NHS Calderdale Clinical Commissioning Group

NHS Yorkshire and Humber Commissioning Support

Commissioning Statement

Treatment	**Botulinum Toxin Type A** *Licensed brands available:* *Botox, Dysport, Xeomin*
For the treatment of	Various indications as described below
Commissioning position	**Calderdale CCG commissions the use of Botulinum Toxin Type A (BTA) under the following circumstances** • Prescribing, administration, disease and drug monitoring remain the responsibility of the specialist • Products licensed for particular indications are used where possible • Treatment is ***discontinued*** if not tolerated or no objective evidence of response is seen **for the following indications:** **1. Chronic anal fissure in adults** A ***single*** treatment course of BTA is routinely funded for the treatment of chronic or recurrent anal fissures in adults where: • the condition has failed to heal spontaneously ***and*** • chronic symptoms (pain and/or rectal bleeding) have persisted for more than 6 weeks ***and*** • all other appropriate non-surgical, pharmacological (e.g. topical diltiazem, topical glyceryl trinitrate) and dietary treatments have been tried and failed **2. Hyperhidrosis** BTA is routinely funded for a maximum of ***2 doses*** per annum per patient for severe hyperhidrosis under the following circumstances: • when medically necessary for intractable, disabling focal primary hyperhydrosis, that has not been adequately controlled by topical aluminium chloride/other extra-strength antiperspirants ***and*** • patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers) if sweating is episodic ***and*** • where excessive sweating has caused demonstrable disruption of professional and/or social life **3. Overactive bladder** BTA is routinely funded for a maximum of ***3 doses*** per annum per patient for the management of overactive bladder under the following circumstances: • diagnosis of overactive bladder has been urodynamically proven (where appropriate) ***and*** • conservative measures have been exhausted (e.g. bladder

	training, antimuscarinic drugs and/or mirabegron) **CCGs will continue to fund usage in current clinical practice until 30th September 2015 whilst providers develop business cases/clinical criteria for CCGs to extend commissioned uses outside the criteria set out above.** **The CCG does *not* routinely commission BTA for cosmetic purposes.** North Kirklees CCG / Greater Huddersfield CCG / Wakefield CCG / Calderdale CCG
Date effective from	29 January 2015
Policy to be reviewed by	30 September 2015
Background information	**National Guidance** Conditions covered by NICE: Migraine (chronic) - botulinum toxin type A (TA260) issued June 2012 Spasticity in children and young people (CG145) issued July 2012 Urinary incontinence in neurological disease (CG148) issued August 2012 Lower urinary tract symptoms (CG97) issued May 2010 Urinary incontinence in women (CG171) issued September 2013 **Treatment pathway** Botulinum toxin is injected into the skin blocking the release of acetylcholine from overactive cholinergic sudomotornerve fibres. The majority of patients will require ongoing treatment. Prescribing, administration, disease and drug monitoring is the responsibility of the specialist.
Summary of evidence / rationale	**Clinical effectiveness** 1. Chronic anal fissure A Cochrane review that the BTA was as effective as glyceryl trinitrate (GTN) and less effective than surgery (although there was a reduced risk of incontinence) (1). 2. Hyperhydrosis BTA, when injected just under the deeper skin layers (subdermally), reduces sweating through the blockage of acetylcholine release from the cholinergic fibres of the sympathetic nervous system, which innervate eccrine sweat glands. The Cochrane Skin Group concluded that this treatment is effective, although injections are painful; they last for six to eight months after which they need to be repeated (2).

3. Overactive bladder

Urinary incontinence in neurological disease (CG148) issued August 2012
Lower urinary tract symptoms (CG97) issued May 2010
Urinary incontinence in women (CG171) issued September 2013

Safety

MHRA Safety Bulletin (Mar13) - updated advice following MHRA Drug Safety Update (Oct 2007):
All patients receiving any product containing botulinum toxin should be warned of the signs and symptoms of toxin spread, such as muscle weakness and breathing difficulties, and advised to seek medical attention immediately if they experience breathing difficulties, choking, or any new or worsening swallowing difficulties, as such side effects may be life-threatening.
Botulinum toxin type A products have rare but serious risks of adverse effects:
(see individual SPCs for details)
Botulinum toxins prevent the release of acetylcholine at neuromuscular or other cholinergic junctions and reversibly denervate muscles or eccrine glands.

a) Spread reactions—including muscle weakness, dysphagia, and aspiration—have been reported rarely with all products that contain botulinum toxin
b) Extreme caution is needed on administration of products that contain botulinum toxin to patients who have neurological disorders, or a history of dysphagia or aspiration
c) Only physicians with appropriate experience (including use of the required equipment) should administer products that contain botulinum toxin
d) Patients or caregivers should be informed about the risk of spread of toxin, and should be advised to seek immediate medical care if problems with swallowing or speech develop, or if respiratory symptoms arise
e) Units of botulinum toxin are not interchangeable from one product to another
f) Recommended administration techniques and specific dosing guidance (including the recommendation to use the minimum effective dose and titrate according to individual need) should be followed.

Cost effectiveness/resource impact

Treatment with BTA for a licensed indication is excluded from PbR tariff and, where commissioned, is funded via the Excluded Drugs mechanism (High Cost Drugs).

Treatments with BTA for an unlicensed indication are considered to be within Tariff.

	Equity of access BTA requires administration by appropriately skilled healthcare professionals and long-term safety has yet to be established. The CCG does ***not*** routinely commission BTA for cosmetic purposes. References 1) Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD003431. DOI: 10.1002/14651858.CD003431.pub3. http://www.cochrane.org/ 2) Shams K, Rzany BJ, Prescott LE, Musekiwa A. Interventions for excessive sweating of unknown cause (Protocol). Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD002953. DOI: 10.1002/14651858.CD002953.pub2. www.cochrane.org.

Product	**Licensed indications**							
	Blepharo spasm	Hemifaci al spasm	Idiopathi c cervical dystonia	Hyperhid rosis	Chronic migraine	Focal spasticity	Bladder dysfuncti on	Dynamic equinus foot in cerebral palsy
Botox	√	√	√	√	√	√	√	
Dysport	√	√	√			√		√
Xeomin	√		√			√ post stroke		

Contact for this policy	**North Kirklees CCG / Gt Huddersfield CCG:** Eric Power **Wakefield CCG:** Joanne Fitzpatrick **Calderdale CCG**: Helen Foster

Date of first draft	11/04/14
Comments (CCGs) on 1st draft by	09/05/14 (received 26/8/14)
Date of 2nd draft	16/9/14
Comments by	14/10/14
Date of 3rd draft	29/10/14
Comments on 3rd draft by	12/11/14
Date of 4th draft	22/12/14
Comments on 4th draft	12/01/15 (for approval at APC on 16/1/15) *NB: further indications to be considered at a future date*
Date of 5th draft	14/01/15
Comments to	Carey.tebby@nhs.net