Block 21: Enter the ICD-10-CM (10) diagnosis code that is appropriate for the patient. The diagnosis code for spasmotic torticollis is G24.3.

Block 24, Column D: Enter the appropriate HCPCS and CPT codes:

- MYOBLOC J0587 – Botulinum Toxin Type B (per 100 Units) for intra-muscular administration.
- JW Modifier – Required to be reported on Part B drug claims for discarded drugs and biologicals. Providers must also document the amount of discarded drugs or biologicals in Medicare beneficiaries’ medical records.
- Administration, e.g., 64616 – Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., cervical dystonia, spasmotic torticollis). Bilateral procedural report 64616 with modifier 50.
- Other administration codes may be appropriate.
- EMG, e.g., 95874 – Needle electromyography for guidance in conjunction with chemodenervation. To be listed separately in addition to code for primary procedure.

The above diagnosis and procedure codes are provided as examples only. The healthcare provider is responsible for determining the appropriate codes for an individual patient.

Block 24, Column G: Enter the number of billing Units

Please note: For J0587, a billing Unit is per 100 Units of MYOBLOC.

Block 19: Some payers may require the NDC number when submitting a claim. If required, the NDC numbers are entered with a “0” (011 digit NDCi) in the 6th position (please see 11-digit NDC numbers below). The NDC number should be indicated in the electronic documentation field (Loop 2300, or 2400, NTE 02) for MOST payers. Please check individual payer requirements prior to submission. If you are permitted to submit paper claims, include this information in Item 19 of the CMS-1500 claim form.

- 10454-0710-10 MYOBLOC 2,500 Units/0.5 mL
- 10454-0711-10 MYOBLOC 5,000 Units/1 mL
- 10454-0712-10 MYOBLOC 10,000 Units/2 mL
Indication

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.

Important Safety Information

**WARNING: DISTANT SPREAD OF TOXIN EFFECT**

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, 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 [see Warnings and Precautions].

MYOBLOC is contraindicated in patients with a known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

MYOBLOC is contraindicated for use in patients with infection at the proposed injection site(s).

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.

Treatment with MYOBLOC 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 months, 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 neck muscles that serve as accessory muscles of ventilation. This may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these accessory muscles. There have been postmarketing reports of serious breathing difficulties, including respiratory failure, in cervical dystonia patients. 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.

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional 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 MYOBLOC.

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 identified for albumin.

Only 9 subjects without a prior history of tolerating injections of type A botulinum toxin have been studied. Treatment of botulinum toxin naïve patients should be initiated at lower doses of MYOBLOC.

Co-administration of MYOBLOC and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within less than 4 months of each other is unknown. However, neuromuscular paralysis may be potentiated by co-administration or overlapping administration of different botulinum toxin serotypes.

It is not known whether MYOBLOC can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. MYOBLOC should be given to a pregnant woman only if clearly needed.

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 reported with doses injected into the splenius capitis, trapezius and sternocleidomastoid muscles. The incidence of dry mouth showed some dose-related increase with doses injected into the splenius capitis, trapezius and sternocleidomastoid muscles.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-888-461-2255, Option 2. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information, including Boxed WARNING and Medication Guide.

For more information about our Reimbursement Services and Patient Assistance Programs, or to obtain application forms, please call 1-888-461-2255, Option 3, or visit our Web site at www.myobloc-reimbursement.com

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