Botulinum Toxin – Indications

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmacy Standards & Governance	N/A

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1. Abstract

1.1 For Members

Botulinum toxin is a protein and neurotoxin produced by a bacterium. Botulinum toxin is a highly toxic substance which can cause botulism, a serious and lifethreatening illness in humans and animals. However, by injecting very tiny amounts into a specific muscle or skin, botulinum toxin is being used for therapeutic purposes for adults like sustained and repetitive contraction of neck muscles, excessive underarm sweating, urinary incontinence, chronic migraine etc.

Daman covers treatment with botulinum toxin if medically necessary and as per the policy terms and conditions of each health insurance plan administered by Daman.

Note: All the patients must know the box warning by FDA before using this medicine, mentioned further in eligibility and coverage criteria section on page no.

1.2 For Medical Professionals

Botulinum toxin, also called "miracle poison," is one of the most poisonous biological substances known. It is a neurotoxin produced by the bacterium Clostridium botulinum, an anaerobic, gram-positive, spore-forming rod.

FDA has approved the use of botulinum toxin for certain therapeutic (mentioned further in eligibility and coverage criteria section) and for cosmetic purposes.

Two forms of botulinum toxin type A (Onabotulinumtoxin A {Botox} and Abobotulinumtoxin A {Dysport}), Botulinum A (Xeomin) and one form of botulinum toxin type B (Rimabotulinumtoxin B {MyoBloc}) are available commercially for various cosmetic and medical procedures.

Daman covers all the types of Botulinum Toxin for therapeutic purposes only, if medically necessary, failed attempts of at least 6 months of alternative treatment and as per policy terms and conditions of each health insurance plan administered by Daman.

2. Scope

This adjudication rule specifies the coverage details for medically necessary indications of botulinum toxin as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Botulinum Toxin is available in 2 types.

1. Type A
    - Onabotulinumtoxin A (Botox)
    - Abobotulinumtoxin A (Dysport)
    - Botulinum A (Xeomin)
2. Type B
    - Rimabotulinumtoxin B (MYOBLOC)

Daman covers all Type A and Type B of Botulinum Toxin:

- If medically necessary.
- Therapeutic purposes only.
- Failed attempts of at least 6 months of alternative treatment.
- As per the policy terms and conditions of each health insurance plan administered by Daman.
- Please apply DOH payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

FDA Approved Indications: *The below list of indications is not all-inclusive.*

Brand Name	Approved Indication
Botox Type A	• Cervical Dystonia • Blepharospasm and Strabismus • Detrusor Over activity associated with a Neurologic Condition • Overactive Bladder • Primary Axillary Hyperhidrosis • Chronic Migraine • Dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older.
Dysport Type A	• Cervical Dystonia • Dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older.
Myobloc Type B	• Cervical Dystonia
Xeomin Type A	• Blepharospasm • Cervical Dystonia • Dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older.

Note: *All the indications given above are indicated to be treated only with Onabotulinumtoxin A (Botox), except cervical dystonia which can also be treated with other kinds of botulinum toxins.*

Botulinum Toxin Indications, duration, dosage and important information table

Indications	Duration of effect between treatments	Dosage **	Red Flags
Urinary Incontinence	10 months (FDA)	Injecting Botox into the bladder using cystoscopy thus relaxing	In people 18 years or older, with overactive bladder due to neurologic disease eg. spinalcord injury and multiple sclerosis
Chronic Migraine	Every 12 weeks (FDA /NICE)	Recommended total dose 155 Units, as 0.1 ronL (5 Units) injections per each site divided across 7 head/neck muscles. weeks	In people 18 years or older, who have 15 or more days each headache month with headache lasting 4 or more hours each day. Botox has not effective for the treatment of migraine that occur 14 days Or less per month.
Overactive bladder	12 weeks *	The recommended dose is 100 Units of BOTOX, and is the maximum recommended dose.	In people 18 years or older, who cannot use or do not adequately respond to a class Of medications known as anticholinergic.

Cervical dystonia	>6 month	Base dosing on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum naive patients	In people 16 years or older, when duration of condition is more than 6 months
Sever primary axillary hyperhidrosis	16 Weeks	50 Units per axilla, Maximum 100 units.	In people 18 years or older, when topical medicines (used on the skin) are failed, The safety and effectiveness of BOTOX® for hyperhidrosis in other body areas have not been established.
Strabismus	Effect lasts for 2-6 weeks and gradually resolve over time	1.25-2.5 Units initially into extra ocular muscle.	Associated with dystonia, in people 12 years or older, if the binocular vision can be corrected with the treatment.
Spasticity	Documented abnormal muscle tone failure to treatment need Surgical intervention	Select dose based on muscle affected, severity of muscle activity, prior response to treatment, and adverse event history; Electromyography guidance recommended.	In people 18 years or older in case of flexor muscles of the elbow, wrist, and fingers, which is common after stroke, traumatic brain injury, or the progression of multiple sclerosis
Blepharospasm		1.25 Units-2.5 Units into each of 3 sites per affected eye	In people 12 years or older, associated with dystonia

Botox warning by FDA:
Botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. These symptoms can happen hours, days, to weeks after you receive an injection of BOTOX. The symptoms include swallowing and breathing difficulties that can be life-threatening. Other than that, there are reported cases for loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control.
The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses

3.2 Requirements for Coverage

- ICD and CPT codes must be coded to the highest level of specificity.
- All the indications given above have to be documented with history of at least 6 months of failed attempts of alternative procedures/medications for botulinum toxin treatment to be covered.
- Adjudication of drug will depend on brand used, approved indication and appropriate patient's age.

Eligible Clinician
Anesthesia / Pain Medicine
Dermatology & Genito Urinary Medicine
General Pediatric
General Surgery
Internal Medicine
Medical Ophthalmology
Neurological Surgery
Orthopedic Surgery/ Traumatology
Pain Medicine
Physical Medicine and Rehabilitation
Urology
Surgical Critical Care Medicine

3.3 Non-Coverage

- Daman does not cover botulinum toxin injections for cosmetic conditions for any plan, as this is a general exclusion for all plans.
- Daman does not cover botulinum toxin injections for basic plan, as they are not tagged as Abu Dhabi in green rain code list.
- Daman does not cover botulinum toxin injections for visitor's plan.

3.4 Payment and Coding Rules

Daman covers all the four types of Botulinum Toxin:

- If medically necessary.
- Therapeutic purposes only.
- Failed attempts of at least 6 months of alternative treatment.
- As per the policy terms and conditions of each health insurance plan administered by Daman.
- Please apply DOH payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

Adjudication Examples

Example 1

Question: A claim received of 25 years old female, premier plan holder for Botox injection for palmar hyperhidrosis. Will this claim be covered?

Answer: No, the claim will be rejected with MNEC-003 as Botox is not indicated for any hyperhidrosis other than axillary.

Example 2

Question: A claim received for 35 years old male holding regional plan, for Botox injection for chronic migraine happening once/twice every month and lasting for an hour. Is this claim payable?

Answer: No, this claim will be rejected with MNEC-003, as treatment with Botox is not indicated for migraine happening less than 15 days every month and lasting for less than 4 hours.

Example 3

Question: A claim received for 3 years old male baby holding regional plan, for Botox injection for strabismus. Is this claim payable?

Answer: No, this claim will be rejected with CODE-014, as treatment with Botox is not indicated for strabismus treatment for less than 12 years of age

Example 4

Question: A claim received for a 50 year old female holding Thiqa plan, for Botox injection for overactive bladder, with more than 6 months history of failure of anticholinergic drugs. Is this claim payable?

Answer: Yes, this claim is payable.

4. Denial Codes

Code	Code Description
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

5. Appendices

5.1 References

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5.2 Revision History

Date	Version No.	Change(s)
1/11/2013	V1.0	Release of V1.0
15/07/2014	V1.1	V1.1: Disclaimer update as per system requirements
22/08/2016	V2.0	V2.0: Review
14/06/2021	V2.1	V2.1: update on the indications
12/10/2022	V2.2	V2.2: Clinician list update
08/03/2023	V2.3	V2.3: Clinician list update
11/12/2024	V3.0	Added dose for Sever primary axillary hyperhidrosis