Effective Date: April 19, 2004
Revised Dates: October 14, 2020
July 8, 2020; July 10, 2019
January 9, 2019; October 10, 2018; October 12, 2016;
July 13, 2016; April 13, 2016; October 14, 2015;
April 10, 2013; April 11, 2012; January 12, 2011; October 13, 2010

CRITERIA FOR PRIOR AUTHORIZATION

Botulinum Toxins

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

OnabotulinumtoxinA (Botox®)
AbobotulinumtoxinA (Dysport®)
RimabotulinumtoxinB (Myobloc®)
IncobotulinumtoxinA (Xeomin®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR ONABOTULINUMTOXINA: (must meet one of the following): [1,2]

- For prophylaxis of headaches in patients with chronic migraines, refer to the migraine prophylaxis agents PA criteria.
- Treatment of upper limb spasticity in elbow, wrist, finger, or thumb flexors.
    - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of lower limb spasticity in patients to decrease the severity of increased muscle tone in ankle or toe flexors.
    - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of cervical dystonia.
    - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
    - Must be prescribed by or in consultation with a dermatologist.
    - Prescriber must provide details of the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.
- Treatment of blepharospasm associated with dystonia or strabismus.
    - Must be prescribed by or in consultation with a neurologist or ophthalmologist.
- Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency or urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury or multiple sclerosis).
    - Patient must have experienced an inadequate response after a 30-day trial of at least 2 anticholinergics at a maximum tolerated dose, OR have a documented intolerance or contraindication to therapy with anticholinergic medications.
    - Must be prescribed by or in consultation with a neurologist or urologist.

- Prescriber must provide details of the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.

CRITERIA FOR RIMABOTULINUMTOXINB: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Must be being used for one of the following: [1,3]
  - Treatment of cervical dystonia.
  - Treatment of chronic sialorrhea in adults.

CRITERIA FOR ABOBOTULINUMTOXINA: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist
- Must be being used for one of the following: [1,4]
  - Treatment of cervical dystonia.
  - Treatment of upper limb spasticity.
  - Treatment of lower limb spasticity.

CRITERIA FOR INCOBOTULINUMTOXINA: (must meet one of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist (or ophthalmologist for blepharospasm).
- Must be being used for one of the following: [1,5]
  - Treatment of cervical dystonia.
  - Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA.
  - Treatment of upper limb spasticity.
  - Treatment of chronic sialorrhea in adults.

LENGTH OF APPROVAL (INITIAL): 6 months. Subsequent authorizations will be granted for up to 2 injections in 6 months; injections must be at least 12 weeks apart, unless otherwise specified in Table 1.

CRITERIA FOR RENEWAL: (must meet all of the following)

- Subsequent authorizations will be granted for up to 2 injections in 6 months.
- Injections must be at least 12 weeks apart, unless otherwise specified in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

Notes: Use of Botulinum Toxins will **NOT** be approved for cosmetic purposes.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for botulinum toxins.[2-5]

Agents	Indication(s)	Age	Dosing Limits
OnabotulinumtoxinA (Botox)	Adult upper limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric upper limb spasticity	≥2 to 17 years	6 Units/kg or 200 Units, whichever is lower every 12 weeks.
	Adult lower limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric lower limb spasticity	≥2 to 17 years	8 Units/kg or 300 Units, whichever is lower every 12 weeks.
	Cervical dystonia	≥18 years	Up to 300 units every 12 weeks.
	Severe axillary hyperhidrosis	≥18 years	Up 100 total units every 28 weeks.
	Blepharospasm	≥12 years	Up to 200 total units every 12 weeks.
	Strabismus	≥12 years	Up to 300 total units every 24 weeks.
	Overactive bladder	≥18 years	Up to 100 units every 24 weeks.
	Detrusor overactivity	≥18 years	Up to 200 units every 42 weeks.
RimabotulinumtoxinB (Myobloc)	Cervical dystonia	≥18 years	Up to 5,000 units every 12 weeks.
	Chronic sialorrhea	≥18 years	Up to 3,500 units every 12 weeks.
AbobotulinumtoxinA (Dysport)	Cervical dystonia	≥18 years	Up to 1,000 units every 12 weeks.
	Adult upper limb spasticity	≥18 years	Up to 1,000 units every 12 weeks.
	Pediatric upper limb spasticity	≥2 to 17 years	16 Units/kg or 640 Units, whichever is lower, every 12 weeks.
	Lower limb spasticity	≥18 years	Up to 1,500 units every 12 weeks.
	Pediatric Lower limb spasticity	≥2 to 17 years	15 Units/kg for unilateral lower limb injections, 30 Units/kg for bilateral injections, or 1000 Units, whichever is lower, every 12 weeks.
IncobotulinumtoxinA (Xeomin)	Cervical dystonia	≥18 years	Up to 120 units every 12 weeks.
	Blepharospasm	≥18 years	Up to 100 units (50 units per eye) every 12 weeks.
	Adult upper limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric upper limb spasticity, excluding cerebral palsy	≥2 years	8 Units/kg or 200 units for unilateral upper limb, 16 units/kg or 400 units for bilateral upper limbs every 12 weeks.
	Chronic sialorrhea	≥18 years	Up to 100 units every 16 weeks.

References:

1. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at https://www.aan.com/Guidelines/home/GuidelineDetail/735. Accessed 6/3/20.
2. Botox (onabotulinumtoxinA) [package insert]. Madison, NJ: Allergan USA, Inc.; September 2020.
3. Myobloc (rimabotulinumtoxinB) [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; October 2019.
4. Dysport (abobotulinumtoxinA) [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2020.
5. Xeomin (incobotulinumtoxinA) [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; August 2020.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE