BOTOX® (onabotulinumtoxinA) Medicare Documentation Checklist for Chronic Migraine

First name _____ Middle _____ Last name _____ DOB _____

☐ Initial Authorization Request ☐ Re-treatment Request

Diagnosis of Chronic Migraine	*Check one*
G43.701 - Chronic migraine without aura, not intractable, with status migrainosus	
G43.709 - Chronic migraine without aura, not intractable, without status migrainosus	
G43.711 - Chronic migraine without aura, intractable, with status migrainosus	
G43.719 - Chronic migraine without aura, intractable, without status migrainosus	
Other:	

Procedure Code(s)	
☐ 64615 ☐ Other	

Initial History of Headaches*	*Baseline*
Duration of illness (months):	
Number of headache days per month *(When determining number of headache days, it may be beneficial to ask the patient how many headache-free days each month the patient is experiencing.)*	
Number of headache hours per day	
☐ Moderate or severe pain intensity ☐ Nausea ☐ Vomiting ☐ Photophobia ☐ Phonophobia ☐ Unilateral ☐ Pulsating	
	Baseline
Disability due to headache/migraine (eg, work, school)?	
ER visit(s) due to headache/migraine?	

Treatment Plan (include frequency of injections):

*Baseline and current assessments may be necessary for documentation required for re-treatment per payer guidelines.
Many policies require documented failure of, contraindication to, or intolerance of multiple acute/abortive medications and at least 2 different migraine prophylaxis medications from 2 different therapeutic drug classes. (See reverse for a list of common medications.)
Majority of plans require 2 or fewer oral prophylactic treatments based on data covering 244,831,608 medical lives.†
†*Data on file, Allergan; Preventives Policy Analysis (May 2012).*

Indication
Chronic Migraine
BOTOX® for injection is indicated for the prophylaxis of headaches in adult patients with Chronic Migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

Limitations of Use
Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in 7 placebo-controlled studies.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® 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, 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 an underlying condition that would predispose them to these symptoms. In unapproved uses and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat Cervical Dystonia and spasticity and at lower doses.

Please see additional Important Safety Information on following pages.

BOTOX® (onabotulinumtoxinA) Medicare Documentation Checklist for Chronic Migraine (continued)

Please check all that apply.

Prophylactic Drug Class Prescribed	*Drug Name*	*Dose*	*Duration*	*Outcome (check)*
☐ Antidepressant ☐ Antiepileptic/Anticonvulsant ☐ ACE Inhibitor/Angiotensin II Receptor Blocker ☐ Beta-blocker ☐ CGRP mAbs ☐ Calcium Channel Blocker				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated
☐ Antidepressant ☐ Antiepileptic/Anticonvulsant ☐ ACE Inhibitor/Angiotensin II Receptor Blocker ☐ Beta-blocker ☐ CGRP mAbs ☐ Calcium Channel Blocker				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated
☐ Antidepressant ☐ Antiepileptic/Anticonvulsant ☐ ACE Inhibitor/Angiotensin II Receptor Blocker ☐ Beta-blocker ☐ CGRP mAbs ☐ Calcium Channel Blocker				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated
☐ Antidepressant ☐ Antiepileptic/Anticonvulsant ☐ ACE Inhibitor/Angiotensin II Receptor Blocker ☐ Beta-blocker ☐ CGRP mAbs ☐ Calcium Channel Blocker				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated

Acute/Abortive Drug Class Prescribed	*Drug Name*	*Dose*	*Duration*	*Outcome (check)*
☐ NSAID ☐ Ergot alkaloid derivative ☐ Triptan ☐ Combination/Other ☐ CGRP small molecules				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated
☐ NSAID ☐ Ergot alkaloid derivative ☐ Triptan ☐ Combination/Other ☐ CGRP small molecules				☐ Effective ☐ Intolerant ☐ Failed ☐ Sub-optimal ☐ Contraindicated

Note: This form provides information commonly used by payer plans to determine prior authorization. It is intended for reference only and does not guarantee approval. Please be sure to check payer policies for the most up-to-date information.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See Boxed Warning.

No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX® for Chronic Migraine at the labeled dose have been reported.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX® 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 BOTOX® cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX® (see *Warnings and Precautions*).

Please see additional Important Safety Information on following pages.

BOTOX® (onabotulinumtoxinA) Medicare Documentation Checklist for Chronic Migraine (continued)

Previous Treatment Date: ____ / ____ / ____

Treatment Date: ____ / ____ / ____ Weeks since last treatment (if applicable): _____

Baseline headache days: _____ Current headache days: _____ Reduction from baseline: _____

Baseline headache hours: _____ Current headache hours: _____ Reduction from baseline: _____

(When determining number of headache days, it may be beneficial to ask the patient how many headache-free days each month the patient is experiencing.)

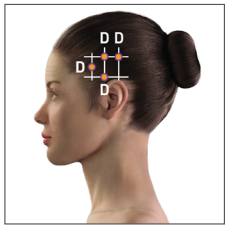
Clinical rationale for BOTOX®: _____

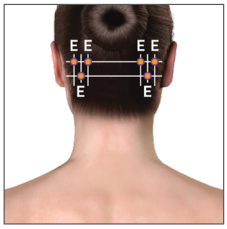
Vial Size/NDC No.	**200 Unit Vial/NDC No.: 0**0023-3921-02[a]	**100 Unit Vial/NDC No.: 0**0023-1145-01[a]
Dilution (200 Units/4 mL or 100 Units/2 mL)	Lot number(s)	Vial expiration date(s)

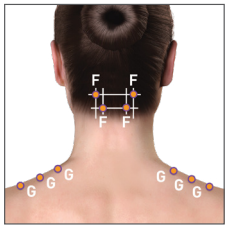
☐ **Please check box if an SP is used.**

[a]For electronic billing, payers require an 11-digit NDC number [5-4-2 configuration] to be reported on the claim form. Therefore, an additional zero should be added to the beginning of the 10-digit NDC listed on the box [eg, **0**0023-3921-02].

BOTOX® Dosing by Muscle Areas for Chronic Migraine







A. Corrugator
BOTOX® dosage: 10 Units divided in
2 sites Right: ____ Left: ____

B. Procerus
BOTOX® dosage: 5 Units in
1 site _____

C. Frontalis
BOTOX® dosage: 20 Units divided in
4 sites Right: ____ Left: ____

D. Temporalis
BOTOX® dosage: 40 Units divided in
8 sites Right: ____ Left: ____

E. Occipitalis
BOTOX® dosage: 30 Units divided in
6 sites Right: ____ Left: ____

F. Cervical Paraspinal
BOTOX® dosage: 20 Units divided in
4 sites Right: ____ Left: ____

G. Trapezius
BOTOX® dosage: 30 Units divided in
6 sites Right: ____ Left: ____

Total Units injected: _____ Total Units discarded: _____

Physician signature: _____

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Dysphagia and Breathing Difficulties
Treatment with BOTOX® 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 oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Please see additional Important Safety Information on following pages.

BOTOX® (onabotulinumtoxinA) Medicare Documentation Checklist for Chronic Migraine (continued)

Listed below are examples of the various acute and prophylactic drug classes. This is not a comprehensive list.

Prophylactic Examples

Antidepressants	Antiepileptics/ Anticonvulsants	Beta-blockers	Calcium Channel Blockers	Angiotensin-Converting Enzyme (ACE) Inhibitors/ Angiotensin II Receptor Blockers (ARB)	Calcitonin Gene-Related Peptide Antagonists (mAbs)
Amitriptyline	Divalproex sodium	Atenolol	Diltiazem	Candesartan	*Aimovig*®
Citalopram	Gabapentin	Metoprolol	Nifedipine	Enalapril	*Emgality*®
Doxepin	Topiramate	Nadolol	Nimodipine	Irbesartan	*Ajovy*®
Fluoxetine	Valproic acid	Propranolol	Verapamil	Lisinopril	*Vyepti*™
Fluvoxamine		Timolol		Losartan	
Mirtazapine				Olmesartan	
Nortriptyline				Ramipril	
Paroxetine				Valsartan	
Protriptyline					
Sertraline					
Venlafaxine					

Acute/Abortive Examples

NSAIDs/ Analgesics	Ergot Alkaloid Derivative	Triptans	Combination/Other	Calcitonin Gene-Related Peptide Antagonists (small molecules)
Acetaminophen	Ergotamine	Almotriptan	Acetaminophen/aspirin/caffeine	Ubrogepant
Aspirin	Dihydroergotamine (DHE)	Eletriptan	Butalbital/acetaminophen/caffeine	Rimegepant
Diclofenac		Frovatriptan	Butalbital/aspirin/caffeine	
Ibuprofen		Naratriptan	Butorphanol	
Naproxen		Rizatriptan	Ergotamine/caffeine	
		Sumatriptan	Sumatriptan/naproxen	
		Zolmitriptan		

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
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 also 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.

ADVERSE REACTIONS
Adverse reactions to BOTOX® for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Please see additional Important Safety Information on following page.

BOTOX® (onabotulinumtoxinA) Medicare Documentation Checklist for Chronic Migraine (continued)

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

Chronic Migraine

The most frequently reported adverse reactions following injection of BOTOX® for Chronic Migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX® are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

DRUG INTERACTIONS

Co-administration of BOTOX® and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin 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. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX®.

For more information on BOTOX®, please see the accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

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BOTOX® onabotulinumtoxinA injection