

## GCHP Medi-Cal Clinical Guidelines

### Botulinum Toxins A & B

**OnabotulinumtoxinA (Botox<sup>TM</sup>), AbobotulinumtoxinA (Dysport<sup>TM</sup>),  
RimabotulinumtoxinB (Myobloc<sup>TM</sup>) and  
IncobotulinumtoxinA (Xeomin<sup>TM</sup>)**

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

	<ul style="list-style-type: none"> <li>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</li> </ul> <p>RimabotulinumtoxinB (Myobloc)</p> <ul style="list-style-type: none"> <li>Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.</li> <li>Treatment of chronic sialorrhea in adults.</li> </ul> <p>DaxibotulinumtoxinA (Daxxify)</p> <ul style="list-style-type: none"> <li>Treatment of cervical dystonia in adults.</li> </ul>
<b>Exclusion Criteria</b>	The use of botulinum toxins for <b>cosmetic indications</b> is not considered medically necessary and is therefore not a benefit per DHCS.
<b>Required Medical Information</b>	<p><b>All of the following:</b></p> <ul style="list-style-type: none"> <li>FDA-approved non-cosmetic indication.</li> <li>FDA-approved dosage (refer to Maximum dosing unit below in <b>Other Criteria/Information</b>)</li> <li>Alternative treatments (e.g., physical therapy, oral medication(s)) have been tried, or considered, have failed and/or are contra-indicated.</li> <li>Clinical notes with treatment plan.</li> </ul> <p>For off-label uses, refer to the General Off-Label clinical criteria.</p>
<b>Age Restriction</b>	<p>&lt; 21 years of age – check for CCS eligibility</p> <p>2 years of age and older - onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport)</p> <p>18 years of age and older – rimabotulinumtoxinB (Mybloc), incobotulinumtoxinA (Xeomin), daxibotulinumtoxinA (Daxxify)</p>

<b>Prescriber Restrictions</b>	<p>Specialty corresponding to the diagnosis as stated below in covered Uses:</p> <ul style="list-style-type: none"> <li>I. Dermatology           <ul style="list-style-type: none"> <li>a. Hyperhidrosis</li> </ul> </li> <li>II. ENT/Otolaryngology           <ul style="list-style-type: none"> <li>a. Laryngeal Dystonia</li> <li>b. Sialorrhea</li> </ul> </li> <li>III. Gastroenterology           <ul style="list-style-type: none"> <li>a. Achalasia</li> <li>b. Anal Fissure</li> </ul> </li> <li>IV. Nephrology           <ul style="list-style-type: none"> <li>a. Overactive Bladder with or without urgency urinary incontinence</li> </ul> </li> <li>V. Neurology           <ul style="list-style-type: none"> <li>a. Blepharospasm</li> <li>b. Cervical Dystonia</li> <li>c. Hemifacial Spasm</li> <li>d. Laryngeal Dystonia</li> <li>e. Migraine</li> <li>f. Motor Tics</li> <li>g. Urinary Incontinence due to Neurogenic Detrusor Overactivity</li> <li>h. Sialorrhea</li> <li>i. Spasticity</li> <li>j. Upper Extremity Focal Dystonia</li> </ul> </li> <li>VI. Ophthalmology           <ul style="list-style-type: none"> <li>a. Blepharospasm</li> <li>b. Strabismus</li> </ul> </li> <li>VII. Physical Medicine and Rehabilitation           <ul style="list-style-type: none"> <li>a. Migraine</li> <li>b. Cervical Dystonia</li> <li>c. Spasticity</li> <li>d. Motor Tics</li> </ul> </li> <li>VIII. Urology           <ul style="list-style-type: none"> <li>a. Overactive Bladder with or without urgency urinary incontinence</li> </ul> </li> </ul>
<b>Coverage Duration</b>	Three months.

<b>Other Criteria/Information</b>	Adapted from DHCS Pharmacy Manual Injections: Drugs B Policy July 2024. <table border="1" data-bbox="507 375 1507 1001"> <thead> <tr> <th data-bbox="507 375 638 424">HCPCS</th><th data-bbox="638 375 1062 424">Description</th><th data-bbox="1062 375 1507 424">Dosing, Units</th></tr> </thead> <tbody> <tr> <td data-bbox="507 424 638 523">J0585</td><td data-bbox="638 424 1062 523">OnabotulinumtoxinA (Botox)</td><td data-bbox="1062 424 1507 523">Maximum billing units: 400 units every 12 weeks</td></tr> <tr> <td data-bbox="507 523 638 623">J0586</td><td data-bbox="638 523 1062 623">AbobotulinumtoxinA (Dysport)</td><td data-bbox="1062 523 1507 623">Maximum billing units: 1,500 units every 12 weeks</td></tr> <tr> <td data-bbox="507 623 638 722">J0587</td><td data-bbox="638 623 1062 722">RimabotulinumtoxinB (Myobloc)</td><td data-bbox="1062 623 1507 722">Maximum billing units: 5,000 units every 12 weeks</td></tr> <tr> <td data-bbox="507 722 638 821">J0588</td><td data-bbox="638 722 1062 821">IncobotulinumtoxinA (Xeomin)</td><td data-bbox="1062 722 1507 821">Maximum billing units: 400 units every 12 weeks</td></tr> <tr> <td data-bbox="507 821 638 1001">J0589</td><td data-bbox="638 821 1062 1001">DaxibotulinumtoxinA (Daxxify)</td><td data-bbox="1062 821 1507 1001">Maximum of 250 units: every three months for a single treatment session</td></tr> </tbody> </table>	HCPCS	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	J0589	DaxibotulinumtoxinA (Daxxify)	Maximum of 250 units: every three months for a single treatment session
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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	2/13/2025
Update	10/15/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics (P&T) Committee	3/01/2026