Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefit plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Botulinum Toxin Injection for chemo-denervation

PRIOR AUTHORIZATION: Not required.

POLICY: The determination of medical necessity for the use of botulinum toxin injections is always made on a case-by-case basis. Botulinum toxin injections utilizing botulinum toxin-A may be considered medically necessary for the treatment of patients presenting with the following conditions:

- Spasticity
- Cervical dystonia (spasmodic torticollis)
- Focal dystonia
- Blepharospasm
- Laryngeal dystonia/spasm
- Hemi-facial spasm
- Upper extremity essential tremor
- Upper or lower extremity focal dystonia
- Axillary hyperhidrosis
- Chronic migraine headaches occurring many times each month.
- Anal fissures failing 2 months of conservative treatment

Repeat botulinum toxin injections are typically not indicated unless there is documented evidence of functional improvement, clinically meaningful reduction in pain, reduction of the need for treatment of musculoskeletal complications, facilitating ease of care, and/or for improving the general appearance, mobility and/or phonation in patients presenting with spasticity or dystonia for a minimum of eight (8) weeks following the injection(s). Based on the typical response of properly administered botulinum toxin injections, injections are typically performed every three (3) months. Injections performed on a more frequent basis may be considered not medically necessary. In addition, more than four (4) injections per region per year are considered not medically necessary.

The use of electrical muscle stimulation (95873) or needle electromyography (95874) may be considered medically necessary for guidance in conjunction with botulinum toxin injections (chemodenervation).

Based on the limited evidence of efficacy and the increased side-effects profile, the use of botulinum toxin type-B may be considered medically necessary ONLY in the management of patients who have become non-responsive to botulinum toxin type-A.
In all other conditions, the use of botulinum toxin injections may be considered NOT medically necessary. Conditions for which botulinum toxin injections are considered NOT medically necessary include, but are not limited to:

- Myofascial trigger points
- Myofascial tender points (Myofascitis or Fibromyositis or Fibromyalgia)
- Neck Pain
- Low Back Pain.

SWHP also considers the use botulinum toxin injections not medically necessary for cosmetic purposes as well as all other indications not explicitly stated as covered in this policy.

OVERVIEW: Botulinum toxin injections are intramuscular injections of botulinum neurotoxins which are purified forms of Clostridium botulinum exotoxins. The botulinum toxin acts by blocking release of acetylcholine at the neuromuscular junction thus reducing the tone of overactive muscles. There are several commercial products (consisting of either serotype-A or serotype-B) currently available for use. Each differs in its unit potency, side effects, and duration of action. The clinical goals for utilizing botulinum toxin injections are to result in a temporary chemodenervation of the effected muscle at the neuromuscular junction thus: reducing pain or increasing comfort, improving function, preventing or treating musculoskeletal complications, facilitating ease of care, and/or for improving the general appearance, mobility and/or phonation in patients presenting with spasticity or dystonia.

The Food and Drug Administration (FDA) has approved Botox injection (onabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine. Chronic migraine is defined as having a history of migraine and experiencing a headache on most days of the month. Migraine headaches are described as an intense pulsing or throbbing pain in one area of the head. The headaches are often accompanied by nausea, vomiting, and sensitivity to light and sound. To treat chronic migraines, Botox is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future symptoms. Botox is not approved to treat migraine headaches that occur 14 days or less per month, or for other forms of headache.

Botulinum toxin injections are not without risk, and can expose patients to potential serious complications. As a result, certain patients may not be optimal candidates for botulinum toxin injections. Optimal candidates include those:

- with a limited number of muscles that need treatment;
- who do not have a fixed contracture.

MANDATES: none

CODES:

Important note: CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

<table>
<thead>
<tr>
<th>CPT Codes:</th>
<th>31513; 31570; 31571; 43201; 43236; 64612; 64613; 64614; 64650; 64653; 67345; 95873; 95874</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT Not Covered:</td>
<td>86609, 64642 - 64645</td>
</tr>
</tbody>
</table>
### MEDICAL COVERAGE POLICY

**SERVICE:** Botulinum Toxin Injection for Chemodenervation

<table>
<thead>
<tr>
<th>Policy Number</th>
<th>011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date</td>
<td>08/11/2015</td>
</tr>
<tr>
<td>Last Review</td>
<td>07/02/2015</td>
</tr>
<tr>
<td>Next Review Date</td>
<td>07/02/2016</td>
</tr>
</tbody>
</table>

**HCPCS codes:** JO585; JO586; S2340; S2341; JO587

**ICD9 codes:**
- 300.89, 333.1, 333.2, 333.6, 333.71, 333.72, 333.79, 333.81, 333.83, 333.84, 333.85, 334.1, 340, 341.0-341.9, 342.10-342.12, 343.0-343.9, 344.00-344.5, 351.8, 438.20-438.53, 438.89, 478.75, 527.7, 530.0, 530.6, 553.3, 564.6, 705.21, 751.3, 784.42

**ICD10 codes:**
- G11.4
- G24.02
- G24.1
- G24.3
- G24.4
- G24.5
- G24.8
- G24.9
- G25.0 - G25.2
- G25.3
- G25.89
- G35
- G36.0, G37.0, G37.3, G37.5, G37.9
- G37.1, G37.2, G37.8
- G37.3
- G43.011
- G43.019
- G43.111
- G43.119
- G43.709, G43.719, G43.701, G43.711
- G51.2, G51.4, G51.8
- G80.0 - G80.9
- G80.3
- G81.10 - G81.14
- G82.20 - G82.22, FG82.50, G82.20, G83.0, G83.10 - G83.34
- H49.881 - H49.889
- H50.00 - H50.08
- H50.10 - H50.18
- H50.30 - H50.34
- H50.40 - H50.43
- H50.50 - H50.55
- H50.60 - H50.69
- H50.81, H50.89
- H51.0 - H51.8
- H51.9
- I69.30 - I69.959
- I69.961 - I69.998
- J38.5
- J38.7
- J39.0 - J39.2
- K11.7, R68.2
- K22.2K
- K44.9
- K59.4
- K60.0 - K60.2
  - K60.1 Chronic anal fissure
MEDICAL COVERAGE POLICY
SERVICE: Botulinum Toxin Injection for Chemodenervation
Policy Number: 011
Effective Date: 08/11/2015
Last Review: 07/02/2015
Next Review Date: 07/02/2016

CMS: No CMS National Coverage Determination (NCD or LCD) was found for botulinum toxin for the treatment of neurologic or ophthalmologic conditions, headache, esophageal achalasia, hyperhidrosis, spasticity or tremors.

POLICY HISTORY:

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>12/17/2010</td>
<td>New policy</td>
</tr>
<tr>
<td>Reviewed</td>
<td>11/15/2012</td>
<td>Reviewed.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>10/03/2013</td>
<td>Revised, ICD10 codes added, ICD9 codes updated.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>06/19/2014</td>
<td>PA requirement removed.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>07/02/2015</td>
<td>No significant changes.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>09/10/2015</td>
<td>ICD10 codes updated.</td>
</tr>
</tbody>
</table>

REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.