General Commissioning Policy

Treatment	**Botulinum Toxin A**
For the treatment of	**Chronic anal fissure (in adults)**
Background	This treatment is excluded from PbR-Tariff. There is limited evidence to support the use of botulinum toxin for the treatment of patients with anal fissures. However, it requires administration by appropriately skilled healthcare professionals and its long-term safety has yet to be established. There is no NICE Technology Appraisal of this product and no recommendation from the Scottish Medicines Consortium (SMC).
Commissioning position	Hull CCG will commission this procedure only when certain criteria are met, outlined below: Botulinum toxin A will only be commissioned for treating chronic or recurrent anal fissures in adults where: • the condition has failed to heal spontaneously • chronic symptoms (pain and / or rectal bleeding) have persisted for more than 6 weeks • all other appropriate non-surgical, pharmacological (e.g. topical diltiazem, glyceryl trinitrate [GTN]) and dietary treatments have been tried and failed. One treatment with Botulinum toxin A will be commissioned - if the anal fissure fails to heal during the three-month period after injection, and chronic symptoms persist, surgical intervention may be indicated. Botulinum toxin A must be administered in accordance with the safety information provided in the Summary of Product Characteristics.
Effective from	October 2013 *(This policy supercedes Hull PCT policy D01/10 dated July 2010)*
Summary of evidence / rationale	An anal fissure (AF) is a painful tear / ulcer of the skin just outside the entry to the rectum. Its persistence is due to spasm of the internal sphincter muscle. Since most chronic anal fissures are associated with a raised internal anal sphincter pressure, treatment aims to reduce vascular anal pressure by diminishing sphincter tone and improving blood supply at the site of the fissure, thus promoting the healing rate. Cochrane review (Ref 1): Botox was equivalent to GTN in terms of efficacy with fewer adverse effects. Doses used in the trials varied from 10 units – 100 units. The investigators reported that it did not seem to matter what dose or type of botulinum toxin was injected. The risk of anal incontinence was reported to be 11%, though in one report incontinence was said to be equal to surgery (no actual numbers were given).

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.

	American Gastroenterological Association Medical Position Statement (Ref 2): Topical therapy and botulinum toxin injection should be considered acceptable options, even if not entirely proven, for the treatment of anal fissure. Their low morbidity profiles allow them to be used as first line treatment, not merely as salvage treatment for failed conservative care. However, further experience will be necessary to determine their definitive role in the algorithm of fissure therapy. UK MEDICINES INFORMATION REVIEW (Ref 3): How effective are topical glyceryl trinitrate, diltiazem and other drugs for anal fissure? Botulinum toxin produces a constant reduction in maximum resting pressure that is sustained over 2-3 months which should lead to improved healing. Side effects such as short-term minor incontinence and urgency are infrequent and transient. Botulinum toxin is associated with a similar rate of healing of anal fissure as GTN but is more expensive. It may be used for a fissure resistant to topical GTN or diltiazem. The technique, dose and site of injection do not affect the rate of healing (Level 1, Grade A). [The dose has varied from 10–100u (mean 23u based on 20 trials) with a mean healing rate of 75.6% and a range of 44–100% irrespective of the technique.] NICE evidence review: (Ref 4) Evidence from 2 systematic reviews and 4 further randomised controlled trials (RCTs) suggests that botulinum toxin type A injection is less effective than surgery, no better or worse than topical glyceryl trinitrate (GTN; mostly 0.2% ointment) or isosorbide dinitrate, and no better than placebo or lidocaine at healing anal fissure. The Medicines and Healthcare products Regulatory Agency (MHRA) has warned healthcare professionals about the rare but serious risk of toxin spread when using all types of botulinum toxin.
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References:

(1) Nelson RL. Non surgical therapy for anal fissure. Cochrane Database of Systematic Reviews 2006, Issue 4. Art.No.: CD003431. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003431.pub3/pdf/abstract

(2) Cross et al. The Management of Anal Fissure: ACPGBI Position Statement (2008) The Association of Coloproctology of Great Britain and Ireland. Colorectal Disease, 10 (Suppl. 3), 1–7. http://www.acpgbi.org.uk/wp-content/uploads/Position-Statements-Management-of-Anal-Fissure-Management-of-Acute-Severe-Colitis.pdf

(3) UKMI Q+A 290.2. January 2013: How effective are calcium channel blockers for anal fissures.

(4) NICE evidence review: ESUOM14: Chronic anal fissure: botulinum toxin type A injection. http://publications.nice.org.uk/esuom14-chronic-anal-fissure-botulinum-toxin-type-a-injection-esuom14

(5) Bhardwaj R, Parker MC. Modern perspectives in the treatment of chronic anal fissures. Ann Surg 2007; 90: 472–8. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2048592/pdf/rcse8905-472.pdf