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SUBJECT/TITLE **Botulinum Toxin A Guidance**	ORIGINAL DATE **Dec 22, 2001** LAST REVISION DATE **Jan 21, 2025**

PREAMBLE

Purified botulinum toxin type A (BTA) has been shown to be useful in the treatment of a variety of neurologic disorders. It binds to the presypnaptic terminal of the motor neurons, blocking release of acetylcholine. Onset may take effect as early as 10-14 days after injection and benefits typically last up to 3 months (Devonshire, 2023). A referral to a specialist or experienced injector is required. While BTA is indicated for various conditions (e.g., dystonia, torticollis, hypersalivation, migraines), the predominant indication for use in continuing care is spasticity.

The Calgary Zone Continuing Care Home (CCH) Type A Pharmacy and Therapeutics committee reviewed BTA products in September. The decision was made to make BTA products non-formulary, effective Nov 1, 2024. These products are eligible benefits on the Alberta government's supplemental drug benefit programs and may be covered under other government or private insurance programs. For clients who do not have coverage, the clinical pharmacist can request funding under the Type A Formulary non-formulary process.

PRODUCT SELECTION

Clinicians should refer to the Alberta Blue Cross Interactive Drug Benefit List (Alberta Health n.d.) or private insurance plan benefit list the clients may have for current BTA product coverage eligibility. The selection of product is at the discretion of the prescriber. Please note that product selection and dosing are not interchangeable between products and that storage requirements may differ. Clinicians are referred to the product monographs for clinical information.

PHARMACY SELECTION

It is highly preferable, but not necessary, for the client to use the Type A home's contracted pharmacy provider to facilitate the dispensing of the BTA (e.g., managing the order information on the eMAR, delivery of product to the clinic for administration, billing to AHS if needed). The client may choose to work with another pharmacy, including any partnering pharmacies of the clinics, to fill their BTA prescription and it would be considered as "Patient's Own Medication" (AHS 2018).

Suggested process for contracted pharmacies of Type A homes

1) Client is identified as having a prescription or order for BTA. The pharmacy should determine the following:

I. where the client will be having BTA administered (at the Type A home or at an off-site clinic)
II. what product, dose and quantity are prescribed
III. date of administration
IV. client drug plan benefit information (e.g., Group 66, AISH)

2) Off-site administration (at a specialist's clinic or office)

I. Up to 2 weeks ahead of the appointment, the contracted pharmacy verifies with client/family or CCH staff that the client is able and willing to attend the appointment.
II. The prescription is dispensed and delivered to the clinic. The pharmacy and clinic should establish a mutually understood delivery process (clinic hours, signatures, cold chain custody). For ease of delivery, the pharmacy can coordinate one delivery for multiple clients.
III. Any changes made to the order and prescription by the physiatrist on the day of the appointment should be communicated to the contracted pharmacy for the purpose of accurate documentation, dispensing and billing.

3) On-site administration at the Type A home

I. Up to 2 weeks ahead of the appointment, the contracted pharmacy verifies with the client/family and home that the client is able and willing to attend the appointment.
II. The prescription is dispensed and delivered to the Type A home. The pharmacy should ensure the home understands storage requirements and accepts cold-chain custody.
III. Any changes made to the order and prescription by the physiatrist on the day of the appointment should be communicated to the contracted pharmacy for the accurate documentation, dispensing and billing.

STEWARDSHIP AND TRANSPARENCY

BTA is a high-cost medication and as such, appropriate assessment and monitoring of BTA use and process is necessary for ongoing sustainability of medication funding. In November 2024, one treatment with 300 units of BTA ranges from $3960.00 to $4500.00 (Alberta Health n.d.).

It may be the case that clinicians, pharmacy providers, or operators receive funding support, either directly or indirectly, from pharmaceutical companies or affiliates to support drug or BTA program

costs. In situations where this occurs, it is strongly recommended that the participants disclose this information to the clients and families.

THERAPEUTIC CONSIDERATION FOR USE OF BTA IN TYPE A CONTINUING CARE

Chronic 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 (Brashear 2011). This is in contrast to **contracture,** which is defined by permanent shortening of a muscle or joint, usually in response to prolonged hypertonic spasticity
BTA is recognized to be effective for spasticity, but ineffective against contracture (Brashear 2011).

Initiation of treatment is guided by client needs and degree to which spasticity interferes with function.
The goals of BTA should ideally be separated into **functional** and **technical** (Davis, et al. 2006).

Examples of Functional Objectives	To improve positioning, transfer ability, hygiene To increase ability to perform care, ADLs To prevent/treat pressure ulcers
Examples of Technical Objectives	To promote focal tone reduction To improve range of motion To improve joint position

Note on Pain: 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 assessed separately.

For Calgary Zone CCH, 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 Type A Continuing Care residents.

GUIDANCE FOR USE

1) Appropriate diagnosis
    - BTA may be appropriate for management of **moderate-to-severe** focal or generalized spasticity with conditions that have upper motor neuron involvement such as:

i. Stroke
ii. Brain injury
iii. Cerebral palsy
iv. Multiple sclerosis
v. Spinal cord injury

2) A trial of at least one oral agent (e.g., baclofen, tizanidine, gabapentin, pregabalin) should be tried for symptoms of generalized (diffuse) spasticity or multifocal spasticity prior to initiation of BTA. Clients may be concurrently treated with both oral and injectable therapy (Devonshire 2023).

- Note: **generalized** spasticity is considered spasticity affecting multiple limbs or systems; **focal or multifocal** spasticity may include involvement of one area or areas at adjoining limb or muscles connected to the primary focal treatment area.

3) Clients should be actively involved with the home's 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) where appropriate. Clients should agree to participation in therapy goals and regular use of positioning devices.

4) Monitoring and Outcomes

- Adverse Effects such as unmasked muscle weakness that could contribute to falls, hypertonia, injection site pain, and side effects related to drug interactions (with anticholinesterase inhibitors, magnesium, aminoglycosides) (Devonshire 2023).
- **Functional** goals should be clearly established prior to initiation of therapy (see Table 1. Examples of Functional Goals). Goals should be clearly defined and reassessed at subsequent appointments to determine if benefit has been achieved. Improvement in at least **one functional goa**l after two distinct treatment courses should be observed. Lack of improvement after two courses could be considered a treatment failure and treatment with BTA should be discontinued.
- **Technical** goals can be assessed and monitored using the Modified Ashworth Scale (MAS) (Baunsgaard, et al. 2016) (see Table 2) or another suitable tool. MAS is a measurement tool that can be used to monitor the degree of muscle spasticity.

i. At baseline, a MAS score is 2 or greater in each injection site is typically seen.
ii. An improvement in MAS score of 1 or more after TWO distinct courses of therapy demonstrates a positive response.

iii. Clients who show little to no improvement from baseline after two courses of BTA should be assessed for BTA discontinuation.

5) Tracking of injection sites (dose and assessment)

- Documentation of dosage (in units) administered into each muscle group and response is recommended for each treatment course.

Table 1. Examples of Functional Goals.

Functional Objective	Detail	Measurement		Assessment
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:** *Hygiene can be performed with:* 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:** *Transfers can be performed with:* 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)* **Note:** assessment with Seating Clinic must be complete prior to initiation of	**Likert Scale:** *Seating in wheelchair happens with:* 1) without difficulty 2) little difficulty 3) moderate difficulty 4) great difficulty 5) cannot be performed	Measurement of improvement over baseline

		therapy with BTA for seating goals		
Positioning Devices	Ability to tolerate use of brace/positioning device with pain/ pressure ulceration	Type of Device 1) 2) 3)	**Likert Scale:** *Positioning device may be used:* 1) without difficulty 2) little difficulty 3) moderate difficulty 4) great difficulty 5) cannot be performed	Measurement of improvement over baseline

Tabel 2. Modified Ashworth Scale (Baunsgaard, et al. 2016)

Measures degree of muscle spasticity	
	Description
Grade 0	No increase in muscle tone
Grade 1	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
Grade 1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
Grade 2	More marked increase in muscle through most of the ROM, but affected part(s) easily moved
Grade 3	Considerable increase in muscle tone, passive movement difficult
Grade 4	Affect part(s) rigid in flexion or extension

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