General Commissioning Policy

Treatment	**Botulinum Toxin A (BTX-A)** **Botox (Allergan) ; Dysport (Ipsen) ; Xeomin (Merz)**
For the treatment of	**Muscle spasticity and contractures**
Background	This commissioning policy is needed because the emerging and sometimes complex evidence base urges a need for clarity on the use of Botulinum Toxin A injections for different indications.
Commissioning position	NHS Hull CCG commissions the use of BTX-A injections, with no prior approval required, in line with the recommendations in NICE Guideline 145 'Spasticity in Children and Young People' (Ref 1 & 2) and in the 2009 RCP Guidelines on the management of Spasticity in Adults using Botulinum Toxin (Ref 3). In all cases where BTX-A is used there should be a potential benefit to improve the range of motion and functional ability by selectively weakening the specific muscles affected either by spasticity or dynamic contractures. NHS Hull CCG does not commission the use of BTX-A for improving the range of movement in any joint affected by a fixed (rather than a dynamic) contracture – ie. where the muscle contracture is present at all times. Surgical interventions are usually indicated in such cases. *Children and Young People (see full recommendations in Ref 1)* (i) Consider BTX-A treatment* in children and young people in whom focal spasticity of the upper limb is: • impeding fine motor function • compromising care and hygiene • causing pain • impeding tolerance of other treatments, such as orthoses • causing cosmetic concerns to the child or young person. (ii) Consider BTX-A treatment* in children and young people where focal spasticity of the lower limb is: • impeding gross motor function • compromising care and hygiene • causing pain • disturbing sleep • impeding tolerance of other treatments, such as orthoses and use of equipment to support posture • causing cosmetic concern to the child or young person. *Specific considerations in Children and Young People:* Consider BTX-A treatment* after an acquired non-progressive brain injury if rapid-onset spasticity is causing postural or functional difficulties.

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

Consider a trial of BTX-A treatment** in children and young people with spasticity in whom focal dystonia is causing serious problems, such as postural or functional difficulties or pain.

Adults (see full recommendations in Ref 3)

(i) Patients should be selected for BTX-A injection on the basis of:
- focal or multifocal problems due to spasticity
- a dynamic spastic component as opposed to contracture
- clearly identified goals for treatment and anticipated functional gains.

(ii) The management of spasticity should be undertaken by a coordinated multidisciplinary team (MDT), rather than by clinicians working in isolation.

(iii) The MDT must ensure that:
- an appropriate physical management programme is in place
- all remediable aggravating factors have been addressed
- a suitable programme of on-going coordinated management is planned.

(iv) BTX-A injection must be part of a rehabilitation programme involving post-injection exercise, muscle stretch and/or splinting to achieve an optimal clinical effect.

(v) Clinicians must be aware that different BTX-A products have different dosage schedules. The current recommended maximum doses used in a single treatment session are 1,000 units Dysport® or 360 units Botox®. (Clinicians should refer to Appendix 2 of the RCP Guideline for the recommended doses for individual muscles.)

Other considerations:

- BTX-A injection may be used in appropriate cases to aid clinical decision making, to decide whether a permanent focal **i**ntervention such as orthopaedic surgery would be of benefit . For example if BTX-A improves the spasticity or dynamic contracture leading to calf tightness and 'toe walking', a surgical lengthening of the muscle may be considered.
- Even when BTX-A is used, conservative measures, such as positioning, stretching and exercise must remain an essential feature of spasticity management.
- Consideration must be given that after repeated use of high doses, antibodies can develop in some individuals, making further treatment with BTX-A ineffective indefinitely.

[Botulinum toxin units are not interchangeable from one product to another. Details of licensed indications and doses for individual products are available at the electronic (http://www.medicines Medicines Compendium.org.uk/emc).

Effective from	September 2016 (This policy replaces Hull PCT policy D05/10 dated Oct 2010)
Summary of evidence / rationale	Spasticity is an involuntary tightening of skeletal muscles, occurring in conditions where the brain and/or spinal cord are damaged or fail to develop normally. These include cerebral palsy, multiple sclerosis, spinal cord injury and acquired brain injury including stroke. Spasticity is treated because it causes pain and limits functional movements, thus impairing activities of daily living. In may be generalised, affecting the whole body, or focal, involving specific muscles. If not treated, spastic muscles, tendons or ligaments become less and less flexible by physically shortening and joints gradually lose function. If normal muscle stretching does not occur on a regular basis to prevent shrinkage, then a joint contracture develops and surgical intervention may be the only way to regain the full range of motion at that joint. Intervening aggressively before this happens with an appropriate therapy and stretching program augmented by medications, injections, physical modalities like heat or cold, braces and serial casts is important. Many rehabilitation techniques and interventions aim to improve the length of contracted spastic muscles. There are two different kinds of contractures. Dynamic contractures that occur during movement (noticed when an individual is trying to use a muscle to move a limb) and fixed contractures that are present at all times. Unfortunately, progression from dynamic to fixed contractures is difficult to prevent. BTX-A has been used for 20 years and is now considered the pharmacological treatment of choice in focal spasticity. By briefly blocking acetylcholine release at neuromuscular junctions, it temporarily weakens targeted muscles and improves the effectiveness of other therapies. BTX-A has been evaluated in various spastic disorders. It can be used to reduce spasticity or excessive muscular contractions to relieve pain; to assist in posturing and walking; to allow better range of motion; to permit better physical therapy; and to reduce severe spasm in order to provide adequate personal hygiene. The pharmacological effect on the treated muscle usually lasts 3-6 months (time to peak effect 7-10 days), depending on the amount of spasticity versus contracture, so injections are commonly repeated every four to six months if the initial injection has been useful and if spasticity has returned to its pre-injection level. (Ref 4)
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Refs:

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2. NICE Care Pathway 'Spasticity in Children and Young People' http://pathways.nice.org.uk/pathways/spasticity-in-children-and-young-people/spasticity-in-children-and-young-people-overview
3. Royal College of Physicians (RCP 2009) 'Spasticity in adults: management using botulinum toxin' http://www.rcplondon.ac.uk/sites/default/files/documents/spasticity-in-adults-management-botulinum-toxin.pdf
4. Pidcock, F S (2007) Spasticity Management, Transverse Myelitis Association, Journal Volume 2 - April 2007 Vol 11 (p54-58) http://www.myelitis.org/newsletters/pdf/TMA_Journal_Volume2.pdf
5. Simpson, et al. Botulinum neurotoxin for the treatment of spasticity (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2008 May 6; 70(19):1691-8. http://www.neurology.org/cgi/reprint/70/19/1691
6. Hoare et al. Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy (UPDATE). Cochrane Database of Systematic Reviews 2010, Issue 1. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003469.pub4/pdf
7. FDA Approves Botox to Treat Spasticity in Flexor Muscles of the Elbow, Wrist and Fingers (March 2010) Press release. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm203776.htm
8. NICE Guideline 8 (Nov 2003) Multiple Sclerosis: National clinical guideline for diagnosis and management in primary and secondary care. http://www.nice.org.uk/guidance/CG8 *(NB. Full Guideline update due Oct 2014 will include recommendations on use of Botulinum to manage spasticity)*
9. Beard et al (2003) Treatments for spasticity and pain in multiple sclerosis Vol. 7: No. 40. http://www.hta.ac.uk/execsumm/summ740.htm
10. BNF Oct 2013 http://www.medicinescomplete.com/mc/bnf/current/PHP3166-torsion-dystonias-and-other-involuntary-movements.htm
11. Rosales RL; Chua-Yap AS (2008) Evidence-based systematic review on the efficacy and safety of botulinum toxin-A therapy in post-stroke spasticity. J Neural Trans, 2008, vol./is. 115/4(617-23) http://www.ncbi.nlm.nih.gov/pubmed/18322637
12. Scottish Medicines Consortium (2011) SMC accepts botulinum toxin type A (Botox®) for focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults. http://www.scottishmedicines.org.uk/files/advice/botulinum_type_A_Botox_2nd_Resub_FINAL_Feb_2011.doc_for_website.pdf