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 benefits 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 other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Botulinum Toxin Injection for chemodenervation

PRIOR AUTHORIZATION: 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
- Blephorospasm
- Laryngeal dystonia/spasm
- Hemi-fascial 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 (Myositis 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:

| CPT Codes: | 31513; 31570; 31571; 43201; 43236; 64612; 64613; 64614; 64650; 64653; 67345; 95873; 95874 |
| HCPCS codes | JO585; JO586; S2340; S2341; JO587 |
| CPT Not Covered: | 86609 |
| 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 |
MEDICAL COVERAGE POLICY

SERVICE: Botulinum Toxin Injection for Chemodenervation

Policy Number: 011
Effective Date: 10/25/2013
Last Review: 10/3/2013
Next Review Date: 10/3/2014

ICD10 codes:
- G04.1
- G11.4
- G23.8
- G23.9
- G24.1 – G25.0
- G35 – G37.9
- G51.3 - G51.8
- G80.0 - G83.9
- G437.701 - G437.719
- I69.031 through I69.069
- I69.131 – I69.169
- I69.231 – I69.269
- I69.331 – I69.369
- I69.831 - I69.869
- I69.931 - I69.969
- K60.1 Chronic anal fissure
- L74.510 Primary focal hyperhidrosis, axilla
- M43.6 Torticollis
- S14.101A - S14.159S
- S24.0xxA - S24.159S
- S34.01xA - S34.3xxS

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>10/3/2013</td>
<td>Revised, ICD10 codes added, ICD9 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.

Botulinum Toxin Injection for Chemodenervation


54. Greene PE, Fahn S. Use of botulinum toxin type F injections to treat torticollis in patients with immunity to botulinum toxin type A. Mov Disord 1993; 8:479-483.


Botulinum Toxin Injection for Chemodenervation

FULL HAYES RATINGS August, 2013

D1 For botulinum toxin A (BTX-A) as a treatment for chronic tension-type headache (CTTH). This Rating reflects the negative results from the majority of randomized controlled trials of BTX-A for the treatment of CTTH.

C For local anesthetic injection therapies for cervicogenic headache and occipital neuralgia.

D2 For local Botox injection therapy for cervicogenic headache and occipital neuralgia.

D2 For cervical radiofrequency lesions for cervicogenic headache and occipital neuralgia.

D2 For discectomy for cervicogenic headache and occipital neuralgia.

B For botulinum toxin type A (BTX-A) treatment of cervical dystonia.

B For botulinum toxin type B (BTX-B) treatment of cervical dystonia.

B For BTX-A treatment of blepharospasm.

C For BTX-A treatment of hemifacial spasm; Meige’s syndrome, oromandibular dystonia; hand dystonias such as writer’s cramp, stenographer’s cramp, and musician’s cramp; laryngeal dystonia; and as an adjunct to surgery or as an alternative to reoperation in patients with infantile esotropia or concomitant strabismus, when interference with normal visual system development is likely to occur and when spontaneous recovery is unlikely.

D For patients with conditions that are considered specific contraindications to BTX treatment. This Rating reflects concerns regarding the safety and/or efficacy of BTX in these patient populations.

D For gastroparesis

Hyperhidrosis

B Botulinum toxin type A (BTX-A) for treatment of axillary hyperhidrosis that is refractory to topical and pharmacological therapies.

C BTX-A for treatment of palmar hyperhidrosis that is refractory to topical and pharmacological therapies.

D BTX-A for digital hyperhidrosis, facial and scalp hyperhidrosis, frontal hyperhidrosis, Frey’s syndrome (gustatory sweating), and plantar hyperhidrosis.

D Botulinum toxin type B (BTX-B) for all forms of hyperhidrosis.

Detrusor overactivity

C For onabotulinumtoxinA (onaBTX-A) as a treatment for idiopathic or neurogenic detrusor overactivity in adults who do not have contraindications to this treatment and who cannot tolerate or have an inadequate response to management and anticholinergic medications. This Rating is based on the finding that although onaBTX-A may reduce the symptoms of detrusor overactivity, the treatment is associated with several risks, the need for repeated treatments is not well characterized, and little is known about how onaBTX-A compares with other current invasive treatments for detrusor overactivity.

D1 For onaBTX-A as a treatment for detrusor overactivity in patients who have contraindications to this treatment, including hypersensitivity to botulinum toxin type A (BTX-A) or a component in its formulation, acute urinary retention, or acute urinary tract infection. This Rating reflects concerns regarding the safety of BTX-A treatment in patients who have these conditions.

D2 For abobotulinumtoxinA (aboBTX-A) as a treatment for idiopathic or neurogenic detrusor overactivity. This Rating is based on the small number and size of high-quality studies evaluating aboBTX-A for these indications.
D2 For BTX-B as a treatment for idiopathic or neurogenic detrusor overactivity. This Rating is based on the absence of randomized clinical trials evaluating this BTX serotype for these indications.

B For botulinum toxin type A (BTX-A) treatment in adult patients with chronic anal fissures of at least 2 months duration that are refractory to conservative therapy.

D For BTX-A treatment in pediatric patients, due to the lack of information on efficacy or safety.

D For BTX-A treatment in patients with secondary anal fissures, due to the lack of information on efficacy or safety.