DEPARTMENT:	Utilization Management
SUBJECT:	Botulinum Toxin
PRODUCT LINE:	All
POLICY NUMBER:	008
ORIGINAL POLICY EFFECTIVE DATE:	10/20/2011
LAST REVISED DATE:	9/2/2023
LAST REVIEWED DATE:	9/2/2023

group health Cooperative of eau claire

KMTSJ, Inc.

SCOPE: To ensure Group Health Cooperative of Eau Claire consistently and correctly administers botulinum toxin benefits to all members according to their policy specifics.

POLICY: It is the policy of Group Health Cooperative of Eau Claire to review requests for prior authorization according to evidence based medical criteria.

PROCEDURE: **Prior authorization required: YES, for all product lines.**

Associated Codes:
J0585 Botox (onabotulinumtoxinA)
J0586 Dysport (abobotulinumtoxinA)
J0587 Myobloc (rimabotulinumtoxinB)
J0588 Xeomin (incobotulinumtoxinA

Coverage Criteria:

The use of botulinum toxin is considered **medically necessary** for the following conditions.

Blepharospasm when the following criteria are met:
1. Is a result of dystonia, AND?
2. Is chronic, AND
3. Prohibits accomplishing ADLs

Strabismus when the following criteria are met:
1. Visual symptoms have been present for at least one month and are unlikely to correct, **AND**
2. As an alternative to surgery or previous failed surgery, when it is determined that abnormal vision will occur

Limb spasticity, including:
1. Equinus varus deformity or other lower limb spasticity in children with cerebral palsy in the absence of significantly fixed deformity
2. Hereditary spastic paraplegia
3. Limb spasticity due to multiple sclerosis
4. Limb spasticity due to other demyelinating diseases of the central nervous system (including adductor spasticity and pain control in children undergoing adductor-lengthening surgery as well as children with upper extremity spasticity)
5. Spastic hemiplegia, such as due to stroke or brain injury.

When the following criteria are met:
1. Documentation that abnormal muscle tone is either interfering with functional ability, or is expected to result in joint contracture with future growth, *and*
2. Documented failure to standard medical treatments, *and*
3. Surgical intervention is considered to be the last option, *and*

4. Treatment is being requested to enhance function or allow additional therapeutic modalities to be employed

Focal hand dystonia (writer's cramp) when the following criteria are met:
1. Persistent pain that interferes with ADLs, AND
2. Documented failure of conservative therapy

Facial nerve (VII) dystonia

Hemifacial spasm

Idiopathic torsion dystonia

Neuromyelitis Optica

Orofacial dyskinesis (ie: jaw closure dystonia)

Laryngeal dystonia

Cervical dystonia (spasmodic torticollis) of moderate or greater severity when all the criteria are met:
1. History of recurrent contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius or posterior cervical muscles, **AND**
2. Sustained head tilt or abnormal posturing with limited range of motion in the neck, **AND**
3. Condition results in pain and/or functional impairment
4. The duration of the condition is greater than 6 months, **AND**
5. Has failed conservative therapy

Achalasia when the following criteria are met:
1. Are at high risk for complications from pneumatic dilation or surgical myotomy, **OR**
2. Advanced age or limited life expectancy, **OR**
3. Have failed a prior myotomy or dilation, **OR**
4. Have had a previous dilation-induced perforation, **OR**
5. Have increased risk of dilation-induced perforation (diverticulum, hiatal hernia or sigmoid-shaped esophagus, **AND**
6. History of failure, contraindication, or intolerance to one of the following:
    a. Calcium channel blocker, **OR**
    b. Long-acting nitrate, **AND**
7. Other causes of dysphagia have been ruled out

Anal Fissures when the following criteria are met:
1. Anal fissure is chronic (greater than 2 months), **AND**
2. Symptoms include one of the following:
    a. Nocturnal pain and bleeding, **OR**

b. Post defecation pain, **AND**

3. Has been unresponsive to conservative measures including nitroglycerin ointment and topical diltiazem cream for 3 months

Neurogenic detrusor (bladder) overactivity or detrusor-sphincter dyssynergia resulting from a spinal cord injury, multiple sclerosis or other neurologic condition when the following criteria are met:

1. Documentation of detrusor overactivity or dyssynergia confirmed by urodynamic testing, **AND**
2. Documented failure of behavioral therapy, **AND**
3. Documented failure/intolerance to at least one adequately titrated anticholinergic medication (oxybutynin, tolterodine, trospium, darifenacin, fesoterodine, solifenacin).

Overactive bladder when symptoms of urge urinary incontinence, urgency, and frequency occur in adults who meet the following criteria:

1. Documented failure of behavioral therapy, **AND**
2. Documented failure/intolerance to at least three adequately titrated prescription overactive bladder medications (e.g., oxybutynin (Ditropan), trospium (Sanctura), tolterodine (Detrol), darifenacin (Enablex), fesoterodine (Toviaz), mirabegron (Myrbetriq), solifenacin (Vesicare), duloxetine (Cymbalta)) or two adequately titrated prescription overactive bladder medications and an OTC bladder medication (oxybutynin transdermal patch (Oxytrol for Women).

Hyperhidrosis if the following is met:

1. Presence of medical complications such as recurrent skin maceration with bacterial or fungal infections or history of recurrent secondary infections, **OR**
2. Significant functional impairment (Functional impairment refers to the inability to perform activities of daily living) as documented in the medical records, **AND**
3. Failed a 6-month trial of at least two of the following nonsurgical treatments:
   a. Topical dermatologics such as aluminum chloride, tannic acid, glutaraldehyde, anticholinergics; **OR**
   b. Systemic anticholinergics, tranquilizers or non-steroid anti-inflammatory drugs

Chronic migraine headaches when all of the following criteria are met:

1. Has a diagnosis of chronic migraine headache (headaches for at least 3months), **AND**
2. Must have migraine for 15 or more days month, **AND**
3. Headaches lasting 4 hours a day or longer on the headache days, **AND**
4. member scored a grade indicating moderate to severe disability on the MIDAS (Migraine Disability Assessment) test, or on a similar validated tool, **AND**
5. Dosing range is no greater than 200 units per treatment, **AND**
6. Has tried and failed at least 2 to 3 agents from each of different classes of medications used in the prophylactic treatment of chronic migraine headaches, e.g. antidepressants, antihypertensives, antiepileptics, and calcitonin gene-related peptide (CGRP) receptor antagonists listed below. An adequate medication trial is at least two months (60 days) duration for each medication.

Migraine Prophylactic Medications include:
Antihypertensives:

a. Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (candesartan, lisinopril)
b. Beta blockers (atenolol, metoprolol, nadolol, propranolol, timolol)
c. Calcium channel blockers (diltiazem, nifedipine, nimodipine, verapamil)

Antidepressants (amitriptyline, clomipramine, doxepin, mirtazapine, nortriptyline, protriptyline)
Anti-epileptic drugs (gabapentin, topiramate, valproic acid)
Calcitonin gene-related peptide (CGRP) receptor antagonists (Aimovig, Emgality, Avjoy)

Vyepti (eptinezumab)

1. Member would need to try and fail Botox in addition to all three subcutaneous CGRP receptor antagonists (Aimovig, Emgality, Ajovy), and 2-3 medications from the antihypertensive, antidepressant, and anti-epileptic drug classes before Vyepti would be approved.

Continued treatment with botulinum toxin injection and/or Vyepti for ongoing prevention of chronic migraine headaches is considered medically necessary when:

1. Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial; **OR**
2. Migraine headache duration was reduced by at least 50% (when compared to the pre-treatment average) by the end of the initial trial.
3. Treatment frequency should not exceed more than one treatment every three months.

Botulinum Toxin is **NOT** covered for the following conditions:

1. Cosmetic: wrinkles
2. Experimental/Investigational
   a. Treatment of headaches other than chronic migraines meeting the criteria above, including, but not limited to, tension, episodic migraine (14 migraine days per month or less), or chronic daily headaches.
   b. Anismus (pelvic floor dyssynergia)
   c. Benign prostatic hyperplasia
   d. Brachial plexus palsy
   e. Carpal tunnel syndrome
   f. Chronic motor tic disorder
   g. Disorders of the esophagus (except as listed above in the medically necessary section)
   h. Epicondylitis
   i. Fibromyalgia/fibromyositis

j. Gastroparesis
k. Low back pain
l. Myofascial pain syndrome
m. Neck pain not related to conditions mentioned above
n. Nystagmus
o. Parkinson's disease
p. Sphincter of Oddi dysfunction
q. Stuttering
r. Tics associated with Tourette's Syndrome
s. Tinnitus
t. Tourette's Syndrome
u. Tremors
v. Urinary and anal sphincter dysfunction (except as listed above in the medically necessary section)
w. Vaginismus
x. Whiplash-related disorders
y. Zygomatic fractures

APPROVED: Michele Bauer MD. DATE: 9/2/2023

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
02/18/2013	Carol E. Ebel, RN HM Mgr.	This is a continuation of the archived P & P.
02/14/2014	Lynne Komanec RN HM Mgr.	Sentence added regarding treatment of overactive bladder.
01/22/2015	Betsy Kelly, RN	Combined botox for migraines with current P&P.
04/22/2016	Betsy Kelly, RN	Reviewed with no changes.
10/18/2017	Michele Bauer, MD	Updated coverage criteria
12/14/2018	Michele Bauer, MD	Update criteria for chronic migraine
1/16/2019	Michele Bauer, MD	Added Aimovig to chronic migraine criteria
4/24/2020	Michele Bauer, MD	Reviewed. Updated Migraine criteria.
4/24/2021	Michele Bauer, MD	Reviewed. No changes.
3/14/2022	Michele Bauer, MD, CMO	Reviewed. No changes.
3/10/2023	Michele Bauer, MD, CMO	Reviewed. No changes.

9/2/2023	Michele Bauer, MD, CMO	Updated to include Vyepti.