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: April 14, 2015
Next Revision: March 2016

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 (Onabotulinumtoxin A) 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). (American Academy of Neurology 2000).

Chronic Migraine is a Headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. (International Headache Society 2013).

When is used in the treatment of chronic migraines; Botox® is given approximately every 12 weeks as multiple injections around the head and neck 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 and headache.

Onabotulinumtoxin A, marketed as Botox® has a Boxed Warning that states the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening.
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 in members of Classicare Line of Business (LOB) with Chronic Migraines, please refer to the following LCD: Local Coverage Determination (LCD) for Botulinum Toxins (L29103).

II. For members of Commercial Line of Business (LOB); Medical Card System, Inc., (MCS) will consider medically necessary the administration of BOTOX® Injection (Onabotulinumtoxin A), for prophylactic (preventive) treatment of headaches in adults with Chronic Migraines when All of the following criterion are met:

1. The member must have a diagnosis of chronic migraines (history of migraine suffering from 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 Propanodol, Amitriptyline, Topiramate or Valproic acid and its derivate. There must be documentation showing that these medications were titrated to the maximum tolerated 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.

   • The trial period of each therapeutic group should have been at least three (3) months with the appropriate therapeutic doses.
4. Botox® Injection should be recommended, monitored and administered by the treating neurologist.

5. For continuation of Botulism 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** covers 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 of wrinkles using Botulinum toxins is considered to be cosmetic, and **NOT** covered.

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

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

6. The recommended re-treatment schedule is every 12 weeks.

7. **MCS WILL NOT** considers the following medical criteria for Botox Therapy due to insufficient literature to support clinical effectiveness: As a first line management for migraine headaches.

CONTRAINDICATIONS

1. Inflammation or infection at the site of injection is presented. - Administration of Onabotulinumtoxin A BOTOX is contraindicated in the presence of infection at the proposed injection site(s).

2. Allergy to drug was observed - Onabotulinumtoxin A 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 is administered with some drugs like aminoglycosides 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

1. **Black Box Warning:**
   Spread of Toxin Effect- 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. **Lack of Interchangeability between Botulinum Toxin Products.** - The potency Units of BOTOX are specific to the preparation and assay method utilized. 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. **Onabotulinumtoxin A** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

5. Safety and effectiveness in patients below the age of 18 years have not been established when BOTOX is administered.

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>

ICD-9 CM® Diagnosis Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD-9 CM® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>346.71</td>
<td>Chronic migraine without aura, with intractable migraine, so stated, <strong>without</strong> mention of status migrainosus</td>
</tr>
<tr>
<td>346.73</td>
<td>Chronic migraine without aura, with intractable migraine, so stated, <strong>with</strong> status migrainosus</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, onabotulinumtoxinaA, 1 unit</td>
</tr>
</tbody>
</table>


ICD-10 Codes (Preview Draft)

In preparation for changes in the coding systems form ICD-9 to ICD-10, this policy includes a sample list of ICD-10 codes for your reference. These codes may become subject to changes or modifications since they will be in effect on **October 1, 2015**.

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

REFERENCES


15. ECRI Institute. Botulinum Toxin for Prevention and Treatment of Migraine. Published: 02/27/2008. Updated 05/28/2008. Searched March 16, 2015. This document has been archived by ECRI Institute and is no longer available. Available at URL address: https://www.ecri.org/Pages/SearchResults.aspx?k=Botulinum%20Toxin%20for%20Prevention%20and%20Treatment%20of%20Migraine&mo=true


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>
</tbody>
</table>
To Coding Information: Added new CPT Code 64615 & Notes 1 & 2. |
| February 7, 2013 | Revised  | 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. |
| May 16, 2013   | Reviewed   | To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy. |
| February 21, 2014 | Revised  | 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. |
| March 18, 2014 | 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:  
1. New information of “Migraine” was added from:  
2. New Concept of “Chronic Migraine” was added from:  
International Headache Society. Headache Classification Committee of the International Headache Society (HIS). 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.

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.