



GCHP Medi-Cal Clinical Guidelines

Botulinum Toxins A & B

OnabotulinumtoxinA (BotoxTM), AbobotulinumtoxinA (DysportTM), RimabotulinumtoxinB (MyoblocTM) and IncobotulinumtoxinA (XeominTM)

PA Criteria	Criteria Details
Covered Uses (FDA approved indications, non- cosmetic)	<p>AbobotulinumtoxinA (Dysport)</p> <ul style="list-style-type: none"> • Treatment of adults with cervical dystonia. • Treatment of spasticity in patients ≥ 2 years of age. <p>IncobotulinumtoxinA (Xeomin)</p> <ul style="list-style-type: none"> • Treatment of adults with blepharospasm. • Treatment of adults with cervical dystonia. • Treatment of chronic sialorrhea in patients ≥ 2 years of age. • Treatment of upper limb spasticity in adults and pediatric patients 2 to 17 years of age (excluding spasticity caused by cerebral palsy). <p>Onabotulinumtoxin A (Botox)</p> <ul style="list-style-type: none"> • Treatment of severe primary axillary hyperhidrosis in adults not adequately managed with topical agents. • Treatment of cervical dystonia in patients ≥ 16 years of age to reduce the severity of abnormal head position and neck pain. • Prophylaxis of chronic migraine headaches (≥ 15 days per month with headache lasting \geq four hours a day) in adults. • Treatment of neurogenic detrusor overactivity in pediatric patients ≥ 5 years of age who have an inadequate response to or who are intolerant to an anticholinergic medication. • Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or who are intolerant to an anticholinergic medication. • Treatment of spasticity in patients ≥ 2 years of age. • Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders, in patients ≥ 12 years of age. • Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.



	<p>RimabotulinumtoxinB (Myobloc)</p> <ul style="list-style-type: none"> • Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. • Treatment of chronic sialorrhea in adults.
Exclusion Criteria	<p>The use of botulinum toxins for cosmetic indications is not considered medically necessary and is therefore not a benefit per DHCS.</p>
Required Medical Information	<p>All of the following:</p> <ul style="list-style-type: none"> • FDA-approved non-cosmetic indication. • FDA-approved dosage (refer to Maximum dosing unit below in Other Criteria/Information). • Alternative treatments (e.g., physical therapy, oral medication(s)) have been tried, or considered, have failed and/or are contra-indicated. • Clinical notes with treatment plan. <p>For off-label uses, refer to the General Off-Label clinical criteria.</p>
Age Restriction	<p>< 21 years of age – check for CCS eligibility 2 years of age and older - onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport) 18 years of age and older – rimabotulinumtoxinB (Myobloc), incobotulinumtoxinA (Xeomin)</p>
Prescriber Restrictions	<p>Specialty corresponding to the diagnosis as stated below in covered Uses:</p> <ol style="list-style-type: none"> I. Dermatology <ol style="list-style-type: none"> a. Hyperhidrosis II. ENT/Otolaryngology <ol style="list-style-type: none"> a. Laryngeal Dystonia b. Sialorrhea III. Gastroenterology <ol style="list-style-type: none"> a. Achalasia b. Anal Fissure IV. Nephrology <ol style="list-style-type: none"> a. Overactive Bladder with or without urgency urinary incontinence V. Neurology <ol style="list-style-type: none"> a. Blepharospasm b. Cervical Dystonia c. Hemifacial Spasm d. Laryngeal Dystonia e. Migraine f. Motor Tics g. Urinary Incontinence due to Neurogenic Detrusor Overactivity



	<div><div><div>h. Sialorrhea</div><div>i. Spasticity</div><div>j. Upper Extremity Focal Dystonia</div></div><div>VI. Ophthalmology</div><div><div>a. Blepharospasm</div><div>b. Strabismus</div></div><div>VII. Physical Medicine and Rehabilitation</div><div><div>a. Migraine</div><div>b. Cervical Dystonia</div><div>c. Spasticity</div><div>d. Motor Tics</div></div><div>VIII. Urology</div><div>a. Overactive Bladder with or without urgency urinary incontinence</div></div>																				
Coverage Duration	Three months.																				
Other Criteria/Information	<div>Adapted from DHCS Pharmacy Manual Injections: Drugs B Policy July 2024.</div> <table><tr><th>HCP</th><th>CS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J0585</td><td></td><td>OnabotulinumtoxinA (Botox)</td><td>Maximum billing units 400 units every 12 weeks.</td></tr><tr><td>J0586</td><td></td><td>AbobotulinumtoxinA (Dysport)</td><td>Maximum billing units 1,500 units every 12 weeks.</td></tr><tr><td>J0587</td><td></td><td>RimabotulinumtoxinB (Myobloc)</td><td>Maximum billing units 5,000 units every 12 weeks.</td></tr><tr><td>J0588</td><td></td><td>IncobotulinumtoxinA (Xeomin)</td><td>Maximum billing units 400 units every 12 weeks.</td></tr></table>	HCP	CS	Description	Dosing, Units	J0585		OnabotulinumtoxinA (Botox)	Maximum billing units 400 units every 12 weeks.	J0586		AbobotulinumtoxinA (Dysport)	Maximum billing units 1,500 units every 12 weeks.	J0587		RimabotulinumtoxinB (Myobloc)	Maximum billing units 5,000 units every 12 weeks.	J0588		IncobotulinumtoxinA (Xeomin)	Maximum billing units 400 units every 12 weeks.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
		1/24/2019	Medical Advisory Committee (MAC)	1/24/2019
	4/25/2019			
		4/23/2020	Medical Advisory Committee (MAC)	4/20/2020
		4/22/2021	Medical Advisory Committee (MAC)	4/22/2021
		4/21/2022	Medical Advisory Committee (MAC)	4/21/2022
	4/20/2023			
Update	4/18/2024	7/18/2024	Medical Advisory Committee (MAC)	7/18/2024
Update	2/04/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	2/13/2025	Pharmacy & Therapeutics (P&T) Committee	3/01/2025