

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

BOTULINUM TOXIN AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ONABOTULINUMTOXINA	BOTOX	04867		BRAND ≠ BOTOX COSMETIC
ABOBOTULINUMTOXINA	DYSPOORT	36477		
RIMABOTULINUMTOXINB	MYOBLOC	21869		
INCOBOTULINUMTOXINA	XEOMIN	36687		

Please use the criteria for the specific drug requested.

GUIDELINES FOR USE

BOTOX

1. Is the request for **ONE** of the following conditions?

- Achalasia
- Chronic Anal fissures
- Essential tremor
- Hemifacial spasm
- Excessive salivation due to advanced Parkinson's disease
- Urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) AND the patient had an intolerance or an inadequate response to an anticholinergic medication

If yes, **approve for 12 months by HICL.**

Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Botox has been approved for a 12-month period.

If no, continue to #2.

2. Is the request for **ONE** of the following conditions?

- Blepharospasm
- Cervical dystonia
- Primary axillary hyperhidrosis
- Spasmodic dysphonia (laryngeal dystonia)
- Strabismus
- Upper limb spasticity
- Lower limb spasticity
- Overactive bladder with urinary incontinence AND the patient had an intolerance or an inadequate response to an anticholinergic medication

If yes, continue to #5.

If no, continue to #3.

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GUIDELINES FOR USE - BOTOX (CONTINUED)

3. Is the request an initial request for the treatment of chronic migraine prophylaxis for a patient who meets **ALL** of the following criteria?
- Patient experiences headaches greater than or equal to 15 days per month
 - Patient completed an adequate trial (greater than or equal to 8 weeks) of at least one of the following oral migraine preventive therapies:
 - Divalproex Sodium (Depakote, Depakote ER)
 - Topiramate (Topamax)
 - Gabapentin (Neurontin)
 - Amitriptyline (Elavil)
 - Venlafaxine (Effexor)
 - Atenolol/ Metoprolol/Propranolol/Timolol/Nadolol
 - Nimodipine/ Verapamil
 - Naproxen/other NSAID
 - Other oral migraine prophylactic therapy considered to be appropriate by the requesting clinician

If yes, continue to #5.

If no, continue to #4.

4. Is the request a renewal request for a patient with chronic migraine prophylaxis who has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy with Botox?

If yes, continue to #5.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT (if non-covered diagnosis): Per your health plan's Botulinum Toxin Agents guideline, Botox is only covered when prescribed for certain medical conditions, such as achalasia, essential tremor, hemifacial spasm, upper or lower limb spasticity. This medication is not covered for **[diagnosis listed on the MRF]**. Your provider did not indicate that you are being treated for a covered medical condition and therefore your request was not approved.

DENIAL TEXT (if a covered diagnosis but additional criteria not met): Per your health plan's Botulinum Toxin Agents guideline, Botox is only covered for **[diagnosis on MRF]** after an inadequate response or intolerance to **[required step medication]**. Your provider did not indicate that you tried one of these medications and therefore your request was not approved.

DENIAL TEXT (initial request for chronic migraine prophylaxis): Per your health plan's Botulinum Toxin Agents guideline, Botox is only covered for chronic migraine prophylaxis if you experience headaches greater than or equal to 15 days per month and if you had an adequate trial (greater than or equal to 8 weeks) with at least one oral migraine preventive therapy, such as topiramate, atenolol, amitriptyline. Your provider did not indicate **[criteria not met]** and therefore your request was not approved.

DENIAL TEXT (renewal request for chronic migraine prophylaxis): Per your health plan's Botulinum Toxin Agents guideline, authorization for renewal of Botox for chronic migraine prophylaxis requires that you achieved at least a 50% reduction in monthly headache frequency since starting Botox. Your provider did not indicate that your monthly headache frequency decreased by at least 50% and therefore your request was not approved.

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5. Is the request for a dose that exceeds one of the following conditions?
- Blepharospasm: 100 units every 12 weeks
 - Cervical dystonia: 100 units every 12 weeks
 - Chronic migraine prophylaxis: 200 units every 12 weeks
 - Overactive bladder with urinary incontinence: 100 units every 12 weeks
 - Primary axillary hyperhidrosis: 100 units every 12 weeks
 - Spasmodic dysphonia: 100 units every 12 weeks
 - Strabismus: 100 units every 12 weeks
 - Upper and/or lower limb spasticity: 400 units every 12 weeks

If yes, continue to #6.

If no, **approve for 12 months by HICL with the following quantity limits.**

IMPORTANT NOTE: Please enter max quantity and max day supply. Please use status code #056 (with QL) and the approval text provided.

- **Blepharospasm: one 100 units vial every 12 weeks**
- **Cervical dystonia: one 100 units vial every 12 weeks**
- **Primary axillary hyperhidrosis: one 100 unit vial every 12 weeks**
- **Spasmodic dysphonia (laryngeal dystonia): one 100 unit vial every 12 weeks**
- **Strabismus: one 100 unit vial every 12 weeks**
- **Upper limb spasticity: 400 units every 12 weeks**
- **Lower limb spasticity: 400 units every 12 weeks**
- **Overactive bladder with urinary incontinence: one 100 unit vial every 12 weeks**
- **Chronic migraine prophylaxis: 200 units every 12 weeks**

APPROVAL TEXT: Your request for Botox has been approved for a 12-month period [**with a quantity of (insert quantity limit)**].

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6. Is the patient currently stabilized on the requested dose or did the provider indicate there is medical necessity for the requested dose?

If yes, **approve for 12 months by HICL for the requested quantity.**

IMPORTANT NOTE: Please enter max quantity and max day supply. Please use the status code #056 (with QL) and the approval text provided.

APPROVAL TEXT: Your request for Botox has been approved for a 12-month period with a quantity up to **[insert quantity limit]**.

If no, **please partially deny the requested quantity. Approve for 12 months by HICL with the following quantity limits.**

IMPORTANT NOTE: Please enter max quantity and max day supply. Please use the status code #056 (with QL) and the partial denial text provided.

- **Blepharospasm: one 100 units vial every 12 weeks**
- **Cervical dystonia: one 100 units vial every 12 weeks**
- **Primary axillary hyperhidrosis: one 100 unit vial every 12 weeks**
- **Spasmodic dysphonia (laryngeal dystonia): one 100 unit vial every 12 weeks**
- **Strabismus: one 100 unit vial every 12 weeks**
- **Overactive bladder with urinary incontinence: one 100 unit vial every 12 weeks**
- **Upper limb spasticity: 400 units every 12 weeks**
- **Lower limb spasticity: 400 units every 12 weeks**
- **Chronic migraine prophylaxis: 200 units every 12 weeks**

PARTIAL DENIAL TEXT: Your request for Botox has been partially approved for a 12-month period with a quantity of **[insert quantity limit]**. Higher quantities are covered if your provider indicates the higher dose is medically necessary. Your provider did not indicate you were stable on the higher dose or that it is medically necessary and therefore the higher quantity was not approved.

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DYSPORT

1. Is the request for treatment for **ONE** of the following conditions?
 - Blepharospasm
 - Cervical dystonia
 - Upper limb spasticity
 - Lower limb spasticity

If yes, **approve for 12 months by HICL**. Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Dysport has been approved for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Botulinum Toxin Agents guideline, Dysport is only covered when prescribed for certain medical conditions, such as blepharospasm, cervical dystonia, and upper or lower limb spasticity. This medication is not covered for **[diagnosis listed on the MRF]**. Your provider did not indicate that you are being treated for a covered medical condition and therefore your request was not approved.

MYOBLOC

1. Is the request for treatment of cervical dystonia (e.g., torticollis)?

If yes, **approve for 12 months by HICL**. Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Myobloc has been approved for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided:

DENIAL TEXT: Per your health plan's Botulinum Toxin Agents guideline, Myobloc is only covered when prescribed for cervical dystonia (e.g., torticollis). This medication is not covered for **[diagnosis listed on the MRF]**. Your provider did not indicate that you are being treated for cervical dystonia and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

XEOMIN

1. Is the request for treatment for **ONE** of the following conditions?

- Blepharospasm for a patient who received prior treatment with Botox (onabotulinumtoxinA)
- Cervical dystonia (e.g., torticollis)
- Upper limb spasticity

If yes, **approve for 12 months by HICL**. Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Xeomin has been approved for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided:

DENIAL TEXT: Per your health plan's Botulinum Toxin Agents guideline, Xeomin is only covered when prescribed for certain medical conditions, such as cervical dystonia (e.g., torticollis), upper limb spasticity, or for blepharospasm if you received prior treatment with Botox. Your provider did not indicate that you **[have one of these conditions or received prior treatment with Botox]** and therefore your request was not approved.

RATIONALE

To ensure that botulinum toxin is used only when medically necessary and is not being used to treat a cosmetic condition.

FDA APPROVED INDICATIONS

Botox is indicated for:

- The treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- The treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in adult patients.
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.
- Treatment of blepharospasm associated with dystonia in patients >12 years of age.
- Treatment of strabismus in patients >12 years of age.
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain

Important Limitations: Safety and effectiveness of Botox have not been established for:

- Prophylaxis of episodic migraine (14 headache days or fewer per month)
- Treatment of upper or lower limb spasticity in pediatric patients
- Treatment of hyperhidrosis in body areas other than axillary

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Dysport is indicated for:

- The treatment of adults with cervical dystonia
- The treatment of upper limb spasticity in adults

Myobloc is indicated for the treatment of patients with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Xeomin is indicated:

- upper limb spasticity
- cervical dystonia
- blepharospasm with onabotulinumtoxinA (Botox) prior treatment

REFERENCES

- Botox [package insert]. Irvine, CA: Allergan, Inc.; January 2016.
- Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; July 2016.
- Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; May 2010.
- Xeomin [package insert]. Dessau-Rosslau, Germany: Merz Pharmaceuticals, LLC.; December 2015
- DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed August 31, 2016.
- AHFS Drug Information. <http://online.lexi.com/lco>. Accessed August 31, 2016.
- Silberstein SD. [Practice parameter: evidence-based guidelines for migraine headache \(an evidence-based review\): report of the Quality Standards Subcommittee of the American Academy of Neurology](#). *Neurology*. 2000;55(6):754-762.
- Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-45.
- [Snow V](#), [Weiss K](#), [Wall EM](#), et al. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. *Ann Intern Med*. 2002;137(10):840-849.
- Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine--revised report of an EFNS task force. *Eur J Neurol*. 2009;16(9):968-981.
- Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(2 Suppl 2):S1-59.
- Simpson DM, Hallett M, Ashman EJ et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology* 2016;86:1818-1826.

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