SAMPLE CMS-1500 CLAIM FORM

For Product Administered in the Physician's Office—Effective 1/01/17

		EE (NUCC) 02/12								PICA
1. MEDICARE MEDIC	_	CHAMPVA		LAN FECA		1a. INSURED'S I.D.	NUMBER		(For Program	in Item 1)
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ZIP CODE	TELEPHONE (Include	Area Code)				ZIP CODE		TELEPHONE	(Include Area)	Code)
9. OTHER INSURED'S NAME	E (Last Name, First Name, N	vliddle Initial) 1	0, IS PATIENT'S	CONDITION RELATED	D TO:	11. INSURED'S PO	ICY GROUP	OR FECA NUM	/ IBER	
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				res No		a. INSURED'S DAT	A PARTY AND A PART	M	JOEA	F
b. RESERVED FOR NUCC USE			b. AUTO ACCIDENT? PLACE (State)			b. OTHER CLAIM I) (Designated	by NUCC)		
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d. INSURANCE PLAN NAME OR PROGRAM NAME			od. CLAIM CODE	S (Designated by NUC	CC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN?			nd 0d	
RE	EAD BACK OF FORM BEFO	DRE COMPLETING 8	SIGNING THIS F	ORM.		13. INSURED'S OR	AUTHORIZE	D PERSON'S S	IGNATURE	authorize
12. PATIENT'S OR AUTHOR to process this claim. I also below.	o request payment of governr	ment benefits either to	myself or to the pa	rty who accepts assignr	ment	payment of med services describ	ed below.	o the undersigne	ad physician o	r supplier for
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BLOCK 21:

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D

E

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

BLOCK 24, COLUMN D: Enter the appropriate HCPCS and CPT codes:

- <u>MYOBLOC</u>: J0587 Botulinum toxin type B (per 100 Units) for intramuscular administration.
- JW Modifier Required to be reported on Part B drug claims for discarded drugs and biologicals. Providers muscalso document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.
- <u>Administration</u>, eg. 64616 Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg. cervical dystonia, spasmodic torticollis). Bilateral procedure, report 64616 with modifier 50.
- Other administration codes may be appropriate.
- <u>EMG</u>, eg, 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 E:

For each HCPCS or CPT code, insert the letter (A-L) corresponding to the appropriate diagnosis code entered in Block 21.

BLOCK 24, COLUMN G:

Enter the number of billing Units <u>Please note</u>: 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 "O" (11-digit NDC number) in the sixth position (please see the 11-digit NDC numbers below). The NDC number should be indicated in the electronic documentation field (Loop 2300, or 2400, NTE, O2) 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

Please see Important Safety Information and Indication (<u>on page 2</u>) and full <u>Prescribing Information</u>, including Boxed WARNING, and <u>Medication Guide</u>.

ICD-CM codes are based on the World Health Organization (WHO) International Classification of Diseases, 10th edition. Solstice Neurosciences, LLC, assumes no liability for information contained herein. Solstice Neurosciences, LLC, claims no ownership or other interest in the ICD-CM codes. ICD-CM codes are provided herein for reference only and are not intended to convey any endorsement or sponsorship by, or affiliation with, the WHO.

CPT® codes are copyrighted property of the American Medical Association (AMA). Solstice Neurosciences, LLC, assumes no liability for information contained herein. Solstice Neurosciences, LLC, claims no ownership or other interest in the CPT codes. CPT codes are provided herein for reference only and are not intended to convey any endorsement or sponsorship by, or affiliation with, the AMA.

CPT code 64616 is the usual CPT code for administration of MYOBLOC for the treatment of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis). Other administration codes may be appropriate.

CPT code 95874 is the CPT code for needle electromyography for guidance in conjunction with chemodenervation (list separately in addition to code for Primary procedure). Other guidance codes may be appropriate.

Abbreviations: CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

MYOBLOC is ready to use and requires no mixing

3 SINGLE-DOSE VIAL SIZES*

*For single-patient use. For patients with demonstrated tolerance to botulinum toxin injection, the recommended initial dose range divided among affected muscles is 2,500 to 5,000 Units.



For more information on MYOBLOC Reimbursement Services, call 1-888-461-2255, Option 3, or visit myoblochcp.com

IMPORTANT SAFETY INFORMATION

WARNING: DISTANT SPREAD OF TOXIN EFFECT

See full prescribing information for complete boxed WARNING.

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 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 an underlying condition that would predispose them to these symptoms.

CONTRAINDICATIONS

MYOBLOC is contraindicated in patients with:

- A known hypersensitivity to any botulinum toxin product or to any of the components in the formulation
- Infection at the proposed injection site(s)

WARNINGS AND PRECAUTIONS

Lack of Interchangeability Between Botulinum Toxin Products

The potency units of MYOBLOC are specific to the preparation and biological activity assay method utilized. Due to differences in the aspects of this assay such as the vehicle, dilution scheme, and laboratory protocols for various potency assays, potency units 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.

Hypersensitivity Reactions

Serious hypersensitivity reactions have been reported with botulinum toxin products. Angioedema, urticaria, and rash have occurred with MYOBLOC treatment. Hypersensitivity reactions can also include anaphylaxis, serum sickness, soft tissue edema, and dyspnea. If serious and/or immediate hypersensitivity reactions occur, discontinue further injection of MYOBLOC and institute appropriate medical therapy immediately. The use of MYOBLOC in patients with a known hypersensitivity to any botulinum neurotoxin or to any of the excipients (human albumin, sucrose), could lead to a life-threatening allergic reaction.

Dysphagia and Breathing Difficulties

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.

– Cervical Dystonia: 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 post-marketing 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. Pre-Existing Neuromuscular Disorders: 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.

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 be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

MOST COMMON ADVERSE REACTIONS (>5% of patients and >5% more than placebo)

Cervical Dystonia: dry mouth, dysphagia, injection site pain, headache

DRUG INTERACTIONS

Aminoglycosides and Other Agents Interfering with Neuromuscular Transmission: 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. Anticholinergic Drugs: Use of anticholinergic drugs after administration of MYOBLOC may potentiate systemic anticholinergic effects. Other Botulinum Neurotoxin Products: The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Muscle Relaxants: Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of MYOBLOC.

INDICATION

MYOBLOC[®] injection is indicated for the treatment of cervical dystonia (CD) to reduce the severity of abnormal head position and neck pain associated with CD in adults.

Please refer to the full Prescribing Information and Medication Guide.



Supernus[®]