



Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

**Botulinum Toxin
Treatment**

Policy Number: HS-218

Original Effective Date: 11/7/2013

**Revised Date(s): 11/6/2014; 9/17/2015;
7/7/2016; 7/6/2017; 6/7/2018**

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Botulinum toxin has been found to be effective in individuals with a variety of medical conditions. Four types of botulinum toxin have received U.S. Food and Drug Administration (FDA) approval. Various botulinum toxin types are used for a range of off-label indications.

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

Botulinum toxin **is considered experimental and investigational** for diagnoses that do not meet the above-listed criteria. This includes use of botulinum toxin for cosmetic purposes as well as for the treatment of episodic migraines (those occurring 14 days or fewer per month), chronic daily headaches and tension headaches. ^{6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18}

AbobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), and rimabotulinumtoxinB (Myobloc) **are considered experimental and investigational** for the treatment of chronic migraine headache. ^{10, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37}

Coverage

Initial Treatment

Botulinum toxin **is considered medically necessary** when all of the following criteria are met:

1. Member meets the following age restriction for the requested drug:
 - A. Botox (onabotulinumtoxinA):
 - 18 years or greater (chronic migraine, upper limb spasticity, primary axillary hyperhidrosis, detrusor over activity)
 - 16 years or greater (cervical dystonia)
 - 12 years or greater (blepharospasm and strabismus)
 - B. Xeomin (incobotulinumtoxinA):
 - 18 years or greater
 - C. Myobloc (rimabotulinumtoxinB):
 - 18 years or greater
 - D. Dysport (abobotulinumtoxinA):
 - 18 years or greater

AND,

2. Member has one of the following diagnoses associated with the requested drug:

- A. Botox (onabotulinumtoxinA):
 - Upper Limb Spasticity; **OR,**
 - Cervical Dystonia; **OR,**
 - Primary Axillary Hyperhidrosis; **OR,**
 - Detrusor Over Activity; **OR,**
 - Blepharospasm; **OR,**
 - Strabismus; **OR,**
 - Headache Prophylaxis (Migraines)

OR,

- B. Dysport (abobotulinumtoxinA):
 - Upper Limb Spasticity; **OR,**
 - Cervical Dystonia

OR,

C. Xeomin (incobotulinumtoxina):

- Upper Limb Spasticity; **OR**,
- Cervical Dystonia; **OR**,
- Blepharospasm

OR,

D. Myobloc (rimabotulinumtoxinb)

- Cervical Dystonia

AND,

3. Member has one of the following diagnoses and meets corresponding criteria:

A. **Upper Limb Spasticity**

- a. Member has a documented diagnosis of upper limb spasticity; **AND**,
- b. Request is for one of the following drugs with the following dosing for the corresponding location:

i. Dysport (abobotulinumtoxinA)

NOTE - IM: Individualize dose based on patient size, number and location of muscle involvement, severity of spasticity, local muscle weakness, response to prior treatment, and/or adverse reaction history. May repeat therapy at intervals \geq 12 weeks (clinical studies: majority of patients re-treated 12 to 16 weeks).

- Adductor pollicis - N/A
- Brachialis - 200-400 units (1-2 injections)
- Brachioradialis - 100-200 units (1-2 injections)
- Biceps - N/A
- Biceps brachii - 200-400 units (1-2 injections)
- Flexor carpi radialis - 100-200 units (1-2 injections)
- Flexor carpi ulnaris - 100-200 units (1-2 injections)
- Flexor digitorum profundus - 100-200 units (1-2 injections)
- Flexor digitorum sublimis - N/A
- Flexor digitorum superficialis - 100-200 units (1-2 injections)
- Flexor pollicis brevis/opponens pollicis - N/A
- Flexor pollicis longus - N/A
- Pronator quadratus - N/A
- Pronator teres - 100-200 units (1 injection)

OR,

ii. Xeomin (incobotulinumtoxinA)

NOTE - IM: Initiate dose at low end of the range and titrate as clinically indicated (base the dosage, frequency and number of injection sites on size, number and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, patient's response to previous treatment and adverse event history). Administer no more frequently than every 3 months. Maximum cumulative dose/treatment session: 400 units.

- Adductor pollicis - 5-30 units (1 injection)
- Brachialis - 25-100 units (1-2 injections)
- Brachioradialis - 25-100 units (1-3 injections)
- Biceps - 50-200 units (1-4 injections)
- Biceps brachii - N/A
- Flexor carpi radialis - 25-100 units (1-2 injections)
- Flexor carpi ulnaris - 20-100 units (1-2 injections)
- Flexor digitorum profundus - 25-100 units (2 injections)

- Flexor digitorum sublimis - N/A
- Flexor digitorum superficialis - 25-100 units (2 injections)
- Flexor pollicis brevis/opponens pollicis - 5-30 units (1 injection)
- Flexor pollicis longus - 10-50 units (1 injection)
- Pronator quadratus - 10-50 units (1 injection)
- Pronator teres - 25-75 units (1-2 injections)

OR,

iii. Botox (onabotulinumtoxinA)

NOTE - IM: Initiate dose at low end of the range and titrate as clinically indicated. Administer ≤50 units/site.

- Adductor pollicis - 20 units (1 injection)
- Brachialis - N/A
- Brachioradialis - N/A
- Biceps - N/A
- Biceps brachii - 100-200 units (4 injections)
- Flexor carpi radialis - 12.5-50 units (1 injection)
- Flexor carpi ulnaris - 12.5-50 units (1 injection)
- Flexor digitorum profundus - 30-50 units (1 injection)
- Flexor digitorum sublimis - 30-50 units (1 injection)
- Flexor digitorum superficialis - N/A
- Flexor pollicis brevis/opponens pollicis - N/A
- Flexor pollicis longus - 20 units (1 injection)
- Pronator quadratus - N/A
- Pronator teres - N/A

OR,

B. Cervical Dystonia

- a. Member has a documented diagnosis of cervical dystonia; **AND,**
- b. Request is for one of the following drugs with the following dosing:
 - i. Dysport (abobotulinumtoxinA) - IM: Initial 500 units divided among affected muscles (may retreat at intervals of ≥12 weeks); adjust dosage in 250 unit increments (dosage range used in studies: 250 – 1,000 units); **OR,**
 - ii. Xeomin (incobotulinumtoxinA) - IM: Initial 120 units (dose and number of injection sites individualized based on prior treatment, response, duration of effect, adverse events, number/location of muscles, and disease severity). Administer no more frequently than every 3 months. Maximum cumulative dose per treatment of 400 units; **OR,**
 - iii. Botox (onabotulinumtoxinA) - IM: Mean dose of 236 units (25-75th percentile range 198 – 300 units) divided among affected muscles for patients previously treated with botulinum toxin (max: ≤50 units/site). Initial dose should be lower for botulinum toxin treatment-naïve patients. Sequential dosing based on the patient's head/neck position, localization of pain, muscle hypertrophy, patient response, and previous adverse reactions. Total dose injected into the sternocleidomastoid muscles ≤100 units to decrease the occurrence of dysphagia; **OR,**
 - iv. Myobloc (rimabotulinumtoxinB) - IM: Initial 2,500 – 5,000 units divided among affected muscles for patients previously treated with botulinum toxin (initial dose should be lower for botulinum toxin treatment-naïve patients). Optimize subsequent doses based off patient response.

OR,

C. Primary Axillary Hyperhidrosis

- a. Member has a documented primary axillary hyperhidrosis, **AND**;
- b. History of failed treatment with prescription strength aluminum chloride (20%) in ethanol or 6.25% aluminum chloride hexahydrate for at least 3 months or documented intolerable side-effects to 20 % aluminum chloride in ethanol or 6.25% aluminum chloride hexahydrate such as irritation or dermatitis not improved with topical corticosteroid application; **AND**,
- c. Request is for the following drug with the following dosing:
 - i. Botox (onabotulinumtoxinA) - Intradermal: 50 units/axilla. Injection area defined by standard staining techniques. Injections evenly distributed into multiple sites (10 – 15), administered in 0.1 – 0.2 mL aliquots, ~1 – 2 cm apart. May repeat when clinical effect diminishes.

OR,

D. Detrusor Over Activity

- a. Member has a documented diagnosis or detrusor over activity; **AND**,
- b. Documented history of trial and failure or intolerable side effects with 2 of the preferred medications, oxybutynin or trospium; **AND**,
- c. Request is for the following drug with the following dosing:
 - i. Botox (onabotulinumtoxinA) - Intradetrusor: 30 injections of 1 mL (recommended concentration: ~6.7 units/mL) for a total dose of 200 units/30 mL (maximum: 200 units); for the final injection, ~1 mL of sterile NS should be injected to ensure that the remaining medication in the needle is delivered to the bladder; may consider re-treatment with diminishing effect but no sooner than 12 weeks from previous administration (median time until second treatment in studies: 42 to 48 weeks).

OR,

E. Blepharospasm or Strabismus

- a. Member has a documented diagnosis of blepharospasm or strabismus; **AND**,
- b. Request is for the following drug with the following dosing:
 - i. Botox (onabotulinumtoxinA)
 - **Blepharospasm (IM):** Initial dose 1.25 – 2.5 units injected into the medial and lateral pretarsal orbicularis oculi of the upper lid and lateral pretarsal orbicularis oculi of lower lid. Dose may be increased up to twice the previous dose if the response from the initial dose lasted ≤ 2 months; maximum dose/site: 5 units. Tolerance may occur if treatments are given more often than every 3 months, but the effect is not usually permanent. Maximum cumulative dose: ≤ 200 units in 30-day period; **OR**,
 - **Strabismus (IM):** Initial dose: vertical muscles and for horizontal strabismus < 20 prism diopters (1.25 – 2.5 units in any one muscle); horizontal strabismus of 20 to 50 prism diopters (2.5 – 5 units in any one muscle); persistent VI nerve palsy ≥ 1 month (1.25 – 2.5 units in the medial rectus muscle). Re-examine patients 7 – 14 days after each injection to assess the effect of that dose. Subsequent doses for patients experiencing incomplete paralysis of the target may be increased up to twice the previous administered dose. Maximum recommended dose as a single

injection for any one muscle is 25 units. Do not administer subsequent injections until the effects of the previous dose are gone; **OR**,

- ii. Xeomin (incobotulinumtoxinA)
 - **Blepharospasm (IM):** Total dose should be the same as previously administered onabotulinumtoxinA dose. If prior onabotulinumtoxinA dose is not known: 1.25 – 2.5 units/injection site (maximum initial dose: 35 units/eye or 70 units/both eyes). Number and location of injection sites based on disease severity and previous dose/response to onabotulinumtoxinA (in clinical trials, a mean number of 6 injections per eye were administered). Cumulative dose should not exceed 35 units/eye or 70 units/both eyes administered no more frequently than every 3 months.

OR,

F. Chronic Migraines

- a. Member has a documented diagnosis chronic migraines;

AND,

- b. Request is for the following drug with the following dosing in the corresponding locations:
 - i. Botox (onabotulinumtoxinA) request is for IM dosing as follows: Administer 5 units/0.1 mL per site. Recommended total dose is 155 units once every 12 weeks. Each 155 unit dose should be equally divided and administered bilaterally, into 31 total sites as described below:
 - Corrugator: 5 units to each side (2 sites);
 - Procerus: 5 units (1 site only) ;
 - Frontalis: 10 units to each side (divided into 2 sites/site) ;
 - Temporalis: 20 units to each side (divided into 4 sites/site) ;
 - Occipitalis: 15 units to each side (divided into 3 sites/site) ;
 - Cervical paraspinal: 10 units to each side (divided into 2 sites/site) ;
 - Trapezius: 15 units to each side (divided into 3 sites/site); **AND**,
 - ii. Documented diagnosis of chronic migraines (frequency of 15 days or more per month with migraines lasting 4 hours per day or longer); **AND**,
 - iii. Prerequisite trial of at least 1 drug from 2 *different* therapeutic drug classes below within the most recent 6 months:
 - Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortriptyline, protriptyline); **OR**,
 - Anti-epileptic drugs (e.g., gabapentin, topiramate, valproic acid); **OR**,
 - Beta blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol); **OR**,
 - Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil); **AND**,
 - iv. Member is 18 years of age or older; **AND**,
 - v. Dose of OnabotulinumtoxinA does not exceed 155 units administered intramuscularly divided over 31 injection sites within 7 specific head and neck muscle areas every 12 weeks; **AND**,
 - vi. Treatment is prescribed by or in consultation with a board certified neurologist.

Continued Treatment of Botox (onabotulinumtoxinA)

Continued treatment for ongoing migraine prophylaxis is approved when the member experiences a beneficial response that may be measured by **one** of the following:

1. Migraine headache frequency was reduced by 7 days per month or more (when compared to pre-treatment average) by the end of the initial trial; **OR**,
2. Migraine headache duration was reduced by 100 total hours per month or more (when compared to pre-treatment average) by the end of the month.

CODING

CPT® Codes – No applicable codes.

HCPCS®* Codes

- J0585** Injection, OnabotulinumtoxinA, 1 unit
J0586 Injection, AbobotulinumtoxinA, 5 units
J0587 Injection, RimabotulinumtoxinB, 100 units
J0588 Injection, Incobotulinumtoxin A, 1 unit

Covered ICD-10-CM Diagnosis Codes – *This list may not be all inclusive*

- G24.1** Genetic torsion dystonia
G24.3 Spasmodic torticollis
G24.5 Blepharospasm
G43.00-G43.911 Migraine
H50.00-H50.9 Other strabismus
H51.0-H51.9 Other disorders of binocular movement
L74510 Primary focal hyperhidrosis, axilla
M62.411-M62.419 Contracture of muscle, shoulder
M62.421-M62.429 Contracture of muscle, upper arm
M62.431-M62.439 Contracture of muscle, forearm
M62.441-M62.449 Contracture of muscle, hand
M62.451-M62.459 Contracture of muscle, thigh
M62.461-M62.469 Contracture of muscle, lower leg
M62.471-M62.479 Contracture of muscle, ankle and foot
M62.48 Contracture of muscle, other site
M62.49 Contracture of muscle, multiple sites
N36.44 Muscular disorders of urethra
R61 Generalized hyperhidrosis

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
6/7/2018	• Approved by MPC. No changes.
7/6/2017	• Approved by MPC. Pharmacy revision of criteria and application.
7/7/2016	• Approved by MPC. Additional indication added for treatment of chronic migraines as well as achalasia.
9/17/2015	• Approved by MPC. Expanded indications for coverage.
11/6/2014	• Approved by MPC. No changes.
11/7/2013	• Approved by MPC. New.