Pharmacy Management Drug Policy

SUBJECT: Botulinum Toxin (Botox, Daxxify, Dysport, Myobloc, Xeomin)
POLICY NUMBER: PHARMACY-77
EFFECTIVE DATE: 12/2019
LAST REVIEW DATE: 03/06/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Botulinum toxin is produced by anaerobic fermentation of the bacterium Clostridium botulinum. A number of different C. botulinum strains have been identified; they produce eight immunologically distinct serotypes (type A–H) and consist of the botulinum neurotoxin complexed with a number of associated proteins. Of the seven immunologically distinct botulinum toxins, only three have been linked to cases of botulism in humans, and only serotypes A and B are available for clinical use.
There are currently four neurotoxin type A (BoNT/A) products on the market, OnabotulinumtoxinA (ONA; Botox), Abobotulinum toxin A (ABO; Dysport), Incobotulinum toxin A (INCO; Xeomin), DaxibotulinumtoxinA-lanm (DAX; Daxxify), and 1 neurotoxin type B, RimabotulinumtoxinB (Myobloc).

In nature, BoNT-A is synthesized as macromolecular protein complexes. These protein complexes are referred to as progenitor toxins and consist of nontoxic accessory proteins (NAPs) bonded to the 150-kD active neurotoxin. The BoNT-A progenitor toxins vary in molecular weight (300–900 kD) depending on the composition of NAPs and the manufacturing process. The 150-kD neurotoxin must dissociate from NAPs to exert its pharmacologic effects. Dissociation occurs in physiologic pH conditions. When administered intramuscularly, these toxins reduce muscle tone by interference with the release of acetylcholine from nerve endings.

Dosing patterns are specific to each biological product and can differ between and within serotypes. Please refer to FDA labeling for current dosing information for each individual product.

Each individual neurotoxin product should be dosed accordingly based on each individual products current FDA approved indication(s) and dosage guidelines. Recent studies have shown that the different serotypes of Botulinum Toxins **can be interchanged**, but **not at a 1:1 ratio**. Currently accepted unit conversion ratios between the various products are provided in the Appendix. As a result, all Botulinum Toxins included within this policy shall be considered interchangeable for each of the indications listed within this policy, unless specifically noted otherwise.

NOTE: Dosing and conversion information is provided as **guidance only**. FDA approved labeling, compendia or primary literature should be referenced for detailed dosage information.

Pharmacy Management Drug Policy
Botulinum Toxin (Botox, Daxxify, Dysport, Myobloc, Xeomin)

The following products, OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) and RimabotulinumtoxinB (Myobloc), are included within this policy and coverage is provided under the medical benefit.

Refer to Corporate Medical Protocol 7.01.11 regarding Cosmetic and Reconstructive Procedures.

POLICY:

For Medicaid (MMC/HARP), Child Health Plus (CHP) and Dual-Eligible Special Needs Plans (D-SNP):

- Prior authorization is required for Botox, Dysport, Xeomin, Daxxify and Myobloc.

For the Commercial, Essential, and Exchange plans ONLY:

- Botox and Xeomin do **NOT** require prior authorization.
- Prior authorization is required for coverage of Dysport, Myobloc and Daxxify.
- For New Starts, coverage for Dysport, Myobloc and Daxxify requires an adequate trial of Botox **AND** Xeomin.

Based upon our criteria and review of the peer-reviewed literature, OnabotulinumtoxinA (ONA; Botox), Abobotulinum toxin A (ABO; Dysport), Incobotulinum toxin A (INCO; Xeomin), DaxibotulinumtoxinA-lanm (Daxxify), and RimabotulinumtoxinB (Myobloc) therapy has been medically proven effective and therefore may be considered **medically appropriate** for the following conditions when the appropriate criteria are met.

I. Cervical Dystonia
(spasmodic torticollis) to reduce the severity of abnormal head position and neck pain.

A. Initial Request:

1. Diagnosis of cervical dystonia **AND**
2. Patient must be 16 years of age or older **AND**
3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **AND**
4. Experiencing involuntary contractions of the neck and shoulder muscles (e.g.: splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulder, or head **AND**
5. Contractions are causing pain and functional impairment **AND**
6. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines located in the Appendix for the appropriate serotype conversion ratios.

a. 400 units is the FDA approved maximum dosing however there is evidence to support the safety and efficacy of total doses up to 600 units. Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response.

b. Dose based 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 toxin naïve patients.
c. Average dose: 198 to 300 units divided among affected muscles; up to 50 units per site.
d. Average duration of effect: 4 - 6 weeks to 3 months. Retreatment no sooner than 12 weeks from last injection.
e. For Daxxify, the recommended dosing is 125 units to 250 units given intramuscularly as divided dose among affected muscles.

B. Recertification:
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration. **AND**
3. Requests for dose increase must not exceed 400 units per treatment session. (Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response, with a maximum allowed dose of 600 units) **AND**
4. May repeat doses when effects have lessened, but no sooner than 12 weeks after previous injection.
5. For Daxxify, the recommended dosing is 125 units to 250 units given intramuscularly as divided dose among affected muscles

II. Blepharospasm (a focal dystonia) or Strabismus
Associated with dystonia, including benign essential blepharospasm or VII nerve disorders

A. Initial Request:
a. Diagnosis of:
   a. Blepharospasm (i.e., abnormal contraction of eyelid muscles) **OR**
   b. Strabismus (i.e., misalignment of the eyes) **AND**
2. Patient must be 12 years of age or older **AND**
3. Prescribed by or in consultation with a neurologist or ophthalmologist **AND**
4. Member has significant disability in daily functional activities due to interference with vision **AND**
5. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines located in the Appendix for the appropriate serotype conversion ratios.

Blepharospasm:
a. Dose does not exceed 5 units per site per treatment session (maximum of 200 units total in a 30-day period)
b. Time to retreat: No sooner than 3 months from previous treatment.

Strabismus:
a. The dose is based on prism diopter correction or previous response to treatment with Botox.
b. Dose does not exceed 25 units per treatment session.

c. Average duration of effect: 2-6 weeks to 3-6 months
d. Time to retreat: No sooner than 6 weeks from previous treatment. Subsequent injections should not be given until the effects of the previous dose have dissipated as evidenced by substantial function in the injected and adjacent muscles.

B. Recertification:
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration. **AND**
3. Requests for dose increase must not exceed for Blepharospasm: 5 units per site per treatment session (maximum of 200 units total in a 30-day period) and for Strabismus: 25 units per muscle per treatment session.

III. Upper Limb Spasticity
Patients ≥ 2 years to decrease the severity of increased muscle tone in elbow, wrist, finger and thumb flexors, that ARE NOT due to Cerebral Palsy (Please see "Spasticity Associated with Cerebral Palsy" below)

A. Initial Request:
1. Diagnosis of upper limb spasticity **AND**
2. Patient must be 2 years of age or older **AND**
3. Focal increased muscle tone causing functional impairment, **AND**
4. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **AND**
5. Failure of an age appropriate, adequate trial of baclofen, tizanidine or dantrolene unless contraindicated, not age appropriate or not clinically appropriate for diagnosis **AND**
6. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines located in the Appendix for the appropriate serotype conversion ratios.

Adults: ≥18 years of age:

a. The FDA approved maximum cumulative dose for adults is 400 units every 12 weeks. However, there is evidence to support the safety and efficacy of total doses up to 600 units. Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response.
b. May repeat doses when effects have lessened, but no sooner than 12 weeks after previous injection.

Children: 2 - 17 years of age:

a. Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history with OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport),

IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) or RimabotulinumtoxinB (Myobloc).

b. The FDA approved maximum total **cumulative** dose is 340 units in a 3-month interval.
c. Repeat treatment may be administered when the effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection.

Limitations: Safety and effectiveness of OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) and RimabotulinumtoxinB (Myobloc), has not been established for the treatment of the upper limb muscle groups other than those specified in the FDA approved labeling (see Appendix) or for the treatment of upper limb spasticity in pediatric patients under 2 years of age. Requests for the treatment of muscle groups other than those specified in the FDA approved labeling, or for the treatment of upper limb spasticity in pediatric patients under 2 years of age will be denied as not medically necessary.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than:
   a. Adults ≥ 18 years of age: 400 cumulative units over the last 3 months (unless there is history of previous approval to use more than 400 units)
   b. Children 2-17 years of age: 340 cumulative units over the last 3 months **AND**
3. It has been 12 weeks (3 months) since the last injection **AND**
4. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Requests for dose increase must not exceed 400 units per treatment session for Adults ≥ 18 years of age*, and 340 units per treatment session for Children 2-17 years of age.
(*Requests exceeding 400 units in adults, will be reviewed on a case-by-case basis, and only authorized if there is evidence that 400 units did not provide an adequate response, with a maximum allowed dose of 600 units. Doses exceeding 340 units in children will not be approved as there is no data available showing doses exceeding 340 units in children is safe or effective).

IV. Lower Limb Spasticity

In patients ≥ 2 years to decrease the severity of increased muscle tone in ankle and toe flexors, that ARE NOT due to Cerebral Palsy (Please see “Spasticity Associated with Cerebral Palsy” below).

A. Initial Request:

1. Diagnosis of lower limb spasticity **AND**
2. Patient must 2 years of age or older **AND**
3. Focal increased muscle tone causing functional impairment, **AND**
4. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **AND**
5. Failure of an age appropriate, adequate trial of baclofen, tizanidine or dantrolene unless contraindicated, not age appropriate or not clinically appropriate for diagnosis **AND**
6. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix or the appropriate serotype conversion ratios.

Adults: ≥18 years of age:

a. Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history with OnabotulinumtoxinA, AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) or RimabotulinumtoxinB (Myobloc).
b. Usual Dosage:
Total dose of 300 to 400 units IM across 5 muscles. Use the lowest dose when starting treatment.
c. Maximum Dose per site: 50 units.
d. The FDA approved maximum cumulative dose for adults is 400 units every 12 weeks. However, there is evidence to support the safety and efficacy of total doses up to 600 units. Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response.
e. May repeat doses when effects have lessened, but no sooner than 12 weeks after previous injection.

Children: 2 - 17 years of age:

a. Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history with OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) or RimabotulinumtoxinB (Myobloc).
b. Usual Dosage: 4 to 8 units/kg IM divided among the affected muscles.
c. Maximum dose: 8 units/kg or 300 units per treatment session, whichever is lower.
d. The FDA approved maximum total **cumulative** dose 340 units in a 3-month interval.
e. Repeat treatment may be administered when the effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection.

Limitations: Safety and effectiveness of OnabotulinumtoxinA (Botox), AbobotulinumtoxinA (Dysport), IncobotulinumtoxinA (Xeomin), DaxibotulinumtoxinA-lanm (Daxxify) and RimabotulinumtoxinB (Myobloc), has not been established for the treatment of the lower limb muscle groups other than those specified in the FDA approved labeling (see Appendix) or for the treatment of lower limb spasticity in pediatric patients under 2 years of age. Requests for the treatment of muscle groups other than those specified in the FDA approved labeling, or for the treatment of lower limb spasticity in pediatric patients under 2 years of age will be denied as not medically necessary.

B. Recertification
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than:
   a) Adults ≥ 18 years of age: 400 cumulative units over the last 3 months (unless there is history of previous approval to use more than 400 units)
   b) Children 2-17 years of age: 340 cumulative units over the last 3 months **AND**
3. It has been 12 weeks (3 months) since the last injection **AND**
4. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Requests for dose increase must not exceed 400 units per treatment session for adults ≥ 18 years of age*, and 340 units per treatment session for Children 2-17 years of age. (*Requests exceeding 400 units in adults, will be reviewed on a case-by-case basis, and only authorized if there is evidence that 400 units did not provide an adequate response, with a maximum allowed dose of 600 units. Doses exceeding 340 units in children will not be approved as there is no data available showing doses exceeding 340 units in children is safe or effective).

V. Spasticity Associated with Cerebral Palsy (CP) In Patients ≥ 2 years

A. Initial Request:

1. Diagnosis of spasticity associated with cerebral palsy (CP) **AND**
2. Patient must be 2 years of age or older **AND**
3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **AND**
4. Indicated in patients who have increased muscle tone that interferes with function or is likely to lead to joint contracture with growth **AND**
5. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 400 units per treatment session.
b. Dosing depends on the muscles injected, body weight, muscle bulk, the number of muscles being injected simultaneously, and the patient's response to previous therapy.
c. Average duration of effect / time to retreat: 12 weeks.
d. The FDA approved maximum cumulative dose for adults is 400 units every 12 weeks.

However, there is evidence to support the safety and efficacy of total doses up to 600 units. Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 400 units over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Requests for dose increase must not exceed 400 units per treatment session. (Requests exceeding 400 units will be reviewed on a case-by-case basis and only authorized if there is evidence that 400 units did not provide an adequate response, with a maximum allowed dose of 600 units)

VI. Chronic Migraine

A. Initial Request:

1. Patient must be 18 years of age or older (Botulinum toxin will not be approved for Chronic Migraine for those under the age of 18 under any circumstances) **AND**
2. Must be used for the prevention of migraine headaches in adult patients with a diagnosis of chronic migraine headache.
3. A diagnosis of chronic migraine headache is defined as a headache occurring on 15 or more days/month for more than 3 months, which, on at least 8 days/month, has the features of migraine headache

    i. The features of migraine, include but are not limited to:
        a. Unilateral location
        b. Pulsating quality
        c. Moderate or Severe pain intensity
        d. Aggravation by or causes avoidance of routine physical activity.
        e. Nausea and/or vomiting.
        f. Photophobia and/or phonophobia
4. The patient must be experiencing 4 or more migraine headache days per month.
5. Prescribed by or in consultation with a neurologist or pain specialist **AND**
6. The provider must attest that the patient has had serious side effects or drug failure, at an effective dose, to at least 3 months of THREE preventative oral medications from THREE different classes including, but not limited to:
    a. Anti-Depressants
    b. Serotonin-Norepinephrine Reuptake Inhibitors
    c. Beta-Blockers
    d. Anti-Convulsant
7. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.
8. For use in combination with an injectable Calcitonin Gene Related Peptide (CGRP) Antagonist, please see Section C. below for additional criteria.
9. Initial approval of therapy for chronic migraines will be for 6 months for up to three (3) treatment sessions. Dose must not exceed 200 units per treatment session at a dosing frequency no less than 12 weeks apart.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 200 units per treatment session.
b. Recommended dose is 155 units given as 5 units into each of 31 sites across 7 specific head/neck muscle areas.
c. Average duration of effect: 3 – 4 months.

Limitations: The safety and effectiveness of botulinum toxin has not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. Requests for prophylaxis of episodic migraine will be denied as not medically necessary.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation or attestation to support a significant reduction in monthly migraine headache frequency and/or intensity after at least 2 treatment sessions and that patient has been able to resume daily living activities previously unable to perform due to headache frequency and/or intensity **AND**
2. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration. **AND**
3. For use in combination with an injectable Calcitonin Gene Related Peptide (CGRP) Antagonist, please see Section C. below for additional criteria.
4. Recertifications will be approved for 12 months for up to a total of 5 treatment sessions. Dose must not exceed 200 units per treatment session at a dosing frequency no less than 12 weeks apart.

C. Additional Criteria for the use of botulinum toxin in combination with injectable Calcitonin Gene Related Peptide (CGRP) Antagonists (including, but not limited to Aimovig, Ajovy, Emgality or Vyepti)

The use of botulinum toxin in combination with CGRPs for the prevention of migraine headaches may be approved after a patient has tried monotherapy with one agent with a partial response (see criteria below). Coverage will not be provided for patients initiating therapy with botulinum toxin and a GCRP at the same time.

1. For botulinum toxin new starts (patients are currently using an injectable CGRP):

a. Patient must meet Initial Request criteria for Chronic Migraine (see Section A above) **AND**
b. Patient must have been using the CRRP for at least 3 months and has demonstrated a partial clinical response to treatment with the CGRP alone (a partial response is defined as a decrease in severity and/or frequency of migraine headaches from baseline) **AND**
c. Documentation must be submitted confirming the patient continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention.
d. Initial approval of therapy for chronic migraines will be for 6 months for up to three (3) treatment sessions. Dose must not exceed 200 units per treatment session at a dosing frequency no less than 12 weeks apart.

2. **For patients currently on botulinum toxin (added an injectable CGRP during the most recent botulinum toxin period):**
   a. Patient must have used botulinum toxin monotherapy for 6 months and demonstrated a partial response to treatment (a partial response is defined as a decrease in severity and/or frequency of migraine headaches from baseline) **AND**
   b. Documentation must be submitted confirming that the patient continued to experience a significant number of migraine headache days or severe migraine days per month on botulinum toxin alone requiring additional therapy for migraine prevention.

3. Recertification criteria for concurrent utilization of botulinum toxin and an injectable CGRP requires documentation of the following:
   a. Patient has had further reduction in the overall number of migraine days or reduction in the number of severe migraine days per month compared to monotherapy with the initial agent **AND**
   b. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
   c. Recertifications will be approved for 12 months for up to a total of 5 treatment sessions. Dose must not exceed 200 units per treatment session at a dosing frequency no less than 12 weeks apart.

VII. Neurogenic detrusor overactivity

Associated with a neurologic condition in pediatric patients 5-17 years of age following inadequate response or intolerance to anticholinergic medication.

A. Initial Request

1. Diagnosis of Neurogenic detrusor overactivity that is associated with a neurologic condition in pediatric patients 5 – 17 years of age who have an inadequate response to or are intolerant of anticholinergic medication **AND**
2. Prescribed by / in consultation with a neurologist or urologist that specializes in pediatrics **AND**
3. Failure of at least a 3-month trial of oxybutynin at appropriate pediatric dosing **AND**
4. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing Guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Usual dosage (less than 34 kg): Refer to weight-based dosage.
b. Usual dosage (34 kg or greater): 200 units
c. Retreatment: Consider re-injection when clinical benefit diminishes, no sooner than 12 weeks

B. Recertification

Previously approved by plan or has met initial approval criteria.

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 200 units over the past 3 months, and it has been at least 12 weeks since the last injection **AND**

3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

VIII. Primary Axillary Hyperhidrosis

A. Initial Request

1. Diagnosis of severe primary axillary hyperhidrosis (e.g., resulting in medical complications such as skin maceration and infection or significant disruption of professional/social life) that is inadequately managed by topical agents **AND**
2. Patient must be 18 years of age or older **AND**
3. Prescribed by / in consultation with a neurologist or dermatologist **AND**
4. Failure of a 6-month trial of topical aluminum chloride, unless contraindicated or serious side effects are experienced **AND**
5. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 50 units per axilla per treatment session (maximum of 100 units total).
b. Average duration of effect: 4-12 months
c. Time to retreat: 8 - 12 weeks

Limitations: The safety and effectiveness of botulinum toxin for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive botulinum toxin for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Requests for hyperhidrosis for any area of the *body other than axillary hyperhidrosis*, will be denied as not medically necessary.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 400 units over the past 3 months and it has been at least 8 -12 weeks (2 - 3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed 50 units per axilla per treatment session.

IX. Overactive Bladder / Urinary Incontinence

Overactive Bladder with symptoms of urge urinary incontinence, urgency and frequency in adults who have experienced serious side effects, drug failure or contraindications to anticholinergic medication

Urinary Incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have experienced serious side effects, drug failure or contraindications to anticholinergic medication

A. Initial request:

1. Diagnosis of:
   a. Overactive Bladder **OR**
   b. Urinary Incontinence (Detrusor Overactivity) associated with a neurologic condition (e.g., spinal cord injury, MS) **AND**
2. Patient must be 18 years of age or older **AND**
3. Prescribed by / in consultation with a neurologist or urologist **AND**
4. Failure of a trial of at least TWO anticholinergic agents (e.g., oxybutynin chloride, tolterodine tartrate), each used for at least 30 days, unless contraindicated or serious side effects are experienced **AND**
5. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

1. Overactive Bladder
   a. Dose does not exceed 100 units per treatment session as 0.5mL (5 Units) injections across 20 sites into the detrusor.
   b. Average duration of effect: 12 weeks
   c. Time to retreat: no sooner than 12 weeks.

2. Urinary Incontinence (Detrusor Overactivity):
   a. Dose does not exceed 200 units per treatment session as 1 mL (6.7 units) injections across 30 sites into the detrusor.
   b. Average duration of effect: 8 – 12 months
   c. Time to retreat: no sooner than 12 weeks.

Limitations: Botulinum toxin is contraindicated in patients with overactive bladder who have a urinary tract infection or with detrusor overactivity associated with a neurologic condition who have urinary retention.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 400 units over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed for Overactive Bladder 100 units per treatment session and for Urinary Incontinence 200 units per treatment session.

OFF-LABEL INDICATIONS

Based upon our criteria and review of the peer-reviewed literature, OnabotulinumtoxinA (ONA; Botox), Abobotulinum toxin A (ABO; Dysport), Incobotulinum toxin A (INCO; Xeomin), DaxibotulinumtoxinA-lanm (Daxxify), and RimabotulinumtoxinB (Myobloc) have been medically proven effective and is considered **medically appropriate** for the following **off-label** indications when other treatments or interventions have been unsuccessful or are contraindicated.

I. Anal Fissure, Chronic: (Off-Label)

A. Initial request:

1. Diagnosis of chronic anal fissure **AND**
2. Patient must be 18 years of age or older **AND**
3. Prescribed in consultation with a gastroenterologist or colorectal surgeon **AND**
4. Must have failure of an adequate trial of nitroglycerin 0.2% to 0.4% ointment or topical calcium channel blocker (such as nifedipine or diltiazem) in addition to supportive measures (fiber, sitz bath, topical analgesic, stool softeners/laxatives) unless contraindicated or serious side effects experienced.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 100 units total
b. Average dose: 5 to 100 units
c. Reinjection for recurrence: at least 12 weeks

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 100 units over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed 100 units per treatment session.

II. Auriculotemporal syndrome / Frey's syndrome: (Off Label)

A rare neurological disorder resulting from damage to or near the parotid glands responsible for making saliva, and from damage to the auriculotemporal nerve often from surgery (i.e., parotidectomy)

A. Initial request:

1. Diagnosis of auriculotemporal syndrome / Frey's syndrome **AND**
2. Patient must be 18 years of age or older **AND**
3. Symptoms of undesirable facial flushing or profuse sweating occurring on the cheek, temple or behind the ears after eating certain foods, which are severe and accompanied by significant disruption in daily activities

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Average dose = 15 to 75 units
b. Average duration of effect / time to retreat: 12 weeks

B. Recertification
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 400 units over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed 400 units per treatment session.

III. Esophageal Achalasia (e.g., Nutcracker esophagus) (off-label)
Achalasia is characterized by a failure in relaxation of the lower esophageal sphincter with swallowing and by a lack of esophageal peristalsis in the distal esophagus.

Treatment of idiopathic, chagastic, previously untreated achalasia and pseudoachalasia.
Improve symptoms of dysphagia, chest pain and regurgitation in idiopathic achalasia

A. Initial request:
1. Diagnosis of esophageal achalasia based on symptoms and diagnostic testing (upper endoscopy, esophageal manometry, barium swallow, endoscopic ultrasound):
   - Dysphagia to solids and foods
   - Heartburn unresponsive to a trial of at least 4 weeks of proton pump inhibitor therapy
   - Retained food in esophagus on upper endoscopy
   - Unusually increased resistance to passage of an endoscope through the esophagogastric junction **AND**
2. Patient must be 18 years of age or older **AND**
3. Must be prescribed by or in consultation with a gastroenterologist **AND**
4. Member is not a candidate for graded pneumatic dilation or surgical myotomy (high surgical risk due to age or comorbidities)

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 100 units
b. Average dose of 20 to 25 units into each of four quadrants of lower esophageal sphincter
c. Time to retreat; at least 12 weeks

B. Recertification
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 100 units over the past 3 months, **and** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed 100 units per treatment session.

IV. Hirschsprung's Disease and Internal Anal Sphincter Achalasia: (off-label)

A. Initial request:
1. Must have diagnosis of either a, b, or c:
   a. Hirschsprung's Disease (a congenital motor disorder of the gut caused by failure of nerve cells to migrate during intestinal development whereby the colon is unable to relax causing functional obstruction; diagnosis occurs during neonatal period or childhood) Obstructive symptoms (including constipation) after surgery may respond to botulinum toxin when there is no mechanical obstruction and repeat biopsy is normal **OR**
   b. Ultra-short segment Hirschsprung disease (USSHD) established by biopsy **OR**
   c. Internal Anal Sphincter (IAS) Achalasia
      - lack of recto-anal inhibitory reflex on anal manometry
      - rectal biopsy demonstrates the presence of ganglion cells thus excluding Hirschsprung disease
      - clinical presentation similar to functional constipation **AND**
2. Patient must be 18 years of age or older **AND**
3. Prescribed by or in consultation with a gastroenterologist **AND**
4. Must have had an adequate trial of stool softeners and laxatives that have been ineffective, or member has become medication dependent

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 100 units
b. Time to retreat if needed: 12 weeks

B. Recertification
Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 100 units over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**
3. Provider submits treatment plan detailing the quantity (in units) of botulinum toxin to be injected in each muscle site, anticipated frequency of injection, and total dose per visit **AND**
4. Requests for dose increase must not exceed 100 units per treatment session

V. **Other Dystonias:** (off-label)

- Dystonia is a movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements, postures, or both
- Dystonic movements are typically patterned, twisting, and may be tremulous
- Dystonia is often initiated or worsened by voluntary action and associated with overflow muscle activation

A. Initial request:

1. Diagnosis of one of the following:
    a. Hemifacial Spasm **OR**
    b. Isolated Oromandibular Dystonia **OR**
    c. Spasm of pharyngoesophageal segment - Total laryngectomy **OR**
    d. Spastic Dysphonia **AND**
2. Patient must be 18 years of age or older **AND**
3. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist **AND**
4. Documentation detailing diagnosis, symptoms, and functional impairment due to dystonia **AND**
5. For Isolated Oromandibular Dystonia and Spastic Dysphonia:
    a. Failure of a trial of carbidopa/levodopa, trihexyphenidyl or tetrabenazine (or other anticholinergic or dopamine receptor blocker if the use of carbidopa/levodopa, trihexyphenidyl or tetrabenazine is not clinically appropriate) unless contraindicated or serious side effects are experienced **AND**
6. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration.

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Hemifacial Spasm
    - 12 to 15 units, injected in divided doses of 2.5 or 5 units into the affected areas; total of 25 units; subsequent treatments every 3 to 4 months

b. Isolated Oromandibular Dystonia
    - Masseters 25 units, temporalis muscles 20 units. If the effect is not satisfying, in addition the internal pterygoid at a dose of 15 can be tried, subsequent treatments no sooner than every 3 months

c. Spasm of pharyngoesophageal segment – Total laryngectomy
    - 20-100 Units: 1 single injection if using unilaterally or bilaterally, 6-7 divided doses if using unilaterally, subsequent treatments no sooner than every 3 months.

d. Spastic Dysphonia
    - 5 to 20 units injected into both right and left cricothyroid muscles.

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than recommended dose for the condition treated over the past 3 months, **AND** it has been 12 weeks (3 months) since the last injection **AND**

3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed off label recommended dosing per treatment session.

VI. **Sialorrhea** Excessive salivation associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy) (Off Label)

A. Initial request:

1. Diagnosis of sialorrhea, excessive salivation or excessive drooling associated with Parkinson's Disease, cerebral palsy or other neurologic disorder that has been present for at least 3 months **AND**
2. Patient must be 2 years of age or older **AND**
3. Prescribed by or in consultation with neurologist or otolaryngologist **AND**
4. Failure of an adequate trial of anticholinergic agent such as glycopyrrolate, trihexyphenidyl, scopolamine, atropine, or amitriptyline to control symptoms **AND**
5. Persistence of medically significant complications due to excessive drooling such as chronic skin maceration or bacterial / fungal skin infections despite standard topical treatments **AND**
6. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration

Dosing guidelines: Unless otherwise specified, dosing provided is based upon OnabotulinumtoxinA (Botox). Please see Dosing / Conversion Guidelines in the Appendix for the appropriate serotype conversion ratios.

a. Dose does not exceed 100 units
b. Dose calculated based on patient weight and rate of salivation
   Recommended dosage ranges from 1 to 5.5 units per kg distributed into 2 to 4 glands.
   Alternative dosing: 15 units/gland (body weight less than 15 kg), 20 units/gland (body weight 15 to 25 kg), or 25 units/gland (body weight greater than 25 kg)
c. Average duration of effect = 3 to 6 months; Time to retreat: 16 weeks

B. Recertification

Previously approved by plan or has met initial approval criteria:

1. Documentation to support a positive response to treatment **AND**
2. Member has not received more than 100 units over the past 3 months, **AND** it has been 16 weeks (4 months) since the last injection **AND**
3. Provider must submit the number of units to be used in each treatment session, total dose per visit and the anticipated frequency of injection administration **AND**
4. Requests for dose increase must not exceed 100 units per treatment session

All Other Non-FDA Approved Indications:

Requests for Non-FDA approved indications which are not addressed above, and are not listed as an excluded diagnosis below, must meet the Off-Label Use of FDA Approved Drugs Policy Criteria.

Excluded diagnoses/indications for which coverage will NOT be authorized:

- **Cosmetic indications:**
  Treatment of wrinkles {such as wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet)} is considered a cosmetic use and is excluded from coverage due to a lack of functional deficit.

- **Unproven and Not Medically Necessary Diagnoses:**

  The following diagnoses are considered unproven and not medically necessary for **ALL** Botulinum Toxin formulations and are excluded from coverage, unless provider can supply literature supporting its use that meets the plan's current Off Label Use of FDA-Approved drugs policy. (Diagnoses for these on this list are reviewed on a regular basis to ensure status as unproven and not medically necessary.)

  Backache, low back pain
  Cervicogenic headache
  Chronic motor tic disorder (other than blepharospasm, hemifacial spasm, Meige syndrome)
  Congenital esotropia
  Dysphagia
  Epicondylitis
  Essential tremor
  Excessive tear production
  Fibromyalgia
  Granuloma of vocal cords
  Hemorrhoidectomy – postoperative pain
  Injury to oculomotor nerve (acute)
  Larynx closure, adjunct to surgical procedure
  Migraine – first line management
  Organic voice tremor
  Spasm, of pharyngoesophageal segment – total laryngectomy
  Stuttering
  Tardive dyskinesia
  Temporomandibular joint disorder
  Tension-type headaches
  Thoracic outlet syndrome
  Trigeminal neuralgia, idiopathic, refractory
  Urinary and anal sphincter dysfunction / detrusor, pelvic floor and sphincter dyssynergia
  Whiplash injury to neck

Approval Time Periods – Initial and Recertification Reviews:

1. Unless otherwise stated within the individual drug criteria, approval time periods are listed in the table below.

2. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary, Also, ongoing use of the requested product must continue to reflect the current policy's preferred products [Recertification reviews may result in the requirement to try most cost-effective treatment alternatives as they become available (i.e., generic or other guideline-supported treatment options)] and the requested dose must continue to meet FDA approved or off-label/guideline supported dosing.

Line of Business	Medical Initial Approval	Medical Recertification
Commercial / Exchange / Essential Plan (EP) /Medicaid Managed Care (MMC) / Child Health Plus (CHP)/ Dual Eligible Special Needs Plan (D-SNP)	Botulinum Toxins for Chronic Migraine: 6 months (12 weeks) All other indications: 12 months	12 months

Appendix:

A. **CURRENTLY ACCEPTED CONVERSION RATIOS:**

Botulinum Toxin Serotype A

OnabotulinumtoxinA (ONA; Botox), Abobotulinum toxin A (ABO; Dysport) and Incobotulinum toxin A (INCO; Xeomin)

Table 1. Botulinum toxin products and protein content/100 units

Nonproprietary Name	150-kD Protein Content (ng)	Total Protein (150 kD and NAP) Content (ng)	Dose Equivalent Units
Onabotulinumtoxin A	0.73	5.00	1
Incobotulinumtoxin A	0.44	0.44	1
Abobotulinumtoxin A	0.65	0.87	2–3

NAP = nontoxic accessory proteins.

ONA (Botox) and INCO (Xeomin) have comparable efficacies with a 1:1 conversion ratio and have demonstrated therapeutic equivalence in different indications including cervical dystonia and blepharospasm. An ONA (Botox) to ABO (Dysport), a conversion ratio ≤1:3 is currently considered the most appropriate.

Please note, there is currently no data on a conversion rate between Botox and Daxxify

Botulinum Toxin Serotype B
RimabotulinumtoxinB (Myobloc)

The most recent available studies suggest that the current conversion ratio for RimabotulinumtoxinB (Myobloc): OnabotulinumtoxinA (Botox) is 50:1 (Myobloc: Botox).

B. **Spasticity Injection Guidelines:**

Botox Dosing by Muscle for Adult Upper Limb Spasticity

Muscle	Recommended Dose Total Dosage (Number of Sites)
Biceps Brachii	60 Units to 200 Units divided in 2 to 4 sites
Brachioradialis	45 Units to 75 Units divided in 1 to 2 sites
Brachialis	30 Units to 50 Units divided in 1 to 2 sites
Pronator Teres	15 Units to 25 Units in 1 site
Pronator Quadratus	10 Units to 50 Units in 1 site
Flexor Carpi Radialis	12.5 Units to 50 Units in 1 site
Flexor Carpi Ulnaris	12.5 Units to 50 Units in 1 site
Flexor Digitorum Profundus	30 Units to 50 Units in 1 site
Flexor Digitorum Sublimis	30 Units to 50 Units in 1 site
Lumbricals/Interossei	5 Units to 10 Units in 1 site
Adductor Pollicis	20 Units in 1 site
Flexor Pollicis Longus	20 Units in 1 site
Flexor pollicis brevis/ Opponens pollicis	5 Units to 25 Units in 1 site

Botox Dosing by Muscle for Adult Lower Limb Spasticity

Muscle	Recommended Dose Total Dosage (Number of Sites)
Gastrocnemius medial head	75 Units divided in 3 sites
Gastrocnemius medial head	75 Units divided in 3 sites
Soleus	75 Units divided in 3 sites
Tibialis Posterior	75 Units divided in 3 sites
Flexor hallucis longus	50 Units divided in 2 sites
Flexor digitorum longus	50 Units divided in 2 sites

Botox Dosing by Muscle for Pediatric Upper Limb Spasticity

Muscle	Recommended Dose and Number of Sites
Biceps Brachii	1.5 Units/kg to 3 Units/kg divided in 4 sites
Brachialis	1 Unit/kg to 2 Units/kg divided in 2 sites
Brachialis	0.5 Units/kg to 1 Unit/kg divided in 2 sites
Flexor Carpi Radialis	1 Unit/kg to 2 Units/kg divided in 2 sites
Flexor Carpi Ulnaris	1 Unit/kg to 2 Units/kg divided in 2 sites
Flexor Digitorum Profundus	0.5 Units/kg to 1 Unit/kg divided in 2 sites
Flexor Digitorum Sublimis	0.5 Units/kg to 1 Unit/kg divided in 2 sites

Botox Doing by Muscle for Pediatric Lower Limb Spasticity

Muscle	Recommended Dose Total Dosage (Number of Sites)
Gastrocnemius medial head	1 Unit/kg to 2 Units/kg divided in 2 sites
Gastrocnemius lateral head	1 Unit/kg to 2 Units/kg divided in 2 sites
Soleus	1 Unit/kg to 2 Units/kg divided in 2 sites
Tibialis Posterior	1 Unit/kg to 2 Units/kg divided in 2 sites

POLICY GUIDELINES:

1. This policy is not applicable to the Medicare Advantage line of business; therefore, prior authorization of the medications listed in this policy does not apply to these lines of business.
2. For treatment of diagnoses not found within this policy – Refer to the Off-label use of FDA Approved Drugs policy for the relevant line of business.
3. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
4. Supportive documentation of previous drug use must be submitted for any criterion that requires the trial of a preferred agent if the preferred drug is not found in claims history.
    a. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    b. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    c. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    d. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    e. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    f. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    g. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
5. Unless otherwise stated within the individual drug criteria, approval time periods are listed in the table above.
6. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, and imaging.

- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.

7. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
8. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
9. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
10. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

UPDATES:

Date	Revision
03/06/2025	Revised
02/01/2025	Revised; P&T Committee reviewed and approved Chronic Migraine criteria changes on 11/21/2024
09/13/2024	Revised
08/15/2024	P&T Committee Review & Approval
06/20/2024	Revised
03/15/2024	Revised
12/01/2023	Revised
9/28/2023	Revised
8/24/2023	Reviewed and approved P&T Committee
8/2023	Reviewed
9/2022	P&T Committee Approval
7/2022	Revised
12/2021	Revised
9/2021	Reviewed / P&T Committee Approval
08/2021	Review / Revision
11/2020	Revision & P&T Committee Approval
3/30/2020	Revision
2/10/2020	Revision
11/15/2019	Revision
9/23/2019	Revised
09/6/2018	Created

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