BOTOX® Injection (Onabotulinumtoxin A) for Chronic Migraine Headaches

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr go to “Comunicados a Proveedores”, and click “Cartas Circulares”.

Medical Policy: MP-RX-01-11
Original Effective Date: March 24, 2011
Revised: June 23, 2017
Next Revision: June, 2018

Related Policies:
- MP-RX-04-10 Botulinum Toxins (Type A and Type B) (Botox®, Dysport™, Myobloc®, Xeomin®)

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract, unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion, and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

The U.S. Food and Drug Administration (FDA) approved Botox® injection (OnabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine in October 2010. Migraine is a highly prevalent disorder characterized by attacks of moderate to severe throbbing headaches that are often unilateral in location, worsened by physical activity, and associated with nausea and/or vomiting, photophobia and phonophobia. (American Headache Society 2015).

To diagnose migraine, it is necessary to exclude secondary headache causes and then determine whether the patient has any other coexisting primary headache (e.g., tension-type headache, hemicrania continua).

Chronic migraine (CM) is a headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headaches on at least 8 days per month. (International Headache Society 2016).

When used in the treatment of chronic migraines, Botox® is administered as multiple injections divided among 7 head and neck muscles to try to dull future headache symptoms. Botox® has not been shown to work for the treatment of migraine headaches that occur 14 days or less per month, or for other forms of headaches. The most common adverse reactions reported by patients being treated for chronic migraine were neck pain, headache, muscular weakness and eyelid ptosis; they were mild to moderate in severity, and generally did not require discontinuance of prophylaxis.

Several weeks may be required for maximum headache relief following onabotulinumtoxinA injections. The manufacturer recommended re-treatment schedule is every 12 weeks. Repeat injections generally are needed after 3-4 months, although duration of response varies.
COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits, and coverage.

INDICATIONS
I. For the evaluation of medical necessity of Botox® Injections in Classicare Line of Business (LOB) Members with Chronic Migraine, please refer to the following LCD:

   CMS Local Coverage Determination (LCD) for Botulinum Toxins (L33274).

II. For Commercial Line of Business (LOB) Members; Medical Card System, Inc., (MCS) will consider the administration of Botox® Injection (onabotulinumtoxinA), for prophylactic (preventive) treatment of headaches in adults with Chronic Migraine medically necessary when All of the following criteria are met:

   1. The member must have a diagnosis of chronic migraine (history of suffering from migraine headaches on 15 or more days per month with headaches lasting four (4) hours a day or longer).

   2. Member must be in a treatment for migraines headaches by a neurologist.

   3. There must be a documentation stating that the traditional methods of treatment have been tried and proven unsuccessful. The documentation must demonstrate the following:

      • Documentation of failed trials of at least three (3) therapeutic groups of preventive medications, where at least one of them is a first line agent, such as propranolol, amitriptyline, topiramate or valproic acid and its derivatives (used in men). There must be documentation showing that these medications were titrated to the maximum tolerated doses.

      • The trial period of each therapeutic group should have been at least three (3) months with the appropriate therapeutic doses.

      • Should a member have a contraindication to a specific treatment or medication group, this is considered as a treatment failure, and must be documented within the progress notes.

   4. Botox® Injection “therapy” should be recommended, monitored and administered by the treating neurologist.
5. For continuation of botulinum toxin therapy the member must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin.

LIMITATIONS

1. MCS will only cover ONE (1) injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as, a single limb, eyelid, face, neck, etc.

2. MCS WILL NOT cover additional injections of botulinum toxin if treatment failure occurs after two (2) consecutive injections, using maximum dose for the size of the muscle.

3. Treatment using botulinum toxins is considered cosmetic when used to improve appearance – for example, as a treatment to smooth out wrinkles – and therefore is NOT covered.

4. To provide coverage for treatment, the medical record must support the specific symptoms and parameters mentioned under the indications section.

5. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month).

6. Botulinum toxin re-treatment is no more frequent than every 12 weeks.

7. MCS WILL NOT consider Botox® therapy as a first line management for migraine headaches due to insufficient literature to support clinical effectiveness.

CONTRAINDICATIONS

1. Inflammation or infection at the site of injection is present. - Administration of onabotulinumtoxinA (Botox®) is contraindicated in the presence of infection at the proposed injection site(s).

2. Allergy to drug was observed - OnabotulinumtoxinA (Botox®) is contraindicated in patients who are hypersensitive to any botulinum toxin preparation or to any of the components in the formulation (e.g., albumin).

3. When administered with drugs such as aminoglycoside antibiotics or other drugs that alter neuromuscular transmission.

4. When administered with muscle relaxants in muscles with excessive weakness or muscle atrophy.
WARNINGS AND PRECAUTIONS (\* = Indicates Black Box Warning)

1. \*Distant Spread of Toxin Effect – Botulism.

2. Lack of Interchangeability between Botulinum Toxin Products - They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of Botox® cannot be compared to nor converted into units of any other botulinum toxin products.

3. Serious adverse reactions including weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received Botox® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of Botox® to the site of the injection and/or adjacent structures. The safety and effectiveness of Botox® for unapproved uses have not been established.

4. OnabotulinumtoxinA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

5. Caution should be exercised when Onabotulinumtoxin A is administered to a nursing woman.

6. Safety and effectiveness in patients below the age of 18 years have not been established when Botox® is administered.

7. The recommended dosage and frequency of administration for onabotulinumtoxinA should not be exceeded – the safety and efficacy of higher dosages have not been evaluated.

CODING INFORMATION

CPT Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)</td>
</tr>
</tbody>
</table>


HCPCS CODES (List may not be all inclusive)

<table>
<thead>
<tr>
<th>HCPCS® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0585</td>
<td>Injection, onabotulinumtoxinA, 1 unit</td>
</tr>
</tbody>
</table>

2017 HCPCS LEVEL II Professional Edition® (American Medical Association)
ICD-10-CM Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD-10-CM® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>G43.711</td>
<td>Chronic migraine without aura, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.719</td>
<td>Chronic migraine without aura, intractable, without status migrainosus</td>
</tr>
</tbody>
</table>


REFERENCES


This document is designated for informational purposes only and is not an authorization, or an explanation of benefits (EOB), or a contract. Medical technology is constantly changing and we reserve the right to review and update our policies periodically.


migraine-in-adults?source=mls&search=when+a+pain+reliever+does+not+control+migraine&selectedTitle=3%7E150&sectionRank=5&anchor=H13436872#H13436872


POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 24, 2011</td>
<td>Origination of Policy</td>
<td></td>
</tr>
<tr>
<td>March 16, 2012</td>
<td>Yearly Review</td>
<td></td>
</tr>
<tr>
<td>May 16, 2013</td>
<td>Reviewed</td>
<td>References updated. ALL changes from February 7, 2013 were reviewed by the Medical Card System (MCS) Medical Advisory Committee (MAC) on May 16, 2013. Final changes that were approved are documented under February 7, 2013.</td>
</tr>
<tr>
<td>February 21, 2014</td>
<td>Revised</td>
<td>To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.</td>
</tr>
<tr>
<td>March 18, 2014</td>
<td>Revised</td>
<td>References updated. To the Coding section: New CPT New code CPT 64616 was added to the Policy. To the References section: Reference # 10 was added to the Policy.</td>
</tr>
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</table>
| April 14, 2015   | Revised  | References updated. To the Title: Word “Chronic” was added to the Title for make a reference in the Type of Migraine contemplated and described into this Medical Policy. To the Description Section: New information of “Migraine” was added from: American Academy of Neurology (AAN). Practice parameter:

This information is still current.

2. New Concept of "Chronic Migraine" was added from:
   International Headache Society. Headache Classification Committee of
   the International Headache Society (IHS). The International
   Classification of Headache Disorders, 3rd edition (beta version). 2013

To the Indications Section:
1. Indications were separated in two different sections; Section I for
   Classicare LOB and Section II for Commercial LOB.
2. Phrase “with the appropriate therapeutic doses” was added to the
   indication #5 as discussed at requested by the MAC April, 14 2015.

To the Limitations Section:
1. Limitation #3 was unified with part of the limitation #8 and then
   deleted from the medical policy as requested MAC April 14, 2015.
2. Limitation #5 was deleted from the policy as requested by Dra.
   Wheeler on April, 2015.

New WARNINGS AND PRECAUTIONS Section was added to the Policy.

To the Coding Information Section:
CPTs codes (64612 and 64616) were deleted from the Policy as informed
in the MAC April 14, 2015.

To the References Section:
New References (#1, 2, 3, 6, 9, 12, 13, 18, 20, 21, 22, 25, 27, and 28) were
added to the Policy.

November 23, 2015 Revised

To the coding section:
• Eliminate ICD-9 codes since they are no longer valid for
diagnosis classification.
• Add new section of ICD-10 codes which are the valid diagnosis
classification since October 1, 2015.

May 5, 2016 Revised

Embedded link for related policy MP-RX-04-10 Botulinum Toxins (Type A
and Type B) (Botox®, Dysport™, Myobloc®, Xeomin®).

To the Description Section:
1. To 2nd paragraph: Deleted citation “(American Academy of Neurology
2000)” to add a second example of coexisting primary headaches:
“hemicrania continua”.
2. To 4th paragraph, 1st sentence: Deleted phrase “given approximately
every 12 weeks: and replaced with word “administered”. Phrase
“around the” was replaced by phrase “divided among 7”. Also added
word “muscles” to sentence.
3. To 4th paragraph, 2nd sentence: Deleted word “and”; added: “muscular
weakness and eyelid ptosis; they were mild to moderate in severity,
and generally did not require discontinuance of prophylaxis.”
4. Deleted 5th paragraph and in substitution added new paragraph which
states: “Several weeks may be required for maximum headache relief
following onabotulinumtoxinA injections. The manufacturer recommended re-treatment schedule is every 12 weeks. Repeat injections generally are needed after 3-4 months, although duration of response varies.”

To the Indications Section:
1. To Indication I: Revised wording order and embedded link to current LCD in reference.
2. To Indication II: Revised wording order in opening statement.
   a. To indication #1: revised wording to phrase to the following: “history of suffering from migraine headaches”.
   b. To indication #3, 1st point: corrected medication name “Propanodol” to “propranolol”.
   c. To indication #3, 2nd point: term “derivate” was replaced by “derivatives”.
   d. To indication #4: Included term “therapy” to sentence.
   e. To indication #5: revised term “Botulism” and substituted to term “botulinum”.

To the Limitations Section:
1. To limitation #1: Revised emphasis on 1st sentence. Removed parentheses to 2nd sentence.
2. To limitation #3: revised and rephrased sentence as follows: Treatment using botulinum toxins is considered cosmetic when used to improve appearance – for example, as a treatment to smooth out wrinkles- and therefore is NOT covered.
3. Rephrased limitation #7 to read as follows: “MCS WILL NOT consider Botox® therapy as a first line management for migraine headaches due to its insufficient literature to support clinical effectiveness.

To the Contraindications section:
1. To contraindication #1: Revised word “presented” to word “present”.
2. To contraindication #3: Revised sentence as follows: “When administered with drugs such as aminoglycoside antibiotics or other drugs that alter neuromuscular transmission.”

To the Warnings and Precautions Section:
1. Added symbol for Black Box Warning with legend in title.
2. Added Black Box Warning symbol and word “distant” to indication #1.
3. To indication #2: replaced term “botulinum toxin” to “Botox”.
4. Added new indication #3: “Serious adverse reactions including weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received Botox® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of Botox® to the site of the injection and/or adjacent structures. The safety and effectiveness of Botox for unapproved uses have not been established.”
5. Added new contraindication #7: “The recommended dosage and frequency of administration for onabotulinumtoxinA should not be exceeded – the safety and efficacy of higher dosages have not been evaluated.”
1. Information unnecessary was deleted from Precaution #1:
   - A boxed warning in the labeling of onabotulinumtoxinA products includes post-marketing reports of the distant spread of botulinum toxic effects that have resulted in symptoms suggestive of systemic botulism (including respiratory compromise and death) after the use of botulinum toxins types A and B. These effects have been seen in patients who received the medication for a variety of conditions and a wide range of doses.

2. Information unnecessary was deleted from Precaution #2:
   - The potency units of Botox® are specific to the preparation and assay method utilized.

To References Section:

1. References #13, 15 and 29 were deleted to the Policy.

2. New References #31 and 32 were added to the Policy.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member’s plan in effect as of the date services are rendered. Medical Card System, Inc. (MCS) medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Medical Card System, Inc. (MCS) reserves the right to review and update its medical policies at its discretion. Medical Card System, Inc (MCS) medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.