PREAMBLE

Purified onabotulinum toxin type A (BONT-A) has been shown to be useful in the treatment of a variety of ophthalmologic and neurologic disorders. It binds to the presynaptic terminal of the motor neurons, blocking release of acetylcholine. Onset of effect is 1 – 2 weeks after injection and benefits last from 2 – 3 months.

PROTOCOL

While BONT-A is indicated for various conditions (e.g. dystonias, torticollis, hypersalivation, apraxia, etc.), this protocol specifically addresses the use of onabotulinum for spasticity. Note: coverage of BONT-A for all other indications still available through NF-SA application (FPP-01)

Spasticity is defined as a motor disorder characterized by velocity-dependent increase in muscle tone with exaggerated tendon jerks, resulting from the hyperexcitability of the stretch reflex and is one component of the upper motor neuron syndrome. This is in contrast to contracture, which is defined by permanent shortening of a muscle or joint; usually in response to prolonged hypertonic spasticity. Onabotulinum is generally recognized to be effective for spasticity, but ineffective against contracture.

The goals of BONT-A should ideally be separated into functional and technical.

<table>
<thead>
<tr>
<th>Functional Objectives</th>
<th>To improve positioning, transfer ability, hygiene/ability to perform care, ADLs, prevent/treat pressure ulcers, and pain relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Objectives</td>
<td>To promote focal tone reduction, improved range of motion, and joint position</td>
</tr>
</tbody>
</table>

For Calgary LTC, the primary goal is improvement in passive function, facilitation of care, and increased quality of life. The technical objectives may be used as measurement parameters, but cannot be the sole determinant for efficacy of therapy for LTC residents.

FUNDING CRITERIA

Use for spasticity is approved under the following conditions:

1) Appropriate diagnosis
   - Management of moderate-to-severe focal or multifocal spasticity with conditions that have upper motor neuron involvement
     - Stroke
     - Brain injury
     - Cerebral palsy
iv. Multiple sclerosis
v. Spinal cord injury

2) Symptoms of diffuse spasticity must have been inadequately controlled with oral agents (e.g. baclofen, tizanidine, gabapentin, dantrolene) prior to initiation of onabotulinum. Clients may be concurrently treated with both oral and injectable therapy.

- Note: diffuse spasticity is considered spasticity affecting multiple limbs or systems; multifocal spasticity may include involvement of adjoining limb and/or muscles connected to the primary treatment area

**Exception:** focal or multifocal spasticity limited to only one treatment area may be treated first line with onabotulinum toxin type A.

3) Resident must be actively involved with facility rehabilitation (physical and/or occupational therapies) team for stretching/range-of-motion (ROM), and/or positioning devices (e.g. splints, braces, wedges, adductor pommels, wheelchair modifications, etc.) where appropriate. Resident must consent to therapy programs and regular use of positioning devices for BONT-A funding to continue.

4) Functional goals must be clearly established prior to initiation of therapy. Goals must be clearly defined and reassessed at subsequent clinics to determine if benefit has been achieved. Improvement in at least one functional goal after two distinct treatment courses must be observed. Lack of improvement after two courses will be considered a treatment failure and treatment should be discontinued.

<table>
<thead>
<tr>
<th>Functional Objective</th>
<th>Detail</th>
<th>Measurement</th>
<th>Assessment</th>
</tr>
</thead>
</table>
| Hygiene              | Ability to perform daily care and cleaning for areas of the body at risk of wounds | **Affected areas:**
  1) Perineum
  2) Axilla
  3) Elbow
  4) Neck
  5) Palmar/Digital
  6) Knee | **Likert Scale:**
  1) without difficulty
  2) little difficulty
  3) moderate difficulty
  4) great difficulty
  5) cannot be performed | Measurement of improvement over baseline |
| Transfers            | Ease and safety of transfer for client | **Degree of Transfer:**
  1) Independent
  2) 1 person assist
  3) 2 person assist
  4) Standing lift
  5) Mechanical lift | **Likert Scale:**
  1) without difficulty
  2) little difficulty
  3) moderate difficulty
  4) great difficulty
  5) cannot be performed | Measurement of improvement over baseline |
| Seating              | Ability to sit comfortably (i.e. reduction of spasms, pain, pressure areas due to increased tone) | **Estimated Time in Chair per day:** (hours) | **Likert Scale:**
  1) without difficulty
  2) little difficulty
  3) moderate difficulty
  4) great difficulty | Measurement of improvement over baseline |
**HIGH COST DRUG**

**onabotulinum toxin type A (Botox®)**

for treatment of **SPASTICITY**

**Positioning Devices**

<table>
<thead>
<tr>
<th>Ability to tolerate use of brace/positioning device with pain/ pressure ulceration</th>
<th>Type of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>2)</td>
</tr>
<tr>
<td>3)</td>
<td></td>
</tr>
</tbody>
</table>

**Likert Scale:**

- 1) without difficulty
- 2) little difficulty
- 3) moderate difficulty
- 4) great difficulty
- 5) cannot be performed

**Measurement of improvement over baseline**

*Note: it is understood that the reduction of pain may be a treatment goal; however, due to the lack of a standardized, generalizable assessment, it is excluded as a functional goal and should instead be described in the "additional comments" section of the HCD form*

**Tracking of Injection Sites (Dose and Assessment)**

Reporting of dosage use into each muscle group as well as the Modified Ashworth Scale (MAS) score for each injection site is required.

Use of BONT-A is only permitted where:

1) MAS score is 2 or greater in each injection site
2) Client shows improvement in MAS score of 1 or more after **TWO** distinct courses of therapy. Clients who show no improvement from baseline after two courses of onabotulinum will not be eligible for further treatment.

**Modified Ashworth Scale**

<table>
<thead>
<tr>
<th>Measures degree of muscle spasticity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No increase in muscle tone</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension</td>
</tr>
<tr>
<td>Grade 1+</td>
<td>Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM</td>
</tr>
<tr>
<td>Grade 2</td>
<td>More marked increase in muscle through most of the ROM, but affected part(s) easily moved</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Considerable increase in muscle tone, passive movement difficult</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Affect part(s) rigid in flexion or extension</td>
</tr>
</tbody>
</table>

Re-submission of HCD-16 is expected:

1) Once every six months
2) Should reflect the **best** MAS score achieved during treatment period between form submissions
CALGARY ZONE

Long Term Care Formulary

SECTION
HIGH COST DRUG

SUBJECT
onabotulinum toxin type A (Botox®)
for treatment of SPASTICITY

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REFERENCES

1. Product monograph
8. Personal communication with Dr. Noorshina Virani, MD, FRCP
Appendix: Treatment Algorithm from Spasticity Study Group\textsuperscript{5}