APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

I. Botox, Myobloc, Dysport and Xeomin may be considered medically necessary and covered for FDA approved indications and selected unlabeled uses as indicated below for up to 12 months, but no more than 1 injection every 3 months. Reassessment must be done and preauthorization obtained for each 12 month period.

Note: Up to 4 injections over a 1-year period may be approved if medical necessity criteria are met.

A. FDA approved indications for rimabotulinumtoxinB (Myobloc):
   1. Cervical dystonia

B. FDA approved indications for onabotulinumtoxinA (Botox):
   1. Blepharospasm
   2. Cervical dystonia
   3. Hemifacial spasm
   4. Migraine headache prophylaxis may be approved for treatment by a neurologist with documentation of the all of the following:
      a. Diagnosis of migraine headache
      b. Documentation of more than 15 headache days per month and four distinct headache episodes lasting >= 4 hours in that month
<table>
<thead>
<tr>
<th>PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY</th>
<th>Drug: Botulinum Toxin Types A and B</th>
</tr>
</thead>
<tbody>
<tr>
<td>c. Trial and failure of oral formulary medications for both migraine treatment and migraine prophylaxis</td>
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<tr>
<td>5. Overactive bladder with incontinence for those who cannot use or do not adequately respond to two of the following anticholinergic medications: Ditropan® XL (oxybutynin), Detrol® LA (tolterodine), Enablex® (darifenacin), Myrbetriq® (mirabegron), Toviaz® (fesoterodine) or Vesicare® (solifenacin).</td>
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<tr>
<td>6. Strabismus</td>
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<td>7. Upper limb spasticity in adults</td>
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<td>8. Urinary incontinence due to detrusor overactivity associated with neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate: a. Response to or are intolerant of an anticholinergic medication. b. Dysfunction of the urinary bladder due to disease of the central or peripheral nervous system pathways involved in micturition. c. Nervous system pathways involved in micturition. d. Detrusor instability in patients with spinal cord injury or multiple sclerosis e. Resistant to antimuscarinics.</td>
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<tr>
<td>C. FDA approved indications for abobotulinumtoxinA (Dysport Brand of Botulinum Toxin Type A): 1. Cervical dystonia</td>
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</tbody>
</table>
14. Tardive dystonia
15. Writer’s cramp

II. When the above criteria I. above are not met, Botox, Myobloc, Dysport and Xeomin is considered investigational and not covered as a treatment for all other conditions, including but not limited to:

A. Any voiding dysfunction with urethral injections
B. Depression
C. Diabetic gastroparesis
D. Chronic pain, including low back pain, mastectomy reconstruction pain, myofacial pain, etc.
E. Headache (tension-type headache, chronic daily headache)
F. Rhinitis
G. TMJ treatment except as procedure of last resort when all conservative measures have been exhausted:
   1. Pharmacological management
   2. Physical therapy
   3. Relaxation therapy and cognitive behavioral therapy
   4. Reversible intraoral appliances

III. Botox, Myobloc, Dysport and Xeomin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face.

CPT/HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business</th>
<th>Prior Authorization Required</th>
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</thead>
<tbody>
<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
</tr>
<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
</tr>
<tr>
<td>31599</td>
<td>Unlisted procedure, larynx</td>
</tr>
<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
</tr>
<tr>
<td>46505</td>
<td>Chemodenervation of internal anal sphincter</td>
</tr>
<tr>
<td>52287</td>
<td>Cystourethroscopy, with injection(s) for chemodenervation of the bladder</td>
</tr>
<tr>
<td>64611</td>
<td>Chemodenervation of parotid and submandibular salivary glands, bilateral</td>
</tr>
<tr>
<td>64612</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)</td>
</tr>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
</tr>
<tr>
<td>64616</td>
<td>Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)</td>
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</tbody>
</table>
DESCRIPTION

Botulinum toxins types A and B are neurotoxins produced by Clostridium Botulinum. The rationale for treatment is to create temporary paralysis of sufficient depth and duration that the injected muscles become slightly atrophied and stretched. The antagonist muscle shortens simultaneously taking up the slack created by agonist paralysis. After several weeks enervation to the injected muscle returns. The safety and efficacy of long term Botox, Myobloc, Dysport or Xeomin is unknown; however, there are recent concerns over adverse systemic side effects.

INSTRUCTIONS FOR USE

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are
available as of the last policy update. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES