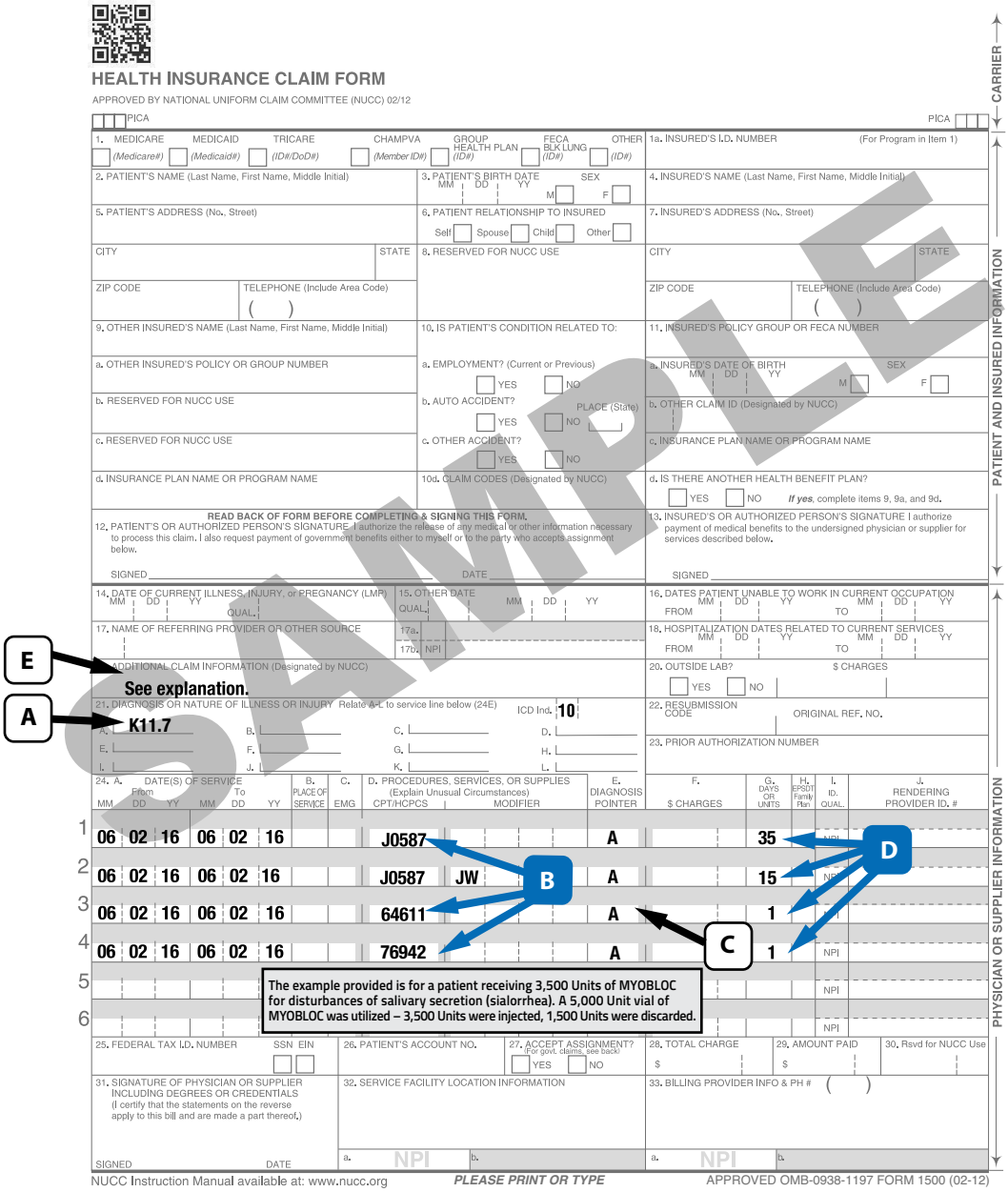
SAMPLE CMS-1500 CLAIM FORM

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

For Product Administered in the Physician's Office—Effective 8/19/19



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

See explanation.

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 10

A. K11.7 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	06	02	16	06	02	16			J0587		A		35		NPI
2	06	02	16	06	02	16			J0587	JW	A		15		NPI
3	06	02	16	06	02	16			64611		A		1		NPI
4	06	02	16	06	02	16			76942		A		1		NPI
5															NPI
6															NPI

The example provided is for a patient receiving 3,500 Units of MYOBLOC for disturbances of salivary secretion (sialorrhea). A 5,000 Unit vial of MYOBLOC was utilized – 3,500 Units were injected, 1,500 Units were discarded.

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

A **BLOCK 21:**
Enter the ICD-10-CM (10) diagnosis code that is appropriate for the patient. The diagnosis code for disturbances of salivary secretion (sialorrhea) is K11.7.

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

- MYOBLOC: J0587 – Botulinum Toxin Type B (per 100 Units) for intra-glandular 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, eg, 64611 – Chemodenervation of parotid and submandibular salivary glands, bilateral.
  - Other administration codes may be appropriate.
- Ultrasound Guidance, eg, 76942 – Ultrasonic guidance for needle placement imaging. 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.

C **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.

D **BLOCK 24, COLUMN G:**
Enter the number of billing Units
Please note: For J0587, a billing Unit is per 100 Units of MYOBLOC.

E **BLOCK 19:**
Some payers may require the NDC number when submitting a claim. If required, the NDC numbers are entered with a "0" (11-digit NDC#) 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, 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

Please see Important Safety Information and Indication (on Page 2) and full Prescribing Information, including Boxed WARNING and Medication Guide.

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 64611 is the usual CPT code for administration of MYOBLOC for chemodenervation of parotid and submandibular salivary glands, bilateral. Other administration codes may be appropriate.

CPT code 76942 is the CPT code for ultrasonic guidance for needle placement imaging. To be listed separately in addition to code for primary procedure.

MYOBLOC is ready to use and requires no mixing

3 SINGLE-DOSE VIAL SIZES*

*For single-patient use.

The recommended dosage of MYOBLOC for chronic sialorrhea is 1,500 to 3,500 Units; 500 to 1,500 Units per parotid gland and 250 Units per submandibular gland; no more frequent than every 12 weeks.

2,500
Units in 0.5 mL

5,000
Units in 1 mL

10,000
Units in 2 mL

For more information on MYOBLOC Reimbursement Services, call 1-888-461-2255, Option 3, or visit myobloc.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.
  – **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)

Chronic Sialorrhea: dry mouth, dysphagia

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. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. **Muscle Relaxants:** 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 chronic sialorrhea in adults

Please refer to the full Prescribing Information and Medication Guide.

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]
myobloc.com

Supernus® Pharmaceuticals