SmartHealth

Ascension

OnabotulinumtoxinA

(Botox®) J0585 (1 unit)

Note: While botulinum therapy is approved for medical and cosmetic purposes, SmartHealth coverage is limited to medically necessary indications.

Covered with prior authorization

OnabotulinumtoxinA (Botox®) may be authorized when the following criteria are met:

- FDA-approved indications, doses, and dosing intervals for adults (≥18 years); **AND**
- Maximum cumulative dose does not exceed a total dose of 400 Units in 3 months regardless of number of indications;

OR

- FDA-approved indications, doses, and dosing intervals for individuals < 18 years; **AND**
- Maximum cumulative dose does not exceed the *lesser* of 10 Units/kg or 340 Units in 3 months regardless of number of indications;

OR

- Additional indications with defined dose and dosing interval for accepted, standard-of-care uses **if** the request is accompanied by sound clinical rationale and supporting literature;

OnabotulinumtoxinA (Botox®) Indications, Dosing and Additional Criteria		
FDA Approved Indications	**Dosing**	**Additional Criteria**
Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency (adult)	Total: 100 Units (across 20 sites into the detrusor)	Adult individual (age ≥18 years); **AND** Trial and failure, inadequate response, or intolerance of at least two agents from either of the following classes: 1) Urinary anticholinergic medications (ie, darifenacin, fesoterodine, flavoxate, oxybutynin, solifenacin, tolterodine, or trospium); **OR** 2) beta-3 adrenergic agonists (ie, vibegron, mirabegron); **AND** Prescribed by, or in consultation with, a urologist or gynecologist
Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] (adult)	Total 200 Units (across 30 sites into the detrusor)	Adult individual (age ≥18 years); **AND** Trial and failure, inadequate response, or intolerance of at least two agents from either of the following classes: 1) Urinary anticholinergic medications (ie, darifenacin, fesoterodine, flavoxate, oxybutynin, solifenacin, tolterodine, or trospium); **OR** 2) beta-3 adrenergic agonists (ie, vibegron, mirabegron); **AND** Prescribed by, or in consultation with, a urologist or gynecologist
Treatment of neurogenic detrusor overactivity (NDO) (pediatric individuals 5 years of age and older)	Weight-based dosing (across 20 sites into the detrusor): ≥ 34 kg Total dose is 200 Units < 34 kg Total dose is 6 Units/kg	Pediatric individual (age ≥ 5 years); **AND** Trial and failure, inadequate response, or intolerance of at least two agents from either of the following classes: 1) Urinary anticholinergic medications (ie, darifenacin, fesoterodine, flavoxate, oxybutynin, solifenacin, tolterodine, or trospium); **OR** 2) beta-3 adrenergic agonists (ie, vibegron, mirabegron); **AND** Prescribed by, or in consultation with, a urologist or gynecologist
Prophylaxis of headaches (adult, chronic migraine)	Total dose: 155 Units (divided across 7 head/neck muscles)	**Initial Authorization Criteria** Adult individual (age ≥18 years); **AND** A diagnosis of chronic migraine defined as a minimum 3 month time period of 15 or more headache-days per month where headache duration is ≥ 4 hours; **AND** A minimum 3-month trial and documented failure, inadequate response, or intolerance to a minimum of **TWO** prescription migraine prevention therapies (at least one agent from any two classes) or has a contraindication to all medications: 1) Antiepileptic drugs (divalproex, sodium valproate, topiramate); **OR** 2) Antidepressants (amitriptyline, duloxetine, nortriptyline, venlafaxine); **OR**

OnabotulinumtoxinA (Botox®) Indications, Dosing and Additional Criteria		
FDA Approved Indications	**Dosing**	**Additional Criteria**
		3) Beta blockers (atenolol, metoprolol, nadolol, propranolol, timolol); **AND** Prescribed by, or in consultation with a board certified pain management specialist, a neurologist, or a physical medicine/rehabilitation specialist. Initial approval duration: **6 months** **Reauthorization Criteria** Individual is requesting continued treatment; **AND** Individual has a historical, previously documented diagnosis of chronic migraine headaches (current therapy impacts the frequency and duration definitions required by initial criteria); **AND** Individual has completed an initial 6-month trial of botulinum therapy (initial request) with the results: Individual has reduction in total number of migraine days per month; **OR** Individual has reduction in number of severe migraine days per month; **AND** Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following: • 50% reduction in frequency of days with headache or migraine; **OR** • Significant decrease in attack duration; **OR** • Significant decrease in attack severity; **OR** • Improved response to acute treatment; **OR** • Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR** • Improvements in health related quality of life and reduction in psychological stress due to migraine; **AND** Prescribed by, or in consultation with a board certified pain management specialist, a neurologist, or a physical medicine/rehabilitation specialist. Reauthorization approval duration: **12 months** **Botox with concurrent CGRP therapy** **Initial Authorization Criteria** Initial requests for botulinum toxin therapy in combination with a CGRP must meet the following conditions: All initial authorization requirements above for prophylaxis of headaches (adult, chronic migraine) must be met; **AND**

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FDA Approved Indications	**Dosing**	**Additional Criteria**
		Individual must have been treated for a minimum 3 month trial with a calcitonin gene-related peptide (CGRP) antagonist or receptor antagonist [such as atogepant (Qulipta); eptinezumab-jjmr (Vyepti); erenumab-aooe (Aimovig); fremanezumabvfrm (Ajovy); galcanezumab-gnlm (Emgality), rimegepant (Nurtex), or ubrogepant (Ubrelvy] for chronic migraine prophylaxis; **AND** CGRP therapy has resulted in a: ● Reduction of overall number of migraine days: **OR** ● Reduction in number of severe migraine days per month; **AND** ● The individual continues to experience at least 4 severe migraine days per month requiring additional therapy for migraine prevention. Initial approval duration: **6 months** **Reauthorization Criteria** Reauthorization requests for botulinum toxin therapy in combination with a CGRP must meet the following conditions: Individual has had further reduction in the overall number of migraine days; **OR** Individual has had further reduction in number of severe migraine days per month compared to CGRP monotherapy Reauthorization approval duration: **12 months**
Treatment of adult spasticity: upper limb	Total dose: 400 Units (divided among affected muscles) Note: safety and efficacy of routine use of doses >500 units has not been evaluated	Adult individual (age ≥18 years); **AND** Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician
Treatment of adult spasticity: lower limb	Total dose: 300 to 400 Units (divided across ankle and toe muscles) Note: safety and efficacy of routine use of doses >500 units has not been evaluated	Adult individual (age ≥18 years); **AND** Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician
Treatment of pediatric spasticity: upper limb	Total dose: 3 Units/kg to 6	Pediatric individual (age ≥ 2 years); **AND**

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	Units/kg to a maximum 200 Units (divided among affected muscles)	Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician
Treatment of pediatric spasticity: lower limb	Total dose 4 Units/kg to 8 Units/kg to maximum 300 Units (divided among affected muscles)	Pediatric individual (age ≥ 2 years); **AND** Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician
Treatment of cervical dystonia (or torticollis or spasmodic torticollis)(adult)	Dosing based on the individual's head and neck position, localization of pain, muscle hypertrophy, individual response, and adverse event history; Use lower initial dose in botulinum toxin-naïve individuals; Mean dose is 236 Units; Range for 25th to 75th percentile is 198 to 300 Units	Adult individual (age ≥18 years); **AND** Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician
Treatment of severe axillary hyperhidrosis	50 Units per axilla	Adult individual (age ≥18 years); **AND** A minimum 6-month trial and documented failure of any one or more non-surgical treatments including topical OTC or prescription antiperspirants or dermatologics (ie, aluminum chlorides, zirconium salts, tannic acid, or glutaraldehyde), oral systemic medication including anticholinergics (glycopyrrolate, oxybutynin, and propantheline), tranquilizers, NSAIDs, propranolol, clonidine, or diltiazem; **AND** Clinical documentation that the condition is: Significantly interfering with the ability to perform age-appropriate activities of daily living; **OR** Causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections and secondary microbial conditions; **AND** Prescribed by, or in consultation with, a dermatologist, an endocrinologist or a neurologist

OnabotulinumtoxinA (Botox®) Indications, Dosing and Additional Criteria		
FDA Approved Indications	**Dosing**	**Additional Criteria**
Treatment of blepharospasm	Total Dose: 1.25 to 2.5 Units into each of 3 sites per affected eye; Note: May be increased up to twice previous dose with maximum per site of 5 Units	individual age ≥12 years; **AND** Blepharospasm must be associated with dystonia; **AND** Prescribed by, or in consultation with, a neurologist or ophthalmologist
Treatment of strabismus	Dose is based on prism diopter correction or previous response to treatment The maximum recommended dose as a single injection for any one muscle is 25 units	individual age ≥12 years; **AND** Prescribed by, or in consultation with, a neurologist or ophthalmologist

OnabotulinumtoxinA (Botox®) Indications, Dosing/Interval and Additional Criteria		
Non-FDA Approved Indications	**Dosing**	**Additional Criteria**
Treatment of functional epiphora (e.g. excessive tear production)	2.5 Units to 7.5 Units per eye	Adult individual (age ≥18 years); **AND** Prescribed by, or in consultation with, a neurologist or ophthalmologist
Treatment of focal dystonias, including hand dystonia, laryngeal spasm (laryngeal dystonia or spasmodic dysphonia), orofacial dystonia, or oromandibular dystonia	Typically up to 30 Units (dependent on specific area)	Adult individual (age ≥18 years); **AND** Prescribed by, or in consultation with, a board certified pain management specialist, a neurologist, otolaryngologist or a physical medicine and rehabilitation physician
Treatment of achalasia, including internal anal sphincter achalasia with confirmation of abnormal rectoanal inhibitory reflex (RAIR) or internal anal sphincter hypertonicity confirmed by anorectal manometry (ARM) or Treatment of anal fissures	Up to 100 units total dose	Adult individual (age ≥ 18 years); **AND** Prescribed by gastroenterologist, surgeon

Exclusion criteria:

Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- Prophylaxis of episodic migraine (14 headache days or fewer per month);
- Treatment of hyperhidrosis in body areas other than axillary

Initial Approval:

- Initial authorization for approved indications is up to four (4) treatments in a 12 month period (1 treatment every 90 days) (unless otherwise specified in Indications, Dosing/Interval and Additional Criteria Table above).

Request for additional treatments or dose increase within an authorization period:

- If the duration of benefit is less than 90 days during the approval period; **OR**

- The approved dose is insufficient to treat the symptoms; **AND**
- Initial approval criteria are met; **AND**
- The requested dose is within recommended dosing limits; **AND**
- Clinical improvement with OnabotulinumtoxinA (Botox®) therapy is documented;
- An approval may be considered upon request for case review:
    - With an increased dose; **OR**
    - With a shorter interval of up to six (6) treatments in a 12 month period (60 day interval);
- If approved, the current PA will be updated to reflect the increased dose or decreased interval.

Reauthorization Approval:

- Initial authorization for approved indications is up to four (4) treatments in a 12 month period (1 treatment every 90 days) unless otherwise specified in Indications, Dosing/Interval and Additional Criteria Table above.
- Annual reauthorizations will require medical chart documentation that the individual has been seen within the past 12 months and that markers of disease are improved by therapy for indications with no additional continuation requirements.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

BOTOX is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- 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
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of neurogenic detrusor overactivity (NDO) in pediatric individuals 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.
- Prophylaxis of headaches in adult individuals with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in individuals 2 years of age and older
- Treatment of cervical dystonia in adult individuals, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult individuals
- Treatment of blepharospasm associated with dystonia in individuals 12 years of age and older
- Treatment of strabismus in individuals 12 years of age and older

References:

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Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Criteria for use developed by Ambulatory Care Expert Review Panel
January 2022	Criteria for use approved by Ambulatory Care Steering Committee
February 2022	Criteria for use approved by Therapeutic Affinity Group
June 2022	Revised criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Revised criteria for use summary approved by Ascension Ambulatory Care Expert Review Panel
July 2022	Revised criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.