neck pain in the botulinum toxin B group. Anatomically guided injections of botulinum toxin B into the parotid and submandibular glands appear to effectively improve sialorrhea without compromising dysphagia in patients with PD.

Ongoing Studies

Chronic Pain

Preliminary data suggest that rimabotulinumtoxinB may be useful in the treatment of myofascial pain syndrome. RimabotulinumtoxinB also reportedly has been used in patients with chronic low back pain and in patients with pain associated with brachial plexopathy. However, additional study is needed to determine optimal injection technique and dosing as well as the relative safety and efficacy of rimabotulinumtoxinB in these disorders.

Temporomandibular Dysfunction or Chronic Orofacial Pain

Efficacy evidence and experience with rimabotulinumtoxinB in the management of temporomandibular dysfunction or chronic orofacial pain are limited. Additional research is needed and reportedly is under way to confirm the safety and efficacy and determine optimal doses of rimabotulinumtoxinB for these disorders.

Headache (tension-type headache, chronic daily headache) / Migraine

Efficacy evidence and experience with botulinum toxin type B in the management of disabling headaches (e.g., migraine, cluster headache) are limited. As with botulinum toxin type A, some clinicians consider treatment with botulinum toxin type B appropriate in patients who have disabling headaches that are refractory to other therapies or in patients who cannot tolerate such therapies. Additional research is needed and reportedly is under way to confirm the safety and efficacy and determine optimal doses of botulinum toxin type B in patients with various types of headache.

Voiding Dysfunction

Efficacy evidence for botulinum toxin type B in neurogenic voiding dysfunction (e.g., detrusor hyperreflexia secondary to multiple sclerosis) is limited.

Adverse Reactions

The most commonly reported adverse events associated with Myobloc treatment in all studies were dry mouth, dysphagia, dyspepsia, and injection site pain. Dry mouth and dysphagia were the adverse reactions most frequently resulting in discontinuation of treatment. There was an increased incidence of dysphagia with increased dose in the sternocleidomastoid muscle. The incidence of dry mouth showed some dose-related increase with doses injected into the splenius capitis, trapezius and sternocleidomastoid muscles.

Coding/Billing Information

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

Covered when medically necessary:

CPT ^{®*} Codes	Description
64613	Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)

HCPCS Codes	Description
J0587	Botulinum toxin type B, per 100 units

ICD-9-CM Diagnosis Codes	Description
333.83	Spasmodic torticollis
527.7 [†]	Disturbance of salivary gland

[†]**Note:** Covered when medically necessary and when used to treat ptyalism/sialorrhea associated with parkinsonism and cerebral palsy that is refractory to pharmacotherapy (including anticholinergics).

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
307.20	Tic disorder, unspecified
307.21	Transient tic disorder
307.22	Chronic motor or vocal tic disorder
307.23	Tourette's disorder
307.81	Tension headache
333.3	Tics of organic origin
339.10-339.12	Tension type headache
344.61	Cauda equine syndrome with neurogenic bladder
346.00 - 346.93	Migraine
350.1	Trigeminal neuralgia
455.0 – 455.8	Hemorrhoids
472.0	Chronic rhinitis
477.0 – 477.9	Allergic rhinitis
524.60	Unspecified temporomandibular joint disorders
524.62	Arthralgia of temporomandibular joint
536.3	Gastroparesis
564.00-564.09	Constipation
723.1	Cervicalgia
724.2	Lumbago
726.32	Lateral epicondylitis of elbow
729.1	Myalgia and myositis unspecified
737.9	Unspecified curvature of spine
784.0	Headache
788.31	Urge incontinence

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare (Myobloc [®])	9/15/2008	5107	RimabotulinumtoxinB
Great-West Healthcare	12/2006	P04.104.2	Botox, Myobloc

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.