JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP024
		Effective Date	10/12/1998
		Review Date	04/01/2015
	Subject **USFHP Medical Botulinum Toxin Injections: Botox, Dysport, Xeomin, Myobloc**	*Revision Date*	10/07/2020
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Botox, Dysport, Myobloc, Xeomin

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I. POLICY

The following procedures involve the injection of small amounts of botulinum toxin into selected muscles for the nonsurgical treatment of the conditions relating to spasticity, various dystonias, nerve disorders, and muscular tonicity deviations:

HCPCS PROCEDURE CODES: J0585, J0586, J0587, J0588

II. POLICY CRITERIA

Botulinum toxin A (AbobotulinumtoxinA [Dysport] /OnabotulinumtoxinA [Botox] /IncobotulinumtoxinA [Xeomin]), Botulinum toxin B (RimabotulinumtoxinB [Myobloc]), and any other Federal Drug Administration (FDA) approved botulinum toxin injectable drugs may be considered for cost-sharing for their FDA approved indications, unless otherwise excluded by the program.

Botox® (OnabotulinumtoxinA) may be considered for off-label cost-sharing for the treatment of chronic anal fissure unresponsive to conservative therapeutic measures, effective May 1, 2007.

Botulinum toxin A injections may be considered for off-label cost-sharing for the treatment of spasticity resulting from Cerebral Palsy (CP), effective November 1, 2008.

Botox® (OnabotulinumtoxinA) and Myobloc® (RimabotulinumtoxinB) injections may be considered for off-label cost-sharing for the treatment of sialorrhea associated with Parkinson's disease patients who are refractory to, or unable to tolerate, systemic anticholinergics, effective October 1, 2009.

Botox® (OnabotulinumtoxinA) injections for laryngeal dystonia (adductor spasmodic dysphonia) and oromandibular dystonia (jaw-closing dystonia) may be considered for cost-sharing.

Botox® (OnabotulinumtoxinA) injections may be considered for off-label cost-sharing for the treatment of palmar hyperhidrosis that is refractory to topical and pharmacological therapies, effective January 1, 2013.

Off-label use. Effective July 27, 2012, off-label uses of Botulinum toxin A:

Botulinum toxin A (AbobotulinumtoxinA [Dysport] /OnabotulinumtoxinA [Botox] /IncobotulinumtoxinA [Xeomin]), Botulinum toxin B (RimabotulinumtoxinB [Myobloc]), and any other FDA approved botulinum toxin injectable drugs may be approved for cost-sharing by the contractor in accordance with Chapter 8, Section 9.1, paragraph 2.2.5.

III. AUTHORIZATION PERIOD/LIMITATIONS

- Initial approval will be restricted to 6 months of therapy
- Approval for continuation of therapy can be extended in 6-month intervals with documentation of clinically significant improvement as a result of treatment

IV. EXCLUSIONS

I. Botulinum toxin A injections are unproven for the following indications:
   1. Lower back pain/lumbago.
   2. Episodic migraine, chronic daily headache, cluster headache, cervicogenic headache, and tension-type headache.

II. Botox® (OnabotulinumtoxinA) for the treatment of muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis is unproven.

III. Botulinum toxin A used for cosmetic indications (e.g., frown lines and brow furrows) is excluded from coverage.

V. REFERENCES

1. TRICARE Policy Manual 6010.60-M, April 1, 2015
2. Department of Defense Pharmacy and Therapeutics Committee. February 2020 Meeting Minutes and Recommendations. Signed by DHA Deputy Director Guy Kiyokawa on April 27th 2020.

VI. APPROVALS

Authority:32 CFR 199.4(c)(2)(iii) and (c)(2)(iv)

DATE OF REVISION	SUMMARY OF CHANGE
04/01/2015	Coverage clarifications
03/04/2019	Minor layout update; added brand names for reference
05/02/2019	Moved this policy criteria to MMDP024 for medical benefit coverage review
06/05/2019	Added coverage exclusion for concurrent use of medical botulinum toxins and CGRP inhibitors
11/19/2019	Clarified criteria based on C-1, March 10, 2017 revision by TRICARE Policy
10/07/2020	Removed coverage exclusion of concurrent use of medical botulinum toxins and CGRP inhibitors based on February 2020 evaluation by the DOD P&T Committee

Review Date: 04/01/2015

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