Clinical Policy: OnabotulinumtoxinA (Botox) for Chronic Migraine

Reference Number: WA.PHAR.232
Effective Date: 07.01.16
Last Review Date: 03.18.25
Line of Business: HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

OnabotulinumtoxinA (Botox®) is an acetylcholine release inhibitor and a neuromuscular blocking agent.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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This policy is to be used for the indication of Chronic Migraines, for all other indications refer to CP.PHAR.232 Clinical Policy: OnabotulinumtoxinA (Botox).
It is the policy of health plans affiliated with Centene Corporation® that Botox is **medically necessary for the use of Chronic Migraine** when one of the following criteria is met:

I. Initial Approval Criteria

A. Chronic Migraine (must meet all)**:**

1. Diagnosis of chronic migraine (defined as ≥ 15 headache days per month of which ≥ 8 days are with migraine) ;
2. Age ≥ 18 years;
3. Failure of at least three of the following pharmacological prophylaxis therapies, from two different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, or c):
   a. Antiepileptics (e.g., divalproex sodium, sodium valproate, topiramate);
   b. Beta-blockers (e.g., metoprolol, propranolol, timolol);
   c. Antidepressants (e.g., amitriptyline, venlafaxine);

4. The condition is appropriately managed for medication overuse. (must meet all):
    a. Botox is not prescribed concurrently with other botulinum toxin products;
    b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
    c. Treatment plan details number of Units per indication and treatment session;
    d. Dose does not exceed 155 Units per treatment session;
    e. Does not exceed five treatment cycles.

Approval duration:
Medicaid/HIM – 12 months

II. Continued Approval

A. Chronic Migraine (must meet all):

1. Member meets one of the following (a or b):
    a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
    b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. If receipt of ≥ 2 Botox treatment sessions, member has experienced and maintained a 50% reduction in monthly migraine headache frequency from baseline;
3. The condition is appropriately managed for medication overuse. (must meet all):
    a. Botox is not prescribed concurrently with other botulinum toxin products;
    b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
    c. Treatment plan details number of Units per indication and treatment session;
    d. Dose does not exceed 155 Units per treatment session;
    e. Does not exceed five treatment cycles.

Approval duration:
Medicaid/HIM – 12 months

III. For all other diagnoses/Indications, refer to CP.PHAR.232 Clinical Policy: OnabotulinumtoxinA (Botox)

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CD: cervical dystonia
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
HD: Hirschsprung disease
IAS: internal anal sphincter
MS: multiple sclerosis
NDO: neurogenic detrusor overactivity
OAB: overactive bladder
OMD: oromandibular dystonia
SCI: spinal cord injury
SCM: sternocleidomastoid
UE: upper extremity

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Chronic migraine		
Examples of oral migraine preventive therapies - • Anticonvulsants: divalproex (Depakote®), topiramate (Topamax®) • Beta blockers: propranolol (Inderal®), metoprolol (Lopressor®), timolol • Antidepressants/tricyclic antidepressants: amitriptyline (Elavil®), venlafaxine (Effexor®)	*Refer to prescribing information for dosing regimens.*	*Refer to prescribing information*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications and Boxed Warnings
- Contraindication(s):
  - Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation
  - Infection at the proposed injection site
  - Intradetrusor injections: urinary tract infection or urinary retention
- Boxed warning(s): distant spread of toxin effect

Appendix D: Botulinum Toxin Product Interchangeability
- Potency Units of Botox are not interchangeable with other botulinum toxin product preparations (e.g., Dysport®, Myobloc®, Xeomin®).

Appendix E: Guideline Support for Botulinum Toxin Use

Indication	Guideline
Migraine prevention	American Academy of Neurology and the American Headache Society (Neurology 2012, Headache 2021)

**American Academy of Neurology (AAN) classifies Botox use for hemifacial spasm and motor tics as category C, and notes that data are inadequate to make a recommendation for lower limb dystonia. All other AAN Botox recommendations above are classified as category B - probably effective.*
***Policy criteria requiring failure of oral medication for dystonias are limited to dystonias affecting the limbs (see Cloud and Jinnah, 2010).*

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Adults: chronic migraine	Up to 5 Units IM per injection across up to 7 head/neck muscles for a total of 155 - 195 Units per treatment session.	

VI. Product Availability

Vials: 100 Units, 200 Units

VII. References

1. Washington State Health Care Authority Health Technology Clinical Committee Findings and Decision for Treatment of chronic migraine and chronic tension-type headache, Available at https://www.hca.wa.gov/assets/program/chronic-migraine-final-findings-decision-revised-20220520.pdf, accessed March 11, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0585	Injection, onabotulinumtoxinA, 1 unit

Reviews, Revisions, and Approvals	Date	P&T or QIC Approval Date
2Q 2020 annual review: CP criteria incorporated under upper/lower limb spasticity; rehabilitation specialist incorporated under physiatrist; previous (last 12 weeks) or concurrent toxin product use restriction added to all initial/continuation criteria; off-label uses limited to those with guideline-based support (laryngeal dystonia, OMD, UE dystonia/essential tremor, HD, IAD, esophageal achalasia - Appendix E); dosing updated per package insert/off-label literature (Section V); initial approval duration shortened to 12 weeks for esophageal achalasia and CCB trial added for chronic anal fissure per guidelines; same-visit treatment for multiple indications is limited to upper/lower limb spasticity (Section III); references reviewed and updated.	03.02.20	05.20
For chronic migraine, clarified requirement for use of two oral migraine preventative therapies that are from different therapeutic classes. RT4: updated FDA approved indication for spasticity which now includes cerebral palsy for lower limb spasticity in pediatric patients.	07.14.20	11.20

Reviews, Revisions, and Approvals	Date	P&T or QIC Approval Date
Per October SDC and prior clinical guidance, added the following redirections: Xeomin and Dysport for cervical dystonia and limb spasticity, Xeomin for blepharospasm. Ad hoc change: Per-injection dosing limitation removed to support individualized treatment for the following indications: OAB/urinary incontinence, chronic migraine, UE/LE, CD, primary axillary hyperhidrosis; CD continuation pediatric dosing is corrected to reflect 300 rather than 340 Units; for esophageal achalasia continuation criteria, prior toxin therapy is corrected to reflect 12 rather than 24 weeks with addition of a 24-week treatment session limitation after 2 or more sessions.	10.08.20	
2Q 2021 annual review: spasticity step therapy criteria updated; treatment plan requirement detailing number of Units per site and treatment session is changed to per indication and treatment session; treatment of multiple indications restriction removed and replaced with total treatment dose limitation (Section III); added duration of trial needed for anal fissure; RT4: added newly FDA-approved diagnosis of pediatric detrusor overactivity; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	02.16.21	05.21
Ad Hoc update: max dose for Xeomin in Appendix B updated to 300 mg for CD per PI.	07.26.21	
Clarified continued approval duration for esophageal achalasia for 2nd dose vs beyond.	09.23.21	
2Q 2022 annual review: no significant changes; WCG.CP.PHAR.232 policy retired per SDC recommendation; removal of required 2 week trial duration of nitroglycerin and nifedipine/diltiazem for chronic anal fissures; adjusted Xeomin blepharospasm dose in Appendix B from 25 units to 50 units per PI; removal of the statement "**The treatment of hyperhidrosis is a benefit exclusion for HIM;*" references reviewed and updated.	02.07.22	05.22
Spelling corrected for "medial" for strabismus in section I and V.	05.05.22	
Added criteria for concurrent use with CGRP therapy requiring supportive evidence from published studies or clinical practice guidelines, positive response with CGRP monotherapy, and continued migraine burden. Template changes applied to other diagnoses/indications and continued therapy section.	07.19.22	11.22
Ad Hoc update: max dose for chronic anal fissures updated from 25 units to 100 units per treatment session per ACG guidelines; updated limitation of use for hyperhidrosis per PI.	01.18.23	
2Q 2023 annual review: for chronic anal fissure, revised maximum dosing allowance up to 25 units for initial therapy and 100 units for continued therapy per treatment session; added chronic sialorrhea off-	02.21.23	05.23

Reviews, Revisions, and Approvals	Date	P&T or QIC Approval Date
label indication; references reviewed and updated. Per February SDC: removed Dysport and/or Xeomin redirection requirement for upper and lower limp spasticity, cervical dystonia, blepharospasm, overactive bladder, chronic migraine, and axillary hyperhidrosis; for Overactive Bladder, updated criteria for adults to require use of two anticholinergic agents or one oral beta-3 agonist medication (previously both were required); changed Medicaid and HIM approval durations to 12 months.		
Revised max dose for OMD from "25 units" to standard language "Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use and member age (prescriber must submit supporting evidence; Units per treatment session does not exceed the lower of 10 Units/kg body weight or 340 Units for pediatrics, or 400 Units for adults)."	08.25.23	11.23
2Q 2024 annual review: for chronic sialorrhea changed age from ≥ 18 years to ≥ 21 months; references reviewed and updated.	01.18.24	05.24
Per SDC, for OAB, revised criteria for adults to require use of one anticholinergic agent (previously two anticholinergics were required).	05.15.24	06.24
For chronic migraine continuation therapy requests, modified maximum dosing to allow up to 195 units per treatment session.	10.01.24	
A WA specific policy was adopted from the CP.PHAR.232 Clinical Policy: OnabotulinumtoxinA (Botox) criteria. • Clarification added to policy criteria that this policy is only to be used for indication of Chronic Migraine. All other indications are to refer to CP.PHAR.232 Clinical Policy: OnabotulinumtoxinA (Botox) • All approval criteria, appendices, dosage and administration and references for indications other than Chronic Migraine have been removed. • Updated initial and continuation approval criteria to reflect limitations of coverage published by HCA's Health Technology Clinical Committee (HTCC). • HTCC guidelines for treatment of chronic migraine added to references.	03.11.25	03.18.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.