

Department:	Pharmacy Management	Original Approval:	04/11/2019
Policy #:	PM570	Last Approval:	04/11/2019
Title:	OnabotulinumtoxinA (Botox) for Migraine		
Approved By:	UM Pharmacy Subcommittee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Botulinum toxin A for subcutaneous use (Botox): History and/or physical examination notes and relevant notes that address the problem and need for the service: -Diagnosis -Age - Medication list (current and past) to include start and end dates of previous trials for migraine headache prophylaxis.

BACKGROUND

Botulinum toxin type A, the active ingredient in Botox (onabotulinumtoxinA), is indicated for the following:

- blepharospasm associated with dystonia, including benign essential blepharospasm or seventh nerve disorders, and strabismus in patients ≥ 12 years of age;
- cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia;
- hyperhidrosis, primary axillary, that is inadequately treated with topical agents;
- migraine headache prophylaxis in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours per day or longer);
- overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have inadequate response to or are intolerant of an anticholinergic medication;
- spasticity, lower limb, in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors;
- spasticity, upper limb, in adult patients to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, finger flexors, and thumb flexors; AND
- urinary incontinence due to detrusor overactivity associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.¹

In addition, botulinum toxin type A has been used to treat a multitude of disorders characterized by abnormal muscle contraction.² The benefit of this drug has also been demonstrated in the treatment of gastrointestinal, genitourinary, ocular, and autonomic nervous system disorders.²⁻³

Botox® Cosmetic (onabotulinumtoxinA) is indicated for the temporary improvement in appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity in adult patients, moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients, and moderate to severe forehead lines associated with frontalis muscle activity.⁴ Botox Cosmetic is not included in this policy.

Toxin distribution varies between the commercially available botulinum toxin A products, Botox and Dysport® (abobotulinumtoxinA), and Xeomin® (incobotulinumtoxinA).^{1,5-6} It has been postulated that differences in albumin concentration control diffusion of toxin from the injection site (Botox contains 500 mcg of albumin, while Dysport contains 125 mcg of albumin and Xeomin contains 1 mg of albumin). This concept has been supported by animal studies revealing a higher safety margin for intramuscularly injected Botox than Dysport. In addition, the labels for the botulinum toxin type A products (Botox, Dysport, and Xeomin) state that there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity.

DEFINITIONS

Prophylactic pharmacologic therapies

- Anticonvulsants- preferred: topiramate or divalproex sodium
- Antidepressants- preferred: venlafaxine, amitriptyline, or nortriptyline
- Beta blockers- preferred: propranolol, metoprolol, or atenolol
- Calcium channel blockers- preferred: verapamil

INDICATIONS/CRITERIA

Medicaid Members	<i>Continue to criteria for approval below.</i>
Medicare Members	<i>Step-utilization of Part D drugs not required.</i>

This clinical coverage criterion is for Migraine Headache Prophylaxis only. Refer to MCG or NCD/LCD for other indications.

- 1. Migraine Headache Prophylaxis in Patients with Chronic Migraine.** Approve for 1 year in patients who meet all of the following conditions (A, B, C, and D):
 - A)** Patient has ≥ 15 migraine headache days per month of which ≥ 8 are with migraine (prior to initiation of Botox therapy);
 - B)** Patient has tried at least three other prophylactic pharmacologic therapies from 2 different classes of drugs (e.g., β-blocker, anticonvulsant, tricyclic antidepressant);
 - C)** Patient meets ONE of the following (i or ii):
 - i. Patient has tried at least one triptan therapy (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan); OR
 - ii. Patient has a contraindication to triptan(s) according to the prescribing physician; AND
 - D)** Condition is appropriately managed for medication overuse.
 - E)** Botox is being prescribed by or after consultation with a neurologist or headache specialist.
 - F)** Patient is not currently using a CGRP Antagonist such as fremanezumab (Ajovy), erenumab (Aimovig), or galcanezumab (Emgality)

Dosing.¹ Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.

Duration of therapy. Extended approvals are allowed if the patient has shown adequate response to treatment (greater than a 50% reduction in headache days per month after 2 treatment cycles).

Conditions not recommended for approval:

Chronic tension headaches

SPECIAL CONSIDERATIONS

None

LIMITATIONS/EXCLUSIONS

Please refer to a product line’s certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	
	<ol style="list-style-type: none"> 1. Botox® for injection [prescribing information]. Irvine, CA: Allergan Pharmaceuticals Ltd.; May 2018. 2. Micromedex®.IBMCorporation.Available at: http://www.micromedexsolutions.com Accessed on 4/4/2019 Search terms: Botox. 3. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. <i>J Neurol Sci.</i> 2005;235(1-2):1-9. 4. Botox® Cosmetic [prescribing information]. Irvine, CA: Allergan Pharmaceuticals Ltd; October 2017. 5. Dysport® for injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc. and Fort Worth, TX: Galderma Laboratories, L.P.; September 2017. 6. Xeomin® for injection [prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC; July 2018.



	7. Washington State Health Care Authority Health Technology Clinical Committee: 20170519B- Treatment of chronic migraine and chronic tension-type headache. Revised 7/13/18.	
CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	<input checked="" type="checkbox"/> WAH	
	<input checked="" type="checkbox"/> IMC	
	<input checked="" type="checkbox"/> MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
04/04/2019	New policy	Jennifer Farley, PharmD
04/11/2019	Approval	UM Pharmacy Subcommittee