General Commissioning Policy

Treatment	Botulinum Toxin A (BTX-A)
For the treatment of	Overactive bladder (OAB) (neurogenic or idiopathic detrusor overactivity [DO])
Background	This commissioning policy is needed to clarify the criteria which must be fulfilled in order for Botulinum Toxin A (BTX-A) injections for overactive bladder to be commissioned by NHS Hull CCG. (Previously this treatment was commissioned only after approval via the Individual Funding Request (IFR) process.)
Commissioning position	NHS Hull CCG will routinely commission BTX-A treatment for overactive bladder in patients where ALL the following criteria are met: **Women** (idiopathic detrusor overactivity – see NICE CG171) 1. Symptoms are refractory to lifestyle modification (caffeine reduction, modification of fluid intake, weight loss if BMI >30); 2. Symptoms are refractory to behavioural interventions: a minimum of 6 weeks of bladder retraining OR 3 months of pelvic floor muscle training (in mixed urinary incontinence only, where there is some stress incontinence as well as OAB); 3. Symptoms are refractory to 4 weeks of anticholinergic medication to a maximal tolerated dose (a number of drugs may be tried in accordance with NICE CG171)[OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290)]; 4. The woman has been referred to secondary care, reviewed by a urinary incontinence MDT and a diagnosis of detrusor overactivity has been confirmed by urodynamic assessment; 5. The woman is willing and able to perform clean intermittent catheterisation; 6. The treatment with BTX-A is initiated by a Consultant Urologist or Gynaecologist within the provider Trust. **Men** (idiopathic detrusor overactivity – see NICE CG97) 1. Symptoms are refractory to conservative management: lifestyle advice, advice on fluid intake, supervised bladder training and use of containment products (pads, sheaths etc); 2. Symptoms are refractory to 4-6 weeks of anticholinergic medication [OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290)]; 3. The man has been referred to secondary care for specialist assessment and a diagnosis of detrusor overactivity has been confirmed; 7. The man is willing and able to self catheterise; 8. The treatment with BTX-A is initiated by a Consultant Urologist within the provider Trust.

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.

	Neurogenic detrusor overactivity (see NICE CG148) in people with spinal cord disease (for example, spinal cord injury or multiple sclerosis): 1. Who have symptoms of an overactive bladder OR where urodynamic investigations have shown impaired bladder storage; 2. In whom a behavioural management programme (for example, timed voiding, bladder retraining or habit retraining) has been ineffective or is not appropriate 3. In whom antimuscarinic drugs have proved to be ineffective or poorly tolerated. 4. Who are able and willing to manage a catheterisation regimen should urinary retention develop after the treatment with BTX-A. With all patients the risks and benefits of BTX-A injections must be fully discussed and informed consent gained. If BTX-A treatment is effective, NHS Hull CCG will commission follow-up at 6 months or sooner if symptoms return for repeat treatment without an MDT referral. Requests to treat patients who do not meet the above criteria should be submitted to NHS Hull CCG for consideration via the IFR process.
Effective from	September 2016 *(This policy replaces Hull PCT policy D03/10 dated July 2010)*
Summary of evidence / rationale	Injection of BTX-A into the bladder is being increasingly used to treat persistent overactive bladder syndrome. This is a disorder characterised by the sudden urge to pass urine, a frequent need to pass urine, and passing urine during the night, with or without incontinence. NICE reviewed relevant evidence for BTX-A injections in idiopathic overactive bladder syndrome in Sept 2012. The RELAX study (Tincello 2010) was a UK randomised blinded placebo-controlled trial of 240 women with symptoms of OAB and DO that were refractory to a single anticholinergic treatment. Patients were injected with 200 units of BTX-A (BOTOX, Allergan) or placebo into the bladder wall (20 sites; 10 units per site in 1 ml saline) and followed up for 6 months. BTX-A gave a statistically significant improvement in voiding frequency, incontinence and urgency episodes and continence in women with IOAB and DO. In the treatment group voiding frequency was reduced from a baseline median of 10.3 to 8.3 episodes per 24 hours; incontinence episodes were reduced from 6.2 to 1.7 episodes per 24 hours; and the percentage of women who were continent increased from 4.9 to 31.3%.
Date	May 2017
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Contact for this policy	Karen Billany, Head of Acute Care, NHS Hull CCG karen.billany@nhs.net

NICE Care Pathways (flowcharts)

http://pathways.nice.org.uk/pathways/urinary-incontinence-in-women

http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men

http://pathways.nice.org.uk/pathways/urinary-incontinence-in-neurological-disease

References:

1. Apostolidiset al (2009) Recommendations on the Use of Botulinum Toxin in the Treatment of Lower Urinary Tract Disorders and Pelvic Floor Dysfunctions: A European Consensus Report. European Urology Volume 55, issue 1, pages 1-260, January 2009 http://www.europeanurology.com/article/S0302-2838(08)01109-3/abstract
2. Duthie et al. Botulinum toxin injections for adults with overactive bladder syndrome (Review). Cochrane database of systematic reviews 2011, issue 12 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005493.pub3/pdf/abstract
3. Naumann et al. (2008) Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2008 May 6; 70(19):1707-14. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.186.2359&rep=rep1&type=pdf
4. NICE Clinical Guideline 97 (May 2010, updated June 2015) Lower Urinary tract symptoms in men. http://www.nice.org.uk/nicemedia/live/12984/48575/48575.pdf
5. NICE Clinical Guideline 148 (2012) Urinary incontinence in neurological disease. http://guidance.nice.org.uk/CG148
6. NICE Clinical Guideline 171 (Sept 2013, updated Nov 2015). Urinary incontinence: The management of urinary incontinence in women. http://guidance.nice.org.uk/CG171
7. NICE Evidence summary: idiopathic overactive bladder syndrome: botulinum toxin A. September 2012. http://publications.nice.org.uk/idiopathic-overactive-bladder-syndrome-botulinum-toxin-a-esnm2#close
8. NICE TAG 290 (June 2013). Mirabegron for treating symptoms of overactive bladder http://www.nice.org.uk/nicemedia/live/14195/64256/64256.pdf
9. Sahai et al. GKT Botulinum Study Group. Efficacy of Botulinum Toxin-A for Treating Idiopathic Detrusor Overactivity: Results From a Single Centre, Randomized, Double-Blind, Placebo Controlled Trial. The Journal of Urology June 2007 (Vol. 177, Issue 6, Pages 2231-2236) http://www.jurology.com/article/S0022-5347(07)00268-6/abstract
10. Tincello D G, Kenyon S, Abrams K R et al. Botulinum Toxin A versus Placebo for Refractory Detrusor Overactivity in Women: A Randomised Blinded Placebo-Controlled Trial of 240 Women (the RELAX Study). European Urology 62 (2012) 507 – 514 http://www.europeanurology.com/article/S0302-2838(11)01441-2/fulltext